# CFIA oversight of authorized seed crop inspection (SWI 142.3.1)

This document describes the Canadian Food Inspection Agency's (CFIA) oversight of the inspection of pedigreed seed crops by Licensed Seed Crop Inspectors (LSCI) operating under the supervision of Authorized Seed Crop Inspection Services (ASCIS).

ASCIS and LSCI are private entities and individuals licensed by the CFIA to provide pedigreed seed crop inspection services. LSCI conduct the inspections and complete Seed Crop Inspection Reports which are verified by the ASCIS before being submitted to the Canadian Seed Growers' Association (CSGA) through the CSGA's SeedCert software package. The CSGA issues a crop certificate for the inspected seed crop based on the submitted Seed Crop Inspection Report.

The CFIA, as the authority for seed certification in Canada, is responsible for overseeing the ASCIS implementation of its quality management system (QMS) and the LSCI delivery of pedigreed seed crop inspection.

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# 1.0 Scope

This specific work instruction (SWI) details the procedures for CFIA oversight of LSCI and ASCIS activities.

# 2.0 Definitions, acronyms and references

For the purposes of this SWI, the definitions given in <u>Seed Program Regulatory Authority</u> (SPRA) 101 Definitions, Acronyms, and References for the <u>Seed Program</u> apply.

# 3.0 General requirements

General requirements for ASCIS and LSCI oversight are described in <u>Quality System Procedure</u> (QSP 142.3) – CFIA Oversight of Authorized Seed Crop Inspection.

# 4.0 Licensing of Licensed Seed Crop Inspectors

Information regarding the LSCI licensing process is found in <u>Quality System Procedure (QSP)</u> 142.2 <u>Licensing of Authorized Seed Crop Inspection Services and Licensed Seed Crop Inspectors.</u>

#### 4.1 LSCI training

LSCIs and ASCISs should refer to <u>QSP 142.2 Section 5.1 LSCI training and evaluation</u> for information regarding the training process.

CFIA trainers should refer to <u>Instructions for trainers of candidate Licensed Seed Crop Inspectors</u> (RDIMS 3810122 accessible only on the Government of Canada network).

#### 4.2 Evaluations of candidate LSCI

LSCIs and ASCISs should refer to QSP 142.2 Section 5.1 LSCI training and evaluation for information on the evaluation process.

CFIA trainers should refer to <u>Instructions for trainers of candidate Licensed Seed Crop Inspectors</u> (RDIMS 3810122 accessible only on the Government of Canada network).

#### **4.2.1** Written evaluation

Each licensing group has a written theory evaluation, offered in person or using an online testing platform. Candidates are required to bring their own current copies of reference materials, which may be in either electronic or paper format. Candidates will be informed of their marks via email. If the candidate is not successful, it is their responsibility to contact their trainer to request a re-evaluation.

#### 4.2.2 Practical evaluation

As indicated in QSP 142.2 Section 5.1, the licensing process of third party LSCIs for groups 1 and 4 includes a practical (in field) evaluation. For non-third party LSCIs, there are practical evaluations for groups 2 and 4. The evaluator will arrange a date and location with the candidate. The candidate will have access to all documents normally available to seed crop inspectors during the performance of their duties.

The evaluator will inform the candidate of their mark. If the candidate is not successful, it is their responsibility to contact their trainer to request a re-evaluation.

# 4.3 Licensing the LSCI

Once the candidate has passed both the written and practical evaluations, the Seed Section issues a licence to the LSCI and notifies the LSCI and the CSGA.

#### 4.4 Post-licensing training and support

The availability of post-licensing training and support will vary by region and, when necessary, will be focused on ASCIS Lead Inspectors who can then distribute the information to the LSCI under their supervision. If there are updates to the training materials for LSCI, the Seed Section will distribute the updated materials to the Lead Inspector of each ASCIS.

This additional training may be attended by LSCI who are not Lead Inspectors, if space is available and if the trainer consents.

# 5.0 Licensing of Authorized Seed Crop Inspection Services

#### 5.1 Application

The application process is described in <u>QSP 142.2 Section 6.1 Application for licensing an ASCIS</u>. The application package must include a copy of the QMS manual of the ASCIS as well as any related procedures documents or forms referred to in the QMS manual.

#### 5.1.1 Application review

The application must be complete, signed and dated. If the application is incomplete, the Seed Section will contact the applicant to obtain the missing information.

#### 5.1.2 ASCIS Quality Management Systems (QMS) manual review

The CFIA's ongoing oversight of the ASCIS assesses the ASCIS's ability to correctly implement its QMS. Therefore, it is essential that the initial review and assessment of the QMS be thorough and comprehensive.

**Note:** The reviewer must be an ASCIS auditor.

The QMS manual must describe the procedures followed by the ASCIS that result in the submission of unbiased, accurate, and comprehensive Seed Crop Inspection Reports to the CSGA. Appendix I is a checklist for review of a QMS manual, which must be completed by the reviewer before the ASCIS can be licensed. This checklist is not static and updates will occur from time to time as required.

If the QMS manual does not satisfactorily meet all the criteria in the checklist, the reviewer contacts the applicant and requests revisions. As deficient sections are amended, the reviewer should update the checklist. The QMS manual is considered complete only when it meets all of the criteria described in the checklist. The final version of the QMS should indicate the date that it was accepted by the CFIA.

All documentation that is received or created by the reviewer during the manual review process, including forms and checklists, should be added to the CFIA electronic folder for that ASCIS.

In some situations, the QMS manual may encompass procedures un-related to seed crop inspection. In this case, the ASCIS need not provide the full manual, but must provide sufficient sections of the QMS manual to demonstrate that the ASCIS is able to meet the objective of delivering seed crop inspection services to the standards expected by the CFIA and the CSGA.

#### 5.2 Recommendation for licensing the ASCIS

When the reviewer is satisfied that the QMS manual meets the requirements of the program, the reviewer completes and signs the Summary of QMS Manual Review (Appendix II) and sends the form to the Seed Section.

#### 5.3 Licensing the ASCIS

The Seed Section will review the Summary of QMS Manual Review and issue the licence to the ASCIS. The name of the ASCIS will be added to the list of licensed ASCIS and the CFIA auditor and the CSGA will be notified.

The ASCIS must apply separately to the CSGA for eligibility to submit Seed Crop Inspection Reports.

# 6.0 Ongoing CFIA oversight of LSCI

The oversight process for LSCI is outlined in QSP 142.3 section 5.0 Oversight of licensed seed crop inspectors.

# 6.1 Check inspections

Check inspections are conducted by CFIA seed crop inspectors. The check inspection process is described in QSP 142.3 section 5.1. Check inspectors should refer to OG-OO 54400 Check inspection of fields inspected by LSCIs (RDIMS 17760575 accessible only on the Government of Canada network) for procedures on conducting check inspections.

When an LSCI inspects a crop kind for the first time (or a new crop kind in a plot), they must notify the CSGA by completing the notification form in SeedCert. Durum wheat and wheat are considered different crop kinds and require separate notifications.

# 6.2 Check inspection frequency

Check inspections are conducted at a frequency that is established by the auditor during the annual ASCIS audit. LSCI in their first year of licensing are subject to a Normal frequency.

Table 1 Check inspection frequencies		
Frequency	Check inspection rate	
Reduced	5%	
Normal	10%	
Tightened	15%	

All LSCI are check inspected at a rate of 20% for their Group 6 (Plot) seed crop inspections. As percentages are used to calculate the number of fields for check inspection, the resulting number is rounded up to the nearest whole number.

These check inspections are subject to CFIA fees charged to the ASCIS.

#### **6.2.1** Additional check inspections

The CFIA may wish to complete additional check inspections in the following circumstances:

- there are specific concerns regarding an LSCI (for example, newly licensed or poor performance history)
- there are specific concerns regarding an ASCIS, for which additional check inspections of the LSCI reporting through the ASCIS is a reasonable course of action
- the Seed Section requests check inspections be conducted on specific crop kinds or in specific geographic areas for additional oversight
- the minimum number of fields (5) required to maintain check inspector status cannot be met based on the required check inspection rates and field numbers

These additional check inspections are not subject to CFIA fees and should not be invoiced to the ASCIS.

#### **6.2.2** Changes to the check inspection frequency

The check inspection frequency may remain the same from year to year, or may be increased 1 level (for example, from normal to tightened) or decreased 1 level (for example, from normal to reduced), depending on the numbers and types of non-conformances assigned to that LSCI. Table 2 describes the criteria for changing the check inspection frequency level.

Table 2 Criteria for changing LSCI check inspection frequency level			
Check inspection frequency change Non-conformances in previous year			
Decrease from tightened to normal	4 or fewer Minor, and no Major or Critical		
Decrease from normal to reduced	4 or fewer Minor, and no Major or Critical		
Increase from reduced to normal	2 or more Major, or 1 or 2 Critical		
Increase from normal to tightened	3 or more Major, or 1 or 2 Critical		
Initiate revocation process	3 Critical		

Where multiple Minor or Major non-conformances of the same type are noted in the same season, they are considered as only 1 non-conformance. If multiple levels of non-conformance are issued to an LSCI for the same criteria, the auditor will apply the highest level. For example, if an LSCI has 2 Minor and 1 Major non-conformance for criteria 8.2, they will receive 1 Major non-conformance.

Based on check inspection data, the auditor will calculate each LSCI's frequency and follow the instructions to update the ASD-Auditors Calculation of Check Inspection Frequency (RDIMS 12518191 accessible only on the Government of Canada network) in the ASCIS Master folder (RDIMS 4097055 accessible only on the Government of Canada network).

If a LSCI is working for more than 1 ASCIS, the number of Minor and Major non-conformances is calculated independently for each ASCIS for which the LSCI conducts inspections in the current crop season. The auditor will calculate the LSCI's frequency per ASCIS and update the ASD-Auditors Calculation of Check Inspection Frequency (RDIMS 12518191 accessible only on the Government of Canada network). Auditors of hybrid corn ASCISs will also add calculated frequencies to this spreadsheet in the designated column. The LSCI's frequency for the following year can only be calculated by Seed Section once all the check inspection frequencies for each ASCIS are received as the highest check inspection frequency will be assigned to the LSCI for the following year. Therefore, an auditor may not be aware of a check inspection frequency from another ASCIS at the time of the audit and should communicate to the LSCI and ASCIS that this will be determined at a later date.

The "LSCI and CI names" tab is updated in the master tracking sheet template (RDIMS 3695396 accessible only on the Government of Canada network) by Seed Section / PASO each year. The names and inspector numbers of newly licensed LSCIs are not added to this spreadsheet until the following year. Regional contacts must add these names to their local spreadsheets manually in the year of licensing.

Check inspection frequencies are not changed during the season. However, unresolved Critical non-conformances can lead to the initiation of the licence revocation process during the seed crop inspection season.

In order for an LSCI to change to a lower check inspection rate, the LSCI must have completed at least 25 field inspections and have had at least 3 check inspections in a single crop inspection season. For crops with multiple inspections per field, each inspection (maximum 3 per field) counts toward the 25. If the LSCI works for more than 1 ASCIS, their number of inspections completed in total for all ASCISs is used to determine this eligibility.

The ASCIS is ultimately responsible for the actions of the LSCI under its supervision and is required to provide re-training or other support to the LSCI to improve their delivery of seed crop inspections as necessary.

#### 6.3 Comparison of Check Inspector and LSCI Seed Crop Inspection Reports

CFIA check inspectors should refer to operational guideline OG-OO 54400 for procedures to conduct comparisons.

#### 6.4 LSCI non-conformances

Descriptions of Minor, Major, and Critical non-conformances of an LSCI are found in Table 3.

Table 3 Types of LSCI non-conformances		
Non-conformance	Description	
Minor	An activity that is not in conformity with an accepted pedigreed seed crop inspection procedure but will not or is unlikely to adversely affect the quality of the pedigreed seed crop inspection when isolated cases are found but that cumulatively may result in a consequential impact on the quality of the pedigreed seed crop inspection	
Major	An activity that is not in conformity with an accepted pedigreed seed crop inspection procedure and may have or is likely to have an adverse impact on the quality of the pedigreed seed crop inspection	
Critical	An activity that is not in conformity with an accepted pedigreed seed crop inspection procedure and will have an adverse impact on the quality of the pedigreed seed crop inspection	

If the LSCI has numerous non-conformances assigned to them, the check inspector may recommend to the CFIA auditor that the LSCI receive re-training within the current seed crop season and additional support or oversight by the ASCIS.

Minor and Major non-conformances are communicated to the ASCIS. Critical non-conformances are communicated to both the LSCI and the ASCIS.

Critical non-conformances are issued regardless of the final pedigree status granted to the inspected crop. CFIA compares to the published CSGA standard including variants, but CSGA may use additional information to assess the report.

# 7.0 Ongoing ASCIS oversight by the CFIA via annual audits

CFIA auditors conduct annual ASCIS audits by interviewing staff, reviewing records and observing procedures. These audits can be either full or partial and must be completed by December 15.

In a full audit, the auditor reviews all components of the QMS using the audit checklist in Appendix III.

In a partial audit, the auditor must review at minimum:

- all criteria listed as 'required for partial audit' on the audit checklist
- half of the remaining optional criteria on the audit checklist (ensuring that all optional criteria are reviewed at least once every 2 years)
- the summary of non-conformances identified in check inspections of each LSCI reporting to the ASCIS during the current seed crop inspection season
- components of the ASCIS QMS where Major and Critical non-conformances were noted in the previous audit and addressed in CARs
- any outstanding CARs from the previous audit
- components of the QMS manual which have changed since the last audit or initial QMS manual review to ensure that they remain in conformance with CFIA guidelines
- training plans and records
- the ASCIS list of their LSCI and their licence scopes

In either case, the audit is conducted according to standard audit protocols using the checklist provided in Appendix III. If non-conformances are identified, CARs are issued. More information on CARs can be found in Section 8.0.

# 7.1 ASCIS audit scope

At the end of its first year of licensing, the ASCIS must be subject to a full audit by the CFIA auditor. In the years following the first audit, an auditor may conduct either a full or a partial audit, depending on the performance history of the ASCIS in the previous audit as noted in Table 4. The auditor must review the summary report from the previous audit to determine if the upcoming audit will be full or partial.

Table 4 Requirement for a full audit of an ASCIS		
Audit conditions	Audit scope	
First year of licensing of the ASCIS	Full audit	
2 or more Critical non-conformances in the previous year's audit	Full audit	

#### 7.2 Creating a check inspection summary

In preparation for the audit, the auditor must review the summary of the check inspections for each LSCI reporting to the ASCIS. Each year, the auditor must combine the check inspection data for the LSCI reporting to that ASCIS from each check inspector's tracking sheets (found in the electronic ASCIS folder) into 1 master tracking sheet that contains check inspection results for all LSCI reporting to that ASCIS. This master sheet should be saved in the ASCIS folder following the naming convention (RDIMS 7372009 accessible only on the Government of Canada network). From this master sheet, the auditor can generate a summary of check inspection results for each LSCI for the year using the 'Summary Data' tab, where each row summarizes the check inspection results for a single LSCI over the entire seed crop inspection season. When the summary is complete the auditor must provide a summary of the nonconformances to the ASCIS.

The auditor should provide the summary to the ASCIS at the end of the season and not later than at the time of the annual audit. The auditor should review the summary of non-conformances and ensure that the descriptions are clear and consistent.

The auditor should also review the 'Additional comments' column in the 'Check Inspection Data' tab of the checklist. Check inspectors may indicate non-conformances to be assigned to the ASCIS in this column and these should be addressed during the audit.

# 7.3 Assessing previously issued ASCIS and LSCI CARs

The auditor must review the non-conformances that were issued to the ASCIS in the previous audit to determine whether they were closed by their resolution dates. Non-conformances that were previously issued to the ASCIS should be filed in the CFIA electronic folder for the ASCIS.

Non-conformances issued to ASCIS during the previous year's audit that were not closed by their resolution dates may be addressed as escalating non-conformances, depending on their severity. Major non-conformances are to be escalated to Critical non-conformances if they have not been resolved by their resolution date. Unresolved Minor non-conformances are escalated to Major non-conformances. Unresolved Critical non-conformances may not be escalated further, but may lead to revocation of the ASCIS licence as per Section 11.0.

Non-conformances that are escalated are issued on new CARs, and should indicate in the comments section that the non-conformance has been escalated as the non-conformance was not closed by the resolution date. The file numbers of the original and new CARs should be cross-referenced on the forms.

The auditor must also review the critical CARs that were issued to LSCIs in the current season. The check inspector who issued the CAR to the LSCI is responsible for follow up as per Section 8.4, and should keep the auditor informed. In some cases, the resolution date will not have passed at the time of the audit and the CAR can remain open. If the resolution date has passed and the CAR has not been resolved, this may lead to revocation of the LSCI license as per Section 11.0.

#### 7.4 ASCIS non-conformances

For an ASCIS, a non-conformance is a failure to follow the procedures of its QMS Manual or meet the standards in QSP 142.2 and the conditions in their ASCIS licence. Descriptions of Minor, Major, and Critical non-conformances of an ASCIS are found in Table 5.

Table 5 Descriptions of ASCIS Minor, Major and Critical Non-Conformances		
Non- conformance	Description	
Minor	A deviation from the QMS such that confidence in the conformance with the QMS is decreased. Minor non-conformances have no immediate or direct impact on the quality of the Seed Crop Inspection Report.	
Major	A significant deviation from the QMS such that conformance with the QMS is in doubt. Major non-conformances indicate a lack of control in the QMS and may negatively affect the quality of the Seed Crop Inspection Report.	
Critical	A deviation from the QMS such that conformance is absent.	

CARs for Critical non-conformances must be issued immediately according to Section 8.0 and resolved as soon as possible. CARs for Major and Minor non-conformances must be issued during the current audit and resolved, at the latest, before the end of the next seed crop inspection season. It is the responsibility of the CFIA auditor to inform the check inspectors of the numbers and types of non-conformances identified in the audit that may affect the activities of the LSCI in the upcoming season.

#### 7.4.1 Assigning LSCI non-conformances to the ASCIS

The ASCIS is responsible for resolving systemic problems that affect all LSCI under their supervision. Where the same non-conformances are noted in multiple LSCI at 1 ASCIS and the root cause can be ascribed to the actions of the ASCIS, a non-conformance is assigned to the ASCIS based on the conditions outlined in Table 6.

Table 6 Conditions where LSCI non-conformances may be assigned to the ASCIS		
Non-conformances assigned to LSCI reporting to an ASCIS	Non-conformance assigned to the ASCIS	
The same Critical non-conformance assigned to 2 or more LSCI or 10% of active LSCI, whichever is greater, reporting to that ASCIS	1 Critical	
The same Major non-conformance assigned to more than 50% of LSCI reporting to that ASCIS	1 Major	
The same Minor non-conformance assigned to 80% of LSCI reporting to that ASCIS	1 Minor	

There are some types of non-conformances for which this table does not apply.

#### 7.4.2 Roll-up of multiple non-conformances assigned to the ASCIS

Multiple non-conformances may indicate a trend in deficiencies that might have little significance when isolated cases are found but may be indicative of a systemic failure if they occur in significant numbers. If 3 Critical non-conformances are assigned to an ASCIS in a single audit, the auditor should inform Seed Section that they are initiating the process to revoke the ASCIS licence. For the purposes of an audit of an ASCIS, there is no roll-up of Major or Minor non-conformances to assign a Critical non-conformance.

#### 7.5 Determining ASCIS audit scope for the next year

The scope of the next audit to be conducted is dependent on the number and type of non-conformances noted against the ASCIS. If 2 or more Critical non-conformances have been identified during the audit, the scope of the next audit will be full, otherwise it will be partial, as indicated in Table 4. The determination of audit scope should be made after the non-conformances from the previous audit and non-conformances assigned to the LSCI reporting to the ASCIS have been 'rolled up' according to Section 7.4.2 as much as possible.

### 7.6 Closing the audit

The audit is to be completed and the audit report received by Seed Section by December 15 of each year. If there are extenuating circumstances such that this deadline will not be met, the auditor should inform Seed Section as far in advance as possible.

The final audit report package which is provided to the ASCIS should include:

- the summary report (Appendix VII)
- summary of LSCI non-conformances
- notification of LSCI check inspection frequency for next season
- CARs issued to ASCIS if non-conformances identified (Appendix VI)

If one or more of these documents has been provided during the course of the audit it is not necessary to provide it again.

All relevant documents are saved in the RDIMS folder for the ASCIS.

# 8.0 Corrective Action Requests (CARs)

A Correction Action Request (CAR) form documents non-conformances and communicates them to the LSCI or ASCIS. The corrective action plan (CAP) developed by the ASCIS or LSCI, and accepted by CFIA, is intended to:

- correct the immediate problem (for example, make amendments to Seed Crop Inspection Reports that had missing or incorrect data)
- identify and correct the root cause of the problem so that the problem does not occur again in the future (for example, forms were inadequate to record the data correctly)
- amend the procedures and/or the QMS manual to put in place the required changes to the procedures (for example, revise the forms)
- provide training or re-training as necessary to personnel responsible for the activity (for example, train on using the new forms)
- put in place check methods to determine if the amended procedure meets the objective of preventing the occurrence of the non-conformance (for example, review 10% of the new forms to verify that they are completed correctly)

The CAP resolution date should be reasonable, should occur as soon as possible and preferably before the end of the next seed crop inspection season.

If the resolution date for a non-conformance has not passed and if additional non-conformances of the same type are identified, the auditor or check inspector will not issue an additional CAR.

Each Critical non-conformance must be reported on a single, unique CAR so that follow-up actions can be more easily tracked.

Auditors may report multiple Major and Minor non-conformances on a single CAR where each type of Major or Minor non-conformance is listed and described only once, but the number of occurrences of that non-conformance is noted on the CAR.

Appendix V contains the template for CARs assigned to the LSCI, and Appendix VI contains the template for CARs assigned to the ASCIS. CAR files are saved in the CFIA electronic folder for the ASCIS.

CARs should only be changed or deleted by the auditor and only if there is evidence to justify the change. If the ASCIS or LSCI provides sufficient evidence for withdrawal of the CAR, the auditor must indicate this in the notes section of the CAR form. The auditor must also ensure that the information in the check inspection tracking sheet is updated.

CARs can be closed if the LSCI or ASCIS has implemented their CAP. Both resolved and unresolved non-conformances issued in the current seed crop inspection season will be considered when calculating the check inspection frequency or audit scope for the next seed crop inspection season.

If a CAR is closed and the non-conformance recurs, the closed CAR should be referenced on the new CAR to ensure that the CAP from the previous CAR is taken into consideration when developing the CAP for the new CAR.

#### 8.1 CAR timelines

When a Critical non-conformance is identified during the seed crop inspection season or during an audit, CAR timelines are as follows:

- within 2 business days of the identification of the non-conformance, the check inspector or auditor issues the CAR to the LSCI or ASCIS (issuing by email is recommended)
- within 2 business days of CAR issuance, the LSCI or ASCIS must acknowledge receipt in writing (email, text message, fax, or hard copy)
- within 3 business days of acknowledging receipt of the CAR, the LSCI or ASCIS must provide a corrective action plan (CAP) to CFIA in writing (email, text message, fax, or hard copy)

The CFIA contact reviews the proposed CAP and resolution date to ensure that it meets the requirements in Section 8.0, including addressing the immediate non-conformance, addressing the root cause, and implementing measures to prevent similar non-conformances in the future. Where applicable, CFIA will request that the ASCIS has the seed crop re-inspected as part of the corrective action plan. If the proposed CAP does not meet all elements, the CFIA contact will ask for a revised CAP. CFIA will confirm in writing once the CAP has been accepted.

If an ASCIS/LSCI wishes to appeal a non-conformance, they must complete the Request for Appeal of Non-conformance form (QSP 142.2 appendix G). This dispute process is separate from the CAR process and the CAR with CAP process must continue even if a dispute is initiated.

If the LSCI or ASCIS does not respond to CFIA in the timelines required, refer to section 11.1.

#### 8.2 CARs issued to LSCI

If a Critical non-conformance is identified by the check inspector, the check inspector will issue a CAR to the LSCI, with copy sent to the Lead Inspector for the LSCI and the auditor of the ASCIS to which the LSCI reports. The CAR with accepted CAP is saved in RDIMS by the check

inspector. The Critical non-conformance is recorded in the check inspection tracking spreadsheet with the RDIMS number for the CAR.

Most CARs issued to LSCIs are issued by check inspectors during the season, but there may be situations where the auditor identifies an issue during the audit requiring a CAR to be issued to an LSCI.

#### 8.3 CARs issued to ASCIS

Although the auditor may issue CARs to the ASCIS during the seed crop inspection season, for example when non-conformances involving conflicts of interest or inappropriate refusals of inspections are identified, the majority of CARs will be issued to the ASCIS during the annual audit. If possible, CARs issued at the audit should be resolved during or immediately after the audit, but it may not be possible to address all of the non-conformances or to confirm their resolution until the next seed crop inspection season is underway or even finished.

The CAP requested during the audit can be developed following the audit as long as it is developed within 2 weeks of the issuance of the CAR.

#### 8.4 Closing CARs

Once the proposed resolution date has passed, the check inspector or auditor must follow up to confirm the CAP was implemented as described. Follow up will vary depending on the CAP; some examples include confirming that the LSCI submitted a corrected report in SeedCert, requesting copies of training records, or confirming that changes were made to the quality manual. CARs with longer term corrective actions should be discussed between check inspector and auditor to determine appropriate follow up.

The check inspector or auditor does not consider the efficacy of the CAP when closing the CAR. However, the auditor or check inspector may issue another CAR if the same non-conformance continues to occur following the CAR resolution date. In this case, the auditor and/or check inspector should reference the original CAR on the second CAR. When the CAR can be closed, CFIA completes the form and documents the resolution date. Documentation of formal disagreements with CARs or non-conformances should be saved in the electronic folder for the ASCIS.

# 9.0 ASCIS or LSCI regulatory non-compliances

A regulatory non-compliance is a failure to meet legislative, regulatory or legal obligations and is subject to a range of enforcement actions depending on the type of non-compliance.

Following are examples of regulatory non-compliances:

- false or misleading information was provided in the ASCIS or LSCI licence application
- false or misleading information was provided to a CFIA inspector

When a regulatory non-compliance is identified during an audit, the auditor should note the non-compliance in the report and complete the remainder of the audit in the usual manner. The auditor should not take action on the non-compliance during the audit as they are on-site at the ASCIS for the purpose of conducting an audit and any other actions are out of scope during the time of the audit. After the audit, inspection and enforcement actions can be initiated as appropriate.

# 10.0 Annual renewal of an LSCI or ASCIS licence

LSCI and ASCIS licences are renewed annually by the Seed Section. The renewal of the LSCI licence is not dependent on the renewal of the licence of the ASCIS to which the LSCI reports.

Licences are not renewed if:

- the licensee indicates they do not wish the licence to be renewed
- the licence revocation process has been initiated by a CFIA auditor or check inspector
- the licensee does not meet the conditions for renewal (for example, completion of 20 inspections in 2 years)
- the licensee has a critical CAR that was not closed by the resolution date

ASCIS licences are renewed based on the recommendation of the auditor following the annual audit using the Audit Summary Report found in Appendix VII. ASCIS licences are not renewed if:

- the ASCIS has assigned their licence to another entity
- the ASCIS does not have insurance
- the ASCIS has not paid their check inspection fees
- the ASCIS has not provided access to CFIA for audits
- the ASCIS has not provided a CAP for CARs assessed during their audit
- the licensee has a critical CAR that was not closed by the resolution date
- the ASCIS has not completed the renewal form and/or accepted the minimum number of inspections for the coming crop inspection season

If an ASCIS chooses to withdraw prior to the audit the auditor must complete the following steps:

- the LSCI summaries
- invoicing for Check Inspections
- the ASCIS audit summary with a statement indicating why the audit was not complete.

# 11.0 Revocation of an LSCI or ASCIS licence

The Seed Section will notify the ASCIS or LSCI of the revocation of its licence by registered mail, and the CSGA, and CFIA auditor by electronic mail.

Section 11.1 outlines the procedures for the revocation of an LSCI or ASCIS licence that should be followed by the CFIA auditor in charge of the ASCIS to which the LSCI reports. Throughout this process, the auditor should be available to the LSCI or ASCIS to respond to questions. The auditor should retain the records leading to the revocation of a licence for 7 years and make them available to the National Manager of Seed Section if the ASCIS or LSCI seeks re-licensing at a future date.

If an ASCIS is no longer conducting inspections, an audit will be completed during the first year and the licence will be revoked the second year. In order to reinstate an ASCIS licence, the ASCIS must first re-apply for licensing.

#### 11.1 Procedures for the revocation of an LSCI or ASCIS licence

Prior to recommending a revocation of an ASCIS or LSCI licence, the CFIA auditor must provide written notification by email to the LSCI or ASCIS that they have unacknowledged, unresolved or 3 Critical non-conformances and that without resolution, these non-conformances may lead to the revocation of the LSCI or ASCIS licence. The CFIA auditor requests confirmation to ensure that the email has been received.

The auditor should include documentation to verify the non-conformances and CARs issued, dates, check inspection reports, etc.

The grounds for revoking the licence must be documented and the records retained according to the CFIA's records retention policy.

The auditor gives the LSCI or ASCIS a date for follow up and records the contact date and content of the interaction in the LSCI or ASCIS file. If possible, the LSCI, ASCIS or their representative should sign and date the record. The auditor will send a copy to the Seed Section.

The auditor will then follow up on the agreed date by phone or in person. If the LSCI or ASCIS is working to resolve the issue, but it is not yet resolved, it is acceptable to extend the deadline for resolution and set a second date for follow up. The auditor should document the contact and date the record. If possible, the LSCI, ASCIS or their representative should sign and date the record. If the deadline for resolution was extended, the auditor should follow up on the second date by phone or in person. It is not appropriate to extend the deadline more than once.

The auditor will follow up on the agreed date by phone or in person.

If no action has been taken, or if actions are inadequate to resolve the CARs, then the auditor will inform the National Manager by email of the situation and recommend revocation of the LSCI or ASCIS licence. The auditor will attach copies of previous correspondence with the LSCI or ASCIS documenting that the above noted procedures have been followed.

The National Manager will then issue a notice of revocation of the licence to the ASCIS or LSCI by registered mail, and the CSGA, and CFIA auditor by electronic mail, as the entity is no longer licensed.

#### 12.0 Re-instatement of an LSCI or ASCIS licence

Refer to QSP 142.2 Section 6.5 for information on re-instatement.

### **13.0 Fees**

The CFIA will charge fees to the ASCIS for check inspections of their LSCI, based on the total number of check inspections completed for the LSCI for that ASCIS. The fees charged should not exceed the number of check inspections that would be required based on the check inspection frequency assigned to the LSCI. The auditor is responsible for billing each ASCIS for which check inspections have been performed. The CFIA maintains the authority to conduct additional check inspections over and above the assigned frequency, but no fees will be charged for these additional check inspections.

Check inspections are invoiced based on the <u>CFIA Fees Notice</u>, <u>Part 14</u>, <u>Table 1</u>, <u>Item 1</u>. The invoice amount is a fixed fee based on 6 quarter hours per check inspection.

# Appendix 0 Work flow and forms

LSCI - Pre-licensing

Action	Reference
Applicant submits application for LSCI licence which is	QSP 142.2 Appendix D
reviewed by Seed Section	
LSCI completes classroom and practical training and evaluations	QSP 142.2 Appendix E
Seed Section issues LSCI licence	Template in QSP 142.2

**LSCI - Post-licensing** 

Action	Reference
Check inspector conducts inspections of seed crops inspected by	QSP 142.2
LSCI	
Check inspector issues CARs to the LSCI for Critical non-	SWI 142.3.1 Appendix V
conformances during the inspection season	
Check inspector completes check inspection tracking sheet as	Each inspector must save
time permits but before ASCIS annual audit	their own copy of check
	inspection tracking sheet
Check inspector may complete and save a Seed Crop Inspection	SWI 142.3.1 Appendix IX (or
Report comparison report for each check inspection before	using tracking sheet)
ASCIS annual audit. This is optional.	

**ASCIS - Pre-licensing** 

Action	Reference
Applicant submits application for ASCIS licence which is	QSP 142.2 Appendix B
reviewed by Seed Section	
Reviewer reviews ASCIS QMS manual and completes checklist	SWI 142.3.1 Appendix I
Reviewer completes recommendation for ASCIS licensing and	SWI 142.3.1 Appendix II
sends to seedsemence@inspection.gc.ca	
Seed Section issues ASCIS licence	Template in QSP 142.2
	Appendix C

**ASCIS - Post-licensing** 

ASCIS - 1 Ost-neensing			
Action	Reference		
Auditor creates summary of LSCI non-conformances using	SWI 142.3.1 Table 6		
ASCIS check inspection tracking sheet and applies them to			
ASCIS as appropriate			
Auditor issues a list of LSCI Minor and Major non-	SWI 142.3.1 Appendix V		
conformances to the ASCIS			
Auditor determines LSCI check inspection frequencies for	SWI 142.3.1 Table 2		
following year			
Auditor visits ASCIS and assesses ASCIS using Audit Checklist	SWI 142.3.1 Appendix III		
Auditor identifies non-conformances and issues CARs to ASCIS	SWI 142.3.1 Appendix VI		
Auditor determines ASCIS audit scope for next year	SWI 142.3.1 Table 4		
Auditor completes Report of ASCIS Audit for Seed Section and	SWI 142 2 1 Appendix VII		
ASCIS	SWI 142.3.1 Appendix VII		

# **Appendix I Pre-licensing ASCIS Quality Management System manual review checklist**

This checklist is to be completed during the pre-licensing ASCIS QMS manual review according to Section 5.1.2 of SWI 142.3.1. Each criterion is to be marked as Satisfactory (S) or Not Satisfactory (NS).

ASCIS Name
ASCIS Mailing Address
ASCIS Telephone
ASCIS Email
Name of ASCIS Quality Manager
ASCIS Quality Manager Email
ASCIS Quality Manager Telephone
Name of CFIA Auditor
CFIA Auditor Email
Date of Review

1.0 Quality Management System manual

No	. Reference	QMS Criteria	Review (S/NS)	Comments
1.	QSP 142.2 Section 4.3 ASCIS Responsibilities	QMS manual exists		

#### 2.0 General criteria – ASCIS and LSCI

No.	Reference	QMS Criteria	Review (S/NS)	Comments
2.1	ASCIS Licence	Manual states that ASCIS operates		
	QSP 142.2	and accepts requests for inspection		
	Section 3.1	only within the geographic area for		
		which it is licensed (unless		
		permitted by the CFIA)		
2.2	ASCIS Licence	Manual states that ASCIS will		
		accept the minimum number of		
		inspections for their Region before		
		refusing service to a seed grower.		
		(Not applicable to non-3 <sup>rd</sup> party)		

No.	Reference	QMS Criteria	Review (S/NS)	Comments
2.2.1	QSP 142.2	Manual states that ASCIS is		
	Section 4.3	committing to pay fees owed to the		
		CFIA for check inspections		
	ASCIS Licence			
2.3	ASCIS Licence	Manual states that ASCIS will		
		notify the CFIA if there are changes		
		in the ownership, majority control,		
		technical or financial competence,		
		location of the workplace, or any		
2.4	A G GYG Y	other changes in its status		
2.4	ASCIS Licence	A procedure stating that the ASCIS		
		is committing to maintain		
2.7	A GOLG I .	appropriate insurance coverage		
2.5	ASCIS Licence	Manual states that ASCIS will		
		notify the CFIA of any proceedings		
		for bankruptcy or insolvency		
2.6	A COLO I .	brought by or against the ASCIS		
2.6	ASCIS Licence	A procedure stating that neither the		
	radii.	ASCIS employees nor the LSCI		
	LSCI Licence	represent themselves as agents,		
2.7	A CCIC I .	employees or partners of the CFIA		
2.7	ASCIS Licence	A procedure stating that neither the		
	I COLL:	licence of the ASCIS nor the		
	LSCI Licence	licence of the LSCI is assigned to		
2.0	OCD 142.2	another entity		
2.8	QSP 142.2 Section 4.3	Manual has a procedure or method		
	Section 4.3	to identify conflict of interest with		
	ASCIS Licence	the ASCIS staff or LSCI, including		
	ASCIS LICEICE	how they handle conflict of interest when identified		
	LSCI Licence	when identified		
2 8 1	[Redacted]			
2.0.1	[[Keuaeteu]			
2.9	QSP 142.2	Manual states that ASCIS maintains		
	Section 4.3	the confidentiality of information		
		on Seed Crop Inspection Reports		
	ASCIS Licence	and other confidential information		
	LSCI Licence			

No.	Reference	QMS Criteria	Review (S/NS)	Comments
2.10	QSP 142.2	Manual states that ASCIS will		
	Section 4.3	submit a list of their LSCI in		
		SeedCert before June 15. The list		
		identifies the Lead and Alternate		
		Lead for each region in which the		
		ASCIS operates.		
2.11	QSP 142.2	Manual states that ASCIS notifies		
	Section 4.3	CFIA and CSGA immediately via		
		the ASCIS roster in SeedCert when		
	ASCIS Licence	their list of LSCI changes.		
2.12	QSP 142.2	Manual states that the Lead		
	Section 4.3	Inspector/Alternate Lead is an LSCI		
		that possesses, as a minimum, the		
		Group 1 Scope.		

# 3.0 QMS manual

No.	Reference	QMS Criteria	Review (S/NS)	Comments
3.1	QSP 142.2 Appendix F QMS Manual	QMS manual includes current information on:  • mailing address  • site location(s), if different from mailing address  • phone number  • email address and  • website (if available)		
3.2	QSP 142.2 Appendix F QMS Manual	<ul> <li>QMS manual includes:</li> <li>organizational chart including reporting structure</li> <li>list of employees currently filling those positions</li> <li>name of Quality Manager</li> <li>name of manager or owner with the ultimate responsibility for decisions at the ASCIS</li> </ul>		
3.3	QSP 142.2 Appendix F QMS Manual	QMS manual describes the roles and responsibilities of positions related to seed crop inspection		
3.4	[Redacted]			

No.	Reference	QMS Criteria	Review (S/NS)	Comments
3.5	QSP 142.2 Appendix F Section 3 QMS Manual	The final version of the QMS manual is approved by the QMS Manager		
3.6	QSP 142.2 Section 4.3	There is a procedure stating that the QMS Manager maintains the QMS manual, that procedures are up to date, and that obsolete documentation is removed from the system		
3.7	QSP 142.2 Appendix F Section 3 QMS Manual	The QMS includes provisions for regular and systematic review of the QMS		
3.8	QSP 142.2 Appendix F Section 3 QMS Manual	There is a procedure stating that amendments to the QMS are tracked.		
3.9	ASCIS Licence	Manual states that CFIA is notified when significant changes to the QMS are planned		
3.10	[Redacted]			
3.11	QSP 142.2 Appendix F Section 2 Management Responsibilities	A procedure exists to inform employees and LSCI to provide feedback to improve the QMS		
3.12	QSP 142.2 Appendix F Section 3 QMS Manual	Quality manual is complete, unambiguous and consistent		
3.13	QSP 142.2 Appendix F Section 3 QMS Manual	QMS manual pages are numbered x of y, and all articles are identified with unique alphanumeric sequences		

# 4.0 Procedures

No.	Reference	QMS Criteria	Review (S/NS)	Comments
4.1	QSP 142.2 Appendix F Section 3 QMS Manual QSP 142.2 Appendix F Section 4 Procedures Section 2 Management Responsibilities	There is a method for staff and LSCI to have access to the most recent versions of any internal, CFIA, or CSGA documents referenced in the QMS manual		
4.2	[Redacted]			
4.3	QSP 142.2 Appendix F Section 4 Procedures	Each procedure clearly indicates any form(s) required to be completed and maintained by that procedure		
4.4	QSP 142.2 Appendix F Section 4 Procedures	Procedure exists for managing requests for re-inspection		
4.5	[Redacted]			
4.6	ASCIS Licence	Manual states that the ASCIS is responsible to ensure that LSCI provides notice of their schedule prior to the inspection date and should be provided 2 days prior to inspections. Where 2 days is not possible, the notice should be entered prior to the inspection being conducted.		
4.6.1	LSCI Licence ASCIS Licence	Manual states that the actual date of inspection is reported by the end of the day on which the inspection is conducted.		

No.	Reference	QMS Criteria	Review (S/NS)	Comments
4.7	QSP 142.2	Manual states that seed crop		
	Section 4.3	inspections will be conducted at an		
		appropriate growth stage		
4.8	ASCIS Licence	A method exists to inform the CFIA		
		of the pest control product		
		application schedule when		
		requested by CFIA		
4.9	QSP 142.2	Manual states that Seed Crop		
	Section 4.3	Inspection Reports will be reviewed		
		prior to submission to the CSGA		
4.9.1	[Redacted]			
4.9.2	QSP 142.2	Manual states that ASCIS approves		
	Section 4.3	the report of crop inspection within		
		3 business days from the inspection		
		date		
4.10	ASCIS Licence	Manual states that the ASCIS		
		and/or the LSCI reports to the CFIA		
	LSCI Licence	the finding of a prohibited noxious		
		weed within 48 hours of its		
		observation during a seed crop		
		inspection		
4.11	ASCIS Licence	Manual states that neither the		
		ASCIS nor the LSCI communicate		
	LSCI Licence	to the seed grower an opinion as to		
		the decision of the CSGA with		
		respect to the results of an		
		inspection		

5.0 Corrective Action Requests (CARs) issued by the CFIA

No.	Reference	QMS Criteria	Review (S/NS)	Comments
	_	A procedure exists to respond to		
	Appendix F	CARs issued by the CFIA to the		
	Section 1	ASCIS and Critical CARs issued to		
		LSCI		
5.2	QSP 142.2	A procedure exists identifying a		
	Appendix F	person who is assigned to		
	Section 5 CARs	coordinate follow-up activities for		
		CARs		
5.3	[Redacted]			

No.	Reference	QMS Criteria	Review (S/NS)	Comments
5.4	QSP 142.2	A procedure exists that describes		
	Appendix F	when a non-conformance is		
	Section 5 CARs	identified, a response should		
		include a time period to resolve the		
		issue, addresses the root cause and a		
		verification action to be		
		implemented		
5.5	QSP 142.2	A procedure exists to address cases		
	Appendix F	where corrective action is not		
	Section 5 CARs	completed within the time frame		
5.6	QSP 142.2	A procedure is in place stating		
	Appendix F	where appropriate, CARs lead to an		
	Section 5 CARs	amendment to the QMS to prevent		
		similar non-conformances or non-		
		compliances from occurring in the		
		future		
<b>5.7</b>	QSP 142.2	A procedure exists to respond		
	Appendix F	internally to non-conformances		
	Section 5 CARs	identified during the ASCIS review		
		of the Seed Crop Inspection Report		

# 6.0 Records

No.	Reference	QMS Criteria	Review (S/NS)	Comments
6.1	QSP 142.2	Manual states that ASCIS retains		
	Section 4.3	records for minimum of 7 years		
	ASCIS Licence			
6.2	QSP 142.2	Manual states that records are		
	Appendix F	stored in a manner that provides for		
	Section 6	their safekeeping and physical		
	Records	protection		
6.3	QSP 142.2	Manual states that records are		
	Appendix F	disposed of by a secure method and		
	Section 6	only by authorized persons		
	Records			

No.	Reference	QMS Criteria	Review (S/NS)	Comments
6.4	QSP 142.2	A procedure exists stating the		
	Appendix F	following records are maintained:		
	Section 6	• revisions and amendments to the		
	Records	QMS manual and procedures		
		<ul> <li>copies of ASCIS and LSCI</li> </ul>		
	QSP 142.2	licences		
	Appendix F	• list of active LSCI		
	Section 8	<ul> <li>records of training and</li> </ul>		
	Training and	qualifications for staff and LSCI		
	Qualifications	• CARs and follow-up actions and		
		any other document directly		
		referenced in the QMS manual		

7.0 Training and qualifications

No.	Reference	QMS Criteria	Review (S/NS)	Comments
7.1	QSP 142.2	Procedure exists stating that the		
	Appendix F	personnel have been trained and are		
	Section 8	competent in the activities for		
	Training and	which they are responsible,		
	Qualifications	including, but not limited to:		
		Lead Inspector		
		Quality manager		
		Records clerk		
		LSCI-training records		
7.2	QSP 142.2	Manual states that the LSCI will		
	Section 4.4	only inspect crop kinds for which		
	LSCI	they have been licensed and are		
	Responsibilities	competent		
	LSCI Licence			
7.3	QSP 142.2	Methods or procedures exist to		
	Appendix F	provide refresher training as		
	Section 8	required		
	Training and			
	Qualifications			
7.4	[Redacted]			

No.	Reference	QMS Criteria	Review (S/NS)	Comments
7.5	QSP 142.2	Procedure exists stating new LSCI		
	Appendix F	are supervised by an experienced		
	Section 8	Lead Inspector		
	Training and			
	Qualifications			
<b>7.6</b>	QSP 142.2	Procedure exists for LSCI		
	Appendix F	inspecting a new crop kind for the		
	Section 8	first time are supervised		
	Training and			
	Qualifications			
7.7	QSP 142.2	Procedure exists to inform CFIA		
	Appendix F	when an LSCI inspects a new crop		
	Section 8	kind for the first time (including a		
	Training and	new crop kind in a plot)		
	Qualifications			
	QSP 142.1			
	Section 4.4			

# 8.0 General conclusions

No.	Reference	QMS Criteria	Review (S/NS)	Comments
8.1	[Redacted]			

Additional comme	dditional comments					

# **Appendix II Summary of ASCIS QMS manual review**

ASCIS Name			
ASCIS Mailing Address			
ASCIS Telephone			
ASCIS Email			
Name of ASCIS Quality Ma			
Email of ASCIS Quality Ma	nager		
Telephone of ASCIS Quality	y Manager		
Name of CFIA Auditor			
Email of CFIA Auditor			
Date QMS manual received			
Date QMS manual review co	omplete		
Part reserved for CFIA use			
Version # of approved QMS	manual		
File #			
Recommended for licensing	: Yes/No		
MRRS Code: 32a10.01			
Time spent on activity			
Comments			
CFIA Auditor			
	G: .		
Name (Print)	Signature	Date	
ASCIS On althy Manager			
ASCIS Quality Manager			
Name (Print)	Signature	Date	
raine (1 mil)	Signature	Daic	

# Appendix III ASCIS audit checklist

The checklist is used to document the assessment of:

- the ability of the ASCIS to implement its documented quality management system
- whether changes to the QMS manual meet the criteria in QSP 142.2

Non-conformances are recorded as Minor, Major or Critical.

ASCIS Name
ASCIS Mailing Address
ASCIS Telephone
ASCIS Email
Name of ASCIS Quality Manager
Telephone of ASCIS Quality Manager
Email of ASCIS Quality Manager
Name of CFIA Auditor
Email of CFIA Auditor
Date of Audit

#### 1.0 Quality System

No.	Reference	QMS Criteria	Non- Conformance	Comments
1.0	`	QMS manual exists	Critical	required for partial audit
	Section 4.3			
	ASCIS			
	Responsibilities			

#### 2.0 General Criteria - ASCIS and LSCI

No.	Reference	QMS Criteria	Non- Conformance	Comments
2.1	ASCIS Licence QSP 142.2 Section 3.1	The ASCIS operated and accepted requests for inspection only within the geographic area for which it is licensed (unless permitted otherwise by the CFIA)	Critical	required for partial audit

No.	Reference	QMS Criteria	Non- Conformance	Comments
2.2	ASCIS Licence	The ASCIS accepted the minimum number of inspections for their Region before refusing service to a seed grower (not applicable to non-third	Critical	required for partial audit
2.2.1	QSP 142.2 Section 4.3 ASCIS Licence	ASCIS paid fees owed to the CFIA for check inspections	Critical	required for partial audit
2.3	ASCIS Licence	The ASCIS notified the CFIA of changes in the ownership, majority control, technical or financial competence, location of the workplace or any other changes in its status	Major	required for partial audit
2.4	ASCIS Licence	The ASCIS maintained appropriate insurance coverage	Major	required for partial audit
2.5	ASCIS Licence	The ASCIS notified the CFIA of any proceedings for bankruptcy or insolvency brought by or against the ASCIS	Major	required for partial audit
2.6	ASCIS Licence LSCI Licence	Neither the ASCIS employees nor the LSCI represented themselves as agents, employees or partners of the CFIA	Critical	required for partial audit
2.7	ASCIS Licence LSCI Licence	Neither the licence of the ASCIS nor the licence of the LSCI was assigned to another entity	Critical	required for partial audit
2.8	QSP 142.2 Section 4.3 ASCIS Licence	The ASCIS has a procedure or a method to identify conflict of interest and took appropriate action when conflicts of interest	Critical	required for partial audit
	LSCI Licence	were identified with the ASCIS staff or LSCI		

No.	Reference	QMS Criteria	Non- Conformance	Comments
2.8.1	4.4	The LSCI and ASCIS were free of any conflict of interest with the seed growers or the seed crops	Critical	required for partial audit
	ASCIS Licence LSCI Licence	which they inspected		
2.9	QSP 142.2 Section 4.3 ASCIS Licence LSCI Licence	The ASCIS maintained the confidentiality of information on Seed Crop Inspection Reports and other confidential information	Major	
2.10	QSP 142.2 Section 4.3		Major	required for partial audit
2.11	QSP 142.2 Section 4.3 ASCIS Licence	The ASCIS notified the CFIA and CSGA immediately via the ASCIS roster in SeedCert when their list of LSCI changed.	Minor Major	required for partial audit
2.12	QSP 142.2 Section 4.3	The Lead Inspector/ Alternate Lead is an LSCI that possesses, as a minimum, the Group 1 Scope.	Major	required for partial audit

#### 3.0 QMS Manual

No.	Reference	QMS Criteria	Non- Conformance	Comments
3.1	QSP 142.2 Appendix F QMS Manual	QMS manual includes current information on:     mailing address     site location(s), if different from mailing address     phone number     email address and     website (if available)	Minor	required for partial audit - changes only

No.	Reference	QMS Criteria	Non- Conformance	Comments
3.2	QSP 142.2 Appendix F QMS Manual	<ul> <li>QMS manual includes:</li> <li>organizational chart including reporting structure</li> <li>list of employees currently filling those positions</li> <li>name of QMS manager</li> <li>name of manager or owner with the ultimate responsibility for decisions at the ASCIS</li> </ul>	Minor	required for partial audit - changes only
3.3	QSP 142.2 Appendix F QMS Manual	QMS manual describes the roles and responsibilities of positions related to crop inspection	Minor	required for partial audit - changes only
3.4	[Redacted]			
3.5	QSP 142.2 Appendix F Section 3 - QMS Manual	The final version of the QMS manual was approved by the QMS Manager	Minor	
3.6	QSP 142.2 Section 4.3	The QMS Manager maintained the QMS manual and procedures up to date	Minor	
3.7	QSP 142.2 Appendix F Section 3 - QMS Manual	The QMS manual has been regularly reviewed	Major	
3.8	QSP 142.2 Appendix F Section 3 - QMS Manual	Amendments to the QMS documentation followed a procedure that tracks the changes	Minor	
3.9	ASCIS Licence	The CFIA was notified of significant changes to the QMS	Minor Major	
3.10	QSP 142.2 Appendix F Section 2 Management Responsibilities	Employees and LSCI were informed of changes to the QMS	Major	

No.	Reference	QMS Criteria	Non- Conformance	Comments
3.11	QSP 142.2	The employees and LSCI	Minor	
	Appendix F	were encouraged to		
	Section 2	provide input which		
	Management	contributes to the continual		
	Responsibilities	improvement of the QMS		
3.12	QSP 142.2	The QMS manual and	Minor	
	Appendix F	related documentation is	Major	
	Section 3 - QMS	complete, unambiguous		
	Manual	and consistent		
3.13	QSP 142.2	QMS manual pages are	Minor	
	Appendix F	numbered x of y, and all		
	Section 3 - QMS	articles are identified with		
	Manual	unique alphanumeric		
		sequences		

# 4.0 Procedures

No.	Reference	QMS Criteria	Non- Conformance	Comments
4.1	QSP 142.2	ASCIS Staff and LSCI	Minor	
	Appendix F	have access to the most	Major	
	-	recent versions of any		
	Manual	internal, CFIA, or CSGA		
	000 140 0	documents referenced in		
	QSP 142.2	the QMS manual		
	Appendix F			
	Section 4			
	Procedures			
	G 4: 2			
	Section 2			
	Management			
4.2	Responsibilities	01 1 1 1	) (°	
4.2	QSP 142.2	Obsolete documentation	Minor	
	Appendix F	was promptly removed		
	1	from all points of use		
4.2	Manual OSP 142.2	Foot and a true of souls.	Minan	
4.3	QSP 142.2	Each procedure clearly	Minor	
	Appendix F	indicates any form(s)	Major	
	Section 4	required by that procedure.		
	Procedures	They are completed and		
		maintained.		

No.	Reference	QMS Criteria	Non- Conformance	Comments
4.4	QSP 142.2 Appendix F Section 4 Procedures	Requests for re-inspection were managed according to procedure	Minor	
4.5	[Redacted]			
4.6	ASCIS Licence	LSCI provides notice of their schedule prior to the inspection date and should be provided 2 days prior to inspections. Where 2 days was not possible, the notice has been entered prior to the inspection being conducted.	Minor	required for partial audit
4.6.1	LSCI Licence ASCI Licence	When seed crop inspections are conducted, the actual date of inspection is reported by the end of the day on which the inspection is conducted	Major	required for partial audit
4.7	QSP 142.2 Section 4.3	Seed crop inspections were conducted at an appropriate growth stage	Major	required for partial audit
4.8	ASCIS Licence	The ASCIS informed the CFIA of the pest control product application schedule when requested	Minor	
4.9	QSP 142.2 Section 4.3	Seed Crop Inspection Reports were correctly reviewed prior to submission to the CSGA	Major	required for partial audit
4.9.1	QSP 142.2 Section 4.4	Seed Crop Inspection Report was submitted	Major	required for partial audit
	Section 4.4	within 2 business days by the LSCI		
4.9.2	QSP 142.2 Section 4.3	ASCIS approved the Seed Crop Inspection Report within 3 business days from the inspection date	Major	required for partial audit

No.	Reference	QMS Criteria	Non- Conformance	Comments
4.10	ASCIS Licence	The ASCIS and/or the	Major	required for partial audit
		LSCI reported to the CFIA		
	LSCI Licence	the finding of a prohibited		
		noxious weed within 2		
		days of its observation in a		
		seed crop inspection		
4.11	ASCIS Licence	Neither the ASCIS nor the	Major	required for partial audit
		LSCI communicated to the	Minor	
	LSCI Licence	seed grower an opinion as		
		to the decision of the		
		CSGA with respect to the		
		results of a seed crop		
		inspection		

5.0 Corrective Action Requests (CARs) issued by the CFIA

5.0	Corrective Action Requests (CARS) issued by the CFIA				
No.	Reference	QMS Criteria	Non- Conformance	Comments	
5.1	QSP 142.2	The ASCIS responded to	Major	required for partial audit	
	Section 4.3	CARs issued by the CFIA			
			Minor		
	QSP 142.2	CARs issued to the LSCI			
	Appendix F	according to procedure:			
	Section 5 CARs	• follow-up activities			
		were coordinated			
		according to procedure			
		<ul> <li>corrective actions</li> </ul>			
		addressed the			
		immediate non-			
		conformance or non-			
		compliance and the root			
		cause			
		a time period was			
		agreed on for resolution			
		• completion of the			
		corrective action was			
		verified			
		• procedure was followed			
		to address cases where			
		corrective action is not			
		completed within the			
		time frame			
		• where appropriate,			
		CARs led to an			
		amendment to the QMS			

No.	Reference	QMS Criteria	Non- Conformance	Comments
	to prevent similar non- conformances or non- compliances from			
		occurring in the future		

# 6.0 Records

No.	Reference	QMS Criteria	Non- Conformance	Comments
6.1	QSP 142.2	ASCIS retains records for	Major	
	Section 4.3	minimum of 7 years		
	ASCIS Licence			
6.2	QSP 142.2	Records are stored in a	Minor	
	Appendix F	manner that provides for	Major	
	Section 6	their safekeeping and	Critical	
	Records	physical protection		
6.3	QSP 142.2	Records were disposed of	Minor	
	Appendix F	by a secure method and		
	Section 6	only by authorized persons		
	Records			
6.4	QSP 142.2	Records include:	Minor	required for partial audit
	Appendix F	<ul> <li>revisions and</li> </ul>	Major	
	Section 6	amendments to the	Critical	
	Records	QMS manual and procedures		
	QSP 142.2	<ul> <li>copies of ASCIS and</li> </ul>		
	Appendix F	LSCI licences		
	Section 8	• list of active LSCI		
	Training and	<ul> <li>records of training and</li> </ul>		
	Qualifications	qualifications for staff		
	Quantitionalous	and LSCI		
		CARs and follow-up		
		actions		
		<ul> <li>any other document</li> </ul>		
		directly referenced in		
		the QMS manual		

7.0 Training and Qualifications

7.0	Training and Qualifications						
No.	Reference	QMS Criteria	Non- Conformance	Comments			
7.1	QSP 142.2 Appendix F Section 8 Training and Qualifications	Personnel were trained and demonstrate competence in the activities for which they are responsible, including, but not limited to:  • Lead inspector  • QMS manager  • Records clerk  • LSCI	Major	required for partial audit			
7.2	QSP 142.2 Section 4.4 LSCI Requirements LSCI Licence	The LSCI only inspected crop kinds for which they are licensed and are competent	Critical	required for partial audit			
7.3	QSP 142.2 Appendix F Section 8 Training and Qualifications	Procedures were followed to provide training as required	Minor				
7.4	[Redacted]						
7.5	QSP 142.2 Appendix F Section 8 Training and Qualifications	New LSCI were supervised by an experienced Lead Inspector	Major				
7.6	QSP 142.2 Appendix F Section 8 Training and Qualifications	LSCI inspecting a new crop kind for the first time were supervised	Major	required for partial audit			
7.7	QSP 142.2 Appendix F Section 8 Training and Qualifications QSP 142.1 Section 4.4	The CFIA was informed when LSCI inspected a new crop type for the first time (including a new crop kind in a plot)	Minor				

### 8.0 General Conclusions

No.	Reference	UNIS C'riferia	Non- Conformance	Comments
8.1	QSP 142.2	The ASCIS appropriately	Minor	required for partial audit
	Section 4.3	oversaw the activities of its	Major	
		LSCI	Critical	
8.2	QSP 142.2	The ASCIS offered	Minor	required for partial audit
	Section 4.3	reasonable cooperation for	Major	
		the CFIA audit of ASCIS	Critical	
		and check inspections of its		
		LSCI. Field maps were		
		available. Accurate planned		
		dates were entered 2 days		
		in advance of inspections.		
8.3	QSP 142.2	QMS procedures were	Minor	required for partial audit
	Section 4.3	implemented correctly	Major	
			Critical	

# 9.0 LSCI Non-conformances assigned to the ASCIS

Non-conformances issued to ASCIS based on non-conformances issued to LSCI. Refer to the Check Inspection Tracking Sheet – Worksheet "ASCIS Rollups." Detail each applicable non-conformance. Do not include LSCI non-conformances for Check Inspection Checklist items 3.4, 3.7, 7.2, 4.4, 11.1 to 11.7 and 13.1 to 13.5. These are already captured in the ASCIS Audit Checklist.

% LSCI with the non-conformance	Description	Minor Major Critical	Comments
			(insert more rows as necessary)

Addition	Additional Comments (other observations, opportunities for improvements):					

# Appendix IV Examples of the classification of nonconformances and non-compliances identified in an ASCIS audit

[Redacted]

# Appendix V Corrective Action Request (CAR) form for LSCI

The text below can be used as the body of an email (recommended) or can be copied into a letter to be sent by mail or fax. Updated contact information for LSCIs and ASCIS leads can be found in the SeedCert Oversight tab.

CFIA oversight of pedigreed seed crop inspection has identified a critical non-conformance. The details of the Corrective Action Request (CAR) are given in Part 1.

Please acknowledge receipt of this CAR by completing Part 2 and responding in writing (email, text message, fax, or hard copy) within 2 business days of the date of CAR issuance.

A Corrective Action Plan (CAP) must be developed by the LSCI or ASCIS. Complete Part 3 and respond in writing within 3 business days of the date of acknowledgement.

### CRITICAL CORRECTIVE ACTION REQUEST

### Part 1 - Completed by CFIA (within 2 business days of identifying the non-conformance)

Name of LSCI:

LSCI number:

LSCI contact info (e-mail/phone number):

**ASCIS:** 

Check inspector name:

Check inspector number:

Check inspector e-mail:

Check inspector phone number:

Date of CAR issuance:

Description of non-conformance (including number from checklist – Appendix IX):

Sequence number of report(s):

Name of CFIA auditor copied:

Name of ASCIS lead copied:

# Part 2 - Completed by LSCI or ASCIS Lead Inspector (within 2 business days of the date of CAR issuance)

LSCI acknowledgement of receipt (signature, digital signature, or confirmed via email or text message):

Date of acknowledgement:

# Part 3 - Completed by LSCI or ASCIS Lead Inspector (within 3 business days of the date of acknowledgement)

Corrective Action Plan (CAP):

Proposed resolution date:

# Part 4 – Completed by CFIA once CAP has been accepted

CAP acceptance date:

# Part 5 - Completed by CFIA when non-conformance is resolved and CAR is closed

Resolution date:

Date completed CAR sent to LSCI and ASCIS:

Completed CAR saved as RDIMS file number:

# **Appendix VI Corrective Action Request (CAR) for ASCIS**

Template in RDIMS 18988459 (accessible only on the Government of Canada network)

CORRECTIVE ACTION REQUEST	
Name of ASCIS:	ASCIS #:
Quality Manager Name:	E-mail/phone number:
<b>Quality Manager Signature:</b>	Date of Receipt:

TO BE COMPLETED BY CFIA	D. C		TO BE COMPLETED BY QUALITY MANAGER		TO BE COMPLETED BY CFIA ON RESOLUTION OF NON- CONFORMAN CE	
Description of non-conformance (include number from checklist – Appendix III)	Reference	Level Minor / Major / Critical	Corrective Action Plan (CAP)	Proposed Resolution Date	Resolution Date	Auditor Initials verifying resolution
(insert more rows as necessary)  Notes:						

# **Auditor:**

Name:	Signature:	Inspector #:
E-mail:	Phone number:	Date of issuance:
Original sent to		Saved as file #
ASCIS		

# **Appendix VII Summary report of ASCIS audit**

This form is prepared by CFIA auditor and provided to the audited ASCIS and Seed Section.

Summary report of ASCIS audit	
Name of ASCIS	
Address of ASCIS	
Date of Audit	
Name of ASCIS Quality Manager	
Name(s) of other ASCIS personnel present at audit	
Name of CFIA auditor	
Name(s) of other CFIA personnel present at audit	

Full
Partial
N/A Audit not complete – provide
details
If Partial audit – specify all optional
QMS criteria that were selected for the
current audit
If Partial audit – specify all optional
QMS criteria to be selected for the
next audit

#### Non-conformances

Non-conformances			
Type of non-conformance	# of Minor N/C	# of Major N/C	# of Critical N/C
Non-conformances issued at			
previous audit and not resolved			
Non-conformances issued at current			
audit including LSCI non-			
conformances assigned to the ASCIS			
Comments			

# **Summary audit observations** – *list key observations and comments*

Section	Scope	Comments
2	General Criteria	
3	QMS Manual	
4	Procedures	
5	Corrective Action	
	Request(s) issued by CFIA	
6	Records	
7	Training and Qualifications	

### Additional comments and other observations

Criteria	Yes	No
Licensee requests renewal		
ASCIS has assigned their licence to another entity (if yes, the licence		
cannot be renewed)		
ASCIS has insurance (if no, licence cannot be renewed)		
ASCIS has provided CFIA access for audits (if no, cannot be renewed)		
ASCIS has provided CAP for CARs from audit (if no, licence cannot be		
renewed)		
Does the ASCIS or any LSCI have any Critical CARs that have not been		
closed by their resolution date?		
CFIA auditor recommends ASCIS for renewal of their agreement		

Note: Seed Section will confirm that all fees owed to the CFIA have been paid prior to renewal of licence.

## Recommendation

Recommendation for subsequent year audit scope	Partial □	Full □	N/A □
Name (print) of CFIA Auditor	Signature	Date	
Name (print) of ASCIS Quality Manager	Signature	Date	

# Appendix VIII Record of invigilation of a written evaluation

[Redacted]

# **Appendix IX Checklist for the comparison of Check Inspector and LSCI Seed Crop Inspection Reports**

To be completed by CFIA Check Inspector. S = Satisfactory; NS = Not Satisfactory. If a non-conformance category is not applicable, mark as Satisfactory.

LSCI name:
LSCI number:
ASCIS name:
Field sequence number:
Crop kind:
Plot $(Y/N)$ :

1.0 Seed tags

No.	Non-conformance	Level	S / NS	Comments
1.1	Failure to verify seed source	Minor		

### 2.0 Land use

No.	Non-conformance	Level	S / NS	Comments
2.1	Failure to verify previous land use	Minor		
2.2	Failure to verify previous land use for a sufficient number of years	Minor		

# 3.0 At the field

No.	Non-conformance	Level	S / NS	Comments
3.1	Failure to report that one or more characteristics in the variety description does not match the inspected variety	Major		
3.2	Inspect incorrect field	Critical		
3.3	Failure to correctly report land location	Minor		
3.4	Conducting inspection at inappropriate growth stage; distinguishing characteristics are somewhat visible although timing is not ideal	Major		
3.5	Conducting inspection at a growth stage where distinguishing characteristics are not visible	Critical		
3.6	Failure to report change in inspection acreage	Minor		

No.	Non-conformance	Level	S / NS	Comments
3.7	Conducting an inspection for which the inspector is not licensed  Note: Check inspector must also assess any potential conflicts of interest and report these to seedsemence@inspection.gc.ca	Critical		
3.8	Failure to correctly report impurities outside of counts (off-types, other crop kinds, weeds reported by count)	Major Minor		
3.9	Failure to separate 2 fields when it was required as per CSGA's field definition	Minor		

# 4.0 Counts

No.	Non-conformance	Level	S/ NS	Comments
4.1	Failure to report altered count area	Major		
4.2	Performing/reporting less than 6 counts or the required number of counts	Major		
4.3	Taking counts in a non-representative manner (clustering)	Major		
4.4	Performing inspection on incorrect plant population	Critical		

5.0 Weeds and other crop kinds reported by frequency

No.	Non-conformance	Level	S/ NS	Comments	
5.1	Failure to correctly identify and report weeds or other crop kinds by frequency	Minor			
5.2	Inaccurate reporting of general weed condition	Minor			
5.3	Reporting weeds by count as weeds by frequency	Major			
5.4	Failure to identify and/or report a Prohibited Noxious weed in the field or 3 metres isolation	Critical			

# 6.0 Plant disease

No.	Non-conformance	Level	S / NS	Comments
6.1	Failure to correctly report smut in barley crop	Minor		

7.0 Isolation

No.	Non-conformance	Level	S / NS	Comments
7.1	Failure to correctly rate the condition of the isolation (good vs. poor)	Major		
7.2	Failure to report what was found in the isolation distance for open pollinated crops	Major		

8.0 Off-types/variants

0.0	5.0 On-types/variants				
No.	Non-conformance	Level	S / NS	Comments	
8.1	Identifying plant morphological deviations due to environmental factors as off-types/variants	Minor			
8.2	Failure to identify and/or quantify off- types/variants	Critical Major Minor			
8.3	Unclear reporting and/or description of off-types/variants	Minor			
8.4	Identifying off-types/variants using only 1 distinguishing characteristic when 2 are required (for soybean, turf grass, or forage crops, or "tall" off-types/variants in any crop)	Minor			

9.0 Other crop kinds and weeds reported by count

No.	Non-Conformance	Level	S / NS	Comments
9.1	Failure to identify and/or quantify crops and/or weeds reported by count	Critical Major Minor		
9.2	Unclear reporting and/or description of crops and/or weeds reported by count	Minor		

10.0 Production methods

No.	Non-conformance	Level	S / NS	Comments
10.1	Failure to report problem areas (for example, lodging or flooding)	Minor		
10.2	Failure to report planting issues in hybrid crops (for example, mix-up of male and female lines)	Major		

11.0 Reporting

11.0 Reporting				
No.	Non-conformance	Level	S/ NS	Comments
11.1	Providing inappropriate comments on Seed Crop Inspection Report	Minor		
11.2	Predicting CSGA decision verbally or on a Seed Crop Inspection Report	Major		
11.3	Information is not supplied in a meaningful, understandable manner	Minor		
11.4	Omissions on Seed Crop Inspection Report (for example, required comments)	Minor		
11.5	Failure to submit an inspection schedule to the CFIA	Minor		
11.6	Failure to notify the CFIA of inspections completed by the end of the day of the inspection(s)	Major		
11.7	Failure to submit initial report in SeedCert within 2 business days of the inspection	Major		

# 12.0 Other non-conformances observed

No.	Non-conformance	Level	S/ NS	Comments
	(insert more rows as necessary)			

Non-conformances observed at check inspection which are rolled up to the ASCIS

No.	Non-conformance	S = 0, NS = 1, N/A = 0
13.1	An accurate map was supplied	
13.2	LSCI reported the actual date of inspection at the end of the day of the inspection(s)	
13.3	Pesticide application schedule provided by the ASCIS to the CFIA when requested by the CFIA	
13.4	ASCIS has notified the CFIA of a Prohibited Noxious Weed observed by the LSCI	
13.5	Final report approved by ASCIS within 3 business days of the inspection	

## Total numbers of non-conformances observed

	Minor	Major	Critical
Total numbers of non-conformances observed			

Check Inspector name:

Date comparison completed:

MRRS Code:

Time Spent on Activity: