

January 12, 2022

US Nuclear Regulatory Commission
ATTN: Document Control Desk
Washington, DC 20555-0001

Subject: Reply to a Notice of Violation

Nuclear Regulatory Commission Inspection of Engine Systems, Inc.,
Report No. 99901362/2021-201 and Notice of Violation

Engine Systems, Inc. (ESI) is in receipt of the above subject inspection report and the related notice of violation. Following please find ESI's response to the NOV.

I. Violation

Section 21.21, "Notification of failure to comply or existence of a defect and its evaluation," of Title 10 of the *Code of Federal Regulations* (10CFR) Part 21, requires that "Each individual, corporation, partnership, dedicating entity, or other entity subject to the regulations in this part shall adopt appropriate procedures to evaluate deviations and failures to comply to identify defects and failures to comply associated with substantial safety hazards as soon as practicable."

Contrary to the above, as of August 19, 2021, ESI failed to adopt appropriate procedures to evaluate deviations and failures to comply and identify defects as soon as practicable. Specifically, Engine Systems received a failed pressure regulating valve on February 24, 2021 from a facility subject to the regulations in 10 CFR Part 50. Due to inappropriate procedures in place, six months elapsed between the arrival of the failed part at ESI and the evaluation of that valve on August 19, 2021 which resulted in a Part 21 notification to the NRC.

II. ESI Response

ESI documented this condition in its Corrective Action Program on ESI CAR 2021-21 on October 11, 2021. The following is taken from the CAR which was reviewed by NRC during the inspection.

1) Reason for the violation:

Warranty orders are normally investigated in a timely fashion in a discovery effort led by Engineering upon receipt of the material. There is typically correspondence between ESI and the plant before the material is received. Because of the correspondence and ESI's awareness of the Part 21 potential, cases such as this have high visibility and have not needed a programmatic mechanism in order to ensure timely investigation.

In this case, the lack of a programmatic mechanism to trigger the investigation allowed the PRV to be overlooked. The PRV was received and placed on the work in process shelf. Without priority, the PRV was overlooked by Engineering and Quality.

IE09
NRR

2) *The corrective steps that have been taken and the results achieved:*

PSP-114, "Warranty Processing Procedure" has been revised to require a Non-Conformance Report (NCR) to be initiated upon receipt of the warranty item(s). Initiation of the NCR gives the item visibility at the Management Level (open NCRs are reviewed at the weekly Management Meeting). Further, ESI's NCR process requires Engineering to determine if a Part 21 evaluation is required within 21 days of initiation of the NCR.

Since identification of this condition and revision of PSP-114, ESI has processed 1 warranty. An NCR was written upon receipt of the items and it was determined that a Part 21 evaluation was not required. Nine (9) days elapsed between ESI receipt of the items and the determination that a Part 21 evaluation was not required.

3) *The corrective steps that will be taken:*

ESI will continue to monitor the warranty process to ensure that the corrective actions are effective.

4) *The date when full compliance will be achieved:*

ESI believes that the new requirement to generate an NCR upon receipt of the material ensures full compliance. ESI CAR 2021-21 will remain open to allow continued monitoring of the process. Because warranty volumes are typically low, ESI expects the CAR to remain open for several months.

Sincerely,
Engine Systems, Inc.



Dan Roberts
Manager, Quality Assurance

c:
Chief, Quality Assurance and Vendor Inspection Branch
Division of Reactor Oversight,
Office of Nuclear Reactor Regulation
Washington, DC 20555-0001