ARCOS INDUSTRIES, L.L.C.
394 Arcos Drive
Mt. Carmel, PA 17851

August 7, 2019

Kerri A. Kavanagh, Chief **/RA/**
Quality Assurance Vendor Inspection Branch
Division of Inspection and Regional Support
Office of Nuclear Reactor Regulation

Re: Reply to a Notice of Nonconformance
Inspection Report No. 99900351/2019-201 and Notice of Nonconformance

Dear Ms. Kavanagh

In response to Inspection Report No. 99900351/2019-201 and Notice of Nonconformance, Arcos' submits the following:

Reply to Nonconformance Report Number 2019-201

The cause of the nonconformance was an error by the Quality Department. Due to the number of nonconforming issues found during the 2018 internal audit there was a rush to get all findings corrected. In that urgency, specific corrective actions were overlooked.

In order to remedy this problem, corrective actions for each finding were opened during the NRC inspection on 12 June 2019. Arcos corrective and preventative actions reports are attached. (See attachments 1 through 7 – 2018 Internal Audit Findings)

To assure that this instance does not occur again, additional wording has been added to the automated annual reminders for internal audits. "Reminder ALL findings shall initiate the corrective action process."

All seven corrective actions of the 2018 Internal Audit have been closed as of August 6, 2019.

In addition to completing and closing the all corrective actions which were related to the 2018 internal audit, a thorough evaluation was preformed, it was determined these findings did not have any effect on safety-related components shipped.

IE09
NRR

Attachment List on following page.

Sincerely,

Harry Wehr, General Manager
Arcos Industries, LLC

ARCOS INDUSTRIES, L.L.C.
394 Arcos Drive
Mt. Carmel, PA 17851

Attachment List

Attachment 1: Corrective Action Report 263, Nonconformance 99900351/2019-201-01

Attachment 2: Corrective Action Report 268, 2018 Internal Audit Finding 1

Attachment 3: Corrective Action Report 269, 2018 Internal Audit Finding 2

Attachment 4: Corrective Action Report 270, 2018 Internal Audit Finding 3

Attachment 5: Corrective Action Report 271, 2018 Internal Audit Finding 4

Attachment 6: Corrective Action Report 272, 2018 Internal Audit Finding 5

Attachment 7: Corrective Action Report 273, 2018 Internal Audit Finding 6

Attachment 8: Corrective Action Report 274, 2018 Internal Audit Finding 7

Attachment 9: Corrective Action Report 262, NCR Inspection Criterion IV minor finding

Attachment 10: Corrective Action Report 264, NRC Inspection, Documentation minor finding

Attachment 11: Corrective Action Report 265, NRC Inspection - Lack of independence of document preparer, reviewer and approval

Attachment 12: Corrective Action Report 266, NRC Inspection - Amend QP-6.4, ISO 17025 provisions for CGD – (anticipated completion date of 8/30/2019)

Attachment 13: Corrective Action Report 275, NRC Inspection, Arcos' Procedures unclear of when 10CFR21 evaluation applies.

FORM #8
Corrective Action Report (CAR)

Report No. 263
Date: 6/12/2019

Area Involved: Internal Audits
Issued To: Arcos Management
Reply Due Date: 7/12/2019

10CFR21 Reportable X No ____ Yes

Nature of Defect / Potential Problem:

Arcos Internal Audit findings have not been entered into Corrective Action program which is in violation of 10CFR50, Appendix B that states *"Measures shall be established to assure that conditions adverse to quality, such as failures, malfunctions, deficiencies, deviations, defective material and equipment, and nonconformances are promptly identified and corrected. In the case of significant conditions adverse to quality, the measures shall assure that the cause of the condition is determined, and corrective action taken to preclude repetition. The identification of the significant condition adverse to quality, the cause of the condition, and the corrective action taken shall be documented and reported to appropriate levels of management."* In addition to Arcos QP-17.1 which requires Internal Audit findings to be entered into the Corrective Action Program and implementation of Correction to be verified during the following Internal Audit.

Cause: Condition Significant or Recurring? Yes ☐ No ☒

Although the Arcos 2018 Internal Audit findings were actively being addressed, an error by the QA Manager and Technical Director failed to enter these findings into the Corrective Action Program to properly document the areas of concern and their resolution in accordance with 10CFR50, Appendix B and Arcos' QP-17.1.

Action Taken:

On June 13, 2019 the 7 findings of Arcos' 2018 Internal Audit were entered into the Corrective Action Program to properly document resolution to the audit findings.

Action Taken By: Sean Williams Date: 6/13/19

Action reviewed to identify any risk or opportunities to interested parties? Yes ☒ No ☐

QA Follow-up

Verified CAR 268 through 274 had been properly documented, corrected and closed accordingly.

QA Follow-up By: Brian Gaal Date: 8/6/19

Final Approval: Sean Williams Date: 8/6/19
Quality Assurance Manager

FORM #8
Corrective Action Report (CAR)

Report No. 268
Date: 6/13/2019

Area Involved: Arcos' Quality System
Issued To: Sean Williams
Reply Due Date: 7/13/2019

10CFR21 Applicable X No ____ Yes

Nature of Defect / Potential Problem:

2018 Internal Audit FINDING 1: Contrary to 10CFR50.55e, 10CFR50.55e has been passed down by a customer, but not met by Arcos. 10CFR50.55e includes posting, procedure, and record retention requirements similar to 10CFR21 with some variations. Arcos does not currently have 10CFR50.55e posted, does not include it in a procedure, and record retention requirements, which are longer than 10CFR21 requirements, are not identified.

Cause: Condition Significant or Recurring? Yes ☐ No ☒

Misinterpretation of meeting the requirements of 10CFR21 satisfied the requirements of 10CFR50.55(e) by previous Arcos QA Manager. As each apply, this is true except for record retention obligation.

Action Taken:

Revised retention record period QP-16.1 (Records) to align with the requirement of 10CFR50.55(e), revised QP-13.4 (10CFR21) to include the provisions of 10CFR50.55(e). Training provided to all employees explaining the additional regulation addition to Arcos' Quality Program and (4) posting locations have been updated.

Action Taken By: Sean R Williams Date: 8/5/19

Action reviewed to identify any risk or opportunities to interested parties? Yes ☒ No ☐

QA Follow-up:

See attached QP-13.4, Rev 7 and QP-16.1, Rev 13.

QA Follow-up By: Brian Hall Date: 8/5/19

Final Approval: Nancy Webb Date: 8/5/2019

~~Quality Assurance~~ Manager
General

10CFR21—REPORTING OF DEFECTS AND NONCOMPLIANCE

**Including Posting and Record Retention Requirements of 10CFR50.55(e)*

1. **PURPOSE**

/1.1 The purpose of this procedure is to ensure that Arcos Industries complies with the requirements of Federal Regulation Title 10, Part 21 (10CFR21) regarding discovery of defective or noncompliant product that has shipped to a commercial nuclear power plant or nuclear power plant activity that could create a substantial safety hazard, **which includes the Posting and Record Retention requirements of 10CFR50.55(e).**

2. **RESPONSIBILITY**

2.1 **General Manager**

2.1.1 The General Manager is responsible for initial notification to the NRC Operations Center by fax at (301) 816-5151 within 2 days of receipt of identification of a 10CFR21 reportable defect or noncompliance by the QA Manager. The General Manager is responsible for calling the NRC Operations Center at (301) 816-5100 to verify receipt of notification.

2.1.2 The General Manager is responsible to provide written notification to the NRC within 30 days of being notified of a 10CFR21 reportable defect or noncompliance.

2.2. **Quality Assurance Manager**

2.2.1 The Quality Assurance Manager shall perform an evaluation of nonconforming material within 60 days of discovery to determine if the defect is a 10CFR21 reportable incident.

2.2.2 If the evaluation cannot be completed within 60 days of discovery, the QA Manager shall prepare an interim report for submittal to the NRC through the General Manager. The interim report shall describe the deviation or noncompliance being evaluated and shall state when the evaluation will be completed. The interim report shall be submitted within 60 days of discovery of the deviation or noncompliance.

Approved By: Sean Williams
QA Manager

2.2.3 The QA Manager shall notify the General Manager as soon as practicable, and in all cases within 5 working days of completion of the evaluation.

2.2.4 If the QA Manager is unable to perform an evaluation for 10CFR21 applicability, he shall meet with Arcos Industries management for assistance. If Arcos Industries determines that it does not have the capability to perform the evaluation, it shall inform the purchasers or the affected utilities within 5 working days of this determination.

2.3. **All Employees of Arcos Industries, LLC.**

2.3.1 It is the responsibility of each employee to bring to the attention of the Quality Assurance Manager instances of defective or noncompliant material before or after shipment.

3. **POSTING**

/3.1 The Quality Assurance Manager is responsible for ensuring that a copy of this Procedure, Title 10 Part 21 of the Code of Federal Regulations, **10CFR50.55(e)**, and Section 206 of the Energy Reorganization Act of 1974 are posted in appropriate locations.

4. **WRITTEN NOTIFICATION**

4.1 Arcos Industries shall provide the NRC with written notification within 30 days after determination of a 10CFR21 defect or noncompliance and it shall include the following information, to the extent known:

- Name, and address of the individual providing the report
- Identification of the nonconforming material or noncompliance for each facility or activity
- Identification of the firm constructing the facility or supplying the basic component that contains the defect or noncompliance
- Nature of the defect and the safety hazard, which is created or could be created
- Date the information of the defect or noncompliance was obtained

Approved By: Sean Williams
QA Manager

- The number and location of the basic component is use at, supplied for, being supplied for, or may be supplied for, manufactured, or being manufactured for one or more facilities or activities
- Corrective actions taken and will be taken, responsible individual, and completion date
- Advice related to the defect or noncompliance
- In the case of early site permit, the entities to whom an early site permit was transferred

5. **RECORDS**

/5.1 The Quality Assurance Manager is responsible for maintaining records relating to shipment of defective or noncompliant product for minimum periods as noted:

- Evaluations of all deviations and failures to comply (**10** years after the evaluation)
- Notifications sent to purchasers and affected licensees (**10** years after date of notification)
- Arcos purchase orders including associated services (**15** years after delivery)

6. **DOCUMENTATION**

6.1 All employees are required to acknowledge receipt of this procedure and training by signing on page 6 of 6. Pages 4 - 6 form Exhibit 1 and will be retained as a training record. Pages 1 -3 shall be provided to the employees during training.

7. **ADMINISTRATION**

7.1 This policy shall be administered by the Quality Assurance Manager under the direction of the General Manager.

Approved by: Harry Wehr
Harry Wehr, General Manager

Date: 8/2/2019

Approved By: Sean Williams
QA Manager

(Exhibit 1)

10CFR21—REPORTING OF DEFECTS AND NONCOMPLIANCE

**Including Posting and Record Retention Requirements of 10CFR50.55(e)*

1. **PURPOSE**

/1.1 The purpose of this procedure is to ensure that Arcos Industries complies with the requirements of Federal Regulation Title 10, Part 21 (10CFR21) regarding discovery of defective or noncompliant product that has shipped to a commercial nuclear power plant or nuclear power plant activity that could create a substantial safety hazard, **which includes the Posting and Record Retention requirements of 10CFR50.55(e).**

2. **RESPONSIBILITY**

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2.1.1 The General Manager is responsible for initial notification to the NRC Operations Center by fax at (301) 816-5151 within 2 days of receipt of identification of a 10CFR21 reportable defect or noncompliance by the QA Manager. The General Manager is responsible for calling the NRC Operations Center at (301) 816-5100 to verify receipt of notification.

2.1.2 The General Manager is responsible to provide written notification to the NRC within 30 days of being notified of a 10CFR21 reportable defect or noncompliance.

2.2. **Quality Assurance Manager**

2.2.1 The Quality Assurance Manager shall perform an evaluation of nonconforming material within 60 days of discovery to determine if the defect is a 10CFR21 reportable incident.

2.2.2 If the evaluation cannot be completed within 60 days of discovery, the QA Manager shall prepare an interim report for submittal to the NRC through the General Manager. The interim report shall describe the deviation or noncompliance being evaluated and shall state when the evaluation will be completed. The interim report shall be submitted within 60 days of discovery of the deviation or noncompliance.

Approved By: Sean Williams
QA Manager

2.2.3 The QA Manager shall notify the General Manager as soon as practicable, and in all cases within 5 working days of completion of the evaluation.

2.2.4 If the QA Manager is unable to perform an evaluation for 10CFR21 applicability, he shall meet with Arcos Industries management for assistance. If Arcos Industries determines that it does not have the capability to perform the evaluation, it shall inform the purchasers or the affected utilities within 5 working days of this determination.

2.3. **All Employees of Arcos Industries, LLC.**

2.3.1 It is the responsibility of each employee to bring to the attention of the Quality Assurance Manager instances of defective or noncompliant material before or after shipment.

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4.1 Arcos Industries shall provide the NRC with written notification within 30 days after determination of a 10CFR21 defect or noncompliance and it shall include the following information, to the extent known:

- Name, and address of the individual providing the report
- Identification of the nonconforming material or noncompliance for each facility or activity
- Identification of the firm constructing the facility or supplying the basic component that contains the defect or noncompliance
- Nature of the defect and the safety hazard, which is created or could be created
- Date the information of the defect or noncompliance was obtained

Approved By: Sean Williams
QA Manager

- The number and location of the basic component is use at, supplied for, being supplied for, or may be supplied for, manufactured, or being manufactured for one or more facilities or activities
- Corrective actions taken and will be taken, responsible individual, and completion date
- Advice related to the defect or noncompliance
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- Notifications sent to purchasers and affected licensees (**10** years after date of notification)
- Arcos purchase orders including associated services (**15** years after delivery)

6. **DOCUMENTATION**

6.1 All employees are required to acknowledge receipt of this procedure, and training by signing below.

7. **ADMINISTRATION**

/7.1 This policy shall be administered by the Quality Assurance Manager under the direction of the **Technical Director &** General Manager.

Signature: _____ Date: _____

Printed Name: _____

Approved By: Sean Williams
QA Manager

ARCOS INDUSTRIES, LLC
394 Arcos Drive
Mt. Carmel, PA 17851
High Performance Welding Alloys

Document	Quality Procedure
	QP-16.1
Revision	13
Date	8/2/2019

RECORDS (QA)

1. PURPOSE

1.1 The purpose of this procedure is to delineate what quality records must be maintained, definition of process packet, filing system, rules governing access to and control over records and their removal from storage and a method for disposing of superceded records. QA Records must be legible, identifiable and retrievable, and protected against damage, deterioration, or loss.

2. DEFINITION

2.1 Packets of process records (Bare Wire) - a file maintained by QA shall include: Work Order, Material to Warehouse Report, Alloy ID Butt-Weld Check form, and Alloy ID Analysis Record.

2.2 Coated Electrodes - production documents delivered to QA from the extrusion area shall consist of the concentricity sheet, and the formulation sheet. (Note - oven charts are filed separately from the packet.)

Approved By: Sean Williams
QA Manager

/3. **RETENTION OF QA RECORDS** SAMPLE TABLE ONLY (Refer to QSM Section 7)

Table #7.1
QA Record Storage

Record	Retention Time	(Δ)Location	Method	Back up Location
Quality Systems Manual	3 Years	QA Office	Dual	Electronic
Quality Procedures Manual	3 Years	QA Office	Dual	Electronic
Work Instruction Manual	3 Years	QA Office	Dual	Electronic
Procurement	7 Years	Chem Lab	Dual	Electronic
*Personnel Qualifications	7 Years	QA Mgr. Office	Single	N/A
Audit and Survey Reports	7 Years	QA Mgr. Office	Dual	Electronic
Packets of Process Records	15 Years	QA Office	Single	N/A
♦Test Reports including Q-Cards	15 Years	QA Office	Dual	Electronic
Customer Certification Packet	15 Years	QA Office	Dual	Electronic
Nonconforming Reports	15 Years	QA Mgr. Office	Dual	Electronic
Corrective Action Reports	15 Years	QA Mgr. Office	Dual	Electronic
**Calibration Records	2 Years	QA Office	Dual	Electronic

* 3 Years after employment ceases
** 2 Years after the instrument has been permanently removed from calibration

♦ Includes Radiographic Film and Inspection Records

ΔControl of records shall be assigned as follows:

QA Manager's Office – QA Manager
QA Office – Quality Systems Specialist
Chem Lab – Chemical Lab Supervisor

Approved By: Sean Williams
QA Manager

4. FILING SYSTEMS (QA DEPARTMENT)

4.1 QA Certification Packet files for ASME Section III and safety related purchase orders shall include certifications, customer purchase orders, and QA Reviews. The packets shall be stored in filing cabinets by Sales Order number (SO#) in the QA Office.

4.2 Nonconforming and Corrective Action Reports shall be filed according to numeral sequence in binders.

4.3 Audit and Survey reports shall be stored in filing cabinets by the QA Manager.

4.4 All other QA records shall be stored in filing cabinets by QA personnel.

4.5 The CMTR is considered the only lifetime record and it is furnished to the customer at shipment and a file is maintained at Arcos for a minimum of ten years.

4.6 Authorized personnel shall access QA Records in the QA Office, Chem Lab, or Production Control department only. Records may be removed for audit purposes and for evaluation by QA personnel as necessary. QA personnel are responsible for ensuring that the records are returned in a timely manner.

5. ACCESS AND CONTROL OF QA FILES

5.1 QA personnel shall maintain and control quality record files, and documents using filing cabinets. Single storage records shall be protected by a dry fire suppression system.

5.2 Superceded records shall be controlled by QA personnel.

5.3 Quality records shall be maintained as noted in Section 3 of the procedure.

5.4 Most QA Records are generated and stored electronically (without signature) and are reproducible from the electronic files. The computer system servers containing the data files shall be backed up daily, and remotely on weekly basis in the Chem Lab.

Approved By: Sean Williams
QA Manager

FORM #8
Corrective Action Report (CAR)

Report No. 269
Date: 6/13/2019

Area Involved: Arcos' Quality System
Issued To: Sean Williams
Reply Due Date: 7/13/2019

10CFR21 Applicable X No ____ Yes

Nature of Defect / Potential Problem:

2018 Internal Audit FINDING 2: Contrary to MIL-E-21562E, sample sizes for some lot sizes are not as required by the standard. MIL-E-21562E ¶4.4.3.2 gives inspection level requirements for sampling in accordance with MIL-STD-105. Based on the inspection levels identified and the corresponding sample sizes identified by MIL-STD-105E, lot sizes of 151 to 500 pounds of 25# spools would require a sample size of 8 rather than the identified 5 in WI-10.19 "Bare Wire Lot Acceptance for: MIL-E-21562E", Rev 1, 2/28/14. Same for 91 to 150 pounds of 2# spools and cut lengths (rods). It was also noted that the inspector essentially rejects on 1 defect rather than the allowance in the sampling plans. If this is the desired practice, it should be written into the sampling plans.

Cause: Condition Significant or Recurring? Yes ☐ No ☒

Arcos Work Instruction WI-10.19, Rev 1 incorrectly set sampling size of 5 at the lowest level of Lot sizes.

Action Taken:

Based on a review of MIL-E-21562E paragraph 4.4.3.2 work instruction WI-10.19 has been amended with the correct sample sizes according to the size of the lot.

Action Taken By: Sean Williams Date: 8/5/19

Action reviewed to identify any risk or opportunities to interested parties? Yes ☒ No ☐

QA Follow-up:

Work Instruction WI-10.19 has been revised to reflect the correct sample size of 8, instead of previously 5 and all Product Inspectors have received training on these changes. (see attached Document of Training)

QA Follow-up By: Brian Graf Date: 8/5/19

Final Approval: Nancy Wahn Date: 8/5/2019
~~Quality Assurance~~ General Manager

DOCUMENT OF TRAINING

Date 8/5/2019
Document No. 1 of 1
Length of Session 15 Minutes
Subject Arcos' WI-10.19, Rev 2
MIL-E-21562E Sampling

Note: The Recording of false, fictitious, or fraudulent statements or entries on this document may be punished as a felony under Federal Statute.

Print Name	Signature
SEAN REISMILLER	
ROBERT MCSURDY	
TOM BARWICK	
CHRIS KRAH	

Instructor: Sean Williams

Comments: Discussed Lot size of 2 – 150 to be a sample size of 8 instead of previously 5 in accordance with MIL-STD-105E.

FORM #8
Corrective Action Report (CAR)

Report No. 270
Date: 6/13/2019

Area Involved: Arcos' Quality System
Issued To: Sean Williams
Reply Due Date: 7/13/2019

10CFR21 Applicable X No ____ Yes

Nature of Defect / Potential Problem:

2018 Internal Audit FINDING 3: Contrary to QP-10.25 "Alloy Identification of Bare Wire (XRF Method)", Rev 3, 10/17/14, XRF Analyzer calibration checks are not being performed in accordance with the procedure. QP-10.25 ¶5 includes start up and calibration check requirements. Based on discussion with the inspector, he has not been performing calibration checks on a daily basis and does not allow 10 minutes after startup for stabilization. The inspector stated that he performs a calibration check weekly in the morning without a 10 minute stabilization period, he then performs a System Check (auto-calibration) that afternoon, but the analyzer is not then checked against an alloy standard until the next week. Also, the calibration check and auto-calibration process is not documented to ensure it is performed.

Cause: Condition Significant or Recurring? Yes ☐ No ☒

Misunderstanding of the Manufacturer's recommendation of the 10-minute stabilization period as described in QP-10.25, Rev 3 by Lead Product Inspector. Investigation proved this to be a non-issue as this is a processing aid and the night shift inspector was aware of the stabilization and had been performing this step nightly and leaving the device active for the daytime Product Inspector's shift start.

Action Taken:

Training with all product inspectors, reviewing Arcos' Quality Procedure 10.25, Rev 3 and daily calibration.

Action Taken By: Sean R Williams Date: 8/5/19

Action reviewed to identify any risk or opportunities to interested parties? Yes ☒ No ☐

QA Follow-up:

See attached Document of Training.

QA Follow-up By: Brian Gail Date: 8/5/19

Final Approval: Nancy Webb Date: 8/5/2019

~~Quality Assurance~~ General Manager

DOCUMENT OF TRAINING

Date 8/5/2019
Document No. 1 of 1
Length of Session 15 Minutes
Subject Arcos' QP-10.25, Rev 3 Daily Calibration

Note: The Recording of false, fictitious, or fraudulent statements or entries on this document may be punished as a felony under Federal Statute.

Print Name	Signature
Sean Retsmiller	
Robert McSurdy	
Tom Barwick	
Chris Krah	

Instructor:

Comments: Training session included discussion of 10-minute stabilization period prior to performing system check (auto-calibration) of XRF analyzer.

FORM #8
Corrective Action Report (CAR)

Report No. 271
Date: 6/13/2019

Area Involved: Arcos' Quality System
Issued To: Sean Williams
Reply Due Date: 7/13/2019

10CFR21 Applicable X No ____ Yes

Nature of Defect / Potential Problem:

2018 Internal Audit FINDING 4: Contrary to QP-11.1 "Calibration of Test Equipment", Rev 12, 1/13/17, Micrometer 3A and Caliper 3A, do not have unique identification. QP-11.1 ¶1.1 states that "Measuring and test equipment in the calibration system shall be uniquely identified with an Arcos serial number or manufacturer's serial number". Due to these items having the same number, incorrect documentation was initially provided during the audit when one of the calibrations was requested.

Cause: Condition Significant or Recurring? Yes ☐ No ☒

Oversight of previous Quality Systems Specialist handling calibration recall to uniquely identify these instruments. Dial Caliper 3A was issued to EB room for dimensional checks of weld inserts and Micrometer 3A was issued to product inspectors for final inspection purposes, each instrument was not being used by the same individuals performing inspections.

Action Taken:

Caliper 3A which was located in the EB room was taken out of service.

Action Taken By: Jesse Mace Date: 6/20/19

Action reviewed to identify any risk or opportunities to interested parties? Yes ☒ No ☐

QA Follow-up:

An inspection of the EB room which took place on 6/19/2019 confirmed that caliper 3A was no longer in service.

QA Follow-up By: Brian Hall Date: 8/5/19

Final Approval: Jerry Wilson Date: 8/5/2019
~~Quality Assurance~~ Manager
General

FORM #8
Corrective Action Report (CAR)

Report No. 272
Date: 6/13/2019

Area Involved: Arcos' Quality System
Issued To: Sean Williams
Reply Due Date: 7/13/2019

10CFR21 Applicable X No ____ Yes

Nature of Defect / Potential Problem:

2018 Internal Audit FINDING 5: Contrary to QSM ¶14.5, an Out of Tolerance Evaluation was not performed for Scale #27. QSM ¶14.5 states that "The QA Manager shall be notified if measuring or testing equipment is found to be out-of-calibration. Previous test records shall be assessed to assure validity of past results since the last calibration". Scale #27 was as-found out of tolerance during calibration by Garber Metrology on 8/14/18.

Cause: Condition Significant or Recurring? Yes ☐ No ☒

An out of tolerance evaluation had been performed at the time of certification review but had not been documented properly but had been noted as being reviewed by QA on the certification.

Action Taken:

An out of Tolerance evaluation was performed on 9/24/2019 see next page. It was determined that the out of tolerance which was reported was insignificant to the task which the scale is used for.

Action Taken By: Brian Saal Date: 6/19/19

Action reviewed to identify any risk or opportunities to interested parties? Yes ☒ No ☐

QA Follow-up:

Scale 27 was calibrated on 4/8/2019 it was found to be in calibration.

QA Follow-up By: Sean Williams Date: 6/19/19

Final Approval: Brian Saal Date: 6/24/19

~~Quality Assurance Manager~~
Technical Director

Out of Tolerance Evaluation

September 24, 2018

Scale: Mettler AE 160 Scale ID: 27

This scale was found to be out of tolerance on 8/14/2018

This scale is used to deter the moisture by weight difference. While it was readying slightly over the expected weight at 40 and 80 grams is was very consistent. Therefore it will not affect any of the results when determining moisture percentage as that calculation is based on a weight difference of two measurements that both use the same scale. An example of the calculation is below:

75.3210 - 75.2755 = 0.0455 grams Mass of collected moisture, by difference

38.7324 - 27.0783 = 11.6541 grams Mass of sample, by difference

Percent moisture (0.0455 / 11.6541) * 100 = 0.39%

(75.3210+0.0012)- (75.2755 +0.0012) = 0.0455 grams Mass of collected moisture, by difference

(38.7324 + 0.0012) – (27.0783 = 0.0012) = 11.6541 grams Mass of sample, by difference

Percent moisture (0.0455 / 11.6541) * 100 = 0.39%

The percent moisture remains the same.

It was confirmed that this scale is only used for mass difference calculation. Based on the example above the results of that calculation are not affected by the out of tolerance condition.

Approved By: Sean Williams

QA Manager

Gm is an ISO 9001 Registered Co. &
ISO/IEC 17025 Accredited Lab

www.garbermetrology.com

GARBER METROLOGY
Weighing Solutions & Precision Calibration

520 East Oregon Road
Suite 101
Lititz, PA 17543
717-393-1708, Fax 717-392-6359

Certificate of Calibration

Certificate#: 660158

Customer:
ARCOS INDUSTRIES, LLC
394 ARCOS DRIVE
MOUNT CARMEL PA 17851

I.D.: 27
Manufacturer: METTLER
Model Number: AE160
Capacity: 0-160 GR. X .0001 GR.
Description: METTLER, AE160, 0-160 GR. X .0001 GR.
Serial Number: D-57390
Department: LAB
Location:

Service Location: ON SITE
Temp/RH: N/A
As Found Condition: OUT OF TOL
Calibration Result: PASS
Cal Date: 8/14/2018
Cal. Due Date: 12/31/2018
Type of Cal: 9001

QA OK
8/23/18

Calibration Notes:
DECREASING LOAD: PASS
RECALIBRATED
1.) ARCOS PO: 0026565
2.) CALIBRATION PERFORMED IN ACCORDANCE WITH GARBER METROLOGY QA MAUAL REV 15. APPROVED BY ARCOS IN HOUSE SURVEY.
3.) HANDBOOK 44 REFERENCE.

A= adjusted reading
F=failed
R=report of value

Description	Nominal	Min. Tol	Max. Tol		As Found	As Left
NO LOAD	0.0000	0.0000	0.0000		0.0000	0.0000
80 GR. SHIFT 1	80.0000	79.9997	80.0003	A	80.0012	80.0001
80 GR. SHIFT 2	80.0000	79.9997	80.0003	A	80.0012	80.0000
80 GR. SHIFT 3	80.0000	79.9997	80.0003	A	80.0012	80.0000
80 GR. SHIFT 4	80.0000	79.9997	80.0003	A	80.0010	80.0000
40 GR. CENTER	40.0000	39.9997	40.0003	A	40.0006	40.0000
80 GR. CENTER	80.0000	79.9997	80.0003	A	80.0012	80.0001
120 GR. CENTER	120.0000	119.9997	120.0003	A	120.0016	120.0001
160 GR. CENTER	160.0000	159.9997	160.0003	A	160.0024	160.0002

CALIBRATION STD(S):	DESCRIPTION	CAL. DUE DATE	TRACEABILITY#
WTS-06804	RICE LAKE 1MG TO 100GR. CLASS 1 WEIGHT KIT.	2/28/2019	631959

Procedure Name	Issue Date	Revision #	Description
CP-0006	6/14/2010	5	SCALES & BALANCES CALIBRATION

Garber certifies this instrument has been calibrated using standards traceable to the National Institute of Standards & Technology (NIST) and/or intrinsic standards. The calibration was completed in accordance with our quality system and ANSI/NCSL Z540.1. Garber is an ISO 9001 registered company. Accuracy: This instrument has been calibrated using written procedures, by qualified technician(s). The standard(s) used during this calibration provide, as a minimum, 4 to 1 test accuracy ratio, unless otherwise stated in the Calibration Notes.

Performed By: TIMOTHY BERNOT

Approved: Service Manager

END OF REPORT

GSC form 500, Rev. 11 11/19/2014

Gm is an ISO 9001 Registered Co. &
ISO/IEC 17025 Accredited Lab

www.garbermetrology.com

GARBER METROLOGY
Weighing Solutions & Precision Calibration

520 East Oregon Road
Suite 101
Lititz, PA 17543
717-393-1708, Fax 717-392-6359

Certificate of Calibration

Certificate#: 701521

Customer:
ARCOS INDUSTRIES, LLC
394 ARCOS DRIVE
MOUNT CARMEL PA 17851

I.D.: 27
Manufacturer: METTLER
Model Number: AE160
Capacity: 0-160 GR. X .0001 GR.
Description: METTLER, AE160, 0-160 GR. X .0001 GR.
Serial Number: D-57390
Department: LAB
Location:

Service Location: ON SITE
Temp/RH: N/A
As Found Condition: IN TOLERANCE
Calibration Result: PASS
Cal Date: 4/8/2019
Cal. Due Date: 8/31/2019
Type of Cal: 9001

5 mw
4/16/19

Calibration Notes:
DECREASING LOAD: PASS
A= adjusted reading
F=failed
R=report of value

Description	Nominal	Min. Tol	Max. Tol	As Found	As Left
NO LOAD	0.0000	0.0000	0.0000	0.0000	0.0000
80 GR. SHIFT 1	80.0000	79.9997	80.0003	80.0001	80.0001
80 GR. SHIFT 2	80.0000	79.9997	80.0003	80.0001	80.0001
80 GR. SHIFT 3	80.0000	79.9997	80.0003	80.0000	80.0000
80 GR. SHIFT 4	80.0000	79.9997	80.0003	79.9999	79.9999
40 GR. CENTER	40.0000	39.9997	40.0003	40.0000	40.0000
80 GR. CENTER	80.0000	79.9997	80.0003	80.0000	80.0000
120 GR. CENTER	120.0000	119.9997	120.0003	120.0000	120.0000
160 GR. CENTER	160.0000	159.9997	160.0003	160.0000	160.0000

CALIBRATION STD(S):	DESCRIPTION	CAL. DUE DATE	TRACEABILITY#
WTS-06804	RICE LAKE 1MG TO 100GR. CLASS 1 WEIGHT KIT.	3/31/2020	700152

Procedure Name	issue Date	Revision #	Description
CP-0006	6/14/2010	5	SCALES & BALANCES CALIBRATION

Garber certifies this instrument has been calibrated using standards traceable to the National Institute of Standards & Technology (NIST) and/or intrinsic standards. The calibration was completed in accordance with our quality system and ANSI/NCSL Z540.1. Garber is an ISO 9001 registered company. Accuracy: This instrument has been calibrated using written procedures, by qualified technician(s). The standard(s) used during this calibration provide, as a minimum, 4 to 1 test accuracy ratio, unless otherwise stated in the Calibration Notes. Calibration results relate only to items calibrated & listed above. It is the responsibility of the customer to maintain the integrity of the calibration after the issuance of the certificate.

Performed By: TIMOTHY BERNOT

END OF REPORT

Approved: Service Manager

GSC form 500, Rev. 11 11/19/2014

FORM #8
Corrective Action Report (CAR)

Report No. 273
Date: 6/13/2019

Area Involved: Arcos' Quality System
Issued To: Sean Williams
Reply Due Date: 7/13/2019

10CFR21 Applicable X No ____ Yes

Nature of Defect / Potential Problem:

2018 Internal Audit FINDING 6: Contrary to NQA-1 Requirement 6, a Critical Characteristic for the dedication/unqualified source material acceptance of Nickel Bronze was removed without approval. NQA-1 Requirement 6 ¶301 states "Changes to documents, other than those defined as minor changes, are considered major changes and shall be reviewed and approved by the same organizations that performed the original review and approval unless other organizations are specifically designated." The Dedication/Unqualified Source Material Plan for Technical Evaluation Report No. 5.7-0 includes a critical characteristic for Positive Material Identification (PMI) in addition to the 100% chemical analysis Critical Characteristic. The chemical analysis was performed, but the PMI was N/A'd without documented explanation or acceptance by the organization(s), Quality and Engineering, implementing the requirement.

Cause: Condition Significant or Recurring? Yes ☐ No ☒

Incoming Inspection incorrectly marked N/A for the PMI step of Technical Evaluation No. 5.7-0, with the thought that due to the Chemical Analysis, PMI would not be needed as this material was not stored within the XRF analyzer library. This was found to be acceptable but should have been signed off by Engineering as being acceptable due the circumstance.

Action Taken:

Training was held with all product inspectors going over the difference between minor and major changes to Quality Documents and when it is acceptable to make changes without approval of Engineering or Technical departments.

Action Taken By: Sean Williams Date: 8/5/19

Action reviewed to identify any risk or opportunities to interested parties? Yes ☒ No ☐

QA Follow-up:

See attached Document of Training.

QA Follow-up By: Brian Ford Date: 8/5/19

Final Approval: Danny Webb Date: 8/5/2019
~~Quality Assurance~~ General Manager

DOCUMENT OF TRAINING

Date 8/5/2019
Document No. 1 of 1
Length of Session 15 Minutes
Subject Documentation Changes

Note: The Recording of false, fictitious, or fraudulent statements or entries on this document may be punished as a felony under Federal Statute.

Print Name	Signature
SEAN REISMILLER	
ROBERT McSURDY	
TOM BARWICK	
Chris Kraly	

Instructor: Sean Williams

Comments: Reviewed differences between major and minor changes to Quality or Technical documents.

FORM #8
Corrective Action Report (CAR)

Report No. 274
Date: 6/13/2019

Area Involved: Arcos' Quality System
Issued To: Sean Williams
Reply Due Date: 7/13/2019

10CFR21 Applicable X No ____ Yes

Nature of Defect / Potential Problem:

2018 Internal Audit FINDING 7: Contrary to NQA-1 Requirement 17, the Source Verification for the Tensile Tester was not correctly updated for the calibration performed on 7/23/18. NQA-1 Requirement 17 ¶200(b) states that "Records shall be traceable to associated items and activities and accurately reflect the work accomplished or information required". The Source Verification lists ASTM E 83-2010a and ASTM E 4-2015, while the 2016 version is current for both and used during the calibration based on the calibration certificate. Also, the PO number was not updated, the Source Verification lists PO #27109, while the calibration certificate lists #27800.

Cause: Condition Significant or Recurring? Yes ☐ No ☒

This was a mistake by the QA Manager, using prior documents for current work being performed.

Action Taken:

Being now aware of this oversight QA Manager has thoroughly documented Source Verification activities being performed.

Action Taken By: Sean Williams Date: 8/6/19

Action reviewed to identify any risk or opportunities to interested parties? Yes ☒ No ☐

QA Follow-up:

See attached exhibits of documented information during Source Verification.

QA Follow-up By: Brian Hall Date: 8/6/19

Final Approval: Danny Walker Date: 8/6/19
~~Quality Assurance~~ General Manager

DOCUMENT: QUALITY PROCEDURE QP-6.5
REVISION: 5
DATE: 11/8/2017

ARCOS INDUSTRIES, LLC

ON-SITE CALIBRATION SERVICES
SOURCE VERIFICATION CHECKLIST

EQUIPMENT **COMPARATOR**
MODEL NO. **J&L Fc14**
CALIBRATION SOURCE INFORMATION:
COMPANY NAME **GNH SERVICES**
ADDRESS **117 ROBIN DRIVE**
BARTO, PA 19504

LOCATION: **EB ROOM**
SERIAL NO: **E25546**
NIST STANDARDS **#821/253515-94**

SERVICE REPRESENTATIVE Dan VanDyke

Acceptable = Y; Not Acceptable = N

		Y	N	N/A	COMMENTS
1)	Traceability of calibration and calibration standards are to nationally recognized standards (e.g. National institute of Standards and Technology (NIST) or equivalent.	Y			**N.I.S.T #821/253515-94**
1a)	Does the calibration standard have a calibration sticker attached or available?	Y			**Calibrated 3/19/2019 Due 3/19/2020**
2)	Calibrations are performed in accordance with written procedures/instructions. If so maintain copy on file.	Y			**WI-750-001 REV A**
2a)	Were the procedures correctly followed by the Calibrator?	Y			
2b)	Was the calibration performed prior to the due date?	Y			**7/16/2019**
3)	Personnel have documented training/qualification.	Y			
4)	Environmental conditions, i.e: temperature, humidity and vibration have been addressed.	Y			**82.6°F**
5)	Adequacy, accuracy, stability, tolerances (uncertainty) and range of measurement standards are addressed.	Y			**..0001"**
6)	There are appropriate intervals of calibration for standards.	Y			**12 Mos.**
7)	There are controls where needed for software, i.e. adequate review/approval, verification, validation, error			N/A	
8)	All gages are identified with the calibration status upon completion of the calibration.	Y			
8a)	Does the sticker reflect: Date calibrated, calibrator's initials, Next due date?	Y			**Calibrated 7/16/2019 - Due 1/31/2020**

Acceptable = Y; Not Acceptable = N	Y	N	N/A	COMMENTS
9) Out of tolerance issues and corrective actions are addressed	Y			**ARCOS IS NOTIFIED WHEN IT IS DISCOVERED**
10) There are controls for subcontractor calibrations			N/A	
11) Calibrations are documented and certified in an appropriate way and worksheets were completed	Y			**Form # GNH 2019-1**
11a) Do records reflect as found and as left condition?	Y			**On Certification**

ADDITIONAL COMMENTS

ARCOS PO# 28097

STATUS: ACCEPTABLE X NOT ACCEPTABLE ____

IF NOT ACCEPTABLE, STATE THE REASON IN THE ADDITIONAL COMMENT SECTION
DEFINE THE ACTION NEEDED TO BE IMPLEMENTED TO OBTAIN AN ACCEPTABLE STATUS.

NAME Dan VanDyke
TITLE Service Technician
DATE 7/16/2019

QA MANAGER APPROVED BY: Sean Williams Sean Williams
DATE 7/16/2019

LEAD AUDITOR APPROVED BY: Brian Hall
DATE 7/19/19

DOCUMENT: QUALITY PROCEDURE QP-6.5
REVISION: 4
DATE: 6/21/17

ARCOS INDUSTRIES, LLC

ON-SITE CALIBRATION SERVICES SURVEILLANCE CHECKLIST

EQUIPMENT **Super L SR2, S-1000, United Tester** LOCATION: **Testing**
MODEL NO. **Tensile Machines** SERIAL NO. **222670, 222669, 0802408**
CALIBRATION SOURCE INFORMATION: NIST STANDARDS **ASTM E 83-2016**
COMPANY NAME **Tinius Olsen** **ASTM E 4-2016**
ADDRESS **1065 Easton Road**
Horsham, PA 19044

SERVICE REPRESENTATIVE **Brian Campbell**

	Acceptable = Y; Not Acceptable = N	Y	N	N/A	COMMENTS
1)	Traceability of calibration and calibration standards are to nationally recognized standards (e.g. National institute of Standards and Technology (NIST) or equivalent.	Y			**ASTM E 4-2016 ASTM E 83-2016**
1a)	Does the calibration standard have a calibration sticker attached or available?	Y			**8/17/19, 2/20/20, 8/17/19, 1/20/20**
2)	Calibrations are performed in accordance with written procedures/instructions. If so maintain copy on file.	Y			**Tinius Olsen Procedure #1000, #2000**
2a)	Were the procedures correctly followed by the Calibrator?	Y			
2b)	Was the calibration performed prior to the due date?	Y			**Due 7/23/2019, performed 7/22/2019**
3)	Personnel have documented training/qualification.	Y			
4)	Environmental conditions, i.e. temperature, humidity and vibration have been addressed.	Y			**24.7°C - 27.7°C**
5)	Adequacy, accuracy, stability, tolerances (uncertainty) and range of measurement standards are addressed.	Y			**Various**
6)	There are appropriate intervals of calibration for	Y			**12 months**
7)	There are controls where needed for software, i.e. adequate review/approval, verification, validation, error			N/A	
8)	All gages are identified with the calibration status upon completion of the calibration.	Y			
8a)	Does the sticker reflect: Date calibrated, calibrator's initials, Next due date?	Y			**Calibrated 7/22/2019 Due 7/22/2020**

Acceptable = Y; Not Acceptable = N	Y	N	N/A	COMMENTS
9) Out of tolerance issues and corrective actions are addressed	Y			**ARCOS IS NOTIFIED WHEN IT IS DISCOVERED**
10) There are controls for subcontractor calibrations	Y			
11) Calibrations are documented and certified in an appropriate way and worksheets were completed	Y			**Certs # HL0EHP01, 02, 03**
11a) Do records reflect as found and as left condition?	Y			

ADDITIONAL COMMENTS

ARCOS PO# 28388
TINIUS OLSEN SERVICE ORDER # 820382
TENSILE MACHINE SR2 WAS FOUND TO BE OUT OF TOLERANCE, SEE OUT OF TOLERANCE REPORT 01-2019 FOR DETAILS.

STATUS: ACCEPTABLE ___X___ NOT ACCEPTABLE ____

IF NOT ACCEPTABLE, STATE THE REASON IN THE ADDITIONAL COMMENT SECTION
DEFINE THE ACTION NEEDED TO BE IMPLEMENTED TO OBTAIN AN ACCEPTABLE STATUS.

NAME Brian Campbell
TITLE Service Technician
DATE 7/22/2019

QA MANAGER APPROVED BY: Sean Wilson
DATE 8/5/19

LEAD AUDITOR APPROVED BY: Brian Campbell
DATE 8/5/19

ARCOS INDUSTRIES, L.L.C.
394 Arcos Drive
Mt. Carmel, PA 17851

Out of Tolerance Report 01-2019

August 5, 2019

On July 22, 2019 the Tinius Olsen Tensile Testing Machine was found to be out of tolerance with a percent error of -1.56. Which is outside the allowable tolerance of +/- 1.00% as allowed by ASTM E 4. The occurrence was immediately review by the Arcos Quality Department.

Results of Investigation

An error of -1.56 % means that the readings with were taken for the machine could actually be slightly higher than what was being reported by Arcos. For the vast majority of the produces which Arcos produces that is not an issue because the limits for tensile strength are based on the minimum values. However, Arcos does produce some low alloy steel electrodes the tensile strength limits for these products do have both a minimum and a maximum value. Each of these tests were reviewed and it was determined that the out of tolerance condition do not affect any of those products.

Brian Gaal

Brian Gaal

Technical Director

FORM #8
Corrective Action Report (CAR)

Report No. 262
Date: 6/12/2019

Area Involved: Material Acquisition
Issued To: Arcos Management
Reply Due Date: 7/12/2019

10CFR21 Applicable X No ____ Yes

Nature of Defect / Potential Problem:

During procurement activities Criterion IV of 10CFR50, Appendix B *"Measures shall be established to assure that applicable regulatory requirements, design bases, and other requirements which are necessary to assure adequate quality are suitably included or referenced in the documents for procurement of material, equipment, and services, whether purchased by the applicant or by its contractors or subcontractors. To the extent necessary, procurement documents shall require contractors or subcontractors to provide a quality assurance program consistent with the pertinent provisions of this appendix."* was not properly being flowed down to Material Organizations that have been Qualified by Arcos in addition to 10CFR Part 21 requirements. Purchased material would go through Commercial Grade Dedication process at the time of receipt by Arcos.

Cause: Condition Significant or Recurring? Yes ☐ No ☒

Provisions of 10CFR21 are being flowed down to approved suppliers by QA attachments.

Action Taken:

QA purchase order attachments include these statements, which flow down the requirements of Part21 reporting:

"The services covered by this purchase order may be used by Arcos Industries for the manufacture of components governed by the requirements of United States regulation 10CFR Part 21, Reporting of Defects and Noncompliance. In order to fulfill these requirements, the vendor is required to notify Arcos Industries of any condition, deviation or deficiency discovered after production which could render the service as unacceptable or indeterminate to specified requirements."

"Notification shall be sent in writing within 15 calendar days to the attention of Arcos Industries Quality Assurance Manager, giving full details of the deficiency and the items or service supplied that could be affected. This information will be used by Arcos Industries in evaluating whether a substantial safety hazard as defined in 10CFR21 has resulted."

Additionally, approved suppliers are also required to certify that these provisions have been met, which is verified during receipt inspection at Arcos.

FORM #8
Corrective Action Report (CAR)

Action Taken By: Sean Williams Date: 8/6/19

Action reviewed to identify any risk or opportunities to interested parties? Yes ☒ No ☐

QA Follow-up

No Corrective Action needed.

QA Follow-up By: Brian Saal Date: 8/6/19

Final Approval: Sean Williams Date: 8/6/19
Quality Assurance Manager

FORM #8
Corrective Action Report (CAR)

Report No. 264
Date: 6/12/2019

Area Involved: Vendor Surveillance/Audits
Issued To: Arcos Management
Reply Due Date: 7/12/2019

10CFR21 Applicable X No ____ Yes

Nature of Defect / Potential Problem:

Arcos Source Surveillance and Vendor Qualification Audits exhibit inconsistent documentation of objective evidence being documented throughout the reports. Some areas document specific objective evidence, where other areas of the reports lacked such evidence although the activity had been performed. Approved Procedures absent from Surveillance Reports and Purchase Orders for material being purchased as Unqualified Source Material from vendors who have had their Identification and Traceability Procedures reviewed and approved.

Cause: Condition Significant or Recurring? Yes ☐ No ☒

Inexperience of Lead Auditors performing Audit/Surveillances lead to the inconsistency of documentation of Objective Quality Evidence.

Action Taken:

Training has been performed by Arcos' General Manager, Harry Wehr, who is an experienced Lead Auditor with 20 years' experience on proper documentation of OQE.

Action Taken By: Harry Wehr Date: 8/2/2019

Action reviewed to identify any risk or opportunities to interested parties? Yes ☒ No ☐

QA Follow-up

See attached Document of Training (QA Form #15)

QA Follow-up By: Brian Ford Date: 8/2/19

Final Approval: Sean E Williams Date: 8/2/19
Quality Assurance Manager

DOCUMENT OF TRAINING

Date 8/2/2019
Document No. 1 of 1
Length of Session 15 Minutes
Subject Consistency of Objective Evidence on Documents

Note: The Recording of false, fictitious, or fraudulent statements or entries on this document may be punished as a felony under Federal Statute.

Print Name	Signature
Brian Gaal	Brian Gaal
Sean Williams	Sean Williams

Instructor: Harry Wehr General Manager

Comments: Reviewed the need to document Objective Quality Evidence on Audit and surveillance Reports. Additionally, discussed ensuring Approved ID & Traceability procedures be listed on Purchase Orders to those suppliers having been approved to supply Unqualified Source Material as one Heat/Lot.

FORM #8
Corrective Action Report (CAR)

Report No. 265
Date: 6/12/2019

Area Involved: Documentation
10CFR21 Applicable: X No ____ Yes
Issued To: Arcos Management
Reply Due Date: 7/12/2019

Nature of Defect / Potential Problem:

Certain documents exhibited lack of independence of who prepared, reviewed and approved the information. This was noted on Audit reports, Source Surveillance, and CARs, the extent of the condition shall be investigated.

Cause: Condition Significant or Recurring? Yes ☐ No ☒

Due to changes in positions, specifically the QA Manager position, this was inconsistent between individuals filling the position.

Action Taken:

Individuals charged with the preparation, review, and approval of mentioned documents are all now aware of the need for independence throughout each step of the processes. Reviewed previous 24 months of documentation to investigate the extent of the condition, discrepancies reviewed and approved independently, as necessary.

Action Taken By: Arcos' Management Date: 8/1/2019

Action reviewed to identify any risk or opportunities to interested parties? Yes ☒ No ☐

QA Follow-up

Verified CARs dating back to 2017 have been reviewed and approved appropriately.

QA Follow-up By: Brian Gual Date: 8/1/19

Final Approval: Sean Williams Date: 8/1/19
Quality Assurance Manager

FORM #8
Corrective Action Report (CAR)

Report No. 266
Date: 6/12/2019

Area Involved: Calibration and Testing
Issued To: Arcos Management
Reply Due Date: 7/12/2019

10CFR21 Reportable: X No ____ Yes

Nature of Defect / Potential Problem:

Arcos' QP-6.4 and QP-6.8 inconsistent with the provisions of ASME B&PVC Section III, Subsection NCA-4255.3(c)(d) and NEI 14-05A, Revision 0 *"GUIDELINES FOR THE USE OF ACCREDITATION IN LIEU OF COMMERCIAL GRADE SURVEYS FOR PROCUREMENT OF LABORATORY CALIBRATION AND TEST SERVICES"*, regarding acceptance of laboratory accreditation by Accreditation Bodies (ABs) that are signatories to the International Laboratory Accreditation Cooperation (ILAC) Mutual Recognition Arrangement (MRA) for calibration and testing services.

Cause: Condition Significant or Recurring? Yes ☐ No ☒

Arcos' QP-6.8, Revision 3 lacks consistent verbiage to align with the requirements of NCA-4255.3 and NEI 14-05, and Arcos' QP-6.4.

Action Taken:

Revisions made to Arcos' QP-6.4 and QP-6.8 to be consistent with the requirements of NCA-4255.3(c)(d) and NEI 14-05A, Revision 0.

Action Taken By: Sean Williams Date: 8/6/19

Action reviewed to identify any risk or opportunities to interested parties? Yes ☒ No ☐

QA Follow-up

QA Follow-up By: _____ Date: _____

Final Approval: _____ Date: _____
Quality Assurance Manager

FORM #8
Corrective Action Report (CAR)

Report No. 275
Date: 6/14/2019

Area Involved: Arcos' Quality System
Issued To: Sean Williams
Reply Due Date: 7/14/2019

10CFR21 Applicable X No ____ Yes

Nature of Defect / Potential Problem:

Arcos' QP-13.1, 13.2, 14.1 all unclear of when a 10CFR21 evaluation applies. Review extent of condition with additional Procedures regarding better detail Arcos actual practices.

Cause:

Condition Significant or Recurring? Yes ☐ No ☒

Arcos Procedures QP-13.1, 13.2, and 14.1 contained verbiage that the Arcos 10CFR21 Procedure would apply but not exactly clear WHEN this would initiate and evaluation.

Action Taken:

Revisions to Arcos QP-13.1, 13.2, and 14.1 now all include proper verbiage as to when a Part 21 evaluation shall occur and directs the reader to QP-13.4 (10CFR21) for guidance.

Action Taken By: Sean Williams Date: 8/5/19

Action reviewed to identify any risk or opportunities to interested parties? Yes ☒ No ☐

QA Follow-up:

See attached QP-13.1 Rev 14, QP-13.2 Rev 7, QP- 14.1 Rev 12.

QA Follow-up By: Brian Good Date: 8/5/19

Final Approval: Nancy Webb Date: 8/5/2019

~~Quality Assurance~~ General Manager

ARCOS INDUSTRIES, LLC
394 Arcos Drive
Mt. Carmel, PA 17851
High Performance Welding Alloys

Document	Quality Procedure
	QP-13.1
Revision	14
Date	8/2/2019

NONCONFORMING PRODUCT

1. Arcos defines Nonconforming Product in QSM section 16.0. Once a product has been found to be nonconforming shall be cause for following this procedure.

2. **IDENTIFYING NONCONFORMING PRODUCT**

2.1 All personnel may initiate a Hold. The QA personnel shall review all holds and decide whether the NCR process is applicable. The NCR (QSM Form #7) shall show the report number, work order number, date, inspector, grade, size, heat/lot, weight, and reason for rejection. The QA Manager shall evaluate the NCR for 10CFR21 applicability.

2.2 The QA personnel shall identify Nonconforming Product by affixing a copy of the Nonconforming Report and a Hold tag to the material. The form must be affixed in such a manner as to ensure the NCR is securely attached to the material and readily visible.

2.3 The QA personnel shall require the timely removal of any rejected material to a designated area for holding nonconforming product.

2.4 Quality Assurance Manager shall review report and determine disposition.

2.5 Upon disposition completion, the Quality Assurance Manager shall approve the NCR.

2.6 The Quality Assurance Manager shall forward copies of the completed NCR to Production and Top Management.

3. **REJECTED PRODUCT STORAGE IN NONCONFORMING AREA**

3.1 All nonconforming product shall be identified with a copy of the NCR and a Hold tag. It shall be segregated from normal production processing.

3.2 Quality Assurance shall maintain a designated area until released for disposition. The area shall be posted with "Nonconforming Product Area".

Approved By: Sean Williams
QA Manager

3.3 Nonconforming rod shall be kept in the rod-receiving area and identified with a copy of the NCR, and an Incoming Inspection Hold tag until it is returned to the supplier.

4. DISPOSTION OF NONCONFORMING MATERIAL

4.1 The Product Inspector shall ensure that identification tags or labels are on the material, and that the work order indicates further processing instructions and the correct wire type, size, heat/lot number and work order number. Reworked product must be re-inspected by the Product Inspector.

4.2 Once the disposition for the material has been determined and it is properly identified it may be removed from the designated Nonconforming Product Area.

4.2.1 QA personnel shall ensure proper identification and storage while the material disposition is being carried out.

5. USE OF CORRECTIVE ACTION PROCEDURE

5.1 The Quality Assurance Manager shall determine when the Corrective Action procedure is used for repetitive nonconformances.

6. 10CFR21 REPORTING

/6.1 A determination shall be made by Quality Assurance as to whether any of the defects noted might have been built into any other products. Customers who received shipped product shall be notified and disposition made accordingly. **The 10CFR21 Procedure (QP-13.4) shall apply when a basic component supplied to such facility or activity fails to comply with the Atomic Energy Act of 1954, as amended, or any applicable rule, regulation, order, or license of the Commission relating to substantial safety hazards or basic component supplied to such facility or activity contains defects, which could create a substantial safety hazard.**

Approved By: Sean Williams
QA Manager

NONCONFORMING PRODUCT-RETURNED

1. The Receiver shall prepare a RMR form (page 2) and forward it to Quality Assurance Manager for review and disposition.

   1.1 All returned products shall be checked for proper identification.

   /1.2 Any product returned for quality reasons shall be reviewed by the Quality Assurance Manager who will determine the testing and/or evaluation to be conducted. A determination shall be made by Quality Assurance as to whether any of the defects noted might have been built into any other products. If so, a QC HOLD tag shall be placed on any such product in the warehouse. Customers who received shipped product shall be notified and disposition made accordingly. **The 10CFR21 Procedure (QP-13.4) shall apply when a basic component supplied to such facility or activity fails to comply with the Atomic Energy Act of 1954, as amended, or any applicable rule, regulation, order, or license of the Commission relating to substantial safety hazards or basic component supplied to such facility or activity contains defects, which could create a substantial safety hazard.**

   1.3 Product returned for non-quality reasons, (e.g. excess stock, wrong product ordered or shipped), shall be returned to the warehouse provided that the packaging and the product is not damaged or compromised.

Approved By: Sean Williams
QA Manager

48233 PENN VALLEY PRINTING CO. SELINSGROVE, PA 717/374-1106

FROM:

RETURNED MATERIALS REPORT No. 2202

TO: ACCOUNTING

R.M.R. DATE_____

MATERIAL REC'D BY_____ DATE REC'D_____

ISSUE CREDIT TO:

AUTHORIZED BY_____ DATE_____

CUSTOMER'S ORDER NO._____ S.O. NO._____

INVOICE NO._____ DATE_____

QUANTITY	DESCRIPTION	LOT NUMBER OR ALLOY NUMBER	UNIT PRICE	EXTENSION	ACCOUNTING DEPT. COST	ACCOUNTING DEPT. EXTENSION

QUALITY CONTROL INSTRUCTIONS	BY	DATE
RESTOCK		
REPACK & RESTOCK		
SALVAGE (WASH WIRE)		
SCRAP		
REWORK SCHEDULED		
REWORK COMPLETED		
RECEIVED IN WHSE.		

COMMENTS

CREDITS	VALUE OF RETURNED MATERIAL		TOTAL
	POSTAGE/FREIGHT		
	OTHER CREDITS		
	TOTAL GROSS CREDIT		
CHARGES	FREIGHT ALLOWANCE		
	DISCOUNT		
	RESTOCKING		
	OTHER CHARGES		
	TOTAL CHARGES		

ISSUE CREDIT SHOWN PER: DATE: AMOUNT OF CREDIT

CREDIT ISSUED PER: DATE:

ND 145-2M-7-87

Approved By: Sean Williams
QA Manager

CORRECTIVE ACTION

1. RESPONSIBILITY

The Quality Assurance Manager is responsible for maintaining a system that shall:

1.1 Assess the cause of material or NCR's requiring corrective or preventive action.

1.2 Advise management of problem areas by means of documented Corrective Action Reports (CAR's).

1.3 Corrective Action Reports are applicable to all in-house activities and subcontractors.

1.4 Provide reports to appropriate levels of management to assure prompt and effective action.

2. RECORDS AND REPORTING

2.1 Quality Assurance shall maintain a log of Corrective Action Reports showing status, due date, and close out dates. The Quality Assurance Manager shall keep the log current and shall conduct a review of Corrective Action Reports every 6 months. Copies of this review shall be forwarded to top management.

3. ELEMENTS OF CORRECTIVE ACTION SHALL INCLUDE

3.1 Appraisal of error cause and identification of required Corrective Action.

3.2 Evaluation of in-process and/or completed products for future preventive action measure.

3.3 Follow-up for effectiveness of corrective action taken.

3.4 Evaluation of risk or potential opportunities relating to implementation of CAR

Approved By: Sean Williams
QA Manager

4. APPLICATION OF CORRECTIVE ACTION

4.1 Vendors shall be issued a CAR if incoming material is rejected. The report shall identify the material and the defect. It shall also request an explanation for the cause of the defect and what corrective action will be taken to prevent recurrence.

4.2 In-Process:

4.2.1 Any defects or potential defects that produce unacceptable products shall be reported to Quality Assurance immediately. Production shall not resume until adequate corrections are made.

4.2.2 All employees have the authority to halt production at their workstation if a non-conforming condition is noted. The Product Inspector or QA Manager shall be notified.

4.2.3 Defective product shall be marked QC Hold or Rejected by quality assurance personnel if it is not salvageable by rework at that workstation. Where applicable, the QA Manager shall issue a Corrective Action Report or Nonconforming Report.

/4.2.4 A determination shall be made by Quality Assurance as to whether any of the defects noted might have been built into any other products. If so, a QC HOLD tag shall be placed on any such product in the warehouse. Customers who received shipped product shall be notified and disposition made accordingly. **The 10CFR21 Procedure (QP-13.4) shall apply when a basic component supplied to such facility or activity fails to comply with the Atomic Energy Act of 1954, as amended, or any applicable rule, regulation, order, or license of the Commission relating to substantial safety hazards or basic component supplied to such facility or activity contains defects, which could create a substantial safety hazard.**

Approved By: Sean Williams
QA Manager

4.3. Finished Material Released to Warehouse or Shipped:

4.3.1 If at any time, there is indication of nonconforming product, either in our warehouse or in the field; the action listed under 4.2.3 must be taken.

4.3.2 A Corrective Action Report shall be issued by the Quality Assurance Manager and sent to Top Management.

4.4 Non-production Areas - Corrective Action in non-production areas shall be as follows:

4.4.1 Purchasing, Production, Quality Assurance and Sales Activities- when quality problems require Corrective Action, a Corrective Action Report shall be issued by the QA Manager.

4.4.2 When failure is noted in the Inspection System, the QA Manager shall issue a Corrective Action Report.

4.5 Audits:

4.5.1 Where this Corrective Action procedure is used as a result of deficiencies disclosed by Internal Audits, the follow-up of corrective action and the results shall be documented with copies forwarded to Top Management.

5. FOLLOW-UP ON CORRECTIVE ACTION

5.1 The QA Manager is responsible for maintaining the log to track Corrective Action replies. Any delinquency shall be solved at the lowest possible level. However, if needed, such problems shall be carried to whatever organizational level is required for a viable solution.

5.2 The QA Manager shall maintain the file of Corrective Action Reports.

5.3 When repetitive Corrective Actions are required, the Quality Assurance Manager, at his discretion, shall be responsible for calling a meeting with applicable personnel. Definite action to solve the Corrective Action problems shall be planned and targeted. The Quality Assurance Manager is responsibility for follow-up of planned actions.

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QA Manager