

POLICY ISSUE
(INFORMATION)

September 29, 2011

SECY-11-0135

FOR: The Commissioners

FROM: Michael R. Johnson, Director
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SUBJECT: STAFF PLANS TO DEVELOP THE REGULATORY BASIS FOR
CLARIFYING THE REQUIREMENTS IN TITLE 10 OF THE *CODE OF
FEDERAL REGULATIONS* PART 21, "REPORTING OF DEFECTS AND
NONCOMPLIANCE"

PURPOSE:

This paper informs the Commission of the staff's plan to develop the regulatory basis to clarify Title 10 of the *Code of Federal Regulations* (10 CFR) Part 21, "Reporting of Defects and Noncompliance" (hereinafter referred to as Part 21). The staff anticipates that modifications to Part 21 and the creation of regulatory guidance will be proposed.

SUMMARY:

Since its inception in 1977, Part 21 has presented compliance challenges to licensees, vendors, and the U.S. Nuclear Regulatory Commission (NRC) staff. The NRC staff has noted a high rate of repetitive inspection findings related to Part 21, including commercial-grade dedication findings, despite the staff's attempts to clarify requirements through generic communications and extensive outreach efforts. Recent Part 21 exemption requests by nonreactor facilities further underscore the need to examine Part 21. In 2010, the staff established an agencywide working group to further explore these inspection findings and identify Part 21's potential areas for improvement.

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The working group identified opportunities to clarify Part 21. These opportunities fall into two categories:

- (1) Evaluating and reporting defects, and
- (2) The dedication process for accepting commercial items and services for use in safety-related applications.

The NRC has not issued regulatory guides for either topic. Therefore, the staff is developing guidance to address ambiguous definitions and clarify expectations with regard to Part 21.

The staff intends to develop the regulatory basis, continue to interact with stakeholders, and propose rule language to make clarifying changes to Part 21 and concurrently issue comprehensive guidance. This effort will clarify the requirements in Part 21. However, the staff does not intend to expand the scope or intent of the regulation. The staff, during its regulatory development, will address the following gaps in the current rule:

- (1) Identification of what information must be provided to a customer when a Part 21 evaluation is passed from a vendor.
- (2) The appropriate quality assurance requirements that customers should specify in their procurement documents.
- (3) The documentation of commercial-grade dedication activities in dedication plans.

The staff's regulatory basis development efforts will be focused on improving Part 21 clarity, maintaining original intent of the rule, and minimizing changes to currently compliant programs.

BACKGROUND:

Part 21

The NRC published the final rule for Part 21 in the *Federal Register* on June 6, 1977. The agency issued the rule to implement Section 206, "Noncompliance," of the Energy Reorganization Act of 1974 (42 U.S.C. 5846). The purpose of Section 206 is to ensure that the NRC receives prompt information that a facility, activity, or a "basic component:" (i) fails to comply with the Atomic Energy Act of 1954, as amended, or any applicable NRC rule, regulation, order or license; or (ii) contains a "defect" which could create a "substantial safety hazard," as defined by NRC regulations. In addition to imposing obligations on certain officers of NRC licensees, Section 206 also imposes obligations on certain officers of non-licensees that construct facilities for or supply components to licensed facilities or activities (i.e., vendors or suppliers).

The NRC amended Part 21 on October 19, 1978 (43 FR 48621), to exempt commercial-grade items from the requirements in Part 21 until those items were dedicated for safety-related use in a nuclear facility. This amendment provided the first definition of the commercial-grade dedication process. The regulatory framework for dedication has remained largely unchanged since the issuance of this 1978 amendment.

The NRC has since amended Part 21 to eliminate duplicate reporting, take operating experience into account, broaden the scope to include new reactors, and address conforming administrative changes. The most notable amendments are as follows:

- In 1991, the NRC amended Part 21 as a result of the Commission's efforts to apply the experience gained from the Three Mile Island accident and to reflect the Commission's experience to date with the existing regulations. The NRC intended the changes to reduce duplicate reporting, clarify the criteria for reporting of defects, and establish uniform time periods for reporting and uniform report content requirements.
- In 1995, the NRC revised Part 21 to provide added flexibility in nuclear power plant licensees' procurement of commercial-grade items for safety-related services. The NRC intended the action to provide the requirements for the procurement of parts and services, which are procured as commercial-grade items and subsequently dedicated for safety-related service, in a manner that avoids unnecessary delay and expense while maintaining an adequate level of safety.

The increase in procurement activity associated with the construction of new reactors presents the ideal timing to initiate rulemaking.

Office of the Inspector General Audits

The Office of the Inspector General (OIG) recently performed two audits related to Part 21: (1) OIG-10-A-20, "Audit of NRC's Vendor Inspection Program," dated September 28, 2010 (Agencywide Documents Access and Management System (ADAMS) Accession No. ML102710583), and (2) OIG-11-A-08, "Audit of NRC's Implementation of 10 CFR Part 21, Reporting of Defects and Noncompliance," dated March 23, 2011 (ADAMS Accession No. ML110820426). In response to recommendations related to Part 21 in the OIG's 2010 audit, the staff committed to develop this Commission paper and address the need and priority for rulemaking, guidance (i.e., regulatory guides), and outreach efforts. Following this audit, NRO also formed an agencywide Part 21 working group.

DISCUSSION:

The Part 21 working group identified areas for improvement in (1) the evaluation and reporting of defects, (2) commercial-grade dedication, and (3) administrative changes. The working group derived the enclosed list of technical topics primarily from findings issued by the vendor inspection branches in NRO and the Office of Nuclear Reactor Regulation (NRR). Since 2007, with the creation of NRO, over half of the approximately 200 vendor inspection report findings have been related to Part 21. Half of these Part 21 findings were attributed to evaluating and reporting deficiencies, and half of them were cited as improper commercial-grade dedication. The potential consequence of evaluating and reporting deficiencies is that substantial safety hazards may not be reported to the NRC. The potential consequence of improper dedication is that it can allow the incorporation of substandard safety-related parts into NRC-licensed facilities.

The scope of the rulemaking basis development will address gaps in Part 21 terminology to improve the rule and thereby its effectiveness. During rulemaking basis development, the staff

will assess changes needed to clarify the rule language and the need for additional guidance. The staff anticipates that a proposed rulemaking to clarify Part 21 would not expand the scope of the regulation. For example, the staff's guidance could clarify requirements for evaluating counterfeit and fraudulent items under Part 21 without expanding requirements to report items currently outside its scope (i.e., nonsafety-related items).

Evaluating and Reporting

Recent findings by NRC vendor inspections have illustrated gaps in the Part 21 requirements for the evaluation and reporting of defects. For example, Part 21 does not provide clear expectations for the mechanisms that must be in place to identify defects. As a result, the staff's inspections have found that vendors often fail to tie their quality assurance programs to Part 21. This failure creates the potential for missing the reporting of defects that are likely to be discovered through the quality assurance program. When vendors properly identify potential Part 21 issues, inspectors have found that the timeliness requirements of Part 21 are missed in some cases because the definition of "discovery" in Part 21 offers ambiguous language on when a Part 21 evaluation period begins.

Another example of a gap is where vendors state they are unable to evaluate a deviation. Part 21 allows vendors to pass the responsibility of evaluating a deviation under Part 21 by informing their customers that they do not have the capability to determine if a defect exists. Inspectors have noted that vendors frequently inform their customers informally and do not provide adequate information to the customer who is now responsible for the evaluation. In these cases, the vendor is satisfying its Part 21 responsibility but not communicating essential information to the customer that may be needed to evaluate the deviation to identify a reportable defect. These examples illustrate areas in Part 21 that require clarification to provide clear requirements that ensure defects and failures to comply associated with a substantial safety hazard are identified and reported as required.

Commercial-Grade Dedication

The supply chain for nuclear power reactors has greatly evolved since initial issuance of Part 21. There has been a reduction in nuclear industry suppliers who implement a quality assurance program that complies with 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." This evolution has prompted an increased reliance by nuclear power reactor licensees on commercial-grade dedication. Dedication is defined in the regulation, in part, as "an acceptance process undertaken to provide reasonable assurance that a commercial grade item to be used as a basic component will perform its intended safety function and, in this respect, is deemed equivalent to an item designed and manufactured under a 10 CFR Part 50, appendix B, quality assurance program." In short, dedication allows the use of commercial parts and services in safety-related applications.

The NRC conceived the regulations for dedication in 1978. At that time, licensees typically performed dedication activities for a small number of basic components which were unavailable from suppliers under Appendix B to 10 CFR Part 50. The regulatory framework for dedication resides solely in the definition of dedication in Section 21.3 of Part 21 and is not discussed in the body of the rule. As such, the regulation is difficult to apply in today's industry; this is

evident by inadequate licensee and vendor interpretation of the dedication process related to the use of commercial calibration laboratories in safety-related applications. As part of the rulemaking effort, the staff expects to include comprehensive guidance on how to dedicate calibration lab services. Nonreactor licensees and applicants face similar challenges due to the lack of specificity in the definitions. This is evident by four recent Part 21 exemption requests from non-reactor facilities. These entities have noted the difficulties in applying the Part 21's terminology to plutonium processing, uranium enrichment, and fuel fabrication.

Schedule and Milestones

NRO, NRR, the Office of Nuclear Material Safety and Safeguards (NMSS), and the Office of the General Counsel (OGC) have participated in the Part 21 working group to form a sound technical foundation for the development of a regulatory basis. In addition, NRO has coordinated its efforts with other NRC offices that are expected to be unaffected by this rulemaking (e.g., the Office of Federal and State Materials and Environmental Management Programs (FSME), the Office of Nuclear Security and Incident Response (NSIR), and Region II). The development of regulatory guides for evaluating and reporting and for dedication activities will be an important part of the rulemaking effort. Wherever possible, these guides will consolidate and expand on existing industry guidance.

The staff recently submitted SECY-11-0032, "Consideration of the Cumulative Effects of Regulation in the Rulemaking Process," dated March 2, 2011, to the Commission (ADAMS Accession No. ML110190027). Based on the staff's plans to develop regulatory guides concurrent with the rulemaking process and on the extensive outreach efforts planned, this rulemaking would be consistent with the guidelines proposed in SECY-11-0032. The table below provides milestones and target dates for these activities.

MILESTONE	TARGET DATE
Public Rulemaking Basis Development Kickoff Begin Development of Regulatory Guides	Fiscal Year 2012
Issue Regulatory Basis	September 2012
Anticipated Publication of Proposed Rule in the <i>Federal Register</i> Complete Initial Drafts of Regulatory Guides	September 2013
Potential Final Rule in the <i>Federal Register</i>	September 2014

Stakeholder Feedback

The staff has received and expects continued extensive stakeholder and public interaction throughout the rulemaking process. The staff also plans to build on the industry's 34 years of experience with Part 21. The staff has given presentations on the proposed rulemaking at the 2011 Regulatory Information Conference, 2011 Nuclear Procurement Issues Committee Vendor Conference, and Electric Power Research Institute joint utility task group meetings. Stakeholders provided positive feedback and offered suggestions during these meetings. The staff hosted a Category 3 public meeting on August 1, 2011, to solicit early stakeholder feedback on the technical topics associated with the potential rulemaking (ADAMS Accession

No. ML112650090). During the meeting, representatives from the Nuclear Energy Institute (NEI) expressed reservations about initiating rulemaking. They noted that industry guidance could be developed to address many of the issues. NEI repeated this position in a letter dated August 22, 2011, from Mr. Doug Walters, Vice President of Regulatory Affairs, NEI, to the NRC (ADAMS Accession No. ML112650013). However, at the August 1, 2011, meeting, representatives of vendors and materials licensees expressed overwhelming support for this rulemaking effort, as did representatives of individual nuclear power plant licensees responsible for procurement and quality assurance. While guidance will be an integral part to the success of this effort, the staff believes that changes to the rule are essential to providing a holistic and effective solution for clarifying Part 21.

The staff considered the need for an Advance Notice of Proposed Rulemaking before developing a proposed rule, but determined it to be unnecessary, as sufficient stakeholder input had been gathered as a result of the activities and meetings described above.

RESOURCES:

The proposed Fiscal Year 2013 Performance Budget to the Office of Management and Budget includes the full-time equivalent (FTE) staff specifically for the high priority Part 21 rulemaking. These resources are consistent with the Common Prioritization Rulemaking Report and thus budgeted accordingly as shown in the following table:

	NRO	NRR	NMSS	FSME	OGC	OIS	ADM
Fiscal Year 2012	0.6	0.25	0.2	0.2	0.1	0.1	0.1
Fiscal Year 2013	1.0	0.5	0.2	0.2	0.1	0.1	0.1

Finally, the staff acknowledges that the agency's priority for Part 21 rulemaking may be impacted by potential rulemakings that the Commission may direct in response to the Near-Team Task Force (NTTF) report (ADAMS Accession No. ML111861807).

The Commissioners

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COORDINATION:

This action has been coordinated with the Office of the Chief Financial Officer. OGC has reviewed this paper and has no legal objection.

/RA/

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Enclosure:

10 CFR Part 21—Proposed Areas
for Improvement

10 CFR PART 21—PROPOSED AREAS FOR IMPROVEMENT

EVALUATING AND REPORTING	Potential Regulation Change	New Requirement	Additional Guidance	Endorse Industry Guidance
(1) Lack of Regulatory Guidance			✓	
(2) Quality Requirements in Procurement Documents	✓	✓	✓	
(3) Lack of Clarity in Definition of Basic Component for Nonreactor Facilities	✓		✓	
(4) Clarification of Point of Discovery	✓		✓	
(5) Evaluating and Reporting Responsibility	✓		✓	
(6) Deferral of Evaluation (10 CFR 21.21(b))	✓	✓	✓	
(7) Use of Licensee Event Reporting (i.e., 10 CFR 50.72 and 10 CFR 50.73)	✓		✓	
(8) Acceptable Forms of Written Notification under 10 CFR 21.21(d)(2) for Nonreactor Facilities	✓		✓	
(9) 10 CFR 50.55e Redundancy	✓			
(10) Evaluation of Counterfeit Fraudulent and Suspect Items under 10 CFR Part 21			✓	
(11) Clarification of Deviation and Delivery	✓		✓	
(12) Contemporary Posting Requirements			✓	
(13) Training			✓	
COMMERCIAL-GRADE DEDICATION				
	Requires Regulation Change	New Requirement	Additional Guidance	Endorse Industry Guidance
(A) Lack of Regulatory Guidance			✓	✓
(B) Proper Place for Dedication	✓			
(C) Definition of Dedication	✓			
(D) Definition of Commercial-Grade Item	✓			
(E) Clarification of Dedication as a Safety-Related Activity			✓	
(F) Dedication Plans and the Importance of Safety Function	✓	✓	✓	✓
(G) Sampling Requirements			✓	✓
(H) Use of Commercial Calibration (and Testing) Laboratories—International Laboratory Accreditation Cooperation Process			✓	✓
(I) Software Dedication			✓	✓
ADMINISTRATIVE CHANGES				
	Requires Regulation Change	New Requirement	Additional Guidance	Endorse Industry Guidance
(i) Addition of “10 CFR Part 52” to the Definition of Dedication	✓			
(ii) Definitions for 10 CFR Part 76 Facilities (i.e., Basic Component and Substantial Safety Hazard)	✓			
(iii) Definition of Critical Characteristics for Nonreactor Facilities	✓			