

United States Department of Agriculture

Agricultural Marketing Service National Organic Program

PRO-CERT ORGANIC SYSTEMS LTD.

Box 100A, RR#3, 475 Valley Road, Saskatoon, Saskatchewan, S7K 3J6, CANADA

meets all the requirements prescribed in the USDA National Organic Program Regulations

7 CFR Part 205

as an Accredited Certifying Agent

for the scope of

Crops, Handling, Livestock, Wild Crops Operations

This certificate is receivable by all officers of all courts of the United States as prima facie evidence of the truth of the statements therein contained. This certificate does not excuse failure to comply with any of the regulatory laws enforced by the U.S. Department of Agriculture.

Status of this accreditation may be verified at http://www.ams.usda.gov

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NATIONAL ORGANIC PROGRAM: AUDIT & CORRECTIVE ACTION REPORT

GENERAL INFORMATION

• Certifier Name Pro-Cert Organic Systems, (PRO)

• **Physical Address** Box 100A, RR#3, 475 Valley Road, Saskatoon,

S7K 3J6, Saskatchewan CANADA

• Audit Type Renewal Assessment

Auditors & Audit Dates
Colleen O'Brien, Renée Gebault King,

Samuel Schaefer-Joel, 05/23/2022 to 06/06/2022

• Audit Identifier NOP-40-22

CERTIFIER OVERVIEW

Pro Cert Organic Systems (PRO) is a for profit business that was initially accredited as a USDA certifying agent on May 24, 2002, to the scopes of Crops, Wild Crops, Livestock, and Handling. PRO has two certification offices (East and West) to handle certification activities in Canada. The main office is the Western Region office in Saskatoon, Saskatchewan, which is responsible for making policy. Both offices make the final certification decisions in addition to inspection scheduling and reviews. The Eastern Office is located in Cambray, Ontario.

PRO currently certifies 311 operations: 171 crop, 103 livestock, 3 wild crop, and 159 handlers. PRO currently does not certify any grower groups. PRO certifies operations in the United States and Canada. The PRO staff consists of 1 General Manager, 1 Assistant Manager / Certification Manger, 1 Regulatory Affairs Officer, 4 Regional Certification Coordinators, 1 Input Review Coordinator, 10 Evaluators/Certification Specialists, 13 Administrative staff members, and 14 Inspectors (12 contract and 2 staff inspectors).

The NOP conducted an onsite audit of PRO's certification activities during the period September 18, 2020 to April 30, 2022. The purpose of the renewal audit was to verify PRO's conformance to the USDA organic regulations.

NOP DETERMINATION:

NOP reviewed the audit results to determine whether PRO's corrective actions adequately addressed previous noncompliances. NOP also reviewed any corrective actions submitted as a result of noncompliances issued from Findings identified during the audit.

Any noncompliance labeled as "Cleared," indicates that the corrective actions for the noncompliance are determined to be implemented and working effectively. Any noncompliance labeled as "Accepted" indicates acceptance of the corrective actions and verification of corrective action implementation will be conducted during the next audit.

Noncompliances from Prior Assessments

AIA-2469-20 - Cleared.

AIA-2502-20 - Cleared.

AIA-2786-20 - Cleared.

AIA-2789-20 - Cleared.

AIA-2790-20 - Cleared.

AIA-2792-20 - Cleared.

AIA-2793-20 - Cleared.

AIA-7013-21 - Cleared.

AIA-2787-20 - Accepted. 7 C.F.R. §205.402(b)(2) states, "The certifying agent shall within a reasonable time: Provide the applicant with a copy of the on site inspection report, as approved by the certifying agent, for any onsite inspection performed."

Comments: PRO does not consistently provide operations with a copy of their approved inspection report. The auditors review of certification files found that PRO is not providing copies of inspection reports for unannounced inspections.

Corrective Action: PRO modified existing procedures to provide the full inspection report (inspection checklist and report summary) to operations after all inspections, including unannounced inspections. The procedure was submitted to NOP. Additionally, PRO is adjusting its process within its Intact database to automate sending the inspection report to the operations. Automation of the process will be completed by the end of March 2022. A copy of the internal memo that was sent to all staff regarding this change was provided to NOP.

Verification of Corrective Action: The auditors confirmed with PRO that operators are still not receiving full inspection reports following inspections because the automation for sending reports has not yet been implemented within the Intact system. The updated software to automate the process was not complete at the time of the audit.

2023 Corrective Action: PRO issued a memo to all staff on October 6, 2023, informing them the Inspection Report must be sent to operations after an unannounced inspection. PRO revised *Directive #1011 Unannounced Inspection Reporting*, on November 17, 2023, to instruct staff to issue a copy of the inspection results to the operation following completion of an inspection. PRO confirmed that "results", as referenced in the directive, is the full inspection report. PRO submitted examples of emails issued to operations with the inspection report attached.

AIA-2788-20 - Accepted. 7 C.F.R. §205.501(a)(4) states, "A private or governmental entity accredited as a certifying agent under this subpart must: Use a sufficient number of adequately trained personnel, including inspectors and certification review personnel, to comply with and implement the organic certification program established under the Act and the regulations in subpart E of this part;"

Comments: PRO does not consistently use adequately trained personnel to comply with and implement its USDA organic certification program. The auditors identified the following issues during interviews with certification staff and the review of documents:

- 1. For one operation, there was no evidence that PRO has verified that a non-organic ingredient used in a product complies with the National List annotation.
- 2. For three operations, a non-organic ingredient was approved without evidence that PRO staff verified compliance with GMO, ionizing irradiation, and sewage sludge requirements.
- 3. For one operation, products produced that are only eligible for the "made with organic" claim were listed under the "organic" claim on the organic certificate.
- 4. For one operation, a review of the ingredient panel on the label found that an organic ingredient was not identified as organic.
- 5. For one operation, the flow chart obtained during the inspection indicated the use of a material (nitrogen gas) on the National List; however, the inspector reported that no materials are used during the handling of organic products and PRO review staff did not follow up with the operator or inspector regarding this discrepancy.
- 6. For one operation, instructions provided to the inspector for an unannounced inspection were to carry out mass balances as well as traceback exercises; however, no mass balance exercises were carried out by the inspector.

Corrective Action: PRO provided a training webinar to all inspectors and staff members on April 21, 2021, which was recorded to be used as required training for all new staff members and inspectors. The training covered new forms, processes, and obtaining and filing supporting documents for nonorganic ingredients. PRO has inspected all relevant operations the since the NOP assessment in 2020 and is reviewing the operation's files to ensure that all the required documentation is in place. In addition:

- 1. PRO updated Section 5.0 and 6.0 of the Inspector and Evaluator Checklist to include verification of nonorganic ingredients to national list annotations. PRO developed and implemented a new document, 6.4.7.1 Non-Organic Ingredients Affidavit, to collect evidence that nonorganic ingredients used by certified processors meet requirements for non-GMO, irradiation, and sewage sludge. PRO provided the new documents to its processor evaluator team. A copy of the instruction email sent to the processor team was provided to NOP. PRO requested the missing ingredient documentation from the operation audited and verified the ingredient's compliance with the USDA organic regulations on December 18, 2020. PRO submitted the information request and updated documentation to the NOP.
- 2. PRO added an extra checkpoint to its evaluator checklist to ensure that all ingredients have been reviewed for compliance and that the documentation is correctly filed in the client's electronic file, including GMO, ionizing irradiation, and sewage sludge compliance requirements.
- 3. PRO updated the evaluator checklist (Intact Template, section 8.0) to include a question that prompts the evaluator to verify each product's correct organic category listing on the organic certificate in Intact. PRO issued a corrected certificate to one operation listing products under the "made with organic" claim. The certificate with the error was issued on September 3,

- 2020, and the corrected certificate was reissued on September 15, 2020. PRO provided a copy of both the incorrect and corrected certificates to NOP.
- 4. PRO informed an operation that one of the ingredients listed on their label was not correctly identified as organic and new labels were submitted by the operation. A copy of the email, the updated label, and PRO's label approval were provided to the NOP. PRO conducted training titled "Errors and Omissions" to address the human error that led to the incorrect label approval. An additional training module for label review is being planned for completion by October 2022.
- 5. PRO updated section 6.0 of the Inspector and Evaluator Checklist to require an explanation when inputs identified in the OSP have not been found in-use by the operation during inspection.
- 6. PRO staff participated in the NOP Organic Learning Center training on conducting mass balances at inspections. PRO developed two mass balance worksheets and a traceback worksheet to address the different types of handling operations. One worksheet is used for single-ingredient products or for products that are distributed and brokered and the other is used for processors of multi-ingredient products. The new worksheets were submitted to NOP along with a memo that was sent to all inspection and review staff about using the forms. Additional training on the new forms will be provided during the 2022 Annual Inspector Training.
- 7. PRO hired a Regulatory Affairs Officer (RAO) in 2021, who is responsible for leading the internal audits of PRO's certification processes, ensuring that corrective actions are implemented, updating certification forms and procedures, carrying out certification staff trainings, and ensuring the organic equivalency processes are compliant. PRO submitted the RAO job description to the NOP.

Verification of Corrective Action: The auditors' review of certification files and interviews with PRO staff determined the corrective actions have been implemented as stated. The auditors verified that PRO maintained sufficient documentation to verify non-organic ingredient compliance with GMO, ionizing irradiation, and sewage sludge requirements. Auditors reviewed a product eligible for the "made with organic" claim and verified that it was correctly identified on the operation's organic certificate. Auditors reviewed labels approved by PRO and verified them to be compliant. PRO's 2022 annual training material introduced new mass balance and traceback worksheets. Auditors verified that inspectors began to incorporate these new forms into their inspections in May 2022. Additionally, PRO certification staff will be required to take the Organic Integrity Learning Center (OILC) module on Traceability Techniques, with expected completion by the end of 2022.

However, the auditors also found examples of the originally identified noncompliance, bullet 1, reoccurring as follows:

- 1. PRO approved a nonorganic ingredient without reviewing sufficient documentation to demonstrate compliance with National List restrictions for that input.
- 2. PRO has not assessed whether previously approved non-organic ingredients have sufficient documentation to demonstrate compliance. Products that have previously been approved are not required to have the updated form, 6.4.7.1 Non-Organic Ingredients Affidavit, completed for those ingredients.

2023 Corrective Action: PRO obtained and reviewed additional documentation for the nonorganic ingredient of concern and submitted evidence of its compliance to NOP. PRO conducted a training on *Input Reviews* and *Requirements and NOP Standards and Highlights* for staff and inspectors in April 2023. PRO created a new *Directive 7001 - Depth of Review – Organic Inputs* to provide additional

instructions to staff on the requirements for input review. PRO submitted two completed crop input reviews as evidence the new directive was implemented. PRO updated its inspection checklists to include additional verification prompts for inspectors to verify inputs. PRO implemented the updated *Producer Inspection Checklist* in November 2023. PRO implemented the updated *Processor/Handler Inspection Checklist* in January 2024. PRO plans to require processor operations to submit a new organic system plan with current input information as part of their 2024 renewal application. PRO plans to review all inputs for processing operations during the 2024 continuation of certification cycle.

AIA-2794-20 - Accepted. 7 C.F.R. §205.501(a)(3) states, "A private or governmental entity accredited as a certifying agent under this subpart must: Carry out the provisions of the Act and the regulations in this part, including the provisions of §\$205.402 through 205.406 and \$205.670;"

Comments: PRO does not consistently review organic system plans (OSPs) for completeness and accuracy. The auditors' review of certification files found organic system plans contain unanswered questions or contradictory information. PRO did not request the missing information or follow-up to clarify the contradictory statements.

Corrective Action: PRO conducted a full day training webinar with all inspectors and staff members on April 21, 2021. The training included the requirements for reviewing OSPs for completeness, inspector reporting of discrepancies, and ensuring OSP's accurately reflect the practices carried out by certified operations. The webinar was recorded and is required training for all new staff members and inspectors. A copy of the training PowerPoint was submitted to NOP. In addition, PRO sent out a memo to inspection and review staff notifying them that if discrepancies are found between the OSP and practices carried out by the operation, a notice of noncompliance should be issued to the operation. A copy of the memo sent to inspection and review staff was provided to the NOP.

Verification of Corrective Action: The auditors reviewed certification files and found several examples of where the operation's OSP contained unanswered questions or contradictory information and PRO did not request this missing information or follow-up to clarify the contradictory statements.

2023 Corrective Action: PRO conducted training for inspectors in April 2023 on *the Role of the Inspector and Inspection Process*, which included the requirement for inspectors to verify if the organic system plan (OSP) is complete and accurate. PRO issued an email on November 11, 2023, instructing evaluators (reviewers) to identify missing or contradictory information in the OSP and to follow-up with operation to obtain additional information though a request for information or notice of noncompliance prior to inspection, if applicable. PRO's email also instructed evaluators to assess whether each section of the OSP contains information and if the depth of the information provided is sufficient to assess compliance. PRO instructed its evaluators to complete the Preliminary Evaluation Checklist question verifying the application is complete and compliant when conducting this assessment.

Noncompliances Identified during the Current Assessment

AIA-1185-22 - Accepted. 7 C.F.R. §205.501(a)(2) states, "A private or governmental entity accredited as a certifying agent under this subpart must: Demonstrate the ability to fully comply with the requirements for accreditation set forth in this subpart."

Comments: *PRO's annual update form does not demonstrate that PRO fully complies with the requirements of § 205.406(a)(3). The auditors' review of certification files found that PRO's annual*

update form does not ask its certified operations for an update on the correction of minor noncompliances previously identified by the certifying agent as requiring correction for continued certification.

Corrective Action: PRO added a new question to its organic system plan (OSP) templates requesting operations to provide an update on the implementation of corrective actions from previous noncompliances. PRO implemented the producer OSP in November 2023 and implemented the processor/handler OSP in January 2024.

AIA-1186-22 - Accepted. 7 C.F.R. §205.501(a)(2) states, "A private or governmental entity accredited as a certifying agent under this subpart must: Demonstrate the ability to fully comply with the requirements for accreditation set forth in this subpart."

Comments: PRO does not demonstrate the ability to fully comply with the requirements for accreditation. The auditors' review of inspection reports and organic system plans (OSP) found that PRO is not fully verifying an operation's compliance with the USDA organic regulations. The following are examples:

- 1. PRO's Livestock OSP (Appendix A) does not prompt producers of organic livestock operations to describe practices implemented to comply with § 205.239(a)(1).
- 2. PRO's Livestock OSP (Appendix A) does not ask the producer of an organic livestock operation to describe the circumstances when temporary confinement is provided pursuant to § 205.239(b), or when ruminant animals are denied pasture or outdoor access pursuant to § 205.239(c).
- 3. PRO's inspection report template does not prompt inspectors to record verification of compliance with temporary confinement of organic livestock pursuant to § 205.239(b), or when ruminant animals are denied pasture or outdoor access pursuant to § 205.239(c).
- 4. PRO's inspection report template does not prompt inspectors to record verification of compliance with input use restrictions.

Corrective Action: PRO updated its *Organic System Plan (OSP) Appendix A (Livestock)*. Appendix A includes a description of when animals receive outdoor access, if not year-round, and reasons for confinement. PRO updated its *Inspection Checklist Appendix A (Livestock)* to include a prompt for the inspector to verify temporary confinement, that inputs are included on the *Input Substance Summary (Doc #8.1.1)*, and to collect product labels and/or MSDS' for inputs not included. PRO updated its *Producer Inspection Checklist* to prompt inspectors to verify input use restrictions. PRO implemented the updated *OSP Appendix A (Livestock)*, *Producer Inspection Checklist, and Inspection Checklist Appendix A (Livestock)* in November 2023.

AIA-1187-22 - Accepted. 7 C.F.R. §205.403(c)(1) states, "The onsite inspection of an operation must verify: The operation's compliance or capability to comply with the Act and the regulations in this part;"

Comments: PRO's inspector did not accurately verify an operation's compliance with the USDA organic regulations. The auditor's review of a crop producer's inspection report found that the inspector did not verify that there was a documented soil deficiency prior to the operator using synthetic micronutrient according to the National List requirement. The operation reported a fertilizer containing micronutrients had been used but the inspector reported, "no micronutrients in use, no soil testing has been done."

Corrective Action: PRO conducted a review of the operation's organic system plan (OSP) and

determined that the fertilizer containing micronutrients was not being used by the operation. PRO updated the operation's *Input Master Data List* to identify the correct fertilizer being used which does not contain micronutrients. PRO conducted annual inspector training in April 2022 after the operation was inspected. The 2022 training instructed inspectors to verify the accuracy of the OSP and to document differences observed. PRO conducted additional training for staff and inspectors in April 2023, on *USDA NOP Overview and Standards Highlights*, that included the requirement to verify compliance with the National List material input annotations. PRO plans to require new inspectors take the training through PRO's Trakster system prior to being assigned inspections. PRO added a verification point to its *Producer Inspection Checklist* implemented in November 2023, to prompt the inspector to verify all inputs are used in accordance with the requirements of the organic regulation.

AIA-1188-22 - Accepted. 7 C.F.R. §205.403(c)(1) states, "The onsite inspection of an operation must verify: The operation's compliance or capability to comply with the Act and the regulations in this part;"

Comments: During the witness audits of PRO inspections for a handling operation and a crop/livestock operation, the auditor observed that the inspector did not fully verify the operation's compliance with the USDA organic regulations, in the following manner:

- 1. The inspector did not review labels onsite with the handling operation to verify compliance with \$205.303.
- 2. The inspector did not verify temporary confinement of ruminant livestock to determine when the livestock were withheld from pasture or restricted from outdoor access according to \$205.239.
- 3. The inspector conducted a mass balance of hay based on interviews with the operator instead of actual feed fed records, which does not meet the requirements of $\S 205.103(b)(4)$ and $\S 205.237(d)(2)$.
- 4. The inspector did not verify the operation's method for calculating dry matter demand and dry matter intake, as required per §205.237(d)(4).

Corrective Action: PRO conducted a training for staff and inspectors in April 2023 on The Inspection Process-Doing it the Pro-Cert Way, Crops & Livestock Auditing, Producer Errors & Omission, Processor Errors & Omissions, Mass Balance and Traceability, and What's in a Label and Should it Be There. PRO confirmed that the inspectors from the witness audits attended the April training or received it through PRO's Trakster system in August 2023. PRO plans to require new inspectors take the training through the Trakster system prior to being assigned inspections. PRO updated its Organic System Plan (OSP) Appendix A (Livestock) to ask the operation for its method of calculating dry matter demand in addition to completing the Dry Matter Intake Worksheet. PRO updated its Inspection Checklist Appendix A (Livestock) to prompt the inspector to verify the operation's reasons for withholding outdoor access and the operation's dry matter intake calculations. PRO implemented the updated OSP Appendix A (Livestock) in January 2024 and Inspection Checklist Appendix A (Livestock) in November 2023.

AIA-1189-22 - Accepted. 7 C.F.R. §205.403(d) states, "The inspector must conduct an exit interview with an authorized representative of the operation who is knowledgeable about the inspected operation to confirm the accuracy and completeness of inspection observations and information gathered during the on-site inspection. The inspector must also address the need for any additional information as well as any issues of concern."

Comments: *PRO's inspectors do not consistently conduct exit interviews. During a witness audit, the auditor observed the inspector did not conduct an exit interview at the conclusion of the inspection.*

Corrective Action: PRO submitted evidence that an exit interview was conducted for the operation on the second day of the inspection which was not part of the NOP witness audit. PRO determined the inspector did not conduct an exit interview during the witness audit because the inspection was going to continue on a second day for another standard. PRO conducted training for staff and inspectors in April 2023 on *The Inspection Process-Doing it the Pro-Cert Way* that included the requirements to conduct an exit interview. The training specified that inspectors are to complete separate exit interviews for each standard when different standards are being inspected on separate days. PRO is exploring options within its Intact Platform for inspectors to complete a separate inspection checklist and exit interview for operations that are certified to multiple standards.

AIA-1190-22 - Accepted. 7 C.F.R. §205.403(c)(2) states, "The on-site inspection of an operation must verify: That the information, including the organic production or handling system plan, provided in accordance with §§205.401, 205.406, and 205.200, accurately reflects the practices used or to be used by the applicant for certification or by the certified operation;"

Comments: During the witness audits of handling, wild crop, and crop/livestock inspections, and in reviewing completed inspection reports, the auditors observed that the inspector did not fully verify the accuracy of the operation's organic system plan (OSP), in the following manner:

- 1. At a livestock operation's inspection, the operator stated calves are given access to pasture at 6 months; the operation's OSP says calves are given pasture access at 3 months. The inspector did not identify the discrepancy.
- 2. At a livestock inspection, the inspector did not verify the purchases of bedding material came from the sources described in the operation's OSP.
- 3. At a wild crop inspection, the operator reported they harvest into burlap sacks; the operation's OSP describes harvesting into metal pots. The inspector did not identify the discrepancy.
- 4. During the four inspections observed by the auditors, PRO's inspectors never referred to the operator's OSP to verify it accurately reflects the practices used or to be used by the operation.
- 5. In reviewing inspection reports, the auditors observed multiple instances when the inspector reported the OSP was accurate, when in fact what they were reporting differed from what was described in the operation's OSP.

Corrective Action: PRO conducted training for inspectors in April 2023 on *The Inspection Process-Doing it the Pro-Cert Way, Crops & Livestock Auditing, Producer Errors & Omission, and Processor Errors & Omissions* to address the verification of OSPs. PRO updated its inspection checklists to include additional prompts for inspectors to verify the organic system plan (OSP)accuracy. PRO identified that inspectors were being provided with an operation's OSP update, and that the complete OSP was not in one document, making it difficult for an inspector to access the OSP for verification. PRO updated its *Processor/Handler OSP* and *Producer OSP* which includes a Livestock or Wild Crop appendix as applicable. PRO plans to require that operations complete and updated OSP for inspection. PRO implemented the updated *Producer OSP* and *Producer Inspection Checklist* in November 2023. PRO implemented the updated *Processor/Handler OSP* and *Processor/Handler Inspection Checklist* in January 2024.

AIA-1191-22 - Accepted. 7 C.F.R. §205.670(d) states, "A certifying agent must, on an annual basis, sample and test from a minimum of five percent of the operations it certifies, rounded to the nearest whole number."

Comments: PRO did not meet the requirement to sample and test from 5% of its certified operations annually in 2020 or 2021. The auditor's review of sample collection files found that PRO sampled from 4.3% and 3.3% of its operations in 2020 and 2021, respectively.

Corrective Action: PRO created and implemented the *Directive 1016 Risk Assessment*, *Unannounced and Sampling Requirements* on July 28, 2023, which identified that Certification Managers are responsible for ensuring samples are taken from at least 5% of NOP operations. PRO's Regulatory Affairs Officer will perform monthly monitoring for the number of samples taken. PRO submitted email correspondence demonstrating the Regulatory Affairs Officer was monitoring the number of samples taken during 2023 and following up with Certification Mangers.

AIA-1192-22 - Accepted. 7 C.F.R. §205.504(b)(6) states, "A private or governmental entity seeking accreditation as a certifying agent must submit the following documents and information to demonstrate its expertise in organic production or handling techniques; its ability to fully comply with and implement the organic certification program established in §\$205.100 and 205.101, §\$205.201 through 205.203, §\$205.300 through 205.303, §\$205.400 through 205.406, and §\$205.661 and 205.662; and its ability to comply with the requirements for accreditation set forth in \$205.501: A copy of the procedures to be used for sampling and residue testing pursuant to §205.670."

Comments: PRO's policies and procedures do not meet the requirements of accreditation as set forth in § 205.501, and as outlined in NOP 2613 Responding to Results from Pesticide Residue Testing and NOP 2610 Sampling Procedures for Residue Testing. The auditors' review of PRO's quality management system and practices observed during witness audits found that PRO does not have procedures for responding to results from pesticide residue testing.

Corrective Action: PRO developed *Directive 4001 NOP – Follow-up to Pesticide Residue Testing* which instructs PRO's Certification Manager to follow the procedure in NOP 2613 when reviewing sampling results. PRO issued a memo to all Inspectors on July 28, 2023, instructing them to always carry sampling kits in order to take samples if a concern is observed at an inspection. PRO also instructed inspectors to contact the PRO Certification Manager (or back-up) while on-site for the inspection to obtain verbal confirmation the sample may be taken and to obtain additional sampling instructions.

AIA-1193-22 - Accepted. 7 C.F.R. §205.663 states, "Any dispute with respect to denial of certification or proposed suspension or revocation of certification under this part may be mediated at the request of the applicant for certification or certified operation and with acceptance by the certifying agent. Mediation shall be requested in writing to the applicable certifying agent. If the certifying agent rejects the request for mediation, the certifying agent shall provide written notification to the applicant for certification or certified operation. The written notification shall advise the applicant for certification or certified operation of the right to request an appeal, pursuant to §205.681, within 30 days of the date of the written notification of rejection of the request for mediation. If mediation is accepted by the certifying agent, such mediation shall be conducted by a qualified mediator mutually agreed upon by the parties to the mediation. If a State organic program is in effect, the mediation procedures established in the State organic program, as approved by the Secretary, will be followed. The parties to the mediation shall have no more than 30 days to reach an agreement following a mediation session. If mediation is unsuccessful, the applicant for certification

or certified operation shall have 30 days from termination of mediation to appeal the certifying agent's decision pursuant to §205.681. Any agreement reached during or as a result of the mediation process shall be in compliance with the Act and the regulations in this part. The Secretary may review any mediated agreement for conformity to the Act and the regulations in this part and may reject any agreement or provision not in conformance with the Act or the regulations in this part."

Comments: PRO's settlement agreements do not comply with the requirements of the USDA organic regulations. The auditor's review of settlement agreements established by PRO found some terms of the settlement agreements do not include a defined period of time for the terms to be completed.

Corrective Action: PRO Certification Managers and Coordinators involved in writing or reviewing settlement agreements completed the OILC Training "NOP-200: Advanced Compliance and Enforcement Topics" as of October 2023. PRO issued a memo to staff on July 28, 2023, regarding the OILC training requirement and included a reminder that settlement agreement terms need to have a defined period of time to be completed.

AIA-1194-22 - Accepted. 7 C.F.R. §205.501(a)(7) states, "A private or governmental entity accredited as a certifying agent under this subpart must: have an annual program review of its certification activities conducted by the certifying agent's staff, an outside auditor, or a consultant who has expertise to conduct such reviews and implement measures to correct any noncompliances with the Act and the regulations in this part that are identified in the evaluation."

Comments: PRO's annual program review does not evaluate all NOP certification activities per the requirements of the USDA organic regulations and **NOP 2025 Instruction Internal Program Review**. The auditors reviewed PRO's 2021 Internal Audit Checklist and determined that the checklist does not address all certification activities specific to the USDA organic regulations. The checklist predominantly focuses on the requirements of the ISO 17065 standard.

Corrective Action: PRO developed the *Directive 1014 Internal Quality Assurance Audit Procedure* that requires a separate annual program review (internal audit) to assess compliance with the USDA organic regulations. PRO conducted an internal audit in May 2023 for the USDA NOP program with an audit checklist that includes all USDA organic certification activities.

AIA-1195-22 - Accepted. 7 C.F.R. §205.501(a)(6) states, "A private or governmental entity accredited as a certifying agent under this subpart must: Conduct an annual performance evaluation of all persons who review applications for certification, perform on-site inspections, review certification documents, evaluate qualifications for certification, make recommendations concerning certification, or make certification decisions and implement measures to correct any deficiencies in certification services."

Comments: PRO is not carrying out regular inspector field evaluations according to its policy, which says field evaluations are to occur once every three years. The auditors reviewed personnel files and interviewed staff and found two instances where the inspector's last field evaluation occurred prior to 2018.

Corrective Action: PRO developed a new Directive 1017 Inspector Field Mentoring in July 2023 instructing PRO certification managers to identify inspectors for field evaluations in the 4th quarter of the year preceding the evaluation year. PRO instructed managers to approve the inspector evaluation plan and monitor the completion of field evaluations quarterly. PRO identified that the two inspectors had received a field evaluation in 2021 for organic inspection activities to another standard. PRO's new directive requires separate field evaluations for each standard including the USDA organic

regulation. Additionally, PRO's *QSM Part I Section 4.4.3.1*, requires witness audits conducted by PRO's accreditation bodies to count as a field evaluation and the two inspectors of concern received USDA witness audits in 2022.

AIA-1196-22 - Accepted. 7 C.F.R. §205.501(a)(2) states, "A private or governmental entity accredited as a certifying agent under this subpart must: Demonstrate the ability to fully comply with the requirements for accreditation set forth in this subpart."

Comments: PRO does not fully implement the NOP's international organic trade arrangement policies and procedures, which are outlined in the NOP's International Trade Policies resources. The auditor's review of PRO's import and export policies and procedures found that:

- 1. For USDA organic exports to Taiwan under the equivalence arrangement: PRO issued a TM-11 export certificate in 2021 that did not include the required attestation statement. Also, the PRO TM-11 template for Taiwan equivalence is missing the correct attestation statement.
- 2. The TM-11 export certificate template for USDA organic exports to Japan under the equivalence arrangement includes an incorrect attestation about prohibited substances. PRO's instructions also incorrectly require USDA organic products to comply with certain material requirements that are not part of the U.S.-Japan equivalence arrangement. PRO's inspection checklist section for verifying compliance to the U.S.-Japan equivalence does not include verification for livestock products, which were added to the scope of the arrangement in mid-2020.
- 3. PRO does not consistently issue the certificate of inspection prior to the USDA organic product leaving the U.S. port, as required by the European Union under the equivalence arrangement.

Corrective Action: PRO created a new position of Trade Document Verification Officer that was filled in January 2023. PRO updated its TM-11 for Japan and Taiwan by removing the incorrect prepopulated attestations. PRO updated its inspection checklists to include verification of livestock products under the U.S.-Japan Organic Equivalency Arrangement. On November 17, 2023, PRO issued a memo to staff instructing them not to follow PRO's incorrect *Quality System Manual (QSM) Part I, sec 1.6.6;* instead PRO provided staff with links to the NOP's webpages for Taiwan and Japan trade arrangements. PRO initiated a project to update its QSM by June 30, 2024. PRO updated its *Guide to Organic Equivalency* to correctly include livestock products under the scope of the U.S.-Japan Organic Equivalency Arrangement and the requirement to issue a certificate of inspection prior to USDA organic product leaving the port, as required by the European Union.

AIA-1197-22 - Accepted. 7 C.F.R. §205.501(a)(2) states, "A private or governmental entity accredited as a certifying agent under this subpart must: Demonstrate the ability to fully comply with the requirements for accreditation set forth in this subpart."

Comments: PRO's material review procedures do not demonstrate the ability to fully comply with the requirements of §§ 205.201(a)(2), 205.401(c)(1) and **NOP 3012 Interim Instruction Material Review**. PRO's procedures do not include expectations regarding the depth of material review or provide direction for the evaluation of manufacturing methodologies of ingredients or products.

Corrective Action: PRO provided training on *The Pro-Cert Organic Input Review Program* to all staff and inspectors in April 2023 that included the minimum requirements for evaluating materials. PRO implemented the new *Directive 7001 Depth of Review – Organic Inputs* in July 2023 that includes expectations regarding the depth of material review and requires a full review of the manufacturing process for materials.

AIA-1198-22 - Accepted. 7 C.F.R. §205.501(a)(3) states, "A private or governmental entity accredited as a certifying agent under this subpart must: Carry out the provisions of the Act and the regulations in this part, including the provisions of §§205.402 through 205.406 and §205.670;"

Comments: PRO does not carry out the provisions of the Act and regulations. The auditor's review of certification files found that PRO does not perform a sufficient review of input materials to verify compliance with $\S\S205.105$ and 205.201(a)(2). The following are examples:

- 1. PRO did not review the manufacturing process of an active ingredient in a livestock health care product to determine the nonsynthetic status; the ingredient is available in both synthetic and nonsynthetic forms.
- 2. PRO approved the use of a fertilizer containing synthetic micronutrients but did not identify all the micronutrients in the product that required documentation of a deficiency prior to use.
- 3. PRO approved a humate ingredient in a fertilizer product based on a statement of compliance to Canadian Organic Standards.

Corrective Action: PRO provided training on *The Pro-Cert Organic Input Review Program* to all staff and inspectors in April 2023 that included verifying the complete ingredient list for soil amendments (fertilizers). PRO created the new *Directive 7001 Depth of Review – Organic Inputs* in July 2023 to instruct staff on the process of conducting material reviews; including a full review of the manufacturing process in order to determine the nonsynthetic and synthetic status of materials. PRO determined that the fertilizer containing micronutrients and humate ingredients was not in use by the operation. PRO updated the operation's *Input Master Data List* to identify the correct fertilizer in use. PRO conducted a review of the livestock healthcare product and determined it was compliant based on the decision of another certifier. PRO determined the errors in material review occurred prior to the updates made to its material review program and training provided in 2023.

AIA-1199-22 - Accepted. 7 C.F.R. §205.501(a)(3) states, "A private or governmental entity accredited as a certifying agent under this subpart must: Carry out the provisions of the Act and the regulations in this part, including the provisions of §§205.402 through 205.406 and §205.670;"

Comments: PRO does not carry out the provisions of $\S 205.403(c)(1)$, which states, "the onsite inspection of an operation must verify: The operation's compliance or capability to comply with the Act and the regulations in this part." The auditors' review of PRO policies, procedures, and certification files, along with observations made during witness audits found the following:

- 1. PRO's inspection templates (Checklist & Report) are a combination of USDA organic and Canadian Organic Regime (COR) verification points. Auditors found that PRO inspectors, reviewers and certification decision makers did not understand when to verify an operation's compliance against the NOP organic regulation instead of the COR standard.
- 2. A PRO inspector conducted a mass balance audit exercise using COR product as part of the NOP inspection.

Corrective Action: PRO provided training on *Traceability & Mass Balance* to all staff and inspectors in April 2023 that included the requirement to conduct a traceback and mass balance on NOP organic products. PRO updated its inspection checklists to include verification prompts for the inspector which are common for all standards and additional prompts identified within the checklists as "COR Only" or "NOP Only". PRO implemented the updated *Producer Inspection Checklist* in November 2023 and the updated *Processor/Handler Inspection Checklist* in January 2024. PRO is exploring options within its Intact Platform for inspectors to complete a separate inspection checklist and exit interview for each standard when operations that are certified to multiple standards.



NATIONAL ORGANIC PROGRAM: AUDIT & CORRECTIVE ACTION REPORT

GENERAL INFORMATION

• Certifier Name Pro-Cert Organic Systems (PRO)

• **Physical Address** Box 100A, RR#3, 475 Valley Road, Saskatoon,

Saskatchewan S7K 3J6, CANADA

• Audit Type Mid-Term Assessment

• Auditor(s) & Audit Dates Jessica Walden, Alison Howard 09/14/2020 - 09/18/2020

• Audit Identifier NOP-42-20

CERTIFIER OVERVIEW

Pro Cert Organic Systems (PRO) is a for profit business that was initially accredited as a USDA certifying agent on May 24, 2002, to the scopes of Crops, Wild Crops, Livestock, and Handling. PRO has two certification offices (East and West) to handle certification activities in Canada. The main office is the Western Region office in Saskatoon, Saskatchewan, which is responsible for making policy. Both offices make the final certification decisions in addition to inspection scheduling and reviews. The Eastern Office is located in Cambray, Ontario.

PRO currently certifies 289 operations: 174 crop, 107 livestock, 3 wild crop, and 138 handlers. PRO currently does not certify any grower groups. PRO certifies operations in the United States and Canada. The PRO staff consists of 1 General Manager/ Founder, 1 Assistant Manager who is also acting as a Certification Manger, 2 Regional Certification Managers, 15 Coordinator/ Evaluators (7 of which are Certification Specialists), 9 Administrative Assistants, and 25 Inspectors (21 contract and 4 staff inspectors).

The NOP conducted a desk audit of PRO's certification activities during the period August 14, 2017 to September 18, 2020. The purpose of the audit was to verify PRO's conformance to the USDA organic regulations

NOP DETERMINATION

NOP reviewed the audit results to determine whether PRO's corrective actions adequately addressed previous noncompliances. NOP also reviewed any corrective actions submitted as a result of noncompliances issued from Findings identified during the audit.



Any noncompliance labeled as "Cleared," indicates that the corrective actions for the noncompliance are determined to be implemented and working effectively. Any noncompliance labeled as "Accepted" indicates acceptance of the corrective actions and verification of corrective action implementation will be conducted during the next audit.

Noncompliances from Prior Assessments

AIA-2464-20 - Cleared

AIA-2465-20 - Cleared

AIA-2466-20 - Cleared

AIA-2467-20 - Cleared

AIA-2468-20 - Cleared

AIA-2470-20 - Cleared

AIA-2471-20 - Cleared

AIA-2472-20 - Cleared

AIA-2469-20 - Accepted. (NP7255ADA.NC4) - 7 C.F.R. §205.404(b)(4) states, "The certifying agent must issue a certificate of organic operation which specifies the:...Name, address, and telephone number of the certifying agent."

Comments: Certificates do not include PRO's telephone number.

2019 Corrective Action: On October 26, 2017, PRO updated its system (E-Cert) to add its phone number to the organic certificates that PRO issues. PRO provided an example certificate from June 15, 2018, as evidence that the correction had been implemented.

Verification of Corrective Action: The auditors reviewed organic certificates issued to PRO's operations and found that PRO's telephone number still does not consistently appear on the organic certificates.

2022 Corrective Action: PRO contacted Intact, its database provider, who confirmed a recent software update caused PRO's phone number to be removed from organic certificates. PRO provided the email correspondence from Intact confirming the root cause of the error was corrected. PRO submitted six organic certificates as evidence that the phone number is now consistently displayed.

Noncompliances Identified during the Current Assessment

AIA-2786-20 – **Accepted.** 7 C.F.R. §205.403(c)(2) states, "The on-site inspection of an operation must verify: That the information, including the organic production or handling system plan, provided in accordance with §§205.401, 205.406, and 205.200, accurately reflects the practices used or to be used by the applicant for certification or by the certified operation;"

Comments: PRO's inspectors are not consistently verifying the accuracy of an operation's organic system plan (OSP). The auditor's review of certification files found that inspectors are not verifying the accuracy of the entire OSP because PRO only provides the inspectors with the



OSP updates for the operation, which only reflect practices that have changed from the previous years.

Corrective Action: PRO implemented the use of the Intact database for inspection assignment and completion which gives inspectors access to the operation's full OSP. PRO provided screenshots of the documents that inspectors are able to access and download for their inspections. These documents include the initial complete OSP and the OSP updates.

AIA-2787-20 - Accepted. 7 C.F.R. §205.402(b)(2) states, "The certifying agent shall within a reasonable time: Provide the applicant with a copy of the on-site inspection report, as approved by the certifying agent, for any on-site inspection performed."

Comments: PRO does not consistently provide operations with a copy of their approved inspection report. The auditors review of certification files found that PRO is not providing copies of inspection reports for unannounced inspections.

Corrective Action: PRO modified existing procedures to provide the full inspection report (inspection checklist and report summary) to operations after all inspections, including unannounced inspections. The procedure was submitted to NOP. Additionally, PRO is adjusting its process within its Intact database to automate sending the inspection report to the operations. Automation of the process will be completed by June 15, 2022. A copy of the internal memo that was sent to all staff regarding this change was provided to NOP.

AIA-2788-20 - Accepted. 7 C.F.R. §205.501(a)(4) states, "A private or governmental entity accredited as a certifying agent under this subpart must: Use a sufficient number of adequately trained personnel, including inspectors and certification review personnel, to comply with and implement the organic certification program established under the Act and the regulations in subpart E of this part;"

Comments: PRO does not consistently use adequately trained personnel to comply with and implement its USDA organic certification program. The auditors identified the following issues during interviews with certification staff and the review of documents:

- For one operation, there was no evidence that PRO has verified that a nonorganic ingredient used in a product complies with the National List annotation.
- For three operations, a nonorganic ingredient was approved without evidence that PRO staff verified compliance with GMO, ionizing irradiation, and sewage sludge requirements.
- For one operation, products produced that are only eligible for the "made with organic" claim were listed under the "organic" claim on the organic certificate.
- For one operation, a review of the ingredient panel on the label found that an organic ingredient was not identified as organic.
- For one operation, the flow chart obtained during the inspection indicated the use of a material (nitrogen gas) on the National List; however, the inspector reported that no materials are used during the handling of organic products and PRO review staff did not follow-up with the operator or inspector regarding this discrepancy.
- For one operation, instructions provided to the inspector for an unannounced inspection



were to carry out mass balances as well as traceback exercises; however, no mass balance exercises were carried out by the inspector.

Corrective Action: PRO provided a training webinar to all inspectors and staff members on April 21, 2021, which was recorded to be used as required training for all new staff members and inspectors. The training covered new forms, processes, and obtaining and filing supporting documents for nonorganic ingredients. PRO has inspected all relevant operations the since the NOP assessment in 2020 and is reviewing the operation's files to ensure that all the required documentation is in place. In addition:

- 1. PRO updated Section 5.0 and 6.0 of the Inspector and Evaluator Checklist to include verification of nonorganic ingredients to national list annotations. PRO developed and implemented a new document, 6.4.7.1 Non-Organic Ingredients Affidavit, to collect evidence that nonorganic ingredients used by certified processors meet requirements for non-GMO, irradiation, and sewage sludge. PRO provided the new documents to its processor evaluator team. A copy of the instruction email sent to the processor team was provided to NOP. PRO requested the missing ingredient documentation from the operation audited and verified the ingredient's compliance with the USDA organic regulations on December 18, 2020. PRO submitted the information request and updated documentation to the NOP.
- 2. PRO added an extra checkpoint to its evaluator checklist to ensure that all ingredients have been reviewed for compliance and that the documentation is correctly filed in the client's electronic file, including GMO, ionizing irradiation, and sewage sludge compliance requirements.
- 3. PRO updated the evaluator checklist (Intact Template, section 8.0) to include a question that prompts the evaluator to verify each product's correct organic category listing on the organic certificate in Intact. PRO issued a corrected certificate to one operation listing products under the "made with organic" claim. The certificate with the error was issued on September 3, 2020, and the corrected certificate was reissued on September 15, 2020. PRO provided a copy of both the incorrect and corrected certificates to NOP.
- 4. PRO informed an operation that one of the ingredients listed on their label was not correctly identified as organic and new labels were submitted by the operation. A copy of the email, the updated label, and PRO's label approval were provided to the NOP. PRO conducted training titled "Errors and Omissions" to address the human error that led to the incorrect label approval. An additional training module for label review is being planned for completion by October 2022.
- 5. PRO updated section 6.0 of the Inspector and Evaluator Checklist to require an explanation when inputs identified in the OSP have not been found in-use by the operation during inspection.
- 6. PRO staff participated in the NOP Organic Learning Center training on conducting mass balances at inspections. PRO developed two mass balance worksheets and a traceback worksheet to address the different types of handling operations. One worksheet is used for single-ingredient products or for products that are distributed and brokered and the other is used for processors of multi-ingredient products. The new worksheets were submitted to NOP along with a memo that was sent to all inspection and review staff



- about using the forms. Additional training on the new forms will be provided during the 2022 Annual Inspector Training.
- 7. PRO hired a Regulatory Affairs Officer (RAO) in 2021, who is responsible for leading the internal audits of PRO's certification processes, ensuring that corrective actions are implemented, updating certification forms and procedures, carrying out certification staff trainings, and ensuring the organic equivalency processes are compliant. PRO submitted the RAO job description to the NOP.

AIA-2789-20 - Accepted. 7 C.F.R. §205.501(a)(9) states, "A private or governmental entity accredited as a certifying agent under this subpart must: Maintain all records pursuant to §205.510(b) and make all such records available for inspection and copying during normal business hours..."

Comments: PRO does not consistently maintain all records related to the review and approval of materials used by certified operators. PRO conducts reviews of materials, including nonorganic ingredients used by their certified operators, and maintains a database of approved materials. For several materials reviewed by the auditors, the documentation that supports PRO's determination is not available.

Corrective Action: PRO appointed an Organic Input Review Coordinator who is responsible for developing and managing the input approval process, as of February 1, 2021. An Internal Input Review diagram (Doc# II.8.1.5) that includes instructions for uploading the input material review documents to the database and linking them with an operation file has been developed and distributed to staff members of the Certification and Evaluation Committee. When inputs are reviewed, the approval status together with all the reviewed documentation is stored in the Intact Platform. PRO provided NOP with a copy of the review diagram and screenshots of how this data is captured in Intact.

AIA-2790-20 – **Accepted.** 7 C.F.R. §205.501(a)(2) states, "A private or governmental entity accredited as a certifying agent under this subpart must: Demonstrate the ability to fully comply with the requirements for accreditation set forth in this subpart."

Comments: PRO does not fully implement the NOP's international organic trade arrangement policies and procedures, which are outlined in the NOP's International Trade Policies. The auditors observed the following:

- For products imported under the US EU Equivalency Arrangement, PRO does not have a system in place for verifying whether NOP operations are obtaining NOP import certificates.
- For products exported under the US Korea Equivalency Arrangement, the current version of the NAQS Import Certificate on the NOP website is not being used.
- The requirement to include the US-Canada Organic Equivalency Arrangement attestation on organic certificates has not yet been implemented.

Corrective Action: PRO updated Section 5.0 of the processor checklist to address the requirements of the US-EU equivalency arrangement and verify that all ingredients imported from the EU are accompanied by an NOP Import Certificate. The updated checklist was



provided to NOP. PRO saved the correct NAQS Import Certificate to its trade arrangements document file on October 6, 2020, for staff to use. PRO has not issued any NAQS Import Certificates since the implementation of their corrective actions. The US-Canada Organic Equivalency Arrangement attestation on organic certificates has been implemented on the Organic Production Summary portion of the certification documents issued by PRO. Compliant certificate templates were provided to the NOP. PRO's new Regulatory Affairs Officer will monitor any changes to trade arrangements and keep the trade arrangements folder up to date with program requirements and forms.

AIA-2792-20 – Accepted. 7 C.F.R. §205.663 states, "Any dispute with respect to denial of certification or proposed suspension or revocation of certification under this part may be mediated at the request of the applicant for certification or certified operation and with acceptance by the certifying agent. Mediation shall be requested in writing to the applicable certifying agent... If mediation is unsuccessful, the applicant for certification or certified operation shall have 30 days from termination of mediation to appeal the certifying agent's decision pursuant to § 205.681..."

Comments: PRO does not consistently require its operations to request mediation or file an appeal to resolve a Notice of Proposed Suspension. The auditors' review of certification files found that PRO accepted corrective actions to resolve a Notice of Proposed Suspension and continued to certify the operation.

Corrective Action: PRO's appeal procedure (PC 7.1 Certification Decision Appeal Procedure) was updated in November 2020 to include the NOP mediation and appeals process. This procedure was provided to the NOP. The Notice of Proposed Suspension letter template was updated in October 2021 and now includes a statement advising the operator that they have a right to mediation and to file an appeal. This template was submitted to the NOP. The NOP Noncompliance and Adverse Actions Flow Chart has been distributed to all members of the PRO Certification and Evaluation Committee to remind them of the compliant NOP adverse action process. A copy of this email notification was provided to the NOP with the corrective action. The NOP Noncompliance and Adverse Actions Flow Chart will be included as a new topic for the annual staff and inspector training from 2022 onwards and will also be distributed to staff. PRO will focus on the use of mediation and management of settlement agreements during its Annual 2022 training.

AIA-2793-20 - Accepted. 7 C.F.R. §205.501(a)(2) states, "A private or governmental entity accredited as a certifying agent under this subpart must: Demonstrate the ability to fully comply with the requirements for accreditation set forth in this subpart."

Comments: PRO's Wild Crops organic system plan (OSP) template does not demonstrate that PRO fully complies with the requirements of §205.201(a)(1)-(6) and NOP 5022 Guidance Wild Crop Harvesting. The OSP template does not prompt the wild crop operation to provide the following:

• A list of any rare, threatened, or endangered terrestrial or aquatic plants or animals that occur in the harvest area;



- Training provided to ensure that all collectors harvest crops in accordance with the OSP and in a manner that does not damage the environment; and
- The recordkeeping system that identifies all collectors, documents management and harvest practices, and provides the quantities and dates of wild crops harvested.

Corrective Action: PRO updated the OSP Appendix D Wild Crop Harvesting in February 2021 to include all requirements. The inspector and evaluator checklist for Wild Crops (Doc# 5.4.4D) was updated to include the relevant additional checkpoints. PRO confirmed the amended OSP addendum, and the inspector and evaluator checklist are now in use by wild crop operations and inspectors as of February 2021. Copies of these updated forms were provided to NOP.

AIA-2794-20 - Accepted. 7 C.F.R. §205.501(a)(3) states, "A private or governmental entity accredited as a certifying agent under this subpart must: Carry out the provisions of the Act and the regulations in this part, including the provisions of §\$205.402 through 205.406 and §205.670;"

Comments: PRO does not consistently review organic system plans for completeness and accuracy. The auditors' review of certification files found organic system plans contain unanswered questions or contradictory information. PRO did not request the missing information or follow-up to clarify the contradictory statements.

Corrective Action: PRO conducted a full day training webinar with all inspectors and staff members on April 21, 2021. The training included the requirements for reviewing OSPs for completeness, inspector reporting of discrepancies, and ensuring OSP's accurately reflect the practices carried out by certified operations. The webinar was recorded and is required training for all new staff members and inspectors. A copy of the training PowerPoint was submitted to NOP. In addition, PRO sent out a memo to inspection and review staff notifying them that if discrepancies are found between the OSP and practices carried out by the operation, a notice of noncompliance should be issued to the operation. A copy of the memo sent to inspectors and review staff was provided to the NOP.

AIA-7013-21 – Accepted. 7 C.F.R. §205.404(b)(1) – (4) states, "The certifying agent must issue a certificate of organic operation which specifies the: Name and address of the certified operation; Effective date of certification; Categories of organic operation, including crops, wild crops, livestock, or processed products produced by the certified operation; and Name, address, and telephone number of the certifying agent.;"

Comments: PRO issued certificates that do not comply with the requirements of the USDA organic regulations and are missing elements in NOP Instruction 2603 Organic Certificates. The auditor's review of files found certificates without an operator address; the statement, "Certified to the USDA organic regulations, 7 CFR Part 205"; and the statement "Once certified, a production or handling operation's organic certification continues in effect until surrendered, suspended or revoked."

Corrective Action: PRO updated the NOP Certificate template in August 2021 to contain the phrase "Once certified, a production or handling operation's organic certification continues in effect until surrendered, suspended or revoked". PRO further corrected the NOP Certificate



template in February 2022 to state "Certified to the USDA organic regulations, 7 CFR Part 205". A copy of the current and compliant template, including operator address and all required elements, was provided to NOP and is now in use.



NATIONAL ORGANIC PROGRAM: CORRECTIVE ACTION REPORT

AUDIT AND REVIEW PROCESS

An onsite renewal assessment of the Pro-Cert Organic Systems, Ltd. organic program was conducted September 12, 2017 through October 26, 2017. The National Organic Program (NOP) reviewed the auditor's report to assess Pro-Cert's compliance to the USDA organic regulations. This report provides the results of NOP's assessment and review of corrective actions.

GENERAL INFORMATION

Applicant Name	Pro-Cert Organic Systems, Ltd. (Pro-Cert)
Physical Address	475 Valley Road, Saskatoon, Saskatchewan, S7K3J6, Canada
Mailing Address	Box 100A, RR#3, 475 Valley Road, Saskatoon, Saskatchewan, S7K3J6, Canada
Contact & Title	J. Wallace Hamm, President
E-mail Address	Wallace.hamm@pro-cert.org
Phone Number	(+1) 306-382-1299
Reviewers & Auditors	Karin French and Rebecca Claypool, NOP Reviewers; Nikki Adams and Penny Zuck, On-site Auditors.
Program	USDA National Organic Program (NOP)
Review & Audit Dates	NOP assessment review: February 5, 2019;
	Onsite audit: September 12, 2017 through October 26, 2017
Audit Identifier	NP7255ADA
Action Required	No
Audit & Review Type	Renewal Assessment
Audit Objective	To evaluate the conformance to the audit criteria; and to verify the implementation and effectiveness of PRO's certification
Audit & Determination Criteria	7 CFR Part 205 National Organic Program, Final Rule, as amended
Audit & Review Scope	PRO's certification services in carrying out the audit criteria during the period: June 26, 2014 through October 26, 2017

Pro-Cert is a for-profit business that was initially accredited as a USDA certifying agent on May 24, 2002 to the scopes of Crops, Wild Crops, Livestock, and Handling. Pro-Cert has two certification offices (East and West) to handle certification activities in Canada. The main office is the Western Region office in Saskatoon, Saskatchewan. This office decides policy, makes the final certification decisions in addition to inspection scheduling and reviews. The Eastern Office is located in Cambray, Ontario. This office conducts reviews and inspections, and the Eastern Regional Manager makes final certification decisions.

Pro-cert currently certifies 254 operations; 151 crop, 102 livestock, 1 wild crop, and 100 handlers; of which 83 are processors, 2 are distributors, 15 are trader/brokers (there are no

retailers). Pro-Cert currently does not certify any grower groups. Pro-Cert certifies operations in the United States and Canada. The Pro-Cert staff consists of 1 President/ Founder, 2 Regional Certification Managers, 5 Coordinator/ Evaluators, 5 Administrative Assistant/ Evaluators, 2 Evaluator/ Inspectors, 3 Administrative staff and 27 Inspectors (23 contract and 4 staff inspectors).

Two witness audits were conducted at the time of the on-site renewal audit to the scopes of crops, livestock, and handling/processing. Both witness audits were of annual renewal inspections and were announced. A witness audit was performed at a handler operation of imported grain and another at a dairy cattle and crop operation.

NOP DETERMINATION

The NOP reviewed the onsite audit results to determine whether Pro-Cert corrective actions adequately addressed previous noncompliances. The NOP also reviewed the findings identified during the onsite audit to determine whether noncompliances should be issued to Pro-Cert.

Any noncompliance labeled as "Cleared," indicates that the corrective actions for the noncompliance are determined to be implemented and working effectively. Any noncompliance labeled as "Outstanding" indicates that either the auditor could not verify implementation of the corrective actions or that records reviewed, and audit observations did not demonstrate compliance. Any noncompliance labeled as "Accepted" indicates acceptance of the corrective actions and verification of corrective action implementation will be conducted during the next onsite audit.

Noncompliances from Prior Assessments

NP4174EEA.NC1 – Accepted. 7 C.F.R. §205.501(a)(21) states, "A private or governmental entity accredited as a certifying agent under this subpart must: Comply with, implement, and carry out any other terms and conditions determined by the Administrator to be necessary." NOP §205.500(c)(2) states, "The foreign government authority that accredited the foreign certifying agent acted under an equivalency agreement negotiated between the United States and the foreign government." NOP 2403 states, "When exported to Japan and Taiwan, U.S Department of Agriculture (USDA) organic products must be accompanied by an organic export certificate (TM-11)." The agreement requires the certifier to assign a unique identification number to each export certificate and for all export certificates that were issued under the Taiwan arrangement for processed products and crops have the required statement, "Organic agricultural products and organic processed products, accompanied by this certificate, were produced or processed using zero prohibited substances."

Comments: The review of two TM-11 documents issued in March 2013 did not contain the unique identifier for Pro-Cert Organic Systems Ltd (PRO) provided on the list of Certifying Agents Approved to Issue TM-11 Export Certificates under an Export Arrangement between the USDA and a Foreign Government. Additionally, the certificates did not contain the statement, "Organic agricultural products and organic processed products, accompanied by this certificate, were produced or processed using zero prohibited substances."

2015 Corrective Action: Pro-Cert developed a guidance document (*Instruction: Use of Export Certificates (TM-11) Under Export Arrangements with the USDA NOP (Doc #1501)*) that outlines the procedures for the completion of the Export Certificate Document. Pro-Cert distributed the document and conducted training with its staff in February 2015. Pro-Cert has now assigned responsibility for the completion of the certificates to the Certification Coordinators and their Administrative Assistants; a review of the certificates by the Certification Manager is required before final signature.

Pro-Cert has also updated its electronic document control system, Pro-Cert System Documents, to include a file for "International Trade Documents." This file includes additional sub-files for each foreign government that maintains an export arrangement with the USDA for organic produce and products. The Japan and Taiwan sub-files have been updated to include a revised Export Certificate template specific to the requirements of each export arrangement. The sub-files have also been updated to include copies of the new Instruction document (*Doc #1501*). Pro-Cert designated a format for certificate numbers issued to Export Certificates and included the required Certifier Code and Country Code on the templates for Japan and Taiwan. The templates for both Japan and Taiwan were also updated to include the language required by the TM-11 documents. Pro-Cert provided copies of the updated documents to the NOP.

2017 Verification of Corrective Action: The auditor verified the use of the Pro-Cert guidance for issuing TM-11's for exported products to Japan and Taiwan and the document control system, including international trade documents for each foreign government trade arrangement. All TM-11s issued by Pro-Cert since the last audit included the unique identifier for Pro-Cert (PRO). One of the four TM-11s issued by Pro-Cert was to Taiwan, and it was issued without the required compliance statement.

2019 Corrective Action: Pro-Cert provided a record to demonstrate that on April 4th, 2019, Pro-Cert emailed a reminder to the staff who issue TM-11s to follow Pro-Cert Instruction Doc # 1501. Pro-Cert stated that it has issued only one TM-11 since the October 26, 2017 NOP Audit; Pro-Cert included a copy of this TM-11 as evidence of compliance with the TM-11 requirements.

Noncompliances Identified during the Current Assessment

NP7255ADA.NC1 - 7 C.F.R. §205.403(c)(1-2) states, "The on-site inspection of an operation must verify: The operation's compliance or capability to comply with the Act and the regulations of this part;... That the information, including the organic production or handling system plan, provided in accordance with §§205.401, 205.406, and 205.200, accurately reflects the practices used or to be used by the applicant for certification or by the certified operation." NOP 2601, section 3.4 states, "The inspection includes, but is not limited to:...Reconciliation of the volume of organic products produced or received with the amount of organic products shipped, handled and/or sold, also known as trace-back audits or in-out balances;..."

Comments: The following activities were not performed by the inspector during one of the witness audits:

- Mass balance and trace back activities.
- Verification of no prohibited livestock materials used by the operation by reviewing livestock health care records.
- Inspection of storage area where crop inputs were stored.

• The inspector did not identify an issue of concern for livestock standing in manure and mud in the open barn area without clean, dry bedding.

Corrective Action: Pro-Cert provided a record to demonstrate that on January 18, 2018, Pro-Cert notified the inspector from the witness audit that he must perform the inspection activities described in NP7255ADA.NC1. Pro-Cert also provided a record to demonstrate that on January 24, 2018, Pro-Cert had a different inspector conduct an unannounced inspection of the operation to cover issues missed during the witness audit. Pro-Cert submitted training records to demonstrate that during its annual training in April 2018, Pro-Cert trained inspectors on verification activities that must be conducted during the inspection. Pro-Cert used the NOP interactive training videos, "The Path to Sound and Sensible Organic Inspections" and "The Investigation: Trail of Evidence," in its training.

NP7255ADA.NC2 - 7 C.F.R. §205.403(e)(1) states, "At the time of the inspection, the inspector shall provide the operation's authorized representative with a receipt for any samples taken by the inspector."

Comments: During one of the witness audits, the inspector did not provide the operator with a receipt for the sample collected during the inspection.

Corrective Action: Pro-Cert provided a record to demonstrate that on November 21, 2017, Pro-Cert emailed the inspector from the witness audit to notify him that he must issue a receipt before leaving the farm. Pro-Cert submitted training records to demonstrate that during its annual training in April 2018, Pro-Cert trained inspectors on the sample collection procedure, including the requirement to provide receipts to operators.

NP7255ADA.NC3 - 7 C.F.R. §205.670(e) states, "Sample collection pursuant to paragraphs (b) and (c) of this section must be performed by an inspector representing the Administrator, applicable State organic program's governing State official, or certifying agent. Sample integrity must be maintained throughout the chain of custody, and residue testing must be performed in an accredited laboratory..." NOP 2610 Section 4.5 states, "The chain of custody ensures the chronological possession of samples from the sample collector to the shipping carrier to the laboratory. Each sample shall be packed by the sample collector using precautions to prevent sample contamination from commingling or contact with prohibited substances. Samples of fresh commodities must be taken using gloved hands (latex or clean rubber gloves) and removed from the plant or storage bins using a clean utensil."

Comments: The auditor witnessed the following issues which occurred during sample collection at a witness audit:

- *The operator collected the sample instead of the inspector.*
- The operator did not use gloves or a clean utensil to collect the sample from the storage tote.

Corrective Action: Pro-Cert provided a record to demonstrate that on November 21, 2017, Pro-Cert notified the inspector from the witness audit that the inspector must be the one to collect samples and the sample must be collected using gloves. Pro-Cert submitted training records to demonstrate that during its annual training in April 2018, Pro-Cert trained inspectors on the sample collection procedure, which requires the use of nitrile gloves and specifies that the inspector must be the one to collect the sample.

NP7255ADA.NC4 – 7 C.F.R. §205.404(b)(4) states, "The certifying agent must issue a certificate of organic operation which specifies the:...Name, address, and telephone number of the certifying agent."

Comments: *Certificates do not include Pro-Cert's telephone number.*

Corrective Action: On October 26, 2017, Pro-Cert updated its system (E-Cert) to add its phone number to the organic certificates that Pro-Cert issues. Pro-Cert provided an example certificate from June 15, 2018 as evidence that the correction had been implemented.

NP7255ADA.NC5 – 7 C.F.R. §205.662(a)(3) states, "When an inspection, review, or investigation of a certified operation by a certifying agent or a State organic program's governing State official reveals any noncompliance with the Act or regulations in this part, a written notification of noncompliance shall be sent to the certified operation. Such notification shall provide: ... the date by which the certified operation must rebut or correct each noncompliance and submit supporting documentation of each such correction when correction is possible."

Comments: The Notices of Noncompliance reviewed do not include the options to rebut or correct each noncompliance. The notices require the operation to submit a "written response" within 30 days.

Corrective Action: Pro-Cert revised its notice of noncompliance templates to include the options to rebut or correct noncompliances. Pro-Cert also instructed its E-Cert administrator to update all NOP Notice of Non-Compliances templates. Pro-Cert provided a copy of the revised notice of noncompliance template as evidence of the correction.

NP7255ADA.NC6 – 7 C.F.R. §205.501(a)(21) states, "A private or governmental entity accredited as a certifying agent under this subpart must:...Comply with, implement, and carry out any other terms and conditions determined by the Administrator to be necessary." NOP 2609, "Unannounced Inspections," Section 4.1.9 states, "An unannounced inspection should not include prior notification of the inspector's arrival. However, there may be special cases where extenuating circumstances make it impossible (e.g. biosecurity issues). In such cases, the certifying agent may notify the operation up to (4) hours prior to the inspector arriving on-site to ensure that appropriate representatives are present."

Comments: Pro-Cert's unannounced inspections procedure in Quality Manual part 2, section 9.4 states no more than 24-hours notice may be given to the operation for unannounced inspection.

Corrective Action: Pro-Cert determined that unannounced inspections procedure in Quality System Manual Part II applied to the Canada Organic Regime rather than NOP. Pro-Cert updated the quality manual to state that for NOP unannounced inspections, Pro-Cert will not give any advance notice to the operator. Pro-Cert provided records to demonstrate that the change had been incorporated in the quality manual.

NP7255ADA.NC7 - 7 C.F.R. §205.504(a)(1) states, "A private or governmental entity seeking accreditation as a certifying agent must submit the following documents and information to demonstrate its expertise in organic production or handling techniques;...A copy of the applicant's policies and procedures for training, evaluating, and supervising personnel;..." NOP

2027, "Personnel Performance Evaluation," Section 3.2b states, "Each inspector should be subject to a regular field evaluation. The field evaluation system should be developed using best practices, such as a risk-based approach (i.e., inspector experience, annual number of inspections, work product assessment, etc.) or another approach sufficient to determine inspector competency. Inspectors who have demonstrated full competency may be field evaluated less regularly but still require an annual performance evaluation."

Comments: The Pro-Cert Quality Manual Part 1, Version 15 includes policies and procedures for training and evaluating of personnel, however, it does not include field evaluations for inspectors. Field evaluations are being conducted, but there is no written policy or procedure indicating the field evaluation system being followed.

Corrective Action: Pro-Cert amended its Quality System Manual Part I Section 4.4.3.1. to include the following: "All inspectors must undergo a periodic Field Evaluation. This Field Evaluation (also referred to as mentoring) must be conducted at least once every 3 years or every 300 inspections conducted, whichever comes first. Field Evaluations shall be conducted by competent persons as determined by Pro-Cert. Witness Audits conducted by Pro-Cert accreditors must also count as a Field Evaluation. The frequency of Field Evaluations may be higher for new inspectors." Pro-Cert provided records to demonstrate that the change had been incorporated in the quality manual.



NATIONAL ORGANIC PROGRAM: CORRECTIVE ACTION REPORT

AUDIT AND REVIEW PROCESS

The National Organic Program (NOP) conducted a mid-term assessment of Pro-Cert Organic Systems, Ltd. An onsite audit was conducted, and the audit report reviewed to determine Pro-Cert's capability to continue operating as a USDA accredited certifier.

GENERAL INFORMATION

Applicant Name	Pro-Cert Organic Systems, Ltd. (Pro-Cert)
Physical Address	475 Valley Road, Saskatoon, Saskatchewan, S7K3J6, Canada
Mailing Address	Same
Contact & Title	J. Wallace Hamm, President
E-mail Address	Byron.Hamm@pro-cert.org
Phone Number	306-382-1299
Reviewer & Auditor	Janna Howley, NOP Reviewer
	Rick Skinner, On-site Auditor
Program	USDA National Organic Program (NOP)
Review & Audit Dates	NOP assessment review: February 27, 2015
	Onsite audit: June 24-26, 2014
Audit Identifier	NP4174EEA
Action Required	None
Audit & Review Type	Mid-Term Assessment
Audit Objective	To evaluate the conformance to the audit criteria; and to verify the
	implementation and effectiveness of Pro-Cert's certification
	system.
Audit & Determination	7 CFR Part 205, National Organic Program as amended
Criteria	
Audit & Review Scope	Pro-Cert's certification services in carrying out the audit criteria
	during the period: September 5, 2012 through June 26, 2014.

Pro-Cert Organic Systems, Ltd. (Pro-Cert) is a for-profit organization, initially accredited as a certifying agent as OCPP/Pro-Cert Canada, Inc. (OCPP) on May 24, 2002 to the USDA National Organic Program (NOP) for the scopes of crop, livestock, wild crop, and handling. In 2013, Pro-Cert had 159 clients certified to the NOP, including 122 crop, 97 livestock, 1 wild crop, and 35 handling operations. Pro-Cert no longer certifies grower groups under the NOP. Pro-Cert NOP clients are certified in the United States.

Pro-Cert has two offices from which certification activities are conducted. The main office is in Saskatoon, Saskatchewan, and a subsidiary office is located in Cambray, Ontario. Pro-Cert staff consists of a General Manager, 2 Certification Managers, 2 Processor Certification Coordinators,

2 Producer Certification Coordinators, 13 Certification/Evaluation Committee members, and 8 staff and 6 contract inspectors. The Saskatoon office was the location of this assessment; however, certification files from both locations were assessed.

NOP DETERMINATION:

NOP reviewed the onsite audit results to determine whether Pro-Cert's corrective actions adequately addressed previous noncompliances. NOP also reviewed any corrective actions submitted as a result of noncompliances issued from Findings identified during the onsite audit.

Non-compliances from Prior Assessments

Any noncompliance labeled as "Cleared," indicates that the corrective actions for the noncompliance are determined to be implemented and working effectively. Any noncompliance labeled as "Outstanding" indicates that either the auditor could not verify implementation of the corrective actions or that records reviewed and audit observations did not demonstrate compliance.

NP2226OOA.NC1 – Cleared NP2226OOA.NC2 – Cleared

Non-compliances Identified during the Current Assessment

Any noncompliance labeled as "**Accepted**," indicates that the corrective actions for the noncompliance are accepted by the NOP and will be verified for implementation and effectiveness during the next onsite audit.

NP4174EEA.NC1 – Accepted. 7 CFR §205.501(a)(21) states, "A private or governmental entity accredited as a certifying agent under this subpart must: Comply with, implement, and carry out any other terms and conditions determined by the Administrator to be necessary." NOP §205.500(c)(2) states, "The foreign government authority that accredited the foreign certifying agent acted under an equivalency agreement negotiated between the United States and the foreign government." NOP 2403 states, "When exported to Japan and Taiwan, U.S Department of Agriculture (USDA) organic products must be accompanied by an organic export certificate (TM-11)." The agreement requires the certifier to assign a unique identification number to each export certificate and for all export certificates that were issued under the Taiwan arrangement for processed products and crops have the required statement, "Organic agricultural products and organic processed products, accompanied by this certificate, were produced or processed using zero prohibited substances."

Comments: The review of two TM-11 documents issued in March 2013 did not contain the unique identifier for Pro-Cert Organic Systems Ltd (PRO) provided on the list of Certifying Agents Approved to Issue TM-11 Export Certificates under an Export Arrangement between the USDA and a Foreign Government. Additionally, the certificates did not contain the statement, "Organic agricultural products and organic processed products, accompanied by this certificate, were produced or processed using zero prohibited substances."

Corrective Action: Pro-Cert developed a guidance document (*Instruction: Use of Export Certificates (TM-11) Under Export Arrangements with the USDA NOP (Doc #1501)*) that outlines the procedures for the completion of the Export Certificate Document. Pro-Cert distributed the document and conducted training with its staff in February 2015. Pro-Cert has now assigned responsibility for the completion of the certificates to the Certification Coordinators and their Administrative Assistants; a review of the certificates by the Certification Manager is required before final signature.

Pro-Cert has also updated its electronic document control system, Pro-Cert System Documents, to include a file for "International Trade Documents." This file includes additional sub-files for each foreign government that maintains an export arrangement with the USDA for organic produce and products. The Japan and Taiwan sub-files have been updated to include a revised Export Certificate template specific to the requirements of each export arrangement. The sub-files have also been updated to include copies of the new Instruction document (*Doc #1501*). Pro-Cert designated a format for certificate numbers issued to Export Certificates and included the required Certifier Code and Country Code on the templates for Japan and Taiwan. The templates for both Japan and Taiwan were also updated to include the language required by the TM-11 documents. Pro-Cert provided copies of the updated documents to the NOP.



AUDIT INFORMATION

Applicant Name:	Pro-Cert Organic Systems, Ltd.
Physical Address:	475 Valley Road, Saskatoon, Saskatchewan S7K3J6 Canada
Mailing Address:	Box 100A, RR #3 Saskatoon, Saskatchewan S7K3J6 Canada
Contact & Title:	J. Wallace Hamm, President
E-mail Address:	procertorganic@yahoo.com
Phone Number:	306-382-1299
Auditor(s):	Betsy Rakola
Program:	USDA National Organic Program (NOP)
Audit Date(s):	November 1 – December 18, 2013
Audit Identifier:	NP2226OOA
Action Required:	No
Audit Type:	Corrective action review
Audit Objective:	To verify review and approve corrective actions addressing the non-compliances identified during the August 14-16, 2012 renewal assessment.
Audit Criteria:	7 CFR Part 205, National Organic Program; Final Rule, dated December 21, 2000; as amended.
Audit Scope:	Pro-Cert's May 7 and December 13, 2013 response letter to the renewal assessment non-compliance report.
Location(s) Audited:	Desk

GENERAL INFORMATION

Pro-Cert Organic Systems, Ltd. (Pro-Cert) is a for-profit organization. Pro-Cert was originally accredited as a certifying agent as OCPP/Pro-Cert Canada, Inc. (OCPP) on May 24, 2002 to the USDA National Organic Program (NOP) for crops, livestock, wild crop, and handling operations. Currently, Pro-Cert has 120 clients certified to the NOP that includes 106 crop, 88 livestock, 1 wild crop, and 14 handling operations. Pro-Cert also had one grower group; however during a review of the file it was determined that the operation did not meet the requirements of a grower group (see Findings). The Pro-Cert NOP clients are certified in the United States (CA, CO, IN, IA, ME, NY, OH, OR, PA, and VT). In addition to the USDA NOP, Pro-Cert is also accredited to the European Union Regulations (EC 834 /2007 and EC 889/2008), the Canadian Organic Standards, Quebec Organic Standards, and Japanese Agricultural Standards (JAS/MAFF). Pro-Cert also assists applicants in obtaining Bio-Suisse (Switzerland) certification and certification to the Brazil Regulations and Standards.

AUDIT INFORMATION

During the August 2012 renewal assessment, the corrective actions for the non-compliances identified during the mid-term assessment were found to be implemented and effective. Those non-compliances were cleared. This audit identified two noncompliances. The NOP notified Pro-Cert of these findings in writing on April 12, 2013. Pro-Cert submitted a response to the

NOP on May 7 and December 10, 2013.

FINDINGS

NP9104OOA.NC1 – Cleared NP9104OOA.NC2 – Cleared

NP2226OOA.NC1 – Accepted. NOP §205.404(b)(3) states, "The certifying agent must issue a certificate of organic operation which specifies the: (3) Categories of organic operation, including crops, wild crops, livestock, or processed products produced by the certified operation." *Certificates for 9 of the 10 certification files reviewed contained the type of products that were being certified but did not contain the correct categories of organic operation as defined in this section (crops, wild crops, livestock, or processed products)*. Pro-Cert corrective action: Pro-Cert submitted a revised certificate template, showing the category of certification. Pro-Cert also submitted two examples of certificates issued on March 31, 2013. Both certificates correctly classified the products produced under one of the 4 NOP certification categories. As evidence of preventive actions, Pro-Cert submitted two emails from December 2012 and December 2013 instructing staff to use the new certificate template. The emails identified the following four categories of certification for NOP certificates: crops, livestock, wild crops, and processed products. In 2014, Pro-Cert plans to implement electronic certificate software to further reduce certificate errors.

NP2226OOA.NC2 – Accepted. NOP §205.501(a)(21) states, "A private or governmental entity accredited as a certifying agent under this subpart must: Comply with, implement, and carry out any other terms and conditions determined by the Administrator to be necessary." Review of 1 grower group file showed Pro-Cert is not in compliance with NOP Program Handbook Policy Memo (PM) 11-10, Certification of Grower Groups. Specifically, the evidence showed that the producers in the grower group were not operating under the guidance of the NOSB Recommendation 2002, Criteria for Certification of Grower Groups, Recommendation #1: "The NOSB recommends that, in order to be certified as a grower group, the following conditions must be met: 1) The crops and farming practices of the producers must be uniform and reflect a consistent process or methodology, using the same inputs." Review of the certification file showed 5 growers conducting a variety of production methods, such as dairy, beef cattle, laying hens, and crop and greenhouse production. It is unclear which producer is doing which activity; but it is clear that one, uniform OSP is not used. Pro-Cert management indicated that this operation was classified as a grower group because they used one singular marketing and distribution entity. Though this is a requirement of grower group certification; this type of certification begins with a uniform OSP for all producers. **Pro-Cert corrective action:** In August 2012, Pro-Cert contacted the head of the grower group to state that the NOSB's 2011 memo meant that they did not qualify as a grower group. Pro-Cert requested that each individual group member apply for certification. The responsible party submitted an application for individual certification, and the other four members applied to a different certifying agent. In May 2013, Pro-Cert sent a memo to its staff stating that grower groups must consist of uniform crops and farming practices, using the same inputs. The memo informed staff that all NOP grower group certification must follow the policies outlined in the NOSB policy. Pro-Cert no

longer has any NOP-certified grower groups. According to their policies, any future grower group applications must be evaluated by the certification manager.	