



United States Department of Agriculture

Agricultural Marketing Service
National Organic Program

CERTIFICATE OF ACCREDITATION

PRIMUS AUDITING OPERATIONS

1259 Furukawa Way, Santa Maria, California, 93458, U.S.A.

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 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>

Certificate No: **USDA-41-19**

Effective Date: **8/2/2019**

Renewal Date: **8/2/2024**

Jennifer Tucker, Ph.D.
Deputy Administrator
National Organic Program



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National Organic Program
1400 Independence Avenue, SW.
Room 2642-South, STOP 0268
Washington, DC 20250-0268

NATIONAL ORGANIC PROGRAM: AUDIT & CORRECTIVE ACTION REPORT

GENERAL INFORMATION

- **Certifier Name** Primus Auditing Operations (PAO)
- **Physical Address** 1265 Furukawa Way, Santa Maria, California 93458, U.S.A.
- **Audit Type** Initial Audit
- **Auditor(s) & Audit Dates** Jessica Walden, Sherry Aultman, 06/15/2020 to 06/19/2020
- **Audit Identifier** NOP-32-20

CERTIFIER OVERVIEW

The National Organic Program (NOP) conducted an initial audit of Primus Auditing Operations' (PAO) certification activities during the period July 14, 2018 to June 19, 2020. The purpose of the audit was to verify PAO's conformance to the USDA organic regulations.

PAO is a for-profit corporation and was initially accredited on August 2, 2019. PAO's main office is in Santa Maria, California, with satellite offices in Mexico and Costa Rica. PAO is accredited to the following scopes: crops and handling. Prior to achieving their own accreditation, PAO conducted certification activities for Primus Labs Inc. (PL) under contract since 2015.

PAO certifies 415 operations under the crops (207) and handling (208) scopes. These operations are certified in Colombia, Costa Rica, Mexico, Ecuador, Guatemala, Peru and domestically in Arizona, California, Florida, Georgia, Illinois, Massachusetts, New Jersey, New York, North Carolina, Oregon, Pennsylvania, Rhode Island, South Carolina, Texas, and Wisconsin. Certification services are performed by the five program directors, 12 inspection coordinators, one scheme manager, two quality managers, 22 inspectors, 12 reviewers and one external assessor.

NOP DETERMINATION:

NOP reviewed the audit results to determine whether PAO'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-1292-20 - Cleared

AIA-1293-20 - Cleared

AIA-1295-20 - Cleared

AIA-1296-20 - Cleared

AIA-1297-20 - Cleared

AIA-1298-20 - Cleared

AIA-1299-20 - Cleared

AIA-1300-20 - Cleared

AIA-1302-20 - Cleared

AIA-1303-20 - Cleared

AIA-1291-20 - Accepted. (NP6025PZA.NC9) 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."

Comments: *During file reviews, the auditor found an operation that was providing attestation statements for organic product shipped to Canada under the U.S.-Canada organic equivalency arrangement. However, PL staff told the auditors that no operations conduct international export or import activities. The PL OSP templates do not ask applicants to describe any international activities, nor do inspection report templates instruct the inspectors to verify international activity during inspections. Additionally, PL does not have procedures for inspectors or reviewers to verify that operations comply with the requirements of USDA NOP international arrangements.*

2016 Corrective Action: PL developed a procedure that requires an addendum be sent to all new or renewing clients; the addendum includes questions on international trade activities (import/export). The new procedure also requires the inspector to verify the answers on the addendum at the onsite inspection. For the U.S.-Canada equivalency arrangement, clients who comply with the requirements will have the attestation statement included on their organic certificate. In addition, clients will be given a self-attestation document to complete and issue with each shipment of product. PL also developed a work instruction describing compliant language for the attestation statement. PL verified that training for the certification staff members was conducted in July 2016 on the requirements for product traded under the U.S.-Canada Equivalency Arrangement.

2017 Verification of Corrective Actions: The auditor verified that the international trade activities addendum is utilized. The addendum does not cover all of the international arrangements and does not indicate other arrangements may apply. PL's checklist does not

require the inspector to verify any other arrangements except the US-Canada and the US-EU equivalency.

2017 Corrective Action: PL updated their Crop and Handling OSPs to include a section for operations to describe their international import and exporting activities. If operators are conducting import/export activities, then they are required to complete PL's International Markets OSP Addendum. PL updated the International Markets OSP Addendum to include all of the export agreements and inquire about imported products.

Inspectors are sent the operator's OSP, International Markets OSP Addendum, and a Review Report of the OSP with instructions from the reviewer to verify import/export activity. PL trained staff on the changes to the documents and the requirements of the NOP International Trade Agreements on October 14, 2017.

2018 Verification of Corrective Action: This corrective action is not completely implemented. (1) An updated Organic System Plan (OSP) template was implemented April 3, 2018. The OSP template instructs operators to indicate whether products and/or ingredients are imported or exported and instructs operators to complete an addendum describing trade activity details. The OSP addendum template was implemented June 13, 2018. (2) The inspection report template has not been updated with a section for inspectors to record verification of import and/or export activities. (3) No procedures or work instructions have been developed to guide certification personnel through the requirements of reviewing and verifying imported and exported products and/or ingredients.

2019 Corrective Action: PAO updated its crop and handling inspection checklists to include a section for inspectors to record verification of import and/or export activities and compliance with organic trade arrangements. PAO also created a work instruction "International Markets Addendum Information Guide" that instructs staff on what information should be covered in an OSP review in cases where operations are importing or exporting to equivalency countries.

2020 Verification of Corrective Action: The auditors verified that PAO implemented the use of the crop and handling inspection checklist and work instruction described in the 2019 corrective actions. However, the auditors' review of operation files with exported and imported products found that the international sections on the organic system plans (OSPs) and the inspection checklists are inconsistently completed by the operations and inspectors; therefore, there is no evidence that inspectors are verifying that operations comply with the requirements of USDA NOP international trade arrangements.

2022 Corrective Action: PAO held a training in July 2021 and August 2022 for inspectors and reviewers that addressed this topic. PAO reminded inspectors to verify that operations who import or export organic products have completed the international addendum. PAO submitted to the NOP attendance records and training materials for the trainings. PAO sent an email memo in July 2022 to inspectors and reviewers reminding inspectors to complete the ORG-058 International Equivalencies Checklist during inspections of operations that import and/or export organic products. This memo also reminded reviewers to verify that inspectors are completing this form and, if not, to notify the QA department. PAO submitted to the NOP a copy of the memo, and an example of a completed International Equivalencies Checklist, international addendum, and the documented review of an operation requesting to export organic products under an equivalency arrangement.

AIA-1294-20 - Accepted. (NOP-83-17.NC2) 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: *PAO inspectors are not consistently conducting or recording in-out balance and trace-back audits as a part of onsite inspections. During the witness audit of a crops operation, the inspector did not conduct an in-out balance or trace-back audit. Additionally, a review of previous inspection reports revealed no evidence that in-out balance and trace-back audits were conducted.*

2019 Corrective Action: PAO issued a notice to all inspectors and reviewers on March 1, 2019 clarifying the policy that in-out balance and traceability exercises should be conducted at all inspections. PAO developed a guidance for reviewers (Org-R008) to instruct them on how to verify that the exercises were conducted properly. PAO updated the mass-balance sections on inspection checklists to make the requirements clearer for inspectors. PAO also added sections to the crops and handling OSP templates that explain to the producer that all documentation must be kept and available for the inspector to complete successful mass-balance and traceability exercises. This will help ensure that operations are ready with the information that inspectors need and alleviate the time pressure for these activities during inspections.

2020 Verification of Corrective Action: The auditors reviewed the notice sent to inspectors on March 1, 2019, the guidance for reviewers (Org R008), and inspection report templates for both crops and handling operations. The documents provide accurate and clear guidance to inspectors and reviewers. However, the auditors’ review of certification files found that inspectors are inconsistently and inaccurately completing mass balance and traceback exercises.

2022 Corrective Action: PAO held a training in July 2021 and August 2022 for inspectors and reviewers that addressed how to complete traceback and mass balance exercises at inspection. Additionally, PAO reminded reviewers to verify that these sections of the inspection report are completed. PAO developed, and submitted to the NOP, the Org-056 R0 Mass Balance and Traceability Form, which is a guide to carrying out these exercises during inspections. PAO submitted to the NOP the attendance records and training material for the 2021 and 2022 trainings.

AIA-1301-20 - Accepted. (NOP-83-17.NC9) 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: *In the case of the unannounced inspection where the operator refused to complete the full inspection, PAO did not issue an unannounced inspection report to the operation.*

2019 Corrective Action: PAO conducted a staff training on March 7, 2019 on audit reports and unannounced inspections. The training instructed staff that an inspection report must always be provided to the operation regardless of whether the inspector was able to do a complete inspection. PAO also develop a template for letters that will be issued to operations following unannounced inspections with the inspection report as an attachment.

2020 Verification of Corrective Action: The auditors reviewed unannounced inspection files and found that PAO did not provide two operations with copies of the inspection reports.

2022 Corrective Action: PAO developed a Master Tracking Log, which verifies that inspection reports are provided to operations following all unannounced inspections. PAO submitted to the NOP a screenshot of the Master Tracking Log, which logs the inspected operation and verification that the inspection report and Org-T025 Unannounced Certification Resolution Letter has been sent to the operation. On December 1, 2022, PAO conducted a training for QA staff as a refresher on the Master Tracking Log. The training included a

reminder that an unannounced inspection report is to accompany Org-T025. PAO provided the NOP with the training attendance sheet.

Noncompliances Identified during the Current Assessment

AIA-1822-20 - Accepted. 7 C.F.R. §205.670(c) states, "A certifying agent must conduct periodic residue testing of agricultural products to be sold, labeled, or represented as "100 percent organic," "organic," or "made with organic (specified ingredients or food group(s))." Samples may include the collection and testing of soil; water; waste; seeds; plant tissue; and plant, animal, and processed products samples. Such tests must be conducted by the certifying agent at the certifying agent's own expense."

Comments: *PAO does not fully carry out the procedures of NOP 2613 Instruction Responding to Results from Pesticide Residue Testing. The auditors' review of pesticide residue analysis reports and a combined notice of noncompliance and denial of certification identified the following:*

- 1. PAO did not send a notification of the residue test results and indication that the product may be sold as organic since no prohibited pesticide residues were detected.*
- 2. PAO did not follow the appropriate instructions for determining EPA tolerances for pesticide residue samples. In one case, PAO used a positive soil sample as the evidence for issuing a notice of denial on the grounds that the crop exceeded the EPA tolerance. In another case, a foliage sample instead of the edible product was tested revealing the presence of a permitted pest control material. PAO mistakenly determined that the edible portion of the crop exceeded the EPA tolerance.*

Corrective Action: PAO submitted to the NOP a "Review Report" checklist that reviewers use when evaluating pesticide residue results. The form addresses the specific questions related to the requirements of NOP 2613, including clarifying that EPA tolerances apply to the edible portion of a crop or product, not to soil or other plant material. PAO also created and submitted to the NOP a letter template that staff use to communicate the residue test results to operations. The letter template includes specific instructions to certification staff who amend the letter according to the type of sample and result. The letter template addresses the requirements of NOP 2613, including when to notify the operation that they may sell their product as organic. PAO management reviews the final letter to ensure it is accurate prior to sending it to the operation. On December 1, 2022, PAO conducted a training for QA staff, which included a segment on NOP 2613. PAO provided the NOP with the training attendance sheet. PAO will send a memo detailing the updates and implementation of the updated section within the "Review Report" document to all technical reviewers and inspectors by December 15, 2022.

AIA-1823-20 - 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: *PAO does not consistently demonstrate the ability to fully comply with the requirements of accreditation. Specifically, PAO is not consistently executing certification processes in a timely manner. The auditors' review of files and interviews with certification staff found the following issues:*

- 1. During an unannounced inspection, the inspector found that the certified operation was no longer operating out of the premises listed on the certificate and had gone bankrupt. Five months later, PAO issued a notice of noncompliance to the company for failing to renew their organic certification.*

2. PAO issued a notice of suspension more than two months after the proposed effective date of suspension identified in the notice of proposed suspension.
3. PAO issued a combined notice of noncompliance and proposed suspension to an operation five months after the inspection revealed noncompliant practices.
4. PAO issued two operators notices of noncompliance more than six months after the operations failed to submit an annual update and pay certification fees.

Corrective Action: PAO implemented the use of an electronic program that logs each inspection, review, notification, and tracks them in the system via a due date. The electronic program sends alerts to PAO staff when deadlines are surpassed, triggering action by PAO to follow up with. PAO trained staff on the use of this program on April 22, 2022. PAO submitted to the NOP a detailed description of how the electronic system works as well as a copy of the training log.

AIA-1830-20 - Accepted. 7 C.F.R. §205.403(a)(1) states, “A certifying agent must conduct an initial on-site inspection of each production unit, facility, and site that produces or handles organic products and that is included in an operation for which certification is requested. An on-site inspection shall be conducted annually thereafter for each certified operation that produces or handles organic products for the purpose of determining whether to approve the request for certification or whether the certification of the operation should continue.”

Comments: PAO did not conduct annual on-site inspections of all its certified operations in 2018 and 2019. The auditors identified two operations that did not receive annual inspections. PAO stated this was because they either failed to timely submit an annual update or were involved in a complaint investigation.

Corrective Action: PAO implemented a new process and the use of an electronic tracking system. PAO sends out an anniversary reminder email to operations one month before their anniversary date. At the beginning of each month, QA staff receive a list of operations that failed to meet their annual update deadline. QA staff then generate and issue notices of noncompliance and track the notification process using the implemented electronic system. Additionally, PAO’s corrective action response clarified that the operation involved in the complaint investigation would not schedule an annual inspection. In response, PAO carried out an unannounced inspection instead of issuing the operation a notice of noncompliance. PAO’s new tracking system also alerts staff when inspections have not been scheduled by the deadline. QA staff generate notices of noncompliance if the operation does not allow for the timely scheduling of an inspection. If the operation does not sufficiently respond to the notice of noncompliance, PAO begins the adverse action process. PAO provided screenshots of the electronic tracking system to the NOP.

AIA-1831-20 - 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: PAO’s *Quality Manual and templates do not demonstrate that PAO has the ability to fully comply with the requirements of the adverse action process in the following manner:*

1. *The Quality Manual, Section D Notice of proposed suspension/revocation incorrectly states, “Once Audit Admin receives client’s reply to the NoPS, then Audit Admin will forward the complete file with corrective actions to the reviewer for approval.” Corrective Actions cannot resolve a Notice of Proposed Suspension according to §205.662(c).*
2. *The Notice of Proposed Suspension and Combined Notice of Noncompliance and Proposed Suspension templates incorrectly state, “Finally, please be advised that you may also at any*

time surrender your certification according to §205.404(c) by written notification to Primus Auditing Ops. Note that if you surrender your certification and apply to another certification agency, you will be required to provide this Notice of Noncompliance and Notice of Proposed Suspension and a description of the actions taken to correct the non-compliance(s) with your application as described in §205.401(c).”An operation’s surrender does not resolve a Notice of Proposed Suspension and the adverse action process continues as stated in 205.662(e)(1).

Corrective Action: PAO submitted to the NOP screenshots of the updated Quality Manual, section D, “Notice of Proposed Suspension or Revocation §205.662(c)(d)” that reflects PAO’s adverse action process and the requirements of the USDA organic regulations. PAO also submitted an updated notice of proposed suspension and combined notice of noncompliance and proposed suspension template that now reflect the requirements of the USDA organic regulations. On December 1, 2022, PAO conducted a training for QA staff, which included a segment on quality manual and template updates. PAO provided the NOP with the training attendance sheet.

AIA-1832-20 - 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: *PAO’s organic certificates are missing elements identified in NOP 2603 Organic Certificates. The auditors’ review of certification files found that certificates do not specify the certifier’s address. In addition, certificates do not display the statement, “Certified to the USDA organic regulations, 7 CFR Part 205.”*

Corrective Action: PAO updated its organic certificate template to include the previously missing elements identified in NOP 2603. PAO submitted to the NOP the updated template and examples of two compliant organic certificates issued in May 2022 as evidence that issued certificates include PAO’s address and the correct statement. To ensure there is no reoccurrence of this issue, PAO is now using an electronic system that generates the accurate template. PAO eliminated all previous templates, so they are no longer available for use.

AIA-1833-20 - Accepted. 7 C.F.R. §205.642 states, “Fees charged by a certifying agent must be reasonable, and a certifying agent shall charge applicants for certification and certified production and handling operations only those fees and charges that it has filed with the Administrator. The certifying agent shall provide each applicant with an estimate of the total cost of certification and an estimate of the annual cost of updating the certification. The certifying agent may set the nonrefundable portion of certification fees; however, the nonrefundable fees must be explained in the fee schedule submitted to the Administrator. The fee schedule must explain what fee amounts are nonrefundable and at what stage during the certification process fees become nonrefundable. The certifying agent shall provide all persons inquiring about the application process with a copy of its fee schedule.”

Comments: *PAO does not provide certification applicants its fee schedule. The auditors’ interview with staff responsible for communicating with new applicants and a review of associated email communications confirmed that PAO’s fee schedule is only provided to applicants upon request.*

Corrective Action: PAO created an instructional document for new and renewing operations

that includes a hyperlink to the most current fee schedule. PAO submitted to the NOP a copy of the instructional document and an email from PAO to a new applicant that included the instructional document containing a hyperlink to the fee schedule.

AIA-1834-20 - 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: *PAO's annual program review (APR) does not fully comply with NOP 2025 Instruction Internal Program Review or the USDA organic regulations. The auditors' review of PAO's 2019 APR found the following issues:*

- 1. The APR was conducted by someone directly involved in the following certification activities: drafting Notices of Noncompliance, Notices of Proposed Suspensions, and Settlement Agreements. This does not comply with NOP 2025, which states that the review is to be conducted by personnel different from those who perform certification activities.*
- 2. The APR was not a review of PAO's certification activities. The review focused only on accepted corrective actions for prior noncompliances.*

Corrective Action: PAO created a job description for the APR reviewer position that it uses to determine whether a particular person meets the NOP Requirements for conducting an APR. The job description specifies that the person completing the APR must not be directly involved in certification decisions and that their responsibilities include conducting an APR that complies with all requirements of NOP 2025. Moving forward, PAO's APR will follow the NOP 2005 checklist and include all PAO's certification activities. PAO submitted to the NOP the new job description and the designated annual program reviewer's resume.

AIA-1835-20 - 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... 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: *PAO's settlement agreements do not comply with the requirements of the USDA organic regulations. The auditors' review of settlement agreements established by PAO found the following:*

- 1. The terms of the settlement agreements do not always include actions the operation must take in order to correct the noncompliance that led to the Notice of Proposed Suspension. The terms for operations who failed to submit timely annual updates do not address the root cause of the noncompliance.*
- 2. The settlement agreements include non-finite terms that require ongoing compliance with a USDA organic regulation. PAO settlement agreements do not indicate deadlines allowing for PAO to verify settlement agreement terms for adequate implementation and closure.*

Corrective Action: PAO submitted an updated Settlement Agreement template that instructs certification staff to state terms that include actions the operator must take to correct the

noncompliance that led to the notice of proposed suspension, terms for operations to address the root cause of the noncompliance, and terms that indicate specified timeframes. On December 1, 2022, PAO conducted a training for QA staff, which included the updates made to the Settlement Agreement template. PAO provided the NOP with the training attendance sheet.

NATIONAL ORGANIC PROGRAM: CORRECTIVE ACTION REPORT

AUDIT AND REVIEW PROCESS

National Organic Program (NOP) auditors conducted a pre-decisional on-site assessment of the Primus Auditing Ops (PAO) organic program on July 8 - 14, 2018. The National Organic Program (NOP) reviewed the auditor's report to assess PAO's compliance to the USDA organic regulations. This report provides the results of NOP's assessment.

GENERAL INFORMATION

Applicant Name	JS Auditing Group Inc. d.b.a. Primus Auditing Ops (PAO)
Physical Address	1259 Furukawa Way, Santa Maria, CA 93458
Mailing Address	1259 Furukawa Way, Santa Maria, CA 93458
Contact & Title	Josie Quevedo, NOP Scheme Manager
E-mail Address	JQuevedo@pao-usa.com
Phone Number	501-312-2962
Reviewer(s) & Auditor(s)	Bridget McElroy, NOP Reviewer; Jason Lopez, Lars Crail, On-site Auditors.
Program	USDA National Organic Program (NOP)
Review & Audit Date(s)	NOP assessment review: October 3, 2018 Onsite audit: July 8 – 14, 2018
Audit Identifier	NOP 83-17
Action Required	Yes
Audit & Review Type	Pre-Decisional Assessment
Audit Objective	To evaluate the conformance to the audit criteria; and to verify the implementation and effectiveness of PAO's certification
Audit & Determination Criteria	<i>7 CFR Part 205, National Organic Program as amended.</i>
Audit & Review Scope	PAO's implementation of USDA NOP certification services.

JS Auditing Group Inc. d.b.a. Primus Auditing Ops (PAO) is a for-profit corporation applying for accreditation to the USDA National Organic Program (NOP) for the scopes of crops and handling. PAO has conducted certification activities for Primus Labs Inc. (PL) under contract since 2015.

The PAO NOP certification program provides certification services to 304 operations under the crops (150) and handler (154) scopes. These operations are certified in Colombia, Costa Rica, Mexico, and domestically in Arizona, California, Florida, Georgia, Illinois, Massachusetts, Missouri, New Jersey, New York, North Carolina, Oregon, Pennsylvania, Rhode Island, Texas, and Wisconsin.

PAO's main office is located in Santa Maria, California with satellite offices in Mexico and Costa Rica. Certification services are performed by the 5 program directors, 12 inspection coordinators, 1 scheme manager, 2 quality managers, 20 inspectors, 12 reviewers and an external assessor.

As part of the pre-decisional assessment NOP auditors conducted two witness audits, observing an annual inspection of a crops operation and an initial inspection of a handling operation.

NOP DETERMINATION

The NOP reviewed the onsite audit results to determine whether PAO's corrective actions adequately addressed previous noncompliances. The NOP also reviewed PAO's corrective actions submitted as a result of noncompliances issued from findings identified during the onsite audit.

Noncompliances 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 "**Accepted**" indicates acceptance of the corrective actions and verification of the implementation of those corrective actions will be conducted during the next onsite audit.

NP6025PZA.NC14 – Cleared.

NP7128JZA.NC1 – Cleared.

NP7128JZA.NC3 – Cleared.

NP7128JZA.NC4 – Cleared.

AIA7264RC.NC1 – Cleared.

AP-54-18.NC1 – Cleared.

NOP-69-17.NC1 – Cleared.

NOP-69-17.NC2 – Cleared.

NOP-69-17.NC3 – Cleared.

NOP-69-17.NC4 – Cleared.

NP6025PZA.NC9 – 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."

Comments: *During file reviews, the auditor found an operation that was providing attestation statements for organic product shipped to Canada under the U.S.-Canada organic equivalency arrangement. However, PL staff told the auditors that no operations conduct international export or import activities. The PL OSP templates do not ask applicants to describe any international activities, nor do inspection report templates instruct the inspectors to verify international activity during inspections. Additionally, PL does not have procedures for*

inspectors or reviewers to verify that operations comply with the requirements of USDA NOP international arrangements.

2016 Corrective Action: PL developed a procedure that requires an addendum be sent to all new or renewing clients; the addendum includes questions on international trade activities (import/export). The new procedure also requires the inspector to verify the answers on the addendum at the onsite inspection. For the U.S.-Canada equivalency arrangement, clients who comply with the requirements will have the attestation statement included on their organic certificate. In addition, clients will be given a self-attestation document to complete and issue with each shipment of product. PL also developed a work instruction describing compliant language for the attestation statement. PL verified that training for the certification staff members was conducted in July 2016 on the requirements for product traded under the U.S.-Canada Equivalency Arrangement.

2017 Verification of Corrective Actions: The auditor verified that the international trade activities addendum is utilized. The addendum does not cover all of the international arrangements and does not indicate other arrangements may apply. PL's checklist does not require the inspector to verify any other arrangements except the US-Canada and the US-EU equivalency.

2017 Corrective Action: PL updated their Crop and Handling OSPs to include a section for operations to describe their international import and exporting activities. If operators are conducting import/export activities, then they are required to complete PL's International Markets OSP Addendum. PL updated the International Markets OSP Addendum to include all of the export agreements and inquire about imported products. Inspectors are sent the operator's OSP, International Markets OSP Addendum, and a Review Report of the OSP with instructions from the reviewer to verify import/export activity. PL trained staff on the changes to the documents and the requirements of the NOP International Trade Agreements on October 14, 2017.

Verification of Corrective Action: This corrective action is not completely implemented. (1) An updated Organic System Plan (OSP) template was implemented April 3, 2018. The OSP template instructs operators to indicate whether products and/or ingredients are imported or exported and instructs operators to complete an addendum describing trade activity details. The OSP addendum template was implemented June 13, 2018. (2) The inspection report template has not been updated with a section for inspectors to record verification of import and/or export activities. (3) No procedures or work instructions have been developed to guide certification personnel through the requirements of reviewing and verifying imported and exported products and/or ingredients.

2019 Corrective Action: PAO updated its crop and handling inspection checklists to include a section for inspectors to record verification of import and/or export activities and compliance with organic trade arrangements. PAO also created a work instruction "International Markets Addendum Information Guide" that instructs staff on what information should be covered in an OSP review in cases where operations are importing or exporting to equivalency countries.

NP7128JZA.NC2 – 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: *PL did not sample and test from a minimum of 5% of total 2016 certified operations.*

2017 Corrective Action: PL developed an unannounced sampling procedure (SOP 22-27) stating that PL must sample from 5% of their certified operations annually. PL conducted a training with the staff responsible for scheduling the sample testing inspections on May 2, 2017. PL also set up bi weekly check-ins with Quality Assurance (QA), to ensure the sampling inspections are on schedule for the year. PL submitted the training log and evidence that bi-weekly meetings are on QA’s calendar.

Verification of Corrective Action: PAO has not effectively implemented the corrective action. PAO did not conduct residue sampling and testing of at least 5% of the total amount of certified operations during 2017.

2019 Corrective Action: PAO identified further improvements were necessary for its residue testing tracking system in each country to ensure that the sampling requirement was fulfilled. Previously, QA in the U.S. was responsible for contacting each country’s coordinators to ensure that samples were scheduled. At times, communication was difficult or delayed, particularly when scheduled samples could not be done and alternatives had to be found. Beginning in 2019, each country’s manager is required to report directly to QA on the status during monthly meetings. PAO’s annual sampling list will also now include alternate operations that managers can use in cases where planned sampling can’t take place. PAO conducted sampling of at least 5% of certified operations in 2018 and is on track to meet this requirement in 2019.

Noncompliances Identified during the Current Assessment

NOP-83-17.NC1 – Accepted. – 7 C.F.R. §205.501(a)(8) states, “A private or governmental entity accredited as a certifying agent under this subpart must: Provide sufficient information to persons seeking certification to enable them to comply with the applicable requirements of the Act and the regulations in this part.”

Comments: *PAO’s OSP templates do not require enough information about the operation for the reviewer or inspector to assess and verify compliance with the act and regulations. The OSP does not allow or prompt the operation to describe its activities (i.e. all organic or mixed operation). Additionally, the use of site-specific OSPs has led to operations limiting their activity descriptions to only the specific site and excluding information about parallel/split production activities causing the OSP to be misleading.*

Corrective Action: PAO submitted updated crops and handling OSP templates that now include sections where applicants are required indicate whether they are involved in nonorganic production and to describe any nonorganic production activities and sites.

NOP-83-17.NC2 – 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: *PAO inspectors are not consistently conducting or recording in-out balance and trace-back audits as a part of onsite inspections. During the witness audit of a crops operation, the inspector did not conduct an in-out balance or trace-back audit. Additionally, a review of previous inspection reports revealed no evidence that in-out balance and trace-back audits were conducted.*

Corrective Action: PAO issued a notice to all inspectors and reviewers on March 1, 2019 clarifying the policy that in-out balance and traceability exercises should be conducted at all inspections. PAO developed a guidance for reviewers (Org-R008) to instruct them on how to verify that the exercises were conducted properly. PAO updated the mass-balance sections on inspection checklists to make the requirements clearer for inspectors. PAO also added sections to the crops and handling OSP templates that explain to the producer that all documentation must be kept and available for the inspector to complete successful mass-balance and traceability exercises. This will help ensure that operations are ready with the information that inspectors need and alleviate the time pressure for these activities during inspections.

NOP-83-17.NC3 – Accepted. – 7 C.F.R. §205.406(a)(1) states, “To continue certification, a certified operation must annually pay the certification fees and submit the following information, as applicable, to the certifying agent: An updated organic production or handling system plan ...”

Comments: *The auditor found annual update OSPs to be incomplete and inaccurate. Missing and inaccurate information was found in the following OSP sections: equipment lists, material input lists and annotations, disclosure of parallel production, undisclosed sites, pest control inputs, seed verification records, and procedures for the prevention of comingling.*

Corrective Action: Previously, reviewers did not have adequate guidance to ensure that OSP reviews were being done in a thorough manner. PAO developed and submitted a guidance for reviewers (Org-R008) to use during OSP reviews. The guidance covers every section of the OSP and provides examples of the types of information that PAO expects operators to provide in each section.

NOP-83-17.NC4 – 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: *The PAO annual program review was conducted by an individual whose documented qualifications on file were insufficient to demonstrate adequate knowledge and expertise of the USDA organic regulations and NOP Policy. The individual's qualifications noted in the annual review were ISO based certifications. The reviewer was not available for interview at the time of the audit to determine any additional qualifications.*

Corrective Action: PAO created and submitted a job description for the person who conducts the certifier's internal audit to ensure that they have the proper qualifications. The job description requires that the auditor have a minimum of two years working in organic agriculture and be familiar with and demonstrate updated training on the USDA organic regulations. The job description was implemented for PAO's 2019 internal audit and the auditor's qualifications were documented.

NOP-83-17.NC5 – 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 Policy Memo 11-10, “*Grower Group Certification*,” refers to the 2008 National Organic Standards Board (NOSB) Recommendation which provides the criteria for the certification of grower groups.

Comments: *The auditor found that PAO's grower group certification procedures do not comply with NOP Policy Memo 11-10 in the following ways:*

- *PAO does not require or request Grower Group Internal Control System (ICS) documents as part of the OSP for review.*
- *PAO does not implement consistent procedures for determining the external inspection sample size for grower groups and documenting the protocol used. For example, PAO does not determine an overall group risk factor to apply in calculating external inspection sample size, though this is stipulated in PAO's work instruction. Additionally, PAO's inspection reports do not document the reason why operations were selected for external inspection (i.e. high risk, random, new member), resulting in protocol that is not transparent.*

Corrective Action: PAO submitted a revised Review Report template (Org-008) which includes a question on grower groups so that the reviewer is reminded to request ICS documentation when reviewing a grower group OSP. PAO also updated its grower group addendum for inspections reports to include: 1) an example for inspectors on how to calculate the number of subunits that need to be inspected; 2) a definition for inspectors of “high risk operations” as growers who have been issued non-compliances, growers identified in complaints to the ICS, and new entrants; 3) a section where inspectors must document the name of each subunit selected for inspection and the reason for selection.

NOP-83-17.NC6 – Accepted. – 7 C.F.R. §205.501(a)(21) states, “Comply with, implement, and carry out any other terms and conditions determined by the Administrator to be necessary.” NOP 2603, Organic Certificates, Section 3.4, states, “Certifying agents should issue a new organic certificate each year.”

Comments: *PAO did not issue an organic certificate to an operation in 2017.*

Corrective Action: PAO's protocol for issuing certificates did not take into account situations where the renewal process takes longer than one year. PAO submitted a new work instruction (Org-WI-028) on Annual Organic Certificates. As described in the instruction, each October, PAO's QA will do a full review of all certified operations to verify that all have been issued a certificate for the year. In cases where operations have not received a certificate and the annual update process is still underway, QA will instruct CR Support to issue an updated certificate and

will follow up with the flagged operations to ensure they complete the annual update process or surrender their certification.

NOP-83-17.NC7 – 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. ... If the certifying agent rejects the request for mediation, the certifying agent shall provide written notification. ... 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. ...The parties to the mediation shall have no more than 30 days to reach an agreement following a mediation session. ...”

Comments: *PAO did not respond to an operation’s January 2018 written mediation request.*

Corrective Action: PAO QA personnel had never received formal training on the mediation process. QA personnel and the NOP scheme manager received training on September 26, 2018 which covered all aspects of adverse actions and mediation, including timeframes and regulatory requirements. PAO also created a Mediation Approval/Denial template and a Mediation Settlement Agreement template to ensure the proper process is followed. PAO submitted documentation with its corrective action showing an example of a compliant mediation and settlement process with a client after staff training and new templates were developed.

NOP-83-17.NC8 – 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 2601 The Organic Certification Process Section 3.4 states, “Once the inspector finishes the inspection report, he or she sends the report to the certifier for review.”

Comments: *In the case of the unannounced inspection where the operator refused to complete the full inspection, the inspector did not submit an inspection report. Instead, the inspector submitted a statement of the events which described how the inspection was terminated before it was complete.*

Corrective Action: PAO updated its unannounced inspection work instruction to include a section on what inspectors should do in cases where the operation does not allow the inspection, the operator is not onsite at the time of inspection, or there are other inspection challenges. The updated work instruction states that in these cases, inspectors must complete an inspection report describing the events that took place even when an inspection is not possible. PAO issued a notice to all inspectors on March 15, 2019 clarifying this requirement.

NOP-83-17.NC9 – 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: *In the case of the unannounced inspection where the operator refused to complete the full inspection, PAO did not issue an unannounced inspection report to the operation.*

Corrective Action: PAO conducted a staff training on March 7, 2019 on audit reports and unannounced inspections. The training instructed staff that an inspection report must always be provided to the operation regardless of whether the inspector was able to do a complete

inspection. PAO also develop a template for letters that will be issued to operations following unannounced inspections with the inspection report as an attachment.

NOP-83-17.NC10 – Accepted. – 7 C.F.R. §205.504(b)(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; 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 to evaluate certification applicants, make certification decisions, and issue certification certificates.”

Comments: *There are no written work instructions or procedures established for reviewing inputs and retaining supporting records of material decision outcomes. The auditor reviewed several inputs that were approved and/or denied, but records were not consistently maintained to support these decisions.*

Corrective Action: PAO submitted a new work instruction for reviewers to use when reviewing inputs for crops and handling. Reviewers were made aware of this new resource via a notice sent to them on March 15, 2019. To ensure documentation of outcomes, PAO updated its review report with a table where reviewers are to document the name of the input reviewed, whether it has already been approved by a recognized MRO, restrictions, additional review observations and the final review determination.

NOP-83-17.NC11 – 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: *Inspectors are inconsistently verifying whether the list of allowed inputs in the Organic System Plan (OSP) includes any inputs with applicable restrictions (annotations) for their use. The auditor identified several OSP input tables that were missing a description of the applicable input restrictions.*

Corrective Action: PAO updated its review report with a table where reviewers are to document the name of the input reviewed, whether it has already been approved by a recognized MRO, restrictions, additional review observations and the final review determination. PAO also revised its inspection checklists to include a question for inspectors to verify compliance with the listed annotations (in the review report) for each input used.