NRC UPDATE

August 9, 2018

EPRI JUTG

Charlotte, North Carolina

Jonathan Ortega and Aaron Armstrong

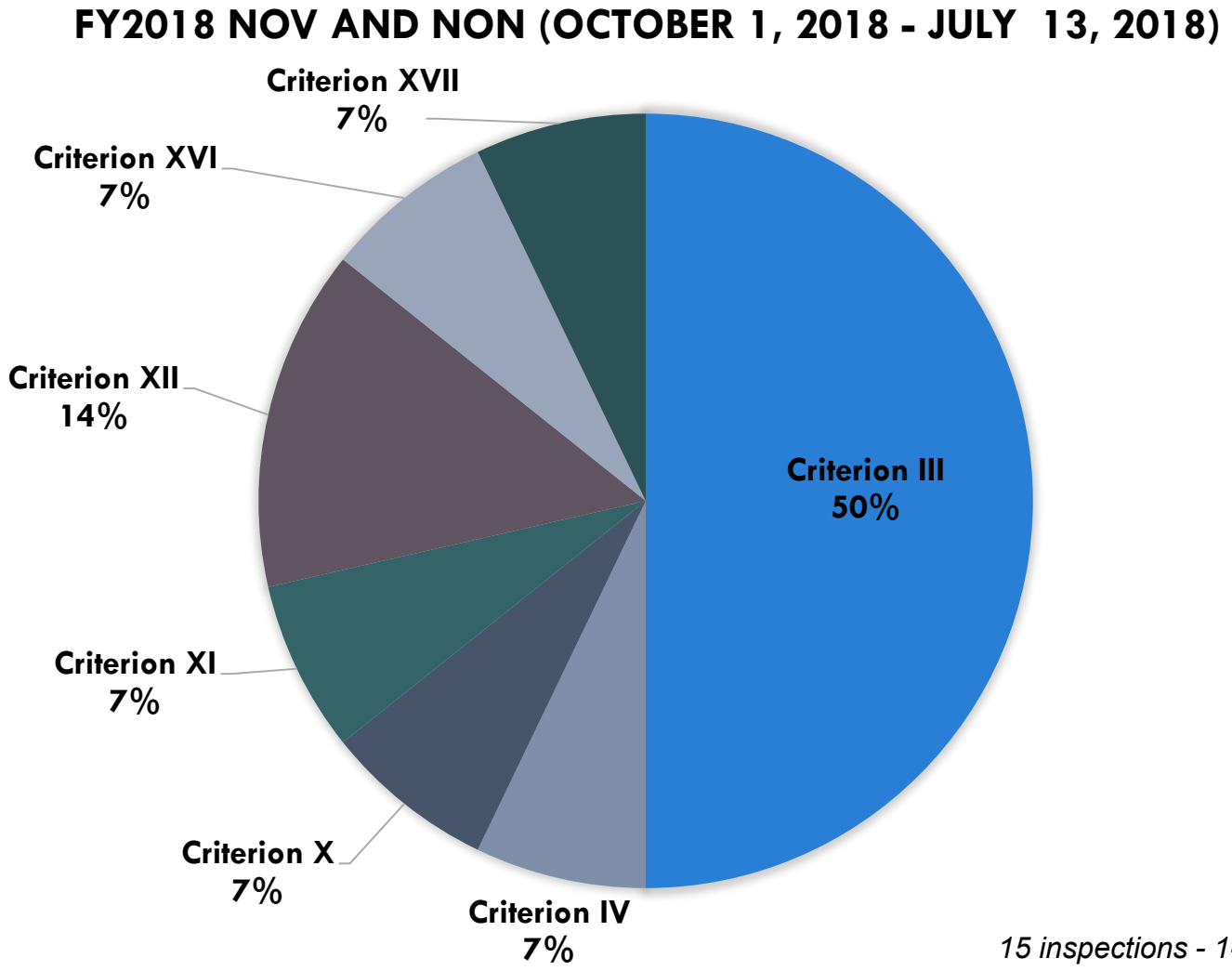
Quality Assurance Vendor Inspection Branch, Office of New Reactors

Topics

- Vendor Inspection Findings
- Part 21- RG 1.234
- Update - Regulatory Issue Summary on Supplier Oversight Issues Identified During NRC Vendor Inspections
- 2018 NRC Workshop on Vendor Oversight

NRC Vendor Inspection Findings

Breakdown of Vendor Inspection Findings



15 inspections - 14 NOVs/NONs

Vendor Inspection Trends

- Significant Findings
  - Design and Test Control
    - Translation of Design Requirements and Testing
  - Commercial-Grade Dedication

Design and Testing Requirements

Gutor Electronic, Wettingen, Switzerland

- Inspection conducted in June 2018 to assess Gutor's quality activities associated with the design, fabrication, and testing of components that comprise the Uninterruptable Power Supply System for the Westinghouse AP1000 reactors being constructed at the Vogtle Units 3 and 4.
- Inspection Results
  - Gutor failed to ensure the suitability of materials, parts, equipment, and processes that are essential to the safety-related functions of the inverters being supplied to the Vogtle Units 3 and 4 nuclear power plants
  - Gutor failed to develop acceptance criteria to ensure that the battery chargers acceptance tests meet the design requirements as stated in Westinghouse's purchase order
  - Take-away: Suppliers need to ensure that design and testing requirements are met and document these design and testing requirements for activities affecting quality.

Design and Testing Requirements

Target Rock (TR) at the East Farmingdale, NY facility

- Inspection conducted in May 2018 to verify TR's design control and testing activities for the NuScale emergency core cooling system (ECCS)
- Inspection Results
  - TR did not provide the information for the first-of-a-kind-engineering (FOAKE) ECCS proof of concept testing as required by NuScale purchase order
  - Also during Safety-Related testing activities TR do not establish controls to ensure the measuring and testing instrumentation used during testing activities affecting quality were adequately controlled, calibrated and adjusted at specified periods to maintain accuracy within necessary limits

Design and Testing Requirements

Target Rock cont'd

- Take-away: Suppliers need to meet the requirements for the design documents and the requirements for the selection and review for suitability of application of materials, parts, equipment, and processes that are essential to the safety-related functions of the structures, systems and components
- Suppliers should be able to demonstrate the adequacy of the design, testing and dedication through retention of auditable records providing reasonable assurance of acceptable for M&TE

Commercial-Grade Dedication

Flowserve Corporation, Lynchburg, VA

- Inspection conducted in January 2018 to assess the design, fabrication, and testing of the Limitorque motor-operated valve actuators
- Inspections Results
  - Flowserve did not verify the validity of the Certificates of Conformance for hardness and tensile strengths of motor shafts material
  - Flowserve did not maintain sufficient records for the commercially-dedicated fasteners
  - Flowserve records lacked evidence that material testing on commercially-dedicated hardware and fasteners confirmed suitability of the parts

Commercial-Grade Dedication

Flowserve cont'd

- Take-away: Suppliers need to ensure that design requirements meet the procurement documents and prescribed dedication activities
- Suppliers should be able to demonstrate the adequacy of the design, testing and dedication through retention of auditable records providing reasonable assurance for acceptability

Commercial-Grade Dedication

Schulz Electric Company (SEC) New Haven, CT

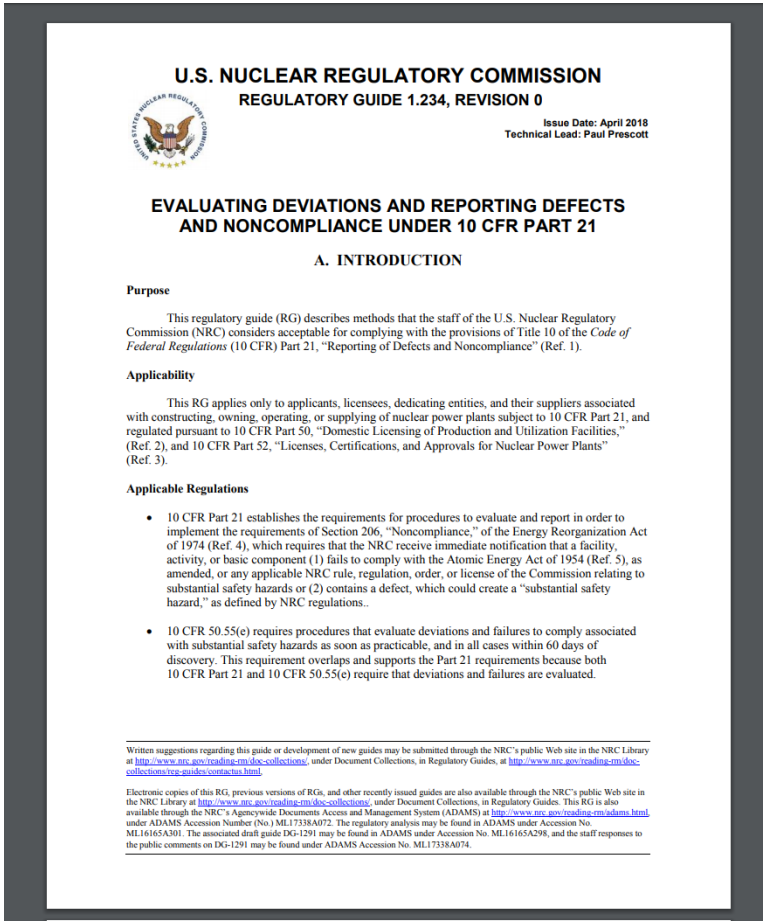
- Inspection conducted in April 2018 to assess SEC's rewinding, repair, reverse engineering and supply of safety-related motors to the nuclear industry
- Inspection Results
  - SEC did not establish and implement an acceptable method to verify the material composition of shafts used in AC motors provided by a commercial supplier
    - SEC failed to provide objective evidence to support the verification of Critical Characteristics by source evaluation and selection, objective evidence of quality furnished by the supplier, inspection at the supplier source, and/or examination of products upon delivery suppliers
  - Take-away: Suppliers need to ensure that technical requirements are met, and ensure that any changes to dedication activities of commercial grade items are documented

Part 21 Evaluation and Reporting

EVALUATING DEVIATIONS AND REPORTING DEFECTS AND NONCOMPLIANCE UNDER 10 CFR PART 21

New Regulatory Guide - RG 1.234 issued April 2018

- Endorses Revision 1 of NEI 14-09, "Guidelines for Implementation of 10 CFR Part 21 Reporting of Defects and Noncompliance"
- Provides clarification on Part 21 requirements for reporting and evaluating



U.S. NUCLEAR REGULATORY COMMISSION

REGULATORY GUIDE 1.234, REVISION 0

Issue Date: April 2018
Technical Lead: Paul Prescott

EVALUATING DEVIATIONS AND REPORTING DEFECTS AND NONCOMPLIANCE UNDER 10 CFR PART 21

A. INTRODUCTION

Purpose

This regulatory guide (RG) describes methods that the staff of the U.S. Nuclear Regulatory Commission (NRC) considers acceptable for complying with the provisions of Title 10 of the *Code of Federal Regulations* (10 CFR) Part 21, "Reporting of Defects and Noncompliance" (Ref. 1).

Applicability

This RG applies only to applicants, licensees, dedicating entities, and their suppliers associated with constructing, owning, operating, or supplying of nuclear power plants subject to 10 CFR Part 21, and regulated pursuant to 10 CFR Part 50, "Domestic Licensing of Production and Utilization Facilities," (Ref. 2), and 10 CFR Part 52, "Licenses, Certifications, and Approvals for Nuclear Power Plants" (Ref. 3).

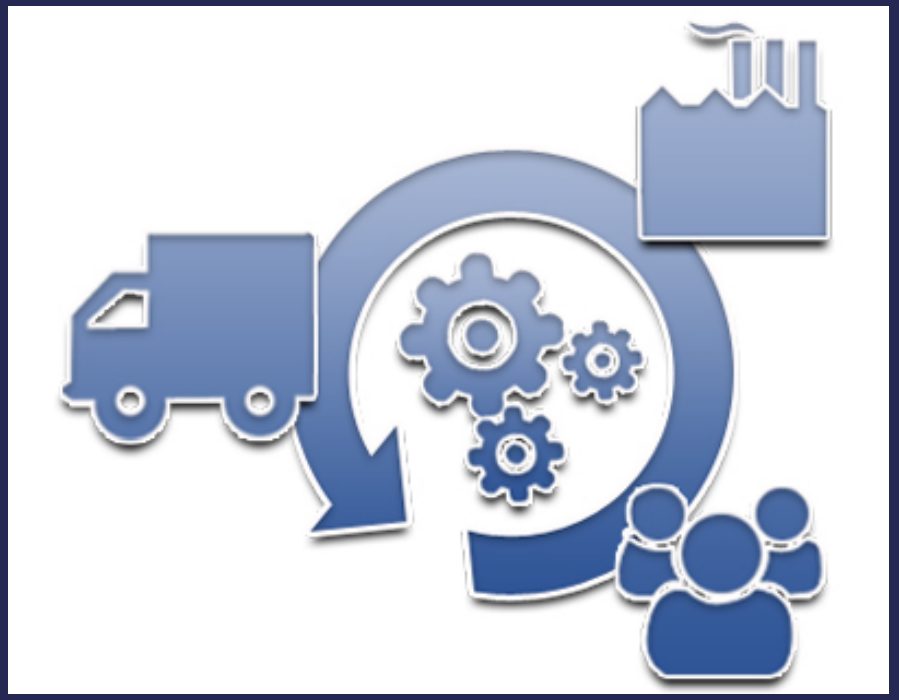
Applicable Regulations

- 10 CFR Part 21 establishes the requirements for procedures to evaluate and report in order to implement the requirements of Section 206, "Noncompliance," of the Energy Reorganization Act of 1974 (Ref. 4), which requires that the NRC receive immediate notification that a facility, activity, or basic component (1) fails to comply with the Atomic Energy Act of 1954 (Ref. 5), as amended, or any applicable NRC rule, regulation, order, or license of the Commission relating to substantial safety hazards or (2) contains a defect, which could create a "substantial safety hazard," as defined by NRC regulations..
- 10 CFR 50.55(e) requires procedures that evaluate deviations and failures to comply associated with substantial safety hazards as soon as practicable, and in all cases within 60 days of discovery. This requirement overlaps and supports the Part 21 requirements because both 10 CFR Part 21 and 10 CFR 50.55(e) require that deviations and failures are evaluated.

Written suggestions regarding this guide or development of new guides may be submitted through the NRC's public Web site in the NRC Library at http://www.nrc.gov/reading-rm/doc-collections/, under Document Collections, in Regulatory Guides, at http://www.nrc.gov/reading-rm/doc-collections/reg-guides/contactus.html.

Electronic copies of this RG, previous versions of RGs, and other recently issued guides are also available through the NRC's public Web site in the NRC Library at http://www.nrc.gov/reading-rm/doc-collections/, under Document Collections, in Regulatory Guides. This RG is also available through the NRC's Agencywide Documents Access and Management System (ADAMS) at http://www.nrc.gov/reading-rm/adams.html, under ADAMS Accession Number (No.) ML17338A072. The regulatory analysis may be found in ADAMS under Accession No. ML16165A301. The associated draft guide DG-1291 may be found in ADAMS under Accession No. ML16165A298, and the staff responses to the public comments on DG-1291 may be found under ADAMS Accession No. ML17338A074.

Regulatory Issue Summary
Supplier Oversight



Update

- **Currently in internal concurrence phase**
- **NRC staff expects to issue this RIS in late Summer/Fall of 2018**
  - Inform our stakeholders of recent NRC inspection findings involving:
    - Inadequate oversight of suppliers (domestic & international)
    - Suppliers not adequately imposing the requirements of Appendix B to 10 CFR Part 50 and 10 CFR Part 21 to their sub-suppliers in the procurement documents

2018 NRC Workshop on Vendor Oversight

2018 NRC Workshop on Vendor Oversight

- The NRC held their Workshop on Vendor Oversight in Cleveland, Ohio on June 14. The Workshop included a plenary session on such issues as safety conscious work environment; reverse engineering; counterfeit, fraudulent, and suspect items; and recent supplier oversight issues. The workshop also included afternoon panel discussions regarding commercial-grade dedication topics and additive manufacturing
  - Audience included approximately 400 attendees
  - 14 Countries

For More Information…

- The Quality Assurance for New Reactors Website offers a variety of information including:
- Vendor Inspection Program (VIP) Plan
- http://www.nrc.gov/reactors/new-reactors/oversight/quality-assurance/vendor-insp/vendor-insp-prog-plan.html
- Vendor Quality Assurance (QA) Inspection Reports for New Reactors
- http://www.nrc.gov/reactors/new-reactors/oversight/quality-assurance/vendor-insp/insp-reports.html
- Quality Assurance (QA) Inspections for New Reactor Licensing
- http://www.nrc.gov/reactors/new-reactors/oversight/quality-assurance/qual-assure-license.html
- Workshop on Vendor Oversight 2018 Conference
- https://www.nrc.gov/reactors/new-reactors/oversight/quality-assurance/vendor-oversight/past/2018/