



RTP Corp.

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May 23, 2008

U.S. Nuclear Regulatory Commission
Attn: Document Control Desk
Washington, D. C. 20555-001

Reference: Reply to Notice of Violations, 99901372/2008-201-1 & 99901372/2008-201-2

Dear Sir/Madam:

RTP acknowledges receipt of your Notice of Violation letter dated, May 2, 2008 and postmarked May 5, 2008. With regard to the above referenced violations, RTP offers the following responses:

Notice of Violation, 99901372/2008-201-1

- 1) RTP's 10 CFR 21 implementing procedure AQ 5.01.3, "Deficiency Reporting (10 CFR 21)" Revision Q10, dated March 17, 2008 was not an appropriate procedure for the interface of the corrective action and non-conformances reporting processes with the Part 21 program to ensure effective identification and evaluation of deviations and failures to comply associated with a substantial safety hazard.
- 2) RTP's 10 CFR Part 21 implementing procedure AQ 5.01.3 was not an appropriate procedure to evaluate deviations and failures to comply to identify defects and failures to comply associated with substantial safety hazards.

Reason for the Violation, or the Basis for Disputing the Violation

The reason for the violation was found to be inadequate procedures and documentation. The AQ 5.01.3 Deficiency Reporting (10 CFR 21) procedure was focused on providing procedural guidance on the proper steps to notify the NRC and affected parties of a defect. RTP does perform evaluations on deviations and has other procedures that address corrective actions and non-conformance such as AQ 6.01 Corrective Action, AQ 4.07 Incoming, Non-Conforming Material, AQ 5.01 WIP, and Non-Conforming Material, as noted in the inspection report. Those procedures together did not offer adequate proof to demonstrate to the inspector the full effectiveness of our program.

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Corrective Steps That Have Been Taken and the Results Achieved

We have reviewed the identified procedures for monitoring deviations in our nuclear safety qualified products and are well underway with the process of correcting the deficiencies. Our staff also reviewed the past 3 years of NCMR dispositions and CAR to confirm that they were correctly handled with regard to 10 CFR 21 evaluations and reporting. The review confirmed the prior dispositions were adequate and no 10 CFR 21 reportable defects were identified.

Corrective Steps That will be Taken to Avoid Further Violation

RTP will revise its procedures to provide procedural guidance for the interface of the corrective action and non-conformance reporting processes with the Part 21 program. Specifically, AQ 6.01 "Corrective Action" will be updated to include a flow chart of procedures that provides an overview of the interfaces between non-conformance procedures and the corrective action procedure that could lead to Part 21 reporting. AQ 6.01 will also serve as the procedure to evaluate deviations and failures to comply to identify defects and failures to comply associated with substantial safety hazards.

In conjunction with this, the following sections in the Quality Assurance Procedure Manual will be revised:

- Incoming Inspection (AQ 4.00.1)
- Supplier Quality Program Survey (AQ 4.01)
- Source Inspection (AQ 4.01.1)
- Incoming Non-conforming Material (AQ 4.07)
- Material Substitution / Deviation Control (AQ 4.07.1)
- WIP, Non-Conforming Material (AQ 5.01)
- Deficiency Reporting (AQ 5.01.3)
- Purge Control System (AQ 5.02)
- Quality Bulletin (AQ 5.02.1)
- Deviation Disposition Request (AQ 5.03)
- Corrective Action (AQ 6.01)
- Calibration Control System (AQ 8.02)
- Field Service Returns (AQ 10.03)

In addition, the following RTP Operating Procedures will also be updated to invoke Corrective Action (AQ 6.01) that can lead to 10 CFR 21 deficiency reporting per AQ 5.01.3:

- Customer Service Operating Procedure 908: Customer Technical Action Request
- Engineering Operating Procedure 709: Technical Action Request

Finally, AQ 5.01.3, "Deficiency Reporting (10 CFR 21)" will be updated to reflect the revised AQ 6.01 "Corrective Action" procedure under which deviations and failure to comply are evaluated as well as provide procedural guidance on 10 CFR 21 reporting and record keeping requirements.

Date When Full Compliance Will Be Achieved

These procedure updates will be completed by June 30, 2008. The process will be verified at the next scheduled internal audits.

Notice of Violation, 99901372/2008-201-2

10 CFR Part 21, Section 21.51, "Maintenance and inspection of records," paragraph (a), requires, in part, each individual, corporation, partnership, dedicating entity, or other entity subject to the regulations in this part shall prepare and maintain records necessary to accomplish the purposes of this part, specifically –

- (1) Retain evaluations of all deviations and failures to comply for a minimum of five years after the date of the evaluation;
- (2) Suppliers of basic components must retain any notifications sent to purchasers and affected licensees for a minimum of five years after the date of the notification;
- (3) Suppliers of basic components must retain a record of the purchasers of basic components for 10 years after delivery of the basic component or service associated with a basic component.

Contrary to the above, as of March 28, 2008:

RTP could not provide objective evidence that it had prepared or maintained records necessary to accomplish the purposes of 10 CFR Part 21, Section 21.51.

Reason for the Violation, or the Basis for Disputing the Violation

The reason for this violation under item (1) of Section 21.51 was found to be inadequate procedures and documentation. RTP has indeed prepared and maintained records necessary to accomplish the purposes of Section 21.51 of 10 CFR 21. RTP's NCMR and CAR records are the objective evidence of our current process for review of deviations; however, these records were found to be insufficient as noted in violation 99901372/2008-201-1. RTP has already taken corrective steps to address this issue as noted above in our response to that violation.

There was no evidence of records of any Part 21 reports found during the NRC inspection because the review of deviations carried out under the procedures audited had not identified any reportable defects over the last 5 years. Our last Part 21 report was in 1994, which is beyond the 5 year recordkeeping requirements in Section 21.51. Although not required, RTP has maintained

records of Part 21 notifications beyond the 5 year requirements and can provide evidence of this if required. Given their age, these records were not readily available in our active QA files at the time of the inspection.

RTP has retained records of the purchasers of basic components for the last 10 years in our active QA file as required by Section 21.51.

Corrective Steps That Have Been Taken and the Results Achieved

RTP has reorganized its quality file system such that evaluations of all deviations and failures to comply records, notifications sent to purchasers and affected licensees and records of the purchasers of basic components are kept in a central location to improve records administration. As noted earlier, our staff also reviewed past deviations (NCMR dispositions, CAR, etc) to confirm that they were correctly handled with regard to 10 CFR 21 evaluations and reporting. The review confirmed that there were no 10 CFR 21 reportable defects.

Corrective Steps That Will be taken to Avoid Further Violation

RTP will update the AQ 1.04 "Records Retention" to clearly reflect the recordkeeping requirements of Section 21.51 of 10 CFR 21. AQ 5.01.3 "Deficiency Reporting (10 CFR 21)" will also be updated to detail the recordkeeping requirements of Section 21.51. The program revisions that RTP will develop in response to violation 99901372/2008-201-1 will improve the quality of the objective evidence of deviation reviews, corrective actions taken, and 10 CFR 21 reporting. This objective evidence will be retained as per the revised AQ 1.04 "Records Retention" procedure.

Date When Full Compliance Will Be Achieved

These procedure updates will be completed by June 30, 2008. The process will be verified at the next scheduled internal audits.

Sincerely,



Sal Provanzano
President
RTP Corp

CC: Director, Division of Engineering
Office of Nuclear Reactor Regulation