Corrective Action Report (CAR)

1	**Assigned To: Korina Looft** **Department: Quality** **Date: 02/28/14**	**CAR Number: 13-14** **Description: Part 21 Deficiencies** **Vendor [ ], check as applicable**
2	**Response Due Date: 3/28/14 *Revised to 5/7/2014 (to incorporate NRC NOV letter**	

3 **Condition or Observations Adverse to Quality/Deficiency:** During the NRC inspection there were several examples of concerns with our Part 21 process and procedures. As a result we received one severity level IV notice of violation.

The Notice of Violation Letter 99901436-2014-201-01 from the NRC on April 11, 2014 stated the following:

Title 10 of the *Code of Federal Regulations* (10 CFR) 21.21, "Notification of failure to comply or existence of a defect and its evaluation," requires, in part, that "Each corporation, dedicating entity or other entities 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."
Section 6.2 of UCI's Quality Control Procedure (QCP), QCP 21.1, "Reporting of Defects and Noncompliance", Revision 9, dated December 2, 2013, states, in part, that "all employees shall be responsible for reporting any deviations (as defined by this procedure) of nuclear related materials or services in writing to the quality manager…this report shall be made soon as the deviation is detected, and evaluated as soon as practicable, and in all cases within 60 days."
Contrary to the above, as of February 28, 2014, in the following examples UCI failed to implement their procedures for performing evaluations of deviations and for determining whether such deviations constitute a substantial safety hazard.

- On October 23, 2012, a customer returned to UCI a relay that was not operating correctly as per its technical requirements. This relay was part of a batch of relays that had been dedicated by UCI and supplied to customers as a basic component. UCI failed to evaluate within 60 days from the date of discovery whether the issue was specific to the returned relay, whether it constituted a substantial safety hazard, or whether it could be generic to other relays supplied.
- Prior to January 12, 2011, UCI performed seismic qualification tests on equipment with test accelerometers not calibrated for the full test range. UCI staff identified and corrected the deficiency; however, UCI failed to evaluate the deviation for reportability or document an analysis of the effect on seismic tests previously performed on safetyrelated equipment.
- In July 2013, UCI identified that the laboratory contracted to calibrate their Rockwell Hardness testing machine had not performed a proper calibration of the scale denoted as HRF. UCI failed to evaluate the deviation for reportability or document an analysis of the effect on hardness tests previously performed on safety-related equipment.

4 **Requirement:** 10CFR Part 21

5	**Root Cause**: Although procedures were in place for Part 21 evaluations and met the regulations, they were not robust enough to guide the nonconformance process toward a thorough evaluation of the defect. This led to the deficiency in the evaluation process.	
6	**Immediate Corrective Action Plan:** **Completion Date: 4/25/2014** 1. Evaluation of past 3 yrs. of NCRs for items returned from the Customer, including relay mentioned above in violation. (Part 21 evaluations are listed in EER-14-94597-01) 2. EER-14-1808-01 was written to address accelerometer calibration range and a part 21 evaluation was completed as part of NCR 7161 **Completion Date**: 4/30/2014 3. Comparison Testing Completed between UCI equipment and Supplier equipment for further verification and acceptance. Part 21 evaluation as part of Car 41-13. **Completion Date**: 4/30/14	
7	**Preventive Action Plan:** 1. Revision of QCPs: 21.1, 14.1, 15.2, and 16.1 and corresponding QA Forms **Completion Date:** 5/30/2014 2. Training for all revised QCPs and QA Forms **Completion Date:** 5/30/2014 3. Monthly NRC Compliance Panel Meeting **Completion Date:** 3/11/2014	
8	**Scheduled Completion Date:** revised to 5/30/2014	
9	**Response Submitted By:** Korina Looft **Date:** 4/25/2014	
10	**Completion Date Extension: May** 30, 2014 **Reason:** To incorporate new examples from the Notice of Violation (NOV): 99901436-2014-201-01 which was received on April 11, 2014.	
11	**Action Plan Approval:** **Department Manager:** Korina Looft **Date:** 5/7/14 **QA:** **Date:** 5/7/14	**If Not Approved, State Reason(s):**
12	**Implementation Verification / Closure Approval:** **Date:**	**Objective Evidence(Attachments):**
13	**Comments:** Part 21 evaluations were completed for the examples noted above and there were no defects found. Also as per EER-14-94597-01 once all Part 21 evaluations were completed for customer returns, from the past three years, there were no defects found.	