NRC FORM 591S PART 1
(11-2020)
10 CFR 2.201

U.S. NUCLEAR REGULATORY COMMISSION

SAFETY INSPECTION REPORT AND COMPLIANCE INSPECTION

1. CERTIFICATE/QUALITY ASSURANCE PROGRAM (QAP) HOLDER:	2. NRC/REGIONAL OFFICE
Alpha-Omega Services, Inc. 9156 Rose Street Bellflower, CA 90706	Headquarters U. S. Nuclear Regulatory Commission Mail Stop TWFN 4A-60 Washington, DC 20555-0001
REPORT NUMBER(S) 71-0086/2021-201	

3. CERTIFICATE/QAP DOCKET NUMBER(S)	4. INSPECTION LOCATION	5. DATE(S) OF INSPECTION
71-0086 (QAP)	Bellflower, CA (Remote)	March 8-11, 2021

CERTIFICATE/QUALITY ASSURANCE PROGRAM HOLDER:

The inspection was an examination of the activities conducted under your QAP as they relate to compliance with the Nuclear Regulatory Commission (NRC) rules and regulations and the conditions of your QAP Approval and/or Certificate(s) of Compliance. The inspection consisted of selective examinations of procedures and representative records, interviews with personnel, and observations by the inspector. The inspection findings are as follows:

☑ 1. Based on the inspection findings, no violations were identified.

☐ 2. Previous violation(s) closed.

☐ 3. The violations(s), specifically described to you by the inspector as non-cited violations, are not being cited because they were self-identified, non-repetitive, and corrective action was or is being taken, and the remaining criteria in the NRC Enforcement Policy, to exercise discretion, were satisfied.

_____ Non-cited violation(s) was/were discussed involving the following requirement(s) and Corrective Actions(s):

☐ 4. During this inspection, certain of your activities, as described below and/or attached, were in violation of NRC requirements and are being cited in accordance with NRC Enforcement Policy. This form is a NOTICE OF VIOLATION, which may be subject to posting in accordance with 10 CFR 19.11.
(Violations and Corrective Actions)

Statement of Corrective Actions

I hereby state that, within 30 days, the actions described by me to the Inspector will be taken to correct the violations identified. This statement of corrective actions is made in accordance with the requirements of 10 CFR 2.201 (corrective steps already taken, corrective steps which will be taken, date when full compliance will be achieved). I understand that no further written response to NRC will be required, unless specifically requested.

TITLE	PRINTED NAME	SIGNATURE	DATE
CERTIFICATE/QAP REPRESENTATIVE	Troy Hedger		04/14/2021
NRC INSPECTOR	Jeremy Tapp	Jeremy E. Tapp Digitally signed by Jeremy E. Tapp Date: 2021.04.15 09:02:18 -04'00'	
BRANCH CHIEF	Leira Cuadrado	Leira Y. Cuadrado-Caraballo Digitally signed by Leira Y. Cuadrado-Caraballo Date: 2021.04.15 09:48:38 -04'00'	

INSPECTOR NOTES COVER SHEET

Licensee/Certificate Holder (name and address)	Alpha-Omega Services, Inc. 9156 Rose Street Bellflower, CA 90706
Licensee/Certificate Holder contact and phone number	Mr. Troy Hedger, CEO 562-804-0604
Docket No.	71-0086
Inspection Report No.	71-0086/2021-201
Inspection Dates(s)	March 8-11, 2021
Inspection Location(s)	Bellflower, CA (Remote inspection)
Inspectors	Jeremy Tapp, Team Leader, Safety Inspector Jon Woodfield, Safety Inspector Matthew Learn, Safety Inspector
Summary of Findings and Actions	The purpose of the inspection was to verify the adequacy of activities related to design, modification, procurement, repair, and maintenance of transportation packagings at Alpha-Omega Services, Inc. (AOS') facility in Bellflower, CA. The focus of the inspection was to determine whether AOS' activities associated with transportation of radioactive material were executed in accordance with the requirements of 10 CFR Parts 21 and 71, Certificate of Compliance 71-9316 and associated Safety Analysis Report (SAR), and AOS' NRC-approved quality assurance (QA) program. The team determined that AOS' implementation of its NRC-approved QA program was adequate based on an examination of selected design, maintenance, and QA activity records and procedures, and interviews with personnel. No issues of more than minor significance were identified.
Lead Inspector Signature/Date	Jeremy E. Tapp Digitally signed by Jeremy E. Tapp Date: 2021.04.15 09:02:53 -04'00' Jeremy Tapp
Inspector Notes Approval Branch Chief Signature/Date	Leira Y. Cuadrado-Caraballo Digitally signed by Leira Y. Cuadrado-Caraballo Date: 2021.04.15 09:49:15 -04'00' Leira Cuadrado

Inspection Background

Alpha-Omega Services, Inc. (AOS) corporate was last inspected in March 2016 and before that in February 2012. The inspection in March 2016 was a full scope review of all aspects of AOS' quality program. The inspection resulted in the identification of two violations of minor safety significance related to independent verification and classification of quality components. Both issues were entered into AOS' corrective action program. In addition, since the last inspection in March 2016, AOS has not fully completed fabrication of any packagings.

Inspection Purpose

The purpose of the full scope inspection was to assess AOS' activities associated with transportation of radioactive material to determine if they were executed in accordance with the requirements of 10 CFR Parts 21 and 71, Certificate of Compliance (CoC) 9316 for the AOS-25/50/100 packagings and associated Safety Analysis Report (SAR), and AOS' NRC-approved QA program. Overall, the team inspected AOS' management, design, and maintenance controls.

The team reviewed QA program implementing procedures and instructions, and selected documents, records, and drawings. The team also reviewed various design and maintenance activities of the AOS-25/50/100 packagings approved by CoC 71-9316. Because AOS has not fully completed fabrication of any packagings since the last inspection, the team focused on performance of maintenance activities for the current packagings in use, and on design activities related to a number of modifications performed.

Primary Inspection Procedures/Guidance Documents

- IP-86001, "Design, Fabrication, Testing, and Maintenance of Transportation Packagings"
- NUREG/CR-6314, "Quality Assurance Inspections for Shipping and Storage Containers"
- NUREG/CR-6407, "Classification of Transportation Packaging and Dry Spent Fuel Storage System Components According to Importance to Safety"

INSPECTOR NOTES: APPLICABLE SECTIONS FROM IP 86001 WERE PERFORMED DURING THE INSPECTION WITH RESULTS DOCUMENTED BELOW UNDER THE BASIC HEADINGS OUTLINED IN NUREG-6314

1.0 Management Controls

Quality Assurance Policy

The team reviewed AOS' Quality Assurance Program (QAP) PR9000 Revision H and implementing AOS Quality Procedures [Standard Operating Procedures (SOPs)] and assessed the effectiveness of the QA program implementation at AOS. The team conducted reviews of AOS' quality program, policies, and procedures, and discussed portions of the reviewed documents with selected AOS staff to determine whether activities subject to 10 CFR Part 71 were adequately controlled and implemented under AOS' NRC-approved QA program. In addition, the team reviewed the AOS quality organization chart and interviewed AOS QA personnel to assess their organizational independence from cost, schedule, and production activities.

The team reviewed procedures and documents regarding training, qualification, and certification of personnel involved in quality activities. Specifically, the team reviewed the following SOPs:

PR9000.1, "Quality Assurance Program and Implementing Procedures," Revision U
PR9001.1, "Organization and Responsibility," Revision F
PR9002.1, "Control of the Quality Assurance Program Revisions," Revision E
PR9002.2, "Indoctrination and Training of Personnel," Revision H

The team reviewed the qualifications and training for selected Quality Managers, Quality Engineers, and Service staff to determine if they met the requirements stated in the QA program. In addition, the team reviewed training records of a random selection of employees in quality related positions to determine if they received the required QA indoctrination and QAP revision training. The team determined that for every AOS staff member's records reviewed, each had completed the required training and attained the applicable qualifications to perform their duties.

The team also reviewed the following AOS SOPs which address a graded approach to quality components and commercial grade dedication of packaging components when required:

PR9003.7, "Identification of Quality Categories and Safety Classifications," Revision C
PR9007.1, "Control of Purchased Material, Equipment, and Services," Revision H
PR9007.5, "Dedication of Commercial Grade Items and Services," Revision F

The team verified that the material commercial grade dedication program/procedure included requirements for the identification, documentation, and implementation of important-to-safety levels in dedication plans. The procedure provided significant guidance on the identification of critical characteristics needed during the dedication process. The dedication report must

provide the acceptance criteria for each critical characteristic and identification of the method of verification. Guidance on the associated audits or approvals of the supplier or testing company commensurate with the safety rating of the part or material being procured is also provided in the procedures.

Overall, the team determined that the quality assurance controls at AOS were adequate and in accordance with their NRC-approved QAP. No issues of more than minor significance were identified.

Nonconformance and Corrective Action Controls

The team reviewed a sample of nonconformance reports (NCRs) and Corrective and Preventive Actions (CAPAs) generated since the previous NRC inspection and interviewed personnel to verify that AOS effectively implemented the nonconformance control and corrective action programs. The team also reviewed AOS SOPs PR9015.1, "Nonconforming Material, Parts, and Components," Revision E and PR9016.1, "Corrective Action," Revision E that govern the nonconformance and corrective action programs, respectively. The team reviewed the SOPs for compliance with the applicable regulations in 10 CFR Part 71.

The team also specifically reviewed the five CAPAs written during the NRC 2016 AOS inspection to assess their corrective and preventive actions, as applicable, and resolution and closure. The team determined that all five CAPAs adequately addressed the issues they were written for and were properly closed.

The team discussed the nonconformance and CAPA program controls with the AOS staff and reviewed a sample of 12 NCRs and 12 CAPAs for appropriate disposition. The team also reviewed the AOS NCR log used to keep track of the status of nonconforming items. The team focused on CAPAs that had cause analyses for a condition adverse to quality or a significant condition adverse to quality. The CAPA sample included a review of SOP compliance issues, audit findings, drawing issues, shipping issues, and nonconformances that needed a CAPA. The team verified that AOS completed CAPAs for identified deficiencies in a technically sound and timely manner.

The nonconformance sample reviewed by the team was focused on reports associated with accept-as-is and repair/rework dispositions. The team determined AOS dispositioned the NCRs in accordance with PR9015.1, as required.

AOS QA is responsible for evaluating quarterly, in conjunction with an NCR review, the effectiveness of the corrective action program. The quarterly report also provides trend analysis and identifies CAPA and NCR recurring issues and deficiencies. After the report is prepared, it is reported to management for review. The team reviewed the latest CAPA and NCR trend analysis report and determined it was thorough in its evaluation for negative trends in quality areas. The team also verified that the CAPAs and NCRs reviewed and the standard forms they were written on had a connection to the 10 CFR Part 21 program.

The team reviewed the AOS program controls for 10 CFR Part 21, "Reporting of Defects and Noncompliances," and the associated SOP PR9015.2, "Regulatory Requirements Reportability," Revision D. The team verified that AOS' procedure adequately implemented the requirements of Part 21.

Since this inspection was performed remotely, AOS provided electronic photographs of the 10 CFR Part 21 postings at their facilities. By reviewing the photographic evidence, the team verified that AOS was meeting the 10 CFR Part 21 posting requirements of both the regulations and PR9015.2. The team determined that AOS posted the 10 CFR Part 21 regulations, Section 206 of the Energy Reorganization Act of 1974, Form 3, and PR9015.2 on boards where employees could easily see them. No issues were identified by the team regarding 10 CFR Part 21 program controls or implementation at AOS.

Overall, the team concluded that AOS had an adequate nonconformance control and corrective action program in place to identify, track, and resolve quality related deficiencies and deviations.

Documentation Controls

The team reviewed AOS' documentation control program to assess the effectiveness of controls established for the approval, issuance, revision and use of quality documents. The team reviewed PR9006.1, "Document Control," Revision G. The team assessed that the procedure provided adequate guidance for the processing of quality document approvals, issuance to internal and external organizations when necessary, and revision control for each documented organization. For a sample of quality documents reviewed, the team verified that the documents were approved per procedure by appropriate personnel and the most current version was available for use. The team observed AOS' use of their document management and storage system for procedure control and use and noted it was controlled in accordance with the applicable requirements of PR9006.1. The team interviewed personnel responsible for the program to ensure they were knowledgeable of the program requirements and were implementing the program as required. The team also verified that a sample of procedure revisions were performed as required, including the associated forms required for the revisions.

In addition, the team reviewed PR9017.1, "Quality Assurance Records," Revision F. The team then discussed with document control and QA personnel how the applicable regulatory and procedural requirements for quality record control were being implemented by AOS' QA program to ensure they were being performed as required. Specifically, the team discussed where and how the quality documents were stored. The team noted that AOS stores multiple copies of electronic records on the company servers and on hard drives made regularly as permanent backups. The company servers are located in different physical locations and the hard drives are stored at a different location than where the company servers are located. The team also verified that selected quality documents were filed and in the appropriate location on one of the quality record file servers.

Overall, the team determined that AOS was implementing its document control program, including quality record control, as required by the applicable regulatory and procedural requirements.

Audit Program

The team reviewed the AOS QAP and the following implementing procedures for performing external audits of AOS vendors on its Approved Suppliers List (ASL) and internal audits of AOS.

PR9002.5, “Qualification and Certification of Quality Assurance Audit Personnel,” Revision E
PR9018.1, “Audits,” Revision C

The team reviewed the qualifications and training records for AOS’ two Lead Auditors to determine if they met the requirements stated in PR9002.5. The team found each had completed the required training and attained the applicable qualifications to perform their duties as lead auditor.

The team reviewed the audits of two vendors on the ASL. The two vendors were on the ASL for: 1) Supplier of Important-To-Safety and Safety-Related Design and Engineering Services, and 2) Provider of Nondestructive Examination Methods (VT, PT, and LT).

The first audit reviewed by the team was a quality assurance program audit performed by AOS in August 2018 of a design and engineering services vendor. The team found the audit package to contain the proper forms for audit summary, nuclear audit checklist, and audit plan. The audit summary identified the product or service provided, activities audited, scope of the audit, summary of results, audit results, effectiveness of the quality system program, conclusion, and audit observations. AOS in correspondence to the vendor identified six observations during the audit. AOS requested a written response from the vendor when actions were completed to address the issues. Overall, AOS found the vendor to be in compliance with its Quality Assurance Program and will be retained on the ASL, however with certain restrictions. These restrictions are shown on the ASL for this vendor. AOS’ audit certification of this vendor will remain in effect for a period of three years until August 27, 2021.

The second audit reviewed by the team was a quality assurance program audit performed by AOS in April 2019 of a nondestructive examination vendor. The team found the audit package to contain the proper forms for audit summary, nuclear audit checklist, and audit plan. The audit summary identified the product or service provided, activities audited, scope of the audit, summary of results, follow-up, effectiveness of the quality system program, conclusion, audit observations, and recommendations. AOS in correspondence to the vendor identified 12 observations and three recommendation findings during the audit. AOS issued CAPAs to the vendor for the findings which required a written response. Overall, AOS found the vendor to be in compliance with its Quality Assurance Program and were retained on the ASL, however with certain restrictions. These restrictions are shown on the ASL for this vendor. AOS’ audit certification of this vendor will remain in effect for a period of three years until April 22, 2022.

The team found the sampled vendor audit results to be very detailed and well documented with the findings, audit checklists, supporting audit documentation reviewed, and vendor written responses all recorded and retrievable. All the requirements of procedure PR9018.1 were found to be met. No concerns were identified by the team in the review of external audits.

The team reviewed the latest AOS internal audit report conducted in July and August 2020, which covered AOS' implementation of their QAP and SOPs and verified compliance with the quality requirements stated in 10 CFR Part 71 Subpart H and 10 CFR Part 21. Internal audits are required to be performed by AOS on a yearly basis per PR9018.1. However, the 2019 internal audit, which was to be performed in March and April of 2020, was delayed until July and August due to the COVID-19 public health emergency, which was past the timeframe allowed by PR9018.1. The inability of AOS to perform the internal audit as required by PR9018.1 was documented in a CAPA to evaluate and track the issue, as required. The audit was also conducted remotely due to the public health emergency. The 2019 audit team consisted of one auditor contracted to AOS. An audit plan, audit checklist, and audit summary were developed as required by PR9018.1.

The team reviewed the audit results in the 2019 report. The audit identified six comments and assigned a CAPA number to address the issues and internal discussions and track them to closure. The 2019 Internal Audit Report also reviewed all the elements of the 2018 Internal Audit and any identified audit findings for completion and adherence to committed actions.

The team found the audit results to be very detailed and the comments, audit checklists, and supporting audit documents reviewed well documented; along with a CAPA assigned to document the comments and discussions identified. The team determined that the internal audit was very effective in its structured approach for finding issues affecting quality at AOS and was performed in accordance with PR9018.1. No concerns were identified by the team in the internal audit review.

Overall, no concerns were identified with the performance of AOS' ASL audits of external suppliers or internal audits.

2.0 Design Controls

The team reviewed the AOS procedures specifically related to design development/control for modification activities and held discussions with AOS engineering and QA personnel. The team also reviewed the training and qualification for selected engineering personnel. The team focused its review on AOS design activities related to Revisions 7, 8, and 9 of CoC 9316 for the Part 71 AOS-025A/050A/100A/100B/100A-S packagings. The team reviewed the following AOS SOPs associated with design control and training to verify they were being properly implemented:

- PR9003.1, "Design Control," Rev. D

- PR9003.2, "Project Plan," Rev. B
- PR9003.3, “Calculations,” Rev. C
- PR9003.5, “Design Review,” Rev. D
- PR9002.6, “Qualification of Engineering Personnel,” Rev. C

The team reviewed the applicable design documentation for the modifications performed for Revisions 7, 8, and 9 of CoC 9316. This included calculations, revised drawings and SAR pages, and design record files. The team verified the applicable drawings were revised per PR9005.1, “Drawings,” Revision C, and calculations performed, as necessary, including proper review and acceptance of those performed by approved suppliers as required by quality procedures.

In addition, the team reviewed a selected licensing drawing to verify the design details were adequately translated to the associated fabrication drawings. Specifically, the team reviewed licensing drawing 166D8137, Revision I and compared it to three related fabrication drawings. For the design details reviewed, all were correctly translated to the fabrication drawings.

Overall, the team found the AOS design control program to be adequate and that implementing procedures were in place to control activities in accordance with the applicable regulations and approved CoC. No issues of more than minor significance were identified.

3.0 Maintenance Controls

Maintenance Activities

The team reviewed AOS' packaging maintenance program which requires a series of routine and periodic inspections. The team specifically reviewed AOS SOP PR9110, "AOS Radioactive Material Transport Packaging System Generic Maintenance and Operating Procedure for Model AOS-025, AOS-050, and AOS-100 Transport Packages," Revision G. AOS stated that procedure PR9110 is provided to all the licensed users of its AOS series packagings. The procedure covers the required actions to properly maintain the packaging, including pre-shipment inspections. The team compared the instructions in the procedure for the various packaging activities against the approved operating procedures and maintenance requirements provided in Chapter 7 and 8 of the AOS packaging SAR and found them to be consistent as it relates to inspection and maintenance.

AOS performs an annual inspection of the AOS packagings or prior to being used after a storage period of more than one year. The annual inspection is performed in accordance with PR9110.1, "Annual Maintenance Procedure for AOS Transport Packaging System," Revision B. The team reviewed AOS Form FM9110.4, "AOS Annual Inspection Plan Check Sheet," that is used to document the annual maintenance was performed on each packaging. After the inspection, AOS generates a certificate of compliance for the packaging user certifying that the annual inspections and maintenance have been performed. The team reviewed the CoC Annual Maintenance Certification for a sample of packagings. The CoC contained detailed information that included an effective date and expiration date (period of one year). The team

found the documentation for the packaging periodic and annual maintenance program at AOS to be complete.

Packaging annual inspections and tests could be outsourced to an AOS approved supplier or performed by AOS personnel who have been qualified and certified in accordance with SOP PR9002.3, "Qualification and Certification of Inspection & Test (I&T) Personnel," and SOP PR9002.4, "Qualification and Certification of Nondestructive Examination (NDE) Personnel." The team reviewed a sample of training records for the individuals that performed annual maintenance. The team found the training records thorough and current.

The team reviewed PR9007.4, "Receiving Inspection," Revision D, and PR9008.1, "Identification and Control of Materials, Parts and Components," Revision C, which address receipt inspection and control of materials. The team reviewed a sample of procurement and receipt inspection of materials.

Tools and Equipment

The team reviewed AOS SOP PR9012.1, “Control of Measuring and Test Equipment,” Revision G for the QA requirements for control of measuring and test equipment (M&TE) to verify that it was being properly implemented. In general, at AOS the calibration of M&TE was subcontracted to and performed by approved suppliers. The team noted that AOS inspection/maintenance personnel are responsible to report on work travelers, or appropriate documentation, the M&TE serial number and calibration data used for all inspections and tests. They are also required prior to use to 1) ensure M&TE is identified with a serial number and a calibration label, 2) the M&TE has been calibrated and the calibration has not expired, and 3) the M&TE is in good working order.

AOS QA prepares and controls the M&TE Equipment Log in a database. The Equipment Log lists all M&TE used in activities affecting the quality of AOS packaging and includes calibration and preventive maintenance requirements. Using the Equipment Log, inspection generates a report to identify the M&TE requiring calibration. The team reviewed the Equipment Log and current calibration documentation/records.

The team reviewed AOS' Acceptance of Calibration Services Form for a sample of calibrated equipment. The team also reviewed Calibration Certificates for a sample of calibrated equipment received from outside vendors.

Overall, the team found the AOS packaging maintenance and M&TE programs to be adequate. No issues of more than minor significance were identified.