U.S.NRC
United States Nuclear Regulatory Commission
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THE VENDOR TIMES

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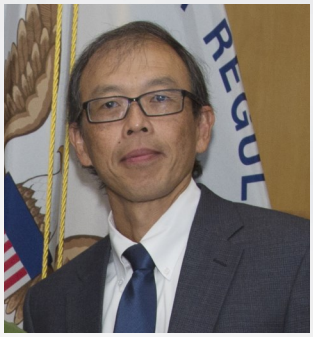
The Director's Cut



MICHAEL CHEOK, Director
Division of Construction Inspection and Operational Programs

PAUL KROHN, Deputy Director
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In fiscal year 2016, the U.S. Nuclear Regulatory Commission's (NRC) vendor inspection program (VIP) conducted routine, reactive, design verification and qualification testing inspections of over 20 vendors that provide components, parts, plant modules, and services to nuclear power plants under construction and to operating nuclear power plants. At these inspections, the NRC evaluates vendor compliance with Title 10 of the Code of Federal Regulations (10 CFR) Part 21, "Reporting of Defects and Noncompliance," and Appendix B, "Quality Assurance Criteria for Nuclear Power Plants and Fuel Reprocessing Plants," to 10 CFR Part 50, "Domestic Licensing of Production and Utilization Facilities". Over the past year, the NRC vendor inspection staff also supported Office of Investigation (OI) and Region II assists at the vendor facilities, aircraft impact assessment (AIA) inspections; joint international inspections under the Multinational Design Evaluation Program (MDEP); Nuclear Procurement Issues Committee (NUPIC) observations; NRC technical staff audit assists; Inspections, Test, Analysis, and Acceptance Criteria (ITAAC) inspections of the AP1000 construction activities; and quality assurance (QA) implementation inspections. Finally, VIP staff started design verification inspections at the vendor facilities during the fabrication of safety-related major plant modifications. This is a pilot activity in support of the recommendations from the San Onofre Nuclear Generating Station lessons learned report.

NRC's vendor inspectors observed mixed vendor performance in the implementation of their quality assurance programs and evaluating and reporting of Part 21. While more than half of the inspections did not result in findings, the NRC continues to identify inadequacies in vendors' conduct of commercial-grade dedication. Dedication is used by some licensees in an increasing number of applications that support operations and maintenance. The NRC is working to develop regulatory guidance to address this area of concern and encourages vendors and NRC licensees to evaluate the implementation of their dedication programs. We have worked with stakeholders including the Electric Power Research Institute for needed and important guidance that will clarify the dedication process.

The NRC noted a decline in the number of violations against 10 CFR Part 21. However, the agency did take enforcement action against a vendor in the past year and the vendor has already initiated action to improve their overall Part 21 program. The inspection reports are publicly available on the NRC's Vendor Quality Assurance (QA) Inspection website at http://www.nrc.gov/reactors/new-reactors/oversight/quality-assurance/vendor-insp.html.

The Vendor Inspection Program continues to meet our safety and program objectives. We continue to verify the effective implementation of the vendor Quality Assurance programs, and to verify that design requirements contained in the licensing documents are correctly implemented into engineering, procurement, fabrication, and testing activities. We are verifying that licensees are providing effective oversight of their supply chain, and that the quality of materials, equipment and services supplied by vendors are consistent with the regulations. Compliance to these regulatory requirements is essential to the NRC's mission to protect public health and safety.

In This Issue

2016 Vendor Inspection Trends

From October 1, 2015 to September 30, 2016, the NRC conducted 20 inspections at vendors supplying safety-related components to U.S. nuclear power reactors. These inspections assessed vendor compliance to 10 CFR Part 21 and the 18 criteria in Appendix B to 10 CFR Part 50. From these inspections, the NRC identified 21 findings and analyzed the findings to identify issues that can be acted upon by vendors, NRC licensees, and the NRC (see Figure 1). Of the 20 vendor inspections, more than half of them (12) did not result in any findings. The NRC found that these vendors had adequately implemented their quality assurance and Part 21 programs. The NRC observed this was a result of maintaining the necessary knowledge and expertise on NRC requirements and promptly and effectively correcting identified issues. In essence, these are characteristics, among others, that play a part in developing a strong safety culture (see http://www.nrc.gov/about-nrc/safety-culture.html for more information on safety culture).

With regards to the inspection findings related to the implementation of a vendor's quality program, the NRC noted that nearly half of the findings (10) involved a failure to comply with Criterion III, "Design Control," of Appendix B to 10 CFR Part 50. Of these ten findings, eight involved commercial-grade dedication issues. The NRC continues to observe issues with identifying and verifying critical characteristics and establishing adequate sampling plans. The main causal factor was insufficient technical justification for determining critical characteristics and sample size.

While not a new procurement method, there were emergent issues noted with the use of reverse engineering, (see "The Importance of Establishing Proper Technical Requirements When Purchasing Equivalent Components on pg. 5). Reverse engineering is a complex activity requiring extensive engineering involvement to establish design, material and fabrication specifications. Reverse engineering may become more prevalent as equipment obsolescence at nuclear power plants increases. Therefore, it is prudent for vendors and NRC licensees alike to assure a thorough technical analyses in reverse engineering procurement activities.

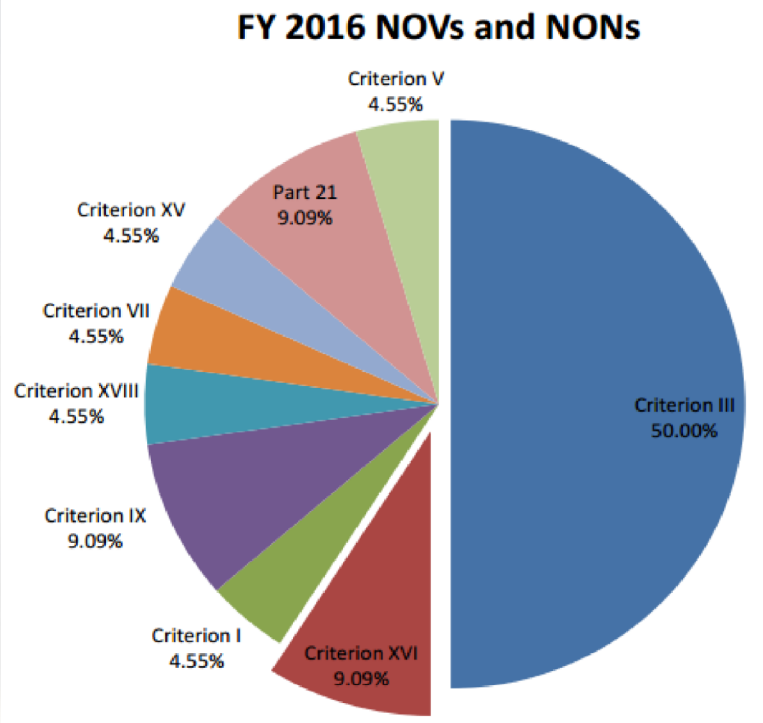


Figure 1. Vendor Inspection Finding

2016 Vendor Workshop

2016 Workshop on Vendor Oversight

On June 23, 2016, the Office of New Reactors (NRO), Division of Construction Inspection and Operational Programs (DCIP), hosted the NRC Workshop on Vendor Oversight in St. Louis, Missouri. This workshop followed the NUPIC vendor meeting to enable maximum participation by suppliers to the nuclear industry. The NRC Vendor Workshop included a keynote address by NRO Office Director, Jennifer Uhle, as well as presentations by members of the NRC staff, NUPIC, NEI, EPRI, reactor licensees, and nuclear vendors. This was the 5th Workshop on Vendor Oversight. The audience included approximately 400 attendees representing companies and organizations from eight countries including vendors, industry groups, government regulatory agencies, and both foreign and domestic utilities. The NRC Workshop on Vendor Oversight included plenary discussions on such issues as industry guidance for commercial-grade dedication, industry guidance on Part 21 evaluation and reporting, counterfeit, fraudulent, and suspect items, and vendor implementation of cybersecurity requirements. The workshop also included break-out sessions on topics such as dedication of design and analysis computer programs, implementation of dedication guidance, reverse engineering, NRC's expanded recognition of the ILAC accreditation process, and procurement documentation.

For more information on the 2016 NRC Workshop on Vendor Oversight, please visit the following link: http://www.nrc.gov/reactors/new-reactors/oversight/quality-assurance/vendor-oversight/past/2016/index.html

Vendor inspection of National SAFER Response Center in support of NRC order for mitigating strategies EA-12-049

Part 21 Rulemaking

In June 2015, the Commission directed the staff to perform a prioritization of work activities conducted by the Agency. The Commission also directed the staff to perform a one-time re-baselining of the staff's work. Project AIM was the outcome, which projected the Agency's workload five years out. The recommendations and outcome can be seen in SECY 16-0009 (Agencywide Document Access Management System (ADAMS) Accession No. ML16028A189). In April of this year, the Commission approved the staff's recommendations to shed a number of rulemaking activities, which included 10 CFR Part 21. The staff concluded that necessary changes can be achieved through clarification of the regulatory guidance as described below.

Commercial Grade Dedication - Draft Guide– 1292

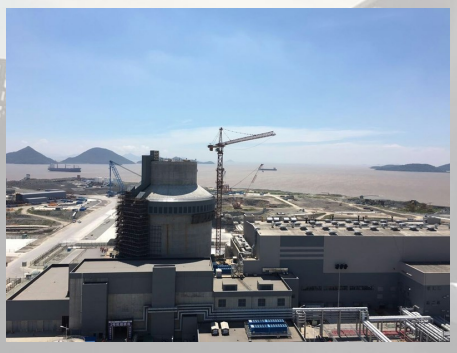
The staff worked with stakeholders on the development of updated guidance for commercial-grade dedication. NRC Draft Guide DG-1292 proposes to endorse the industry guidance contained in Revision 1 of Electric Power Research Institute (EPRI) NP-5652 and TR-102260. The guidance was determined to be in alignment with staff positions. Issuance of the final version of DG-1292 is expected in Spring 2017. The NRC is currently in the process of resolving comments received during the public comment period. For more information on DG-1292, please visit the following link: http://www.nrc.gov/docs/ML1531/ML15313A425.pdf

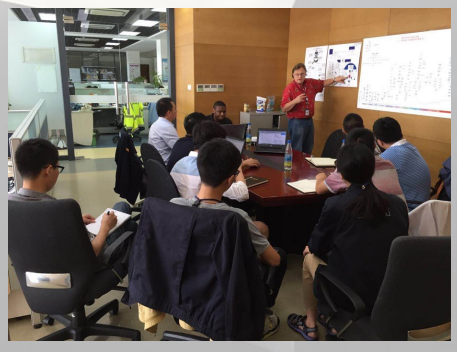
"Guidelines for Implementation of 10 CFR Part 21 Reporting of Defects and Non-compliance," - Draft Guide-1291

The Nuclear Energy Institute (NEI) submitted to the NRC for endorsement, NEI 14-09, "Guidelines for Implementation of 10 CFR Part 21 Reporting of Defects and Noncompliance," Revision 0, dated August 2014 (ADAMS Accession No. ML14245A416). NEI's purpose for this guidance document is to promote consistent implementation of NRC requirements for evaluation and reporting. The guidance document incorporates previous guidance in NUREG-0302, to add additional clarity in specific areas where issues have historically occurred and includes experience gained from nearly 30 years of complying with 10 CFR Part 21. This guidance document referenced NUREG-0302, SECY-11-0135, and different statements of consideration from NRC rulemakings since the NRC first issued the Part 21 proposed rule.

In October and November of 2015, the NRC held two public meetings with NEI. Subsequently, NEI submitted Revision 1 of NEI 14-09 on February 2, 2016 (ADAMS Accession No. ML16054A825). The NRC staff has reviewed the new revision and has developed Draft Guide DG-1291 which is expected to be published for public comment in Spring 2017.

Vendor Inspection Team at General Atomics Electromagnetic Systems





AP1000 Initial Test Program at Sanmen Site:

- NRC inspectors Coleman Abbott and Tim Chandler in Sanmen Unit 2 Containment (left)
- Construction of Sanmen Unit 2 (middle)
- NNSA (National Nuclear Safety Administration) and NRC bi-lateral knowledge and insight exchange (right)

NRC's Expanded Recognition of the International Laboratory Accreditation Process

By a letter dated August 28, 2014, NEI submitted Revision 1 of NEI 14-05 (ADAMS Accession No. ML14245A392), "Guidelines for the Use of Accreditation in Lieu of Commercial Grade Surveys for Procurement of Laboratory Calibration and Test Services," to the NRC for review and endorsement. NEI 14-05 provides an approach for licensees and suppliers of basic components to use laboratory accreditation by accreditation bodies that are signatories to the ILAC Mutual Recognition Arrangement (hereafter referred to as the ILAC accreditation process) in lieu of performing commercial-grade surveys for procurement of calibration and testing services performed by domestic and international laboratories accredited by signatories to the ILAC accreditation process.

By letter dated February 9, 2015, (ADAMS Accession No. ML14322A535) the NRC issued its safety evaluation report (SER) on Revision 1 of NEI 14-05. NRC's endorsement of Revision 1 of NEI 14-05 expands the NRC's acceptance of the ILAC accreditation process first documented in a SER (ADAMS Accession No. ML052710224) for an Arizona Public Service (APS) license amendment request. NRC's earlier acceptance in the APS license amendment was limited to laboratory calibration services accredited by specific U.S. accreditation bodies. By letter dated April 1, 2016 (ADAMS Accession No. ML16089A167), the NRC staff approved a request to change the Quality Assurance Manual for Callaway Plant, Unit 1, pursuant to 10 CFR 50.54(a), to incorporate the use of the ILAC accreditation process in lieu of performing a commercial-grade survey for ILAC accredited laboratories. With this approval, other licensees may also use the ILAC accreditation process in lieu of performing commercial-grade surveys for procurement of calibration and testing services performed by domestic and international laboratories accredited by signatories to the ILAC accreditation process, provided the bases of the NRC approval are applicable to the licensee's facility pursuant to the requirements of 10 CFR 50.54(a)(3)(ii). The NRC issued Regulatory Issue Summary (RIS) 2016-01, "Nuclear Energy Institute Guidance for the Use of Accreditation in Lieu of Commercial Grade Surveys for Procurement of Laboratory Calibration and Test Services," to announce and clarify the NRC's technical position on the use of the ILAC accreditation process in lieu of performing a commercial-grade survey. For more information on Regulatory Issue Summary (RIS)-2016-01, please visit the following link: http://www.nrc.gov/docs/ML1532/ML15323A346.pdf

It's important to note the NRC continues to find the APS SER to be acceptable as a method for using the ILAC accreditation process. However, licensees and suppliers should be aware of the differences between the APS SER and Revision 1 of NEI 14-05. For example, the APS SER is limited to acceptance of accreditation for calibration services from domestic suppliers, while Revision 1 of NEI 14-05 supports ILAC accreditation for the procurement of calibration and testing services from both domestic and international laboratories.

-Yamir Diaz-Castillo, NRC Reactor Operations Engineer

Yamir Diaz-Castillio at 2016 Vendor Workshop

Regulatory Issue Summary 2016-01

The NRC also issued Regulatory Issue Summary (RIS) 2016-01, "Nuclear Energy Institute Guidance for the Use of Accreditation in Lieu of Commercial Grade Surveys for Procurement of Laboratory Calibration and Test Services," to announce and clarify the NRC's technical position on the use of the ILAC accreditation process in lieu of performing a commercial-grade survey.

Technical Corner—The Importance of Establishing Proper Technical Requirements When Purchasing Equivalent Components

Due to the growing obsolescence of original components, many utilities are opting to replace safety-related components with non-like-for-like, but equivalent components (also called alternative replacement components). In some cases, these procurements are being done proactively to address issues associated with the availability of future replacement components or to address reliability issues associated with older equipment. Sometimes, entire families of equipment are involved (e.g., replacement of obsolete circuit breakers with circuit breakers from another manufacturer). In such cases, there may be unique operating requirements for each application of the component. In other cases the procurements are reactive, with definitive time constraints, and may be limited to a single component or subcomponent. Such components are oftentimes obtained from third-party dedicators/suppliers who procure commercial components and then perform the testing and analysis necessary to ensure suitability for use in safety-related applications. Reverse engineering techniques are often utilized to develop prototype designs.

Jeffery Jacobson at the 2016 Vendor Workshop

To ensure alternative replacement components are truly equivalent, licensees usually perform "equivalency evaluations" which are intended to provide assurance the replacement components can perform reliably in service. The challenge in performing equivalency evaluations is that licensees are often limited in their knowledge of the original component designs they are evaluating. If the component being supplied is custom designed, for example a replacement circuit board for a safety-related component, licensees may have very little knowledge of the detailed design, and possibly little knowledge of the potential failure modes of the component. Likewise, third-party dedicators/suppliers are often limited in their knowledge of the plant or system-level designs of their customers (licensees). It is this procurement interface that exists between licensees and suppliers that requires enhanced attention.

When procuring equivalent components, licensees need to understand that full-scope technical requirements/specifications need to be developed and provided to their suppliers. This requires extensive engineering involvement and a thorough understanding of both system-level and component-specific design requirements. It may require the performance of a failure modes and effects analysis, as oftentimes the introduction of equivalent components can introduce new failure modes into the system. For example, digital replacement components may be more susceptible to noise interference than their analog predecessors. In such cases, new and more extensive technical requirements may need to be developed beyond those applied to the original components.

Achieving an adequate design interface between customers and suppliers usually requires extensive and continuous communication between licensee and supplier engineers to ensure all design interfaces have been appropriately identified. Suppliers need to ensure that replacement components are fully suitable for their intended applications. When verifying the adequacy of a component's design for safety-related use, suppliers need to establish bounding parameters that reflect assumptions made during the design verification process, including any assumptions made for components requiring formal equipment qualification such as those required by 10 CFR 50.49, "Environmental qualification of electric equipment important to safety for nuclear power plants." In some cases, the design verifications performed only support certain applications of the component. Suppliers need to take into account system-level interactions that could render the component unsuitable for potential applications.

-Jeffrey Jacobson, NRC Senior Reactor Operations Engineer

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We welcome useful and informative feedback on the content of this newsletter.

Please contact Nicholas Savwoir, Reactor Operations Engineer, Quality Assurance Vendor Inspection Branch-1, by telephone at 301-415-0256 or by email at Nicholas.Savwoir@nrc.gov.