February 28, 2018

Mr. Anton Andrashov, Director
Research and Production Company RadICS
29 Geroyiv Stalingradu Street
25009 Kirovohrad, Ukraine

SUBJECT: REGULATORY AUDIT PLAN FOR APRIL 2-5, 2018, "RADICS TOPICAL REPORT" (CAC NO. MF8411; EPID: L-2016-TOP-0010)

Dear Mr. Andrashov:

By letter dated September 20, 2016 (Agencywide Documents Access and Management System Accession (ADAMS) No. ML16274A346), Research and Production Corporation Radiy (RPC Radiy) submitted for U.S. Nuclear Regulatory Commission (NRC) staff review Licensing Topical Report (LTR) "RadICS Topical Report." The LTR is supported by documentation that includes plans, requirements, design specifications, programming and hardware testing, independent verification and validation, and equipment qualification testing.

The U. S. Nuclear Regulatory Commission (NRC) staff is currently reviewing the LTR for use in safety system equipment at nuclear power plants. As part of its review, the NRC staff will be performing a regulatory audit of RadICS. The dates for this audit will be April 2-5, 2018.

The audit will determine the degree that the processes and outputs used have resulted in satisfying regulatory requirements for safety system applications at nuclear power plants. This audit will provide information necessary to complete the NRC staff's evaluation of the LTR. Enclosed is a copy of the plan the NRC staff will follow on the audit.

If you any questions or require any additional information, please feel free to contact me at 301-415-7297 or via electronic mail at Joseph.Holonich@nrc.gov.

Sincerely,

/RA/

Joseph J. Holonich, Sr. Project Manager
Licensing Processes Branch
Division of Licensing Processes
Office of Nuclear Reactor Regulation

Enclosure:
Audit Plan

Docket No. 99902032

cc: Mr. Mark Burzynski, Licensing Manager
Research and Production Company RadICS
2036 Marina Cove Dr.
Hixson, TN 37343

SUBJECT: REGULATORY AUDIT PLAN FOR APRIL 2-5, 2018, "RADICS DIGITAL I&C PLATFORM TOPICAL REPORT" (CAC NO. MF8411; EPID: L-2016-TOP-0010) DATED: FEBRUARY 28, 2018

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ADAMS Accession No.: ML18051A700; *concurred via e-mail **NRR-106**

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U. S. Nuclear Regulatory Commission Staff
RadICS I&C Platform Regulatory Audit Plan
Toronto, Canada

Background

The Nuclear Regulatory Commission (NRC) staff is currently performing a review of the RadICS licensing topical report (LTR), 2016-RPC003-TR-001, ""RadICS Topical Report," Revision 0 (Agencywide Document Access and Management System (ADAMS) Accession No. ML16274A349). RadICS is seeking generic approval of the RadICS platform for use in safety systems in nuclear power plants. This regulatory audit is intended to assist the NRC staff in confirming information submitted as part of the LTR.

Regulatory Audit Bases

As part of its evaluation, the NRC staff is reviewing RadICS design and development processes used for the RadICS platform. To support this review, the NRC staff will visit the Kinectrics qualifications testing facility located in Toronto, Canada, where current RadICS instrumentation and control (I&C) platform testing is being performed. The primary purpose of this audit is to review evidence that supports the NRC staff determination as to whether the RadICS LTR addresses:

- Commercial Grade Dedication: Title 10 of the *Code of Federal Regulations* (10 CFR) Part 21, "Reporting of Defects and Noncompliance," and the commercial grade dedication processes and methods as accepted for use by the NRC staff in Electric Power Research Institute TR-106439, "Guideline on Evaluation and Acceptance of Commercial Grade Digital Equipment for Nuclear Safety Applications" (ADAMS Accession Nos. ML103360462 and ML12205A284).
- Digital Safety System Software Quality and Processes: 10 CFR Part 50, Appendix B, "Quality Assurance Criteria for Nuclear Power Plants and Fuel Reprocessing Plants," as discussed in branch technical position (BTP) 7-14 (ADAMS Accession No. ML070670183) and applicable regulatory guides (RGs).
- Secure Development Environment: 10 CFR Part 50 as elaborated in RG 1.152, Revision 3, "Criteria for Use of Computers in Safety Systems of Nuclear Power Plants" (ADAMS Accession No. ML102870022).

A secondary purpose of the audit will be to gain a better understanding of the RadICS development life-cycle processes to support the safety evaluation of the RadICS platform. Also, the audit will assess the capabilities of the RadICS platform to determine if a RadICS based I&C safety system will be capable of meeting acceptance criteria as described in Chapter 7 of the NRC Standard Review Plan, NUREG-0800 (ADAMS Accession No. ML052340534). The NRC staff will use the results of this audit to support its evaluation conclusions.

Enclosure

Regulatory Audit Scope

This audit will be conducted in accordance with NRC Office Instruction LIC-111, "Regulatory Audits" (ADAMS Accession No. ML082900195). The NRC staff will review supporting procedures and records related to the RadICS platform development processes. The NRC staff will also evaluate the effectiveness of software development activities. It will also confirm that processes described in the RadICS LTR are being implemented correctly to achieve a high-quality system that can be used to perform safety-related functions in a nuclear facility and whether the results of these actions substantiate that processes described in the LTR are being followed.

Audit Requirements

- Software Verification and Validation (V&V) - Verify the RadICS platform software V&V plan meets the criteria of IEEE Std. 1012, "IEEE Standard for Software Verification and Validation," and the V&V program is implemented in a manner which reliably verifies and validates the design outputs at each stage of the RadICS software development process.
- Configuration Management - Verify the RadICS configuration management processes include appropriate hardware and software under configuration management and the configuration management system is effectively controlling the items being managed by these processes.
- Software Quality Assurance (SQA) - Verify the SQA plan is effective in controlling the RadICS software and field, programmable gate array (FPGA) logic-development process to assure regulatory quality of the RadICS platform software and FPGA logic.
- Software Safety - Verify that software safety plans and procedures used for safety-analysis activities are adequate to determine that RadICS software and FPGA developed logic is safe to be used for safety-related nuclear power plant operations.
- Secure Development Environment - Evaluate the RadICS platform development environment. The results of this audit activity will be used to determine conformance to the secure development environment requirements of RG 1.152, Revision 3.

Information Necessary for the Regulatory Audit

In addition to the documents listed in Appendix A of this audit plan and other listed regulatory review items, RadICS should have documentation and information prepared at the start of the audit that demonstrate utilization and implementation of the regulatory acceptable processes and procedures for the following regulatory audit topics:

- Requirements Tracing
    - Provide documentation, from the requirements phase through the testing phase (i.e., records related to requirements, design, coding, testing, and verification), to gain an overview of the RadICS platform hardware and software development processes.
- Commercial Grade Dedication
    - Provide a dedication report for a dedicated component of the RadICS Platform. NRC staff would like to review the records from the internal audit. If practical,

the NRC staff would also like to interview RadICS personnel involved in the handling and acceptance of components that have undergone commercial grade dedication.

  - Provide the procedures followed for processing of non-conformance reports. Those procedures, as well as recent examples of records related to non-conformance reports, would be valuable for the staff to review during the audit.

- Digital Safety System Software and FPGA Logic Development
  - Provide documentation to confirm the V&V processes are implemented, with a focus on record keeping, documentation, and management activities (including identification of documents associated with safety-related components).
  - Provide documentation to confirm configuration management processes are implemented, with a focus on record keeping, documentation, and management activities (including identification of documents associated with safety related components).

- Secure Development Environment
  - Provide documentation to support the NRC staff's review of the RadICS development environment NRC staff would also like to interview RadICS personnel involved in this activity.

- RadICS FPGA Logic Implementation
  - Provide documentation for the RadICS Platform FPGA logic development processes and procedures used to configure and implement the FPGA logic.
  - Provide documentation of the Radiy Product Configuration Toolset (RPCT) processes used to implement the RadICS module FPGA logic electronic design (ED) and to configure the module units. Observations made during this activity will be documented in the audit report and referenced by the safety evaluation to provide a basis for the safety conclusions.

Team Assignments

The NRC staff performing the audit will be:

- Ken Mott – audit team lead; Software Processes (focus: independent V&V and Software Safety activities and FPGA and module unit logic toolset development activities, RadICS toolset selection and evaluation, automated code generation)
- Richard Stattel – software processes (focus: Requirements Thread Reviews, Quality Assurance Programs, Configuration-Management Programs and Secure Development Environment assessment).

Logistics

The audit will take place at the Kinectrics facility in Toronto, Canada. The audit will start on the morning of April 2, 2018 (Monday) and conclude at the close of business April 5, 2018 (Thursday). The tentative schedule for the audit is as follows:

- Monday, April 2, 2018 (8:30 am – 5:00 pm)
    - 8:30 am – Entrance meeting (NRC staff – purpose of audit; RadICS staff – brief overview of platform and testing facilities)
    - 10:00 am – Presentations and demonstration of platform operation by RADICS
    - 1:00 pm – audit team to jointly work on a requirements thread to see an overview of the entire platform ED and application ED software and FPGA logic development process.
- Tuesday, April 3, 2018 (8:30 am – 5:00 pm)
    - 9:00 a.m. – Morning meeting between the NRC staff and RadICS to discuss activities and logistics for the day
    - 9:30 a.m. – Review of RadICS documentation and interviews with key RadICS personnel – NRC staff may work together or individually, as circumstances dictate
    - 4:00 p.m. – NRC staff internal meeting
    - 4:30 p.m. (as needed) - NRC staff and RadICS discuss any observations from the day.
- Wednesday – April 4, 201 (8:30 am – 5:00 pm)
    - 9:00 am – Morning meeting between NRC staff and RadICS staff to discuss activities and logistics for the day
    - 9:30 am – Review of RadICS documentation – NRC staff may work together or individually, as circumstances dictate
    - 1:00 pm – RadICS FPGA Logic ED Programming Demonstration/Discussion
    - 4:00 pm – NRC staff internal meeting
    - 4:30 pm (as needed) - NRC staff and RadICS discuss any observations from the day
- Thursday, April 5, 2018 (8:30 am – 5:00 pm)
    - 9:00 am – NRC staff internal meeting - identification/resolution of any open items
    - 2:00 pm – Exit meeting (NRC staff – general overview of observations and identification of any open items)

As circumstances dictate, the above schedule can be modified.

Special Requests

Because RadICS development activities are performed in Kirovograd, Ukraine, the NRC staff will not be able to directly audit the secure development environment during the audit at the Toronto Kinectrics facility. To compensate for this limitation, the NRC staff requests that a RadICS representative who is familiar with the physical attributes and network configuration of the RadICS/Radiy development facilities be present to discuss security measures in place to establish the secure RadICS platform development environment. The NRC also requests that documentation of the RadICS/Radiy Facility development environment such as the network architecture be available for NRC staff review during the audit.

Deliverables

The NRC regulatory audit report should be issued by May 18, 2018.

Appendix A
Table of Proprietary Documents Provided via
Research and Production Corporation Radiy September 20, 2016, Letter

Document Number	Description	Rev
2016-RPC003-TR-001	RadICS Topical Report	0
D2.1	RadIC Functional Safety Management Plan	3.0
D2.2	RadiCS Configuration Management Plant	3.0
D2.4	RadICS Overall Verification and Validation Plan	3.0
D2.8	RadICS Security Analysis Report	1.1
D2.10	RadICS Functional Safety Management Plan Phase 3 Extension	1.0
D3.1	RadICS Safety Requirements Specification	3.0
D4.0	RadICS Safety Validation Test Plan	3.0
D5.1	RadICS Product Architecture Document	3.3
D10.1	RadICS Integration Test Plan	3.0
2016-RTS002-EQTP-004	Equipment Qualification Test Plan	0
2015-RTS001-CGDP-DIM-003	Commercial Grade Dedication Plan for Logic Module	1
2015-RTS001-CGDP-LM-101	Commercial Grade Dedication Plan for Logic Module	1
2015-RTS001-CGDP-DOM-102	Commercial Grade Dedication Plan for Digital Output Module	1
2015-RTS001-CGDP-AIM-103	Commercial Grade Dedication Plan for Analog Input Module	2
2015-RTS001-CGDP-AOM-104	Commercial Grade Dedication Plan for Analog Output Module	1
2015-RTS001-CGDP-OCM-106	Commercial Grade Dedication Plan for Optical Communication Module	1
2015-RTS001-CGDP-CH-107	Commercial Grade Dedication Plan for Dedication Plan for Chasis	1
2015-RTS001-CGDP-IOPM-131	Commercial Grade Dedication Plan for Input/Output Connections Protection Module	1
2015-RTS001-CGDP-VM-132	Commercial Grade Dedication Plan for Ventilation Module	1