FINAL REGULATORY BASIS TO CLARIFY 10 CFR PART 21, "REPORTING OF DEFECTS AND NONCOMPLIANCE"

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CONTENTS

CHAPTER 1
INTRODUCTION

The purpose of a regulatory basis is to identify a regulatory problem, to consider which regulatory options are available to solve the problem, and to recommend a solution that solves that problem. If the recommended solution is to amend the Nuclear Regulatory Commission's (NRC's) regulations, the staff develops a proposed new rule or changes to the existing rule. NRC rulemaking involves publication of a proposed rule in the *Federal Register* along with a request for public comments on the proposal. If the NRC proceeds with a final rule, the staff will address these public comments with the final rule when it is published in the *Federal Register*. The NRC will also publish any necessary regulatory guidance documents in support of the rulemaking as draft and final documents concurrent with the publication of the proposed draft and final rule. If the regulatory basis recommends other solutions, such as issuance of NRC Generic Communication or NRC reliance on voluntary industry initiatives, the NRC will ordinarily seek views from members of the public and other stakeholders on the recommended solutions before they are finalized. The goals of the NRC's Cumulative Effects of Regulation (CER) efforts have been met through extensive public interaction during the development of this final regulatory basis, and will continue to be met through the steps described in this section.

This regulatory basis describes the need to clarify Title 10 of the *Code of Federal Regulations* (10 CFR) Part 21, "Reporting of Defects and Noncompliance" (Part 21). The proposed Part 21 rule changes are intended to clarify the requirements for the evaluation and the reporting of defects and provide the proper regulatory framework that is needed for the commercial-grade dedication process. The staff's preliminary evaluation of the provisions in the proposed rulemaking find that the majority of the provisions do not impose new or revised staff positions or requirements on operating nuclear power reactors and materials facilities. However, the staff is aware of existing industry concerns that some proposed changes may constitute backfitting. A complete backfit analysis will be performed during development of the proposed rule for those facilities provided with backfitting protection licensed under Parts 50, 70, 72, 76; and issue finality provisions for those facilities licensed under Part 52. The recommendations in this regulatory basis, if pursued, will simplify and clarify the rule language in Part 21 rule; will provide consolidated regulatory guidance; and will enhance regulatory stability and predictability for the entities to which Part 21 applies.

Documents associated with the development of this regulatory basis can be found on the NRC public Web site (www.nrc.gov) and also on the Federal Government's regulations Web site (www.regulations.gov) by searching for "NRC-2012-0012."

Background

Part 21 was designed to implement Section 206 of the Energy Reorganization Act (ERA) of 1974. Section 206 was not part of the Act as it was passed by the House of Representatives. This section was added by the Senate committee. The purpose of the section as explained by the Senate committee in its report was, "to upgrade the system of detecting and anticipating the effects that increasingly have plagued the nuclear power industry and threatens its safety record on a daily basis."[1] The basis given for conceiving Section 206 was that component failures accounted for more than half of the abnormal occurrences in nuclear power plants. Often, the defective components were relatively noncomplex hardware items.

[1] S. Rep. No. 93-980 (1974), *reprinted in* 1974 U.S.C.C.A.N. 5470, 5527.

The determination of the intent of Section 206 was a difficult task for the Commission, since the legislative guidance was not as detailed as the guidance concerning other sections of the Energy Reorganization Act of 1974. Congress essentially gave the Commission significant leeway to develop Part 21. What was fairly clear was that Congress wanted the Commission to address basic components that have been identified to contain a defect, which could result in the plant failing to meet its licensing basis.

The regulations in 10 CFR Part 21 established procedures and requirements for the implementation of Section 206 of the Energy Reorganization Act of 1974. Section 206 requires any individual director or responsible officer of a firm constructing, owning, operating, or supplying the components of any facility or activity that is licensed or otherwise regulated pursuant to the Atomic Energy Act of 1954, as amended, or the Energy Reorganization Act of 1974, who obtains information reasonably indicating (1) that the facility, activity, or basic component supplied to such facility or activity fails to comply with the Atomic Energy Act of 1954, as amended, or any applicable rule, regulation, order, or license of the Commission relating to substantial safety hazards, or (2) that the facility, activity, or basic component supplied to such facility or activity contains defects that could create a substantial safety hazard, to immediately notify the Commission of such failure to comply or such defect, unless he has actual knowledge that the Commission has been adequately informed of such defect or failure to comply.

The intent of Part 21 is to contribute to public health and safety by ensuring that the Commission is adequately informed of any loss of safety function to the extent that there is a major reduction in the degree of protection provided to the public health and safety. The regulation requires directors and responsible officers of firms and organizations building, operating, or owning NRC-licensed facilities to report failures to comply with regulatory requirements relating to substantial safety hazards and defects in components that may result in a substantial safety hazard. This regulation also applies to directors and responsible officers of firms and organizations supplying safety-related components, including safety-related design, testing, inspection, and consulting services. Part 21 also requires these entities to adopt procedures to ensure that safety-related defects and noncompliance are brought to the attention of their responsible officers and directors (or their designees). In turn, the responsible officers and directors (or their designees) are required to notify the Commission by filing an initial report followed by a written report regarding the defect or noncompliance.

History of Part 21

The NRC published the final rule for Part 21 in the *Federal Register*, on June 6, 1977 (42 FR 28891), to implement Section 206, “Noncompliance,” of the Energy Reorganization Act of 1974, as amended (42 U.S.C. 5846). The purpose of Section 206 is to ensure that the NRC receives immediate notification that a facility, activity, or “basic component” (1) fails to comply with the Atomic Energy Act of 1954, 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. In addition to imposing obligations on certain officers of NRC licensees, Section 206 also imposes obligations on certain officers of nonlicensees that construct facilities for, or supply components to, licensed facilities or activities (i.e., vendors or suppliers).

When that final rule was issued, the NRC acknowledged that issuing a detailed regulation at that time was not practical. Furthermore, the NRC staff anticipated that it would make clarifying changes and develop guidance after gaining experience with Part 21. The statement of considerations for the final rule states the following (42 FR 28891, at 28893):

> The Commission intends to examine closely the implementation of new Part 21 [requirements] with a view to making any clarifying or other changes that may be warranted in light of experience. In particular, insufficient experience has been accumulated to permit the writing of a detailed regulation at this time that would provide a precise correlation of all factors pertinent to the question of what is a significant safety hazard. Part 21 is intended in this regard as an initial effort to identify a number of the factors involved with the question of significant safety hazard. Further, additional guidance in the form of regulatory guides may be developed should experience with the application of Part 21 indicate the need for such guidance. In this regard, we expect that the implementation efforts of the staff and those subject to the rule, and the views of interested members of the public, should provide the necessary data base for such further guidance.

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 NRC has since amended Part 21 to eliminate duplicate reporting, account for operating experience, broaden the scope of the regulations to include new reactors, and address conforming and administrative changes. Notable amendments are as follows:

- In 1991, the NRC amended Part 21 (56 FR 36081; July 31, 1991) 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 intent of the changes was 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 amended Part 21 (60 FR 48369; September 19, 1995) to provide added flexibility in the ability of nuclear power plant licensees to procure commercial grade items for safety-related services. The intent of the action was 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.

Addressing Part 21 Compliance Challenges

Since it was codified in 1977, Part 21 has presented compliance challenges to licensees, vendors, and to the NRC staff.[2] The NRC staff has documented repetitive inspection findings related to Part 21, including commercial grade dedication findings, despite attempts to clarify requirements through NRC Generic Communications and extensive outreach efforts. Recently

[2] Throughout this document, the terms "vendors" and "suppliers" are used interchangeably.

approved Part 21 exemption requests for nonreactor facilities further underscore the need to reexamine Part 21. The exemption requests underscore the deficiencies in the current Part 21 regulations because the current regulations cannot be logically applied to some nonreactor facilities. More fundamentally, the NRC staff has not clarified the nexus between Part 21 requirements and the recent advances in NRC safety requirements for fuel cycle facilities that are aimed, in part, to maintain the availability and reliability of items that are relied on for the safety of licensed operations. Developing this regulatory basis relating to Part 21 affords the NRC staff and stakeholders the opportunity to consider improvements to the regulatory consistency and clarity among the requirements in Part 21 and 10 CFR Part 70, "Domestic Licensing of Special Nuclear Material" (Part 70).

NRC findings related to failures to report in accordance with Part 21 are also important. The NRC considers the safety and security implications of noncompliances that may affect the agency's ability to carry out its statutory mission. Many of the surveillance, quality control, and auditing systems that both the NRC and its licensees rely on to monitor compliance with safety standards are based primarily on complete, accurate, and timely recordkeeping and reporting. Therefore, the NRC may consider a failure to make a required report that impedes its ability to take regulatory action to be significant, even if that failure was inadvertent or did not result in an actual consequence.

In 2010 and 2011, the NRC's Office of the Inspector General (OIG) performed two audits related to Part 21[3]. The OIG's audits provided 15 recommendations, most of which were related to clarifying Part 21.

Following the 2010 OIG audit, the staff established an agencywide working group to explore Part 21 inspection findings and to identify potential areas for improvement. The staff identified 25 potential areas for improvement, including several areas related to requirements for materials licensees. The 25 areas can be divided into three categories: (1) evaluating and reporting, (2) commercial grade dedication, and (3) administrative changes.

In response to OIG's recommendations, the NRC staff advanced its ongoing initiatives to clarify Part 21. The staff hosted a public meeting on August 1, 2011, to solicit early stakeholder feedback on the technical topics associated with the potential rulemaking (ADAMS Accession No. ML112650090). Then on September 29, 2011, the NRC staff issued Commission paper SECY-11-0135, "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'" (ADAMS Accession No. ML112430138). The paper discussed the staff's plan for developing a regulatory basis to clarify Part 21. Specifically, it addressed the need and priority for rulemaking, guidance development (i.e., regulatory guides), and extensive outreach efforts.

The staff also engaged stakeholders and provided presentations on the need for rulemaking in various other public forums, such as the 2011 Regulatory Information Conference, the 2011 Nuclear Procurement Issues Committee annual vendor workshop, the annual Fuel Cycle Information Exchange in 2011 and 2012, and the biennial NRC workshop on vendor oversight for new reactor construction in 2012.

[3] (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 more than one hundred questions received during the workshops on vendor oversight held in 2008 and 2010, the NRC staff prepared two "Questions and Answers" documents relating to Part 21[4]. The NRC staff considered those efforts largely insufficient in clearing up the legal and technical nuances of the rule, as demonstrated by the continued extensive NRC public outreach on Part 21 related issues.

The staff has hosted a number of public meetings on Part 21 rulemaking to provide early opportunities for stakeholder outreach and to solicit feedback. The public meetings provided additional areas for improvement and, as noted, informed SECY-11-0135, and this regulatory basis.

The NRC public meetings pertaining to Part 21 rulemaking are listed in Table 1-1.

Table 1-1 Public Meetings

DATE	MEETING SUBJECT	MEETING SUMMARY
August 1, 2011	Discuss potential rulemaking to revise 10 CFR Part 21.	ADAMS Accession No. ML112650090
January 26, 2012	Discuss regulatory basis and guidance development to clarify Part 21.	ADAMS Accession No. ML12027A133
January 24, 2013	Discuss the NRC staff's draft regulatory basis to clarify Part 21.	ADAMS Accession No. ML13052A700
April 10, 2013	Discuss Section 10, "10 CFR 50.55(e) Redundancy," of Chapter 2 of the NRC staff's draft regulatory basis to clarify Part 21.	ADAMS Accession No. ML13107B460
April 11, 2013	Discuss the status of several initiatives involving the fuel cycle industry.	ADAMS Accession No. ML13113A251
May 30, 2013	Discuss evaluating and reporting related to the NRC staff's draft regulatory basis to clarify Part 21.	ADAMS Accession No. ML13172A093
March 6, 2014	Discuss lessons learned from visits to fuel facilities related to licensees' implementation of Part 21	ADAMS Accession No. ML14072A113
April 28, 2015	Discuss Revision 1 of the draft regulatory basis to clarify the requirements of Part 21.	ADAMS Accession No. ML15139A513

In December 2012, the staff published Revision 0 of the draft regulatory basis to clarify Part 21. Based on feedback received from public meetings, the staff made changes which are reflected in Revision 1 of the draft regulatory basis (ADAMS Accession No. ML14135A207), which was issued in March 2015. In the first revision of the draft regulatory basis, the staff included

[4] (1) "Revision 1 to NRC Responses to 10 CFR Part 21 and Fuel Cycle Facility Questions Received During the Vendor Workshop on New Reactor Construction in December 2008," dated October 5, 2009 (ADAMS Accession No. ML092660129), and (2) "Nuclear Regulatory Commission Responses to Questions Received During the Workshop on Vendor Oversight for New Reactor Construction Held in June 2010," dated May 10, 2012 (ADAMS Accession No. ML12137A440).

proposed draft rule language so that stakeholders can further understand the staff's insights on potential changes to the regulations and provide an additional opportunity for comments in advance of the proposed rule public comment period.

Each chapter of the regulatory basis provides the existing regulatory framework, the definition of a regulatory problem, and options to resolve the regulatory problem. In developing options to resolve the regulatory problems, the staff considered changes to the rule's language, NRC guidance documents, voluntary industry initiatives (e.g., industry efforts planned or underway), and the effects of not taking action. These options are not presented as discrete choices. The staff expects that, for most of the sections, a combination of options will likely be the most effective way to resolve each regulatory problem. Appendix A contains draft rule language to illustrate the potential changes that may be offered in a proposed rule. The staff expects to incorporate stakeholder input, including feedback on the options to resolve the regulatory problems, in the final version of this regulatory basis.

CHAPTER 2
EVALUATING AND REPORTING

1. Lack of Regulatory Guidance

a. Existing Regulatory Framework

The NRC has no formal guidance (*e.g.*, regulatory guide) on how to evaluate and report under Part 21. NUREG-0302, "Remarks Presented (Questions/Answers Discussed) at Public Regional Meetings To Discuss Regulations (10 CFR Part 21) for Reporting of Defects and Noncompliance: July 12–26, 1977," issued October 1977, provides answers to some frequently asked questions, based on NRC outreach efforts from July 12–26, 1977, in support of the initial promulgation of Part 21. However, NUREG-0302 does not provide comprehensive NRC-approved guidance and is outdated in many areas.

b. Description of Regulatory Problem

There is currently no comprehensive NRC-issued guidance for an acceptable form of evaluating and reporting under Part 21. The applicability of Part 21 is broader than most NRC regulations. These regulations apply to individuals, partnerships, corporations, and all entities holding or applying for an NRC license. In addition, Part 21 applies not only to entities licensed by the NRC, but also to non-licensed entities and individuals. Finally, Part 21 applies to licensees and vendors across different types of activities and facilities regulated by the NRC.

Although all power reactor licensees and certain nonreactor[5] licensees have NRC-approved quality assurance (QA) programs, most vendors do not submit their programs to the NRC for formal review. Vendor programs are audited by their purchasers, and vendors only need to implement programs that meet their scope of supply. For instance, a supplier of engineering services would not be expected to have a QA program that mirrors one of a supplier of fasteners. Therefore, QA programs across the industry vary from one vendor to the next as evident in how vendors identify and resolve problems in their corrective action and nonconformance programs. Deviations and defects are typically found through corrective action and nonconformance programs that identify problems. Because Part 21 applies to a wide range of facility types, and the vendors that support them, developing programs that implement the requirements of the regulation pose somewhat different challenges for the licensees and vendors.

For fuel cycle facilities, Part 21 does not reflect recent advances in the regulatory framework that address risk management and application of management measures, to ensure, in part, that items relied on for safety (IROFS) are available and reliable to perform their intended safety function. More specifically, in 2000, the Commission issued a risk-informed and performance-based approach through Subpart H, "Additional Requirements for Certain Licensees Authorized To Possess a Critical Mass of Special Nuclear Material," of Part 70. The regulations at 10 CFR 70.62, "Safety Program and

[5] Facilities and activities licensed under 10 CFR Parts 30, 40, 50 (other than nuclear power plants), 60, 61, 63, 70, 71, or 72 of Title 10, Chapter I - Nuclear Regulatory Commission.

Integrated Safety Analysis," address the need for a safety program that includes three elements: (1) process safety information, (2) integrated safety analysis (ISA), and (3) management measures. An ISA is a systematic analysis to identify facility and external hazards and their potential for initiating accident sequences. The ISA identifies the potential accident sequences, their likelihood and consequences, and the IROFS used to prevent events and/or mitigate their consequences. Subpart H allows licensees to use administrative controls in conjunction with engineered controls as IROFS to prevent or mitigate the consequences of events that could exceed performance requirements established in 10 CFR 70.61, "Performance Requirements." Part 70 licensee ISAs use combinations of various controls and management measures to ensure that IROFS are available and reliable to perform their functions when needed. Part 21 and its existing implementing guidance do not acknowledge the use of administrative controls,[6] as addressed in the ISAs. Furthermore, staff guidance does not clearly define the applicability of Part 21 to non-IROFS systems or equipment required by Part 70 (i.e., nuclear criticality monitoring and alarm systems).

Despite the history of Part 21 regulatory challenges for both reactor and nonreactor licensees and their supporting vendors, the NRC has never issued formal comprehensive guidance to provide an acceptable approach to comply with the evaluating and reporting requirements of Part 21. Furthermore, attempts to provide guidance for evaluating and reporting under Part 21 for power reactor licensees and vendors (e.g., presentations and questions and answers issued in conjunction with vendor workshops, generic communications, etc.) have been unable to reduce the incidence of inspection findings associated with inadequate implementation of Part 21.

c. Options To Resolve Regulatory Problem

- Proposed Changes to NRC Regulations

  Changes to NRC regulations would not address the problem of a lack of regulatory guidance.

- NRC Guidance Development

  The NRC's regulatory guides typically provide guidance to stakeholders on the implementation of specific parts of the NRC's regulations, techniques used by the NRC staff in evaluating specific problems or postulated accidents, and data needed by the staff to perform its safety mission. The staff could develop a regulatory guide on evaluating and reporting. The staff's guide in this area would provide an acceptable approach for compliance with the evaluating and reporting requirements in Part 21.

[6] NUREG-1520, "Standard Review Plan for the Review of a License Application for a Fuel Cycle Facility," Revision 1, (ADAMS Accession No. ML101390110) provides guidance for the review of license applications for nuclear fuel cycle facilities licensed in accordance with 10 CFR Part 70. NUREG-1520 defines an "administrative control" as "Either an augmented administrative control or a simple administrative control, as defined herein." The NUREG defines "augmented administrative control" as "A procedurally required or prohibited human action, combined with a physical device that alerts the operator that the action is needed to maintain safe process conditions or that otherwise adds substantial assurance of the required human performance" and defines "simple administrative control" as "A procedural human action that is prohibited or required to maintain safe process conditions."

A regulatory guide to address evaluating and reporting requirements would provide clear expectations to Part 21 stakeholders. The staff has begun developing draft guide (DG)-1291, "Evaluating Deviations and Reporting Defects and Noncompliance."

- Voluntary Industry Initiatives

  The Nuclear Energy Institute (NEI) recently developed general guidance to describe what it believes to be an acceptable approach to comply with the requirements for evaluation and reporting in 10 CFR Part 21. That guidance, contained in NEI 14-09, "Guidelines for Implementation of 10 CFR Part 21 Reporting of Defects and Noncompliance, Revision 0," dated August 28, 2014 (ADAMS Accession No. ML14245A415) is currently under review by the NRC staff.

- No Action

  Under this alternative, the NRC staff would rely on existing regulations and guidance documents (i.e., NUREG-0302). No changes to regulatory language would be proposed. Taking no action would likely result in continued confusion and lack of clarity on implementing Part 21. Taking no action would also be non-responsive to the recommendations listed in OIG audit reports OIG-10-A-20 and OIG-11-A-08. The many repetitive problems with licensees and vendors implementing Part 21 that were identified during inspections and stakeholder interactions are significant enough to warrant action. Therefore, the "no action" alternative is not a desirable option.

2. Quality Requirements in Procurement Documents

a. Existing Regulatory Framework

10 CFR 21.31, "Procurement Documents," requires that procurement documents specify the applicability of 10 CFR Part 21:

> Each individual, corporation, partnership, dedicating entity, or other entity subject to the regulations in this part shall ensure that each procurement document for a facility, or a basic component issued by him, her, or it on or after January 6, 1978, specifies, when applicable, that the provisions of 10 CFR Part 21 apply.

For nuclear power plants licensed under 10 CFR Part 50 ("Domestic Licensing of Production and Utilization Facilities") or Part 52 ("Licenses, Certifications, and Approvals for Nuclear Power Plants"), 10 CFR 21.3(1)(ii) defines basic components to be those designed and manufactured under a quality assurance program complying with Appendix B, "Quality Assurance Criteria for Nuclear Power Plants and Fuel Reprocessing Plants," to 10 CFR Part 50 (Appendix B). Criterion IV, "Procurement Document Control," of Appendix B requires that applicable regulatory requirements be included or referenced in the procurement documents. Further, Criterion IV of

Appendix B states that procurement documents must require that suppliers provide a quality assurance program consistent with the pertinent provisions of Appendix B.

For nonreactor facilities, appropriate quality requirements, which may include Appendix B or measures similar to those in Appendix B (e.g., 10 CFR 70.62(d), "Management Measures," Subpart H, "Quality Assurance," of 10 CFR Part 71, "Packaging and Transportation of Radioactive Material," Subpart G, "Quality Assurance," of 10 CFR Part 72, "Licensing Requirements for the Independent Storage of Spent Nuclear Fuel and High Level Radioactive Waste, and Reactor Related Greater Than Class C Waste," etc.), must also be invoked.

For nonpower reactors 10 CFR Part 50, Appendix B is not applicable. However, Title 10, Section 50.34(a)(7), of the *Code of Federal Regulations* requires each applicant for a construction permit to build a production or utilization facility to include, in its preliminary safety analysis report, a description of the quality assurance program to be applied to the design and construction of the structures, systems, and components of the facility. Furthermore, 10 CFR 50.34(b)(6)(ii) and requires that each applicant for a license to operate a production or utilization facility include, in the final safety analysis report, a description of the managerial and administrative controls to be used to ensure safe operation. In the case of power reactors, the applicants for a facility license typically present a discussion as to how each requirement for the Appendix B Quality Assurance program will be satisfied. In place of 10 CFR Part 50 Appendix B; the staff has endorsed the use ANSI/ANS-15.8-1995, "Quality Assurance Program Requirements for Research Reactors," in Regulatory Guide 2.5, "Quality Assurance Program Requirements for Research Reactors," June 2010, Revision 1 as a method that the NRC considers acceptable in meeting 10 CFR 50.34(a)(7) and 10 CFR 50.34(b)(6)(ii) requirements.

b. Description of Regulatory Problem

The requirements to invoke Part 21 and quality assurance (e.g., Appendix B for power reactor facilities) in procurement documents are located in different regulations. 10 CFR 21.31 states that procurement documents for basic components must specify that the provisions of Part 21 apply, but does not require that procurement documents specify applicable quality requirements, such as Appendix B for power reactor facilities. The staff has found several instances where vendors failed to invoke Appendix B along with Part 21 in procurement documents and vice versa. This has led to omission of the necessary requirements that must be imposed on safety-related items and services from the purchasers' procurement documents.

c. Options To Resolve Regulatory Problem

- Proposed Changes to NRC Regulations

  The staff considered revising the regulations to expressly state that appropriate QA requirements (e.g., Appendix B for nuclear power plants licensed under 10 CFR Part 50 or Part 52, or other appropriate requirements for nonpower reactors and nonreactor licensees) must be invoked in procurement documents, along with 10 CFR Part 21. However, the staff determined that codifying the requirement would likely cause additional burden with minimal safety gains. Therefore, the staff is not proposing changes to the regulations.

- NRC Guidance Development

  Appropriate regulatory guidance could be developed to address the fundamental concept of the link between the quality assurance requirements and Part 21. The staff intends to detail the inclusion of quality assurance and Part 21 requirements in procurement documents in DG-1291. The staff would describe the requirements for invoking both the appropriate QA requirements and Part 21 requirements in the procurement documents, for both nuclear power plants and nonreactor facilities. For nonpower reactors appropriate guidance exists in Section 2.4 of ANSI/ANS-15.8-1995, "Quality Assurance Program Requirements for Research Reactors," which the NRC has approved for use in Regulatory Guide 2.5, "Quality Assurance Program Requirements for Research Reactors," June 2010, Revision 1.

- Voluntary Industry Initiatives

  NEI recently developed guidance on invoking QA and Part 21 requirements in procurement documents. That guidance, contained in NEI 14-09, "Guidelines for Implementation of 10 CFR Part 21 Reporting of Defects and Noncompliance, Revision 0," dated August 28, 2014 (ADAMS Accession No. ML14245A415) is currently under review by the NRC staff.

- No Action

  Under this alternative, the NRC staff would rely on existing regulations and guidance documents. No changes to regulatory language would be proposed. Taking no action would likely result in continued misunderstanding of regulatory requirements by some vendors, therefore increasing the potential that purchasers may be procuring safety-related items and services without clearly imposing appropriate QA requirements. Therefore, the "no action" alternative is not a preferred option.

3. Lack of Clarity in the Definition of Basic Component for Nonreactor Facilities and Activities

a. Existing Regulatory Framework

For nonreactor facilities and activities, "basic component" is currently defined in 10 CFR 21.3, "Definitions":

> When applied to other facilities and other activities licensed under 10 CFR parts 30, 40, 50 (other than nuclear power plants), 60, 61, 63, 70, 71, or 72 of this chapter, basic component means a structure, system, or component, or part thereof, that affects their safety function, that is directly procured by the licensee of a facility or activity subject to the regulations in this part and in which a defect or failure to comply with any applicable regulation in this chapter, order, or license issued by the Commission could create a substantial safety hazard.

The statement of considerations issued with promulgation of 10 CFR Part 21 (42 FR 28891, at 28892) identified that future changes may likely be needed to clarify the rule, particularly with respect to significant [substantial] safety hazards, which are directly tied to the definition of basic components for nonreactors. The statement of considerations identified that:

> The Commission intends to examine closely the implementation of new Part 21 [requirements] with a view to making any clarifying or other changes that may be warranted in light of experience. In particular, insufficient experience has been accumulated to permit the writing of a detailed regulation at this time that would provide a precise correlation of all factors pertinent to the question of what is a significant safety hazard. Part 21 is intended in this regard as an initial effort to identify a number of the factors involved with the question of significant safety hazard. Further, additional guidance in the form of regulatory guides may be developed should experience with the application of Part 21 indicate the need for such guidance. In this regard, we expect that the implementation efforts of the staff and those subject to the rule, and the views of interested members of the public, should provide the necessary data base for such further guidance.

Since its issuance, experience from implementation of the rule has shown the need for additional clarity with respect to the scope of Part 21 terminology applicable to nonreactor facilities, to include the definition of basic component for fuel cycle facilities. This has been evidenced through exemptions and licensing requests related to Part 21 terms as they apply to nonreactor facilities.[7] One example of a definition that has been approved through this process for uranium enrichment and fuel fabrication facilities licensed under Part 70 reads, in part, as follows:

> Basic component means a structure, system, or component, or part thereof that affects their IROFS [items relied on for safety] function, that is directly procured by the licensee or activity subject to the regulations in this part and in which a defect or failure to comply with any applicable regulation in this chapter, order, or license issued by the Commission could create a substantial safety hazard (i.e., exceed performance requirements of 10 CFR 70.61). In all cases, basic components includes IROFS-related design, analysis, inspection, testing, fabrication, replacement parts, or consulting services that are associated with

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[7] Exemptions to terminology related to Part 21 implementation for fuel cycle facilities have been granted in the following letters and reports:

1. NRC letter entitled, "Approval of Louisiana Energy Services Part 21 Exemption Request and Amendment 13 to License," dated February 11, 2009 (ADAMS Accession No. ML083400454)
2. NRC letter entitled, "Approval of the Mixed Oxide Project Quality Assurance Plan, Revision 6, Change 1," dated November 13, 2008 (ADAMS Accession No. ML082320259)
3. NRC letter entitled, "Partial Approval of Changes to the Mixed Oxide Project Quality Assurance Program, Revision 10," dated June 17, 2011 (ADAMS Accession No. ML111600016)
4. NRC letter entitled, "Approval of AREVA Enrichment Services' Part 21 Exemption Request," dated July 28, 2010 (ADAMS Accession No. ML101690142)
5. Section 1.2.4, "Evaluation Findings," of NUREG-2120, "Safety Evaluation Report for the General Electric-Hitachi Global Laser Enrichment, LLC Laser-Based Uranium Enrichment Plant in Wilmington, North Carolina," issued February 2012 (ADAMS Accession No. ML12060A007)

the component hardware whether these services are performed by the component supplier or others.

Exempted definitions have been requested by and granted to multiple applicants and licensees that are constructing and operating new fuel cycle facilities. The exempted definitions have been very similar to the definition cited above and have all sought to define a basic component in terms that are defined within the regulatory structure of 10 CFR Part 70 (i.e., IROFS and performance requirements).

b. Description of Regulatory Problem

The definition of a basic component as it applies to Part 70 licensees is difficult to interpret. Whereas the power reactor facility definition for a basic component is specific to power reactor terminology and consequences (i.e., the definition of basic component in Part 21 references maintaining the integrity of the reactor coolant pressure boundary), the nonreactor definition applies to multiple facilities and activities and does not include sufficient specificity for such varied activities and facilities. As a result, applicants and licensees have had difficulty in applying the definition as written, and numerous enrichment and fuel fabrication facilities have requested approval via exemptions and licensing requests to implement a basic component definition that uses terminology directly applicable to Part 70 regulatory requirements.

The submittal of alternate definitions by applicants and licensees to clarify the term basic component as it applies to fuel cycle facilities is illustrative of the lack of clarity in the existing definition. In developing and revising the draft regulatory basis, staff engaged stakeholders in multiple public meetings as well as a series of site visits at fuel cycle facilities. These interactions indicated that there was a wide interpretation of the meaning of “basic component” at different fuel cycle facilities. Specifically, some facilities interpret the definition to include all systems, structures, and components designated as IROFS in accordance with 10 CFR 70.61(e), whereas other facilities interpret the definition as applying only to those IROFS that are the sole item relied on to prevent high consequence events as defined in 10 CFR 70.61(b) or mitigate their effects.

The varying interpretations of the term “basic component” among applicants and licensees demonstrates the need to clarify the definition to ensure appropriate, consistent and enforceable application of the term and to provide regulatory stability within 10 CFR Part 21. In the absence of definitive rule text, applicants and licensees will continue to apply varying interpretations of the rule, which limits the evaluation and reporting of defects and noncompliances and negates the intent of Part 21 and the underlying provisions of Section 206 of the Energy Reorganization Act.

c. Options To Resolve Regulatory Problem

- Proposed Changes to NRC Regulations

The staff is considering adding a definition in Part 21 for "basic component" that is specific to Part 70 licensees[8] because of (1) the inconsistency in implementation of the definition among fuel cycle applicants and licensees and (2) the inability of the definition to provide regulatory stability as written, as evidenced by the number of exemptions requested and approved for construction of new fuel cycle facilities. This definition change is important because of the wide array of interpretations among licensees as to which items are basic components. Although many facilities licensed after the addition of Subpart H of Part 70 have adopted the position that all items relied upon for safety are basic components, facilities licensed before implementation of Subpart H have varying interpretations of the definition of basic component under Part 21.
In the absence of clear, precise rule text, applicants and licensees will continue to implement differing and sometimes incorrect interpretations of Part 21.
For instance, one incorrect interpretation of the definition of "basic component" to fuel cycle facilities is that fuel facility operations, such as enrichment or fuel fabrication, are not capable of creating substantial safety hazards. While it is true that fuel assemblies are supplied to nuclear power plants as basic components and defects in such assemblies, or parts thereof, could meet the substantial safety hazard threshold, hazards associated with the processing of nuclear material as part of the nuclear fuel cycle must also be considered under Part 21 because defects in items relied upon for these activities also have the potential to create substantial safety hazards (e.g., an inadvertent criticality).

In order to avoid continued inconsistencies in interpretation and implementation of Part 21 for fuel cycle facilities, the staff recommends adding a definition of "basic component" to the rule that is specific to fuel cycle facilities subject to Subpart H of Part 70 and uses terminology that is defined in the Part 70 rule. Because Part 21 defines a basic component, in part, as a system, structure, or component in which a defect or failure to comply could create a substantial safety hazard, the staff compared existing regulatory guidance related to basic components and substantial safety hazards with the requirements of Part 70 to determine how to best clarify the definition of basic component using the risk-informed, performance-based regulations in Part 70.

10 CFR 70.62(c) requires applicants and licensees to perform an integrated safety analysis (ISA) to identify (i) radiological hazards related to possessing or processing licensed material; (ii) chemical hazards of licensed material and hazardous chemicals produced from licensed material; (iii) facility hazards that could affect the safety of licensed materials and thus present an increased radiological risk; (iv) potential accident sequences caused by process deviations or other events internal to the facility and credible external events, including

[8] The NRC staff intends that this definition also be applicable to 10 CFR Part 40 licensees who have a regulatory requirement (i.e., license condition) to develop an ISA or were licensed using 10 CFR Part 70, Subpart H, performance requirements in accordance with the staff requirements memorandum for SECY-07-0146 (ADAMS Accession No. ML072830536).

natural phenomena; and (v) the consequence and the likelihood of occurrence of each potential accident sequence identified. The requirements of 10 CFR 70.61 specify performance requirements (thresholds for radiological, chemical, and criticality events) that must be limited based on the risk of credible events that may occur at a facility, as identified in the ISA. Regulations in 10 CFR 70.61(e) require that each engineered or administrative control or control system necessary to comply with the performance requirements of 10 CFR 70.61 be designated as an IROFS. In the context of Part 70, IROFS represent those engineered and administrative controls that ensure facility safety; therefore, engineered IROFS should be considered within the meaning of the term “basic component” since the failure of these systems, structures, and components has the potential to result in major reduction to the level of protection provided to public health and safety (i.e., create a substantial safety hazard) by increasing the risk of an event or decreasing the capability to mitigate the consequences of an accident.

Regulatory guidance related to substantial safety hazards can be found in the statement of considerations issued with promulgation of the Part 21 rule, NUREG-0302, NRC guidance related to abnormal occurrences, and Information Notice 91-39. These documents provide descriptions that relate to thresholds for determination of a substantial safety hazard.

The statement of considerations issued with the promulgation of Part 21 (42 FR 28891, at 28893) states:

> Substantial safety hazard has been defined in terms of a major reduction in the degree of protection provided to the public health and safety. Criteria that are appropriate for determination of creation of a substantial safety hazard include:
>
> - Moderate exposure to, or release of, licensed material.
> - Major degradation of essential safety-related equipment.
> - Major deficiencies involving design, construction, inspection, test or use of licensed facilities or material.
> - To the extent that failures to comply or defects in a security system can contribute to a substantial safety hazard, such failures and defects are within the scope of Part 21.

NUREG-0302 provides some examples of substantial safety hazards using the criteria above. Specifically, NUREG-0302 identifies exposure in excess of 25 rem whole body and exposure to an individual in an unrestricted area of 0.5 rem as guidelines for determining "moderate exposure." It states that “major degradation" is considered to be a loss of redundancy if, in conjunction with a single failure, a required safety function could not be performed. It explains "major deficiency" as a condition or circumstance which, under normal operating conditions or anticipated transients, could contribute to exceeding a safety limit or cause an accident or in the event of an accident due to other causes could, considering an independent single failure, result in a loss of safety function necessary to mitigate the consequences of the accident.

NUREG-0302 also provides a reference to the Commission's Policy Statement for Abnormal Occurrence Reports (42 FR 10950, February 24, 1977) and Appendix A to NUREG-0090, "Report to Congress on Abnormal Occurrences" (prepared annually), for criteria consistent with problems that may be considered substantial safety hazards. The Commission's Policy Statement for Abnormal Occurrence Reports, updated most recently in 2006 (71 FR 60198; October 12, 2006), defines abnormal event reporting criteria that the Commission considers significant from the standpoint of public health and safety. Such events represent a moderate or severe impact on public health or safety and could include (1) moderate exposure to, or release of, radioactive material licensed or otherwise regulated by the Commission, (2) major degradation of essential safety-related equipment, or (3) major deficiencies in the design, construction, or use of management controls for facilities or radioactive material. Because the abnormal event reporting criteria align with the criteria for determination of a substantial safety hazard, as described in the Part 21 statement of considerations cited above, the events defined as abnormal occurrences can reasonably be taken to represent substantial safety hazards.

The NRC issued Information Notice (IN) 91-39, "Compliance with 10 CFR Part 21, 'Reporting of Defects and Noncompliance," (ADAMS Accession No. ML031190504) on June 17, 1991, to remind materials licensees of the applicability of Part 21 reporting requirements to their facilities and activities. Among other guidance, IN 91-39 identifies criteria for determining whether a substantial safety hazard exists and provides a sample procedure for identifying and reporting defects under Part 21. Examples of significant events defined in the abnormal occurrence criteria include unintended radiation exposure to an adult of 25 rem and a 24-hour averaged release of radioactive material to an unrestricted area in excess of 5,000 times the values in Table 2 of Appendix B, "Annual Limits on Intake (ALIs) and Derived Air Concentrations (DACs) of Radionuclides for Occupational Exposure; Effluent Concentrations; Concentrations for Release to Sewerage," to 10 CFR Part 20, "Standards for Protection against Radiation." Additionally, IN 91-39 identified a substantial safety hazard as an exposure to an occupationally exposed worker of greater than 25 rem (whole body or its equivalent to other body parts) in a period of a year or less; exposure to an individual in an unrestricted area of 0.5 rem (whole body or its equivalent to other body parts) in a period of 1 year or less; and the release of radioactive material in concentrations which, if averaged over 24 hours, would exceed 5,000 times the values in Table 2 of Appendix B to 10 CFR Part 20.

The "high consequence" radiological events identified in the performance requirements of 10 CFR 70.61 include a 100 rem dose to a worker and a 25 rem dose to an individual located outside the controlled area. The "intermediate consequence" radiological events include a 25 rem dose to a worker, a 5 rem dose to an individual located outside the controlled area, and a 24-hour average release of radioactive material to an unrestricted area in concentrations exceeding 5,000 times the values in Table 2 of Appendix B to 10 CFR Part 20.

The criteria for determination of substantial safety hazards identified in the Part 21 statements of considerations, NUREG-0302, the Commission's

Policy Statement for Abnormal Occurrence Reports, and IN 91-39 are consistent with the radiological high and intermediate consequence events defined in the performance requirements in 10 CFR 70.61. Therefore, it can be concluded that those SSCs and equipment designated as IROFS necessary to comply with the performance requirements of 10 CFR 70.61 are also necessary, like basic components, to prevent or mitigate the consequences of substantial safety hazards.

The staff notes that Part 70 also includes performance requirements related to criticality and chemical exposure, which are concerns unique to the nature of these facilities. The performance requirements in 10 CFR 70.61 include, in addition to the radiological exposure hazards described above, chemical hazards resulting from radiological material or hazardous chemicals produced from radiological material and radiological hazards resulting from criticality events.

A Memorandum of Understanding between the NRC and the Occupational Safety and Health Administration (OSHA), "Worker Protection at NRC-Licensed Facilities," dated September 6, 2013 (ADAMS Accession No. ML11354A432), identifies the NRC's responsibilities as generally covering radiation risk produced by radioactive materials, chemical risks produced by radioactive materials, and plant conditions that affect the safety of radioactive materials. Because the NRC regulates chemical hazards produced by NRC-licensed material and hazardous chemicals produced from licensed material, the staff believes that these chemical hazards may be within the scope of substantial safety hazards identified in Part 21. Therefore, the SSCs and equipment designated as IROFS that are necessary to protect against chemical hazards to the worker and public resulting from radiological material or from processing radiological material need to be evaluated to determine whether they are basic components. Chemical hazards to the worker and public that are not from radiological material or from processing radiological material are regulated by OSHA and the U.S. Environmental Protection Agency, respectively, and, as such, are not subject to Part 21.

The Commission's Policy Statement for Abnormal Occurrence Reports (71 FR 60198) identified the relevance of chemical hazards to significant events. It requires reporting by the NRC in the event that a condition exists in which there are no controls in place to protect against an NRC-regulated lethal chemical or radiological hazard. The Commission Policy Statement is consistent with the failure of IROFS needed to protect against the high consequence criterion in 10 CFR 70.61 for acute chemical hazards that could endanger the life of a worker. Intermediate chemical consequences are those that could lead to irreversible or other serious, long-lasting health effects to a worker, or could cause mild transient health effects to any individual located outside the controlled area. The effects of these consequences are similar to those of intermediate radiological consequences. Thus, both the high and intermediate chemical consequences in Part 70 can reasonably be taken to represent substantial safety hazards.

Finally, the 10 CFR 70.61 performance requirements state that the risk of nuclear criticality accidents must be limited by ensuring that, under normal and credible abnormal conditions, all nuclear processes are subcritical, including use of an approved margin of subcriticality for safety. Because an inadvertent criticality could have life-threating consequences to workers due to potentially lethal radiation doses, an inadvertent criticality at a nonreactor facility is a Part 21 substantial safety hazard.

The staff noted during public meetings related to the Part 21 rulemaking initiative that the performance requirements in 10 CFR 70.61 include criteria for worker protection. A substantial safety hazard, as defined in Part 21, is a "major reduction in the degree of protection provided to public health and safety." NUREG-0302 states that the term "public" includes the worker,[9] although designation of a substantial safety hazard for a worker would differ in magnitude from that applied to a member of the public. Thus, the fact that the performance requirements in 10 CFR 70.61 provide for protection of the worker is not contrary to equating these requirements with the Part 21 definition of substantial safety hazard. Additionally, the fact that thresholds for hazards to the worker in Part 70 are substantially higher than those for members of the public is also consistent with NUREG-0302.

Based on the history of the approved exemption requests and on the regulatory guidance related to basic components and substantial safety hazards, as described above, the staff is considering modification of the definition of basic component for fuel facilities subject to Subpart H of Part 70 to identify basic components as those engineered IROFS whose failure, in the absence of administrative IROFS and redundant IROFS, could cause the performance requirements of 10 CFR 70.61 to be exceeded. One possible approach for revising the definition of basic component in 10 CFR 21.3 is included in Appendix A of this document. The definition is focused on engineered IROFS, consistent with the intent of Part 21 to identify hardware-related defects and failures to comply that could result in a major reduction to the degree of protection provided to public health and safety. The NRC staff acknowledges that some licensees designate SSCs beyond the minimum set required for compliance with 10 CFR Part 70 as IROFS in order to provide additional protection against the risk of potential accidents and their consequences. In such instances, the proposed definition does not penalize licensees from such approaches because only those engineered IROFS whose potential failure (in the absence of administrative IROFS and redundant IROFS) could result in the performance requirements being exceeded would meet the threshold for designation as a basic component. The definition proposed in Appendix A for fuel facility basic components excludes SSCs from being a basic component if diverse SSCs exist whose independent action could prevent the performance requirements of § 70.61 from being exceeded. This is consistent with established

[9] The term "public" in Section 21.3(k) of NUREG-0302 includes all individuals (i.e., both employees at a facility or activity licensed or otherwise regulated by the Commission and members of the general public). Of course, the degree of protection afforded and the criteria for determining whether a substantial safety hazard could be created will vary for different types of individuals (e.g., radiation workers as opposed to members of the general public), depending on whether the event is a low-probability major accident or a more probable occurrence and whether the potential release is to a restricted or an unrestricted area.

NRC positions in NUREG-0302 on the meaning of “major degradation” and “major deficiency.”

For instance, for an SSC designated as an IROFS and credited with a preventative or mitigative function for a high consequence event sequence:

- The SSC would be a basic component if the failure of the SSC (in the absence of administrative IROFS and redundant IROFS) could result in the accident sequence not being “highly unlikely” or could result in an inability to mitigate the consequences of the event such that they are less severe than the thresholds identified in paragraphs (b)(1)-(4) of §70.61.

- The SSC would not be a basic component if a diverse, engineered SSC was designated as an IROFS and was able (in the absence of administrative IROFS and redundant IROFS) to maintain the accident sequence as “highly unlikely” or mitigate the consequences of the event such that they are less severe than the thresholds identified in paragraphs (b)(1)-(4) of §70.61.

Clarification of the definition as proposed would alleviate the need for further exemption requests by fuel cycle applicants and licensees that find the regulation unclear and would ensure clarity, effectiveness, and consistent implementation of the Part 21 regulations.

Because no such problems have been encountered with other licensees using the existing definition, the staff recommends leaving the definition unchanged for those licensees under 10 CFR Part 30, “Rules of General Applicability to Domestic Licensing of Byproduct Material”; 10 CFR Part 40, “Domestic Licensing of Source Material” (other than those licensees who are required to develop an ISA or where licensed using the performance requirements of Subpart H to Part 70); Part 50 (other than nuclear power plants); 10 CFR Part 60, “Disposal of High-Level Radioactive Wastes in Geologic Repositories”; 10 CFR Part 61, “Licensing Requirements for Land Disposal of Radioactive Waste”; 10 CFR Part 63, “Disposal of High-Level Radioactive Wastes in a Geologic Repository at Yucca Mountain, Nevada”; Part 70 (other than facilities and activities subject to the requirements in Subpart H of Part 70); Part 71; and Part 72.

- NRC Guidance Development

As stated above, the NRC staff is recommending that the existing Part 21 definition of “basic component” be revised by adding a section to the definition that would be specific to fuel cycle facility licensees who are subject to the Part 70 Subpart H requirements. Because such an action would require rulemaking guidance alone would be insufficient to clarify the definition and its application. As part of any change to the definition of basic component in 10 CFR 21.3, the staff would provide guidance in DG-1291.

- Voluntary Industry Initiatives

  The use of voluntary industry initiatives is not an acceptable substitute for clear and enforceable regulatory text. The NRC staff would consider voluntary initiatives proposed by industry to ensure consistent application of Part 21 as it applies to fuel cycle facilities; however, in order to ensure regulatory stability and enforceability, voluntary industry initiatives would need to be documented as commitments in the licensing basis for fuel cycle facilities. Further, industry has not, to date, expressed interest in the development or implementation of such initiatives for fuel cycle facilities. As a result, the use of voluntary industry initiatives to clarify the definition of basic component as applied to fuel cycle facilities is neither practical nor recommended.

- No Action

  Under this alternative, the NRC staff would rely on existing regulations and guidance documents. No changes to regulatory language would be proposed. Taking no action on this problem is not appropriate because confusion concerning the definition of a basic component has safety implications. The "no action" alternative would not meet the intent of clarifying the definition of basic component as it applies to fuel cycle facilities, and is therefore not a desirable option.

4. Clarification of Discovery

a. Existing Regulatory Framework

"Discovery" of a deviation or failure to comply is currently defined in 10 CFR 21.3 as follows:

> Discovery means the completion of the documentation first identifying the existence of a deviation or failure to comply potentially associated with a substantial safety hazard within the evaluation procedures discussed in § 21.21(a).

The requirements of 10 CFR 21.21(a) "Notification of failure to comply or existence of a defect and evaluation," requires, in part, those entities subject to the Part 21 regulations to

> evaluate deviations and failures to comply to identify defects and failures to comply… as soon as practicable, and…in all cases within 60 days of discovery, in order to identify a reportable defect or failure to comply that could create a substantial safety hazard, were it to remain uncorrected[.]

In SECY-91-150 (ADAMS Accession No. ML12255A614), "Proposed Amendments to 10 CFR Part 21 and 10 CFR 50.55(e)," (the SECY for the proposed rule which led to the current rule language) the staff stated that the discovery process is not completed until the documentation identifying the existence of a deviation or failure to comply is complete.

b. Description of Regulatory Problem

The "completion" of the documentation that first identifies the existence of a deviation or failure to comply is not defined in the current regulations. In practice, the phrase "completion of documentation" as used in the definition of discovery has been subject to diverse interpretation and implementation by licensees and vendors. Inasmuch as the current regulation does not set forth a specific period of time or other limitation on the time for completion of the documentation the staff has found several instances where an inordinate length of time passed between (1) the point at which a licensee or vendor possessed sufficient information to determine the existence of a deviation or failure to comply associated with a basic component and (2) the time that the date of discovery was actually recorded. Such delay in the completion of the documentation identifying a deviation is not consistent with the intent of Section 206 of the Energy Reorganization Act of 1974 which indicates that the Commission should be notified immediately of defects and failures to comply associated with a substantial safety hazard.

In addition, the staff has found that licensees and vendors have interpreted the phrase, "potentially associated with a substantial safety hazard" as it applies to the definition of discovery to mean that discovery cannot occur until a Part 21 evaluation under 10 CFR 21.21(a) is initiated. Such interpretation of the definition of discovery is contrary to the staff's position. The staff's position is that discovery occurs when it is determined that a deviation exists and that deviation is first documented in a formal reporting process. Furthermore, the qualifier "potentially associated with a substantial safety hazard" could be understood to apply to "deviation or failure to comply." By definition, any basic component could be potentially associated with a substantial safety hazard. As such, any evaluation period necessary to determine if a substantial safety hazard exists should occur independently of discovery.

c. Options To Resolve Regulatory Problem

- Proposed Changes to NRC Regulations

  The staff is considering revising the definition to expressly address the time allowed for discovery, and to more clearly delineate what matters are subject to the discovery process. A revised definition would indicate that discovery is the time at which a deviation is first documented in a formal process (i.e., condition report, corrective action report) as part of a QA program (e.g., Appendix B for power reactor applicants and licensees and certain nonreactor licensees, and management measures for uranium enrichment and fuel fabrication facilities, etc.). When it can be determined that, based upon the evidence collected, a deviation in a basic component exists, the deviation should be documented and that documentation date becomes the date of discovery.

  When a potential deviation is identified, the licensee should take action without delay to confirm if a deviation exists. For example, licensees should not wait to complete extensive evaluations before entering the condition into their problem identification/corrective action process.

Modifying the definition of discovery may impact applicants', licensees', and vendors' current Part 21 evaluation and reporting processes to comply with the proposed change. The proposed definition change would help ensure that applicants, licensees, and vendors are timely in the completion of Part 21 evaluations in accordance with 10 CFR Part 21.21(a). A revised definition would help ensure that substantial safety hazards are reported in a timely manner and that the NRC is able to fulfill its responsibility to respond accordingly. One possible approach for revising the definition of discovery in 10 CFR 21.3 is included in Appendix A of this document.

- NRC Guidance Development

  The NRC staff has engaged in extensive interaction with industry and understands that the definition of discovery, as written, is subject to interpretation and is thus being implemented inconsistently and, in some cases, incorrectly, among those entities subject to the Part 21 regulations. It became evident to staff as revealed through NRC inspections and stakeholder outreach efforts, that the discovery process is not broadly understood by those entities subject to the regulations of Part 21 as evidenced by the varying interpretations of the phrase “completion of the documentation” in the definition of discovery. For example, the staff attempted to address the definition of discovery in the Questions and Answers Session of the 2008 Vendor Workshop (ADAMS Accession No. ML092660129). However, the staff considered those efforts ineffective in clearing up confusion surrounding the interpretation of the discovery.

  The staff has found that the information disseminated in the 2008 Questions and Answers session has largely not reached the broader industry, to include vendors. NRC inspections have also continued to identify examples of vendors' and suppliers' Part 21 screening/discovery processes that are not in alignment with the staff’s position regarding “completion of the documentation” such that in some cases, the investigation of defects is delayed. For these reasons, the staff does not believe that guidance alone would be an effective solution for clarifying the definition of discovery in 10 CFR 21.3. However, as part of any change to the definition of discovery in 10 CFR 21.3, the staff intends to provide additional information on the NRC expectations in DG-1291 to enhance the clarity of the staff’s expectations of discovery under Part 21.

- Voluntary Industry Initiatives

  The staff believes that definitive rule text is necessary to properly apply the definition of discovery to ensure appropriate, consistent and enforceable application of the term and to provide regulatory stability within 10 CFR Part 21. In the absence of definitive rule text, applicants and licensees are likely to continue to apply varying interpretations of the rule, which limits the evaluation and reporting of defects and noncompliances and negates the intent of Part 21 and the underlying provisions of Section 206 of the Energy Reorganization Act. For these reasons, the staff does not believe that industry guidance is the most effective tool to resolve problems associated with definition of discovery. However, it should be noted that NEI has recently developed guidance on

the discovery process. That guidance, contained in NEI 14-09, "Guidelines for Implementation of 10 CFR Part 21 Reporting of Defects and Noncompliance, Revision 0," dated August 2014 (ADAMS Accession No. ML14245A415) is currently under review by the NRC staff.

- No Action

  Under this alternative, the NRC staff would rely on existing regulations and guidance documents. No changes to regulatory language would be proposed. Taking no action in this area would not address the interpretations of the definition of discovery for purposes of starting the clock on reporting. Entities may (as some have currently done) decide that they have not "completed" discovery, thereby indefinitely postponing the start of the clock for timely reporting. In addition, the "no action" alternative would not address the inconsistency in licensees' and vendors' interpretation of discovery. Therefore, the "no action" alternative would not meet the intent of clarifying the definition of discovery, and is therefore not a preferred option.

5. Clarification of Defect

a. Existing Regulatory Framework

10 CFR Part 21 requires those entities subject to the regulations to immediately notify the Commission of defects that could create a substantial safety hazard. A defect is defined in 10 CFR 21.3 as follows:

Defect means:

> (1) A deviation in a basic component delivered to a purchaser for use in a facility or an activity subject to the regulations in this part if, on the basis of an evaluation, the deviation could create a substantial safety hazard;
> (2) The installation, use, or operation of a basic component containing a defect as defined in this section;
> (3) A deviation in a portion of a facility subject to the early site permit, standard design certification, standard design approval, construction permit, combined license or manufacturing licensing requirements of part 50 or part 52 of this chapter, provided the deviation could, on the basis of an evaluation, create a substantial safety hazard and the portion of the facility containing the deviation has been offered to the purchaser for acceptance;
> (4) A condition or circumstance involving a basic component that could contribute to the exceeding of a safety limit, as defined in the technical specifications of a license for operation issued under part 50 or part 52 of this chapter; or
> (5) An error, omission or other circumstance in a design certification, or standard design approval that, on the basis of an evaluation, could create a substantial safety hazard.

b. Description of Regulatory Problem

The definition of "defect" in 10 CFR 21.3 is complex and industry asserts it is difficult to interpret. The definition of defect is critical because it is the basis for determining whether a Part 21 notification is required.

10 CFR 21.3 contains multiple definitions of "defect," each intended to be directed at a specific entity: offsite supplier, purchaser, on-site supplier, and licensee. Interactions between those entities subject to Part 21 regulations have led to confusion on how to apply the definition. The staff attempted to address this aspect in detail in NUREG-0302, "Remarks Presented (Questions Answered/Discussed) at Public Regional Meetings to Discuss Regulations (10 CFR Part 21) for Reporting of Defects and Noncompliance," Revision 1, dated July 12-26, 1977.

For example, the definition of defect contains the terms "installation, use, or operation of a basic component." This has been interpreted by some in the industry to mean that deviations identified in basic components that have been delivered, but have not been installed or neither in use, cannot be defects. The July 31, 1991 amendment to Part 21 reporting requirements (56 FR 36081, at 36084) communicated the NRC position that deviations identified in basic components that are delivered and accepted by a purchaser but are not installed must still be evaluated under 10 CFR 21.21(a). Interpreting "defect" in such a way that excludes deviations in basic components that have been delivered, but not installed contradicts this staff position and potentially allows such defects to go unreported.

The definition of defect is further complicated by the concept of delivery, as the definition of defect and the concept of delivery are interrelated (first definition of defect under 10 CFR 21.3).[10] This has led to confusion in the industry, and contributed in some cases to Part 21 evaluations taking longer than the 60 days allotted by 10 CFR 21.21(a). The staff attempted to address several industry concerns associated with the relationship between defect and delivery in the Questions and Answers Session of the 2008 Vendor Workshop (ADAMS Accession No. ML092660129). However, the staff considered those efforts ineffective in clearing up confusion surrounding the relationship between the two terms. The staff has also found that the information disseminated in the 2008 Questions and Answers session has largely not reached the broader industry, to include vendors.

c. Options To Resolve Regulatory Problem

- Proposed Changes to NRC Regulations

  The staff is considering modifying the definition of defect in 10 CFR 21.3. The revised definition of defect would be simplified by removing much of the variation in the definition such that a defect is simply defined as "a deviation in a basic component delivered to a purchaser that could create a substantial safety hazard."

[10] The concept of delivery is discussed in Section 6, "Clarification of Delivery."

The staff believes that this simplified definition fully envelopes the intent of the current definition under of defect under 10 CFR 21.3, and this revised definition will reduce burden on those entities subject to the Part 21 regulations without compromise in safety significant information or any reduction to the health and safety of the public.

A possible approach for the revised definition of defect under 10 CFR 21.3 is included in Appendix A of this document.

- NRC Guidance Development

  As part of any revision to the definition of defect in 10 CFR 21.3, the staff would develop regulatory guidance on the NRC's expectations in DG-1291 to enhance the clarity of the staff's expectations on the definition of defect under Part 21. This addition would explain that delivery occurs when there is acceptance after a receiving inspection.

  The NRC staff provided further clarity to the definition of defect during the Questions and Answers Session of the 2008 Vendor Workshop (ADAMS Accession No. ML092660129). The staff believes that clear, consistent, and enforceable text is necessary to properly apply the definition of defect to ensure that those entities subject to the Part 21 regulations can appropriately understand the definition of defect and therefore implement the regulations accordingly.

- Voluntary Industry Initiatives

  The staff believes that a definitive rule text is necessary to properly apply the definition of defect to ensure appropriate, consistent and enforceable application of the term and to provide regulatory consistency within 10 CFR Part 21. In the absence of definitive rule text, the staff anticipates that vendors and licensees will continue to misinterpret the definition such as in the example of the misinterpretation of the terms "installation, use, or operation of a basic component." as previously discussed. Such misinterpretation of the definition could result in unreported defects. Absent of a rule change, the staff does not believe that industry guidance alone is the most effective solution to resolve problems associated with the definition of defect.

  It should be noted, however, that NEI has recently developed guidance on the definition of defect. That guidance, contained in NEI 14-09, "Guidelines for Implementation of 10 CFR Part 21 Reporting of Defects and Noncompliance, Revision 0," dated August 2014 (ADAMS Accession No. ML14245A415), is currently under review by the NRC staff.

- No Action

  Taking no action in this area does not address the problem of a lack of clarity in the definition of defect. In addition, taking no action does not provide clarity to a problem that has caused industry misunderstanding. Therefore, taking no action is not a desirable option.

6. Clarification of Delivery

a. Existing Regulatory Framework

The concept of delivery is contained in the 10 CFR 21.3 definition of defect. A defect is defined in 10 CFR 21.3, in part, as:

> A deviation in a basic component *delivered* to a purchaser for use in a facility or an activity subject to the regulations in this part if, on the basis of an evaluation, the deviation could create a substantial safety hazard (*emphasis added*).

10 CFR 21.21(a) requires, in part, those entities subject to the Part 21 regulations to "evaluate deviations to identify defects associated with substantial safety hazards as soon as practicable." If that evaluation determines that a defect exists, then the defect must be reported to the NRC under § 21.21(d)(1).

b. Description of Regulatory Problem

The concept of delivery, which is critical to Part 21 reporting, is not defined in the current regulations. The concept of delivery is critical because it represents the transfer of ownership of facility, activity, or basic component between purchaser and supplier, including the Part 21 reporting responsibilities. However, the lack of a clear definition has resulted in repeated misinterpretations of the responsibilities associated with the transfer of ownership of basic components between purchasers and suppliers. In some cases, misinterpretation and consequent misapplication of the concept of delivery has resulted in entities' failing to meet the evaluation and notification requirements in 10 CFR 21.21.

The timely reporting of defects and failures to comply is important because complete, accurate, and timely reporting ensures that the Commission obtains all the information necessary to evaluate and take corrective action in reference to defects that could create substantial safety hazards. Any delay or failure to report a substantial safety hazard could have significant implications for public health and safety. Such delay or failure to report impedes the NRC's ability to perform its regulatory function. If the agency is unaware that noncompliances exist, the agency is unable to use appropriate regulatory tools to address those noncompliances.

"Delivery" applies when the basic component has been received and accepted by the purchaser of the component. It has been the NRC staff's position that a basic component has been "delivered" when the purchaser has accepted the item through a formal acceptance process (i.e., receipt inspection). This position was stated in NUREG-0302, "Remarks Presented (Questions Answered/Discussed) at Public Regional Meetings to Discuss Regulations (10 CFR Part 21) for Reporting of Defects and Noncompliance," Revision 1, dated July 12-26, 1977.

Once a basic component has been delivered to the purchaser (i.e., the item was accepted through the purchasing entity's receipt inspection process), the ownership of the basic component transfers to the purchaser. It is only after delivery of a basic

component containing a deviation and the determination, by an evaluation, that the deviation is a defect and a Part 21 report needs be made.

c. Options to Resolve Regulatory Problem

- Proposed Changes to NRC Regulations

  The staff is considering adding a definition of "delivery" in Part 21 in effort to minimize further misinterpretation of the concept. In the new definition, delivery would mean that a purchaser has accepted a basic component through a formal acceptance process (i.e., receipt inspection). A definition of delivery would also clarify the delineation of evaluating and reporting responsibility between purchaser and supplier (Chapter 2, Section 7, "Delineation of Evaluation and Reporting Responsibilities between Purchasers and Suppliers").

  The staff is also considering revising 10 CFR 21.21(a) to include the distinction of delivery. Specifically, 10 CFR 21.21(a) would be revised to require those entities subject to the Part 21 regulations to identify failures to comply and deviations only in those basic components that have been delivered. Deviations that are identified in a basic component that has been delivered must be evaluated to determine ability to create a "substantial safety hazard." If the deviation in a delivered basic component could create a substantial safety hazard, then a defect exists.

  A possible amendment to the definition of delivery and the revised changes to 10 CFR 21.21(a) are included in Appendix A of this document.

  The addition of the definition of delivery and proposed revision to 10 CFR 21.21(a) are important to reduce ambiguity in the current rule language. Such clarity is necessary in effort to (1) reduce burden on the licensee and vendor resources to unnecessarily perform Part 21 evaluation on basic components that have not been delivered; and (2) provide clarity in the delineation of evaluation and reporting responsibility between purchasers and suppliers. In the absence of clear, precise rule text, licensees and vendors may continue to implement differing and sometimes incorrect interpretations of Part 21 which may result in the delay or failure to report defects that could create substantial safety hazards.

- NRC Guidance Development

  Regulatory guidance could be developed to address the concept of delivery. A detailed description of delivery would be included in DG-1291. This addition would explain that delivery occurs when there is acceptance after a receiving inspection.

  Also, as part of the addition of a definition of delivery in 10 CFR 21.3, the staff intends to provide additional information on the NRC expectations in DG-1291 to enhance the clarity of the staff's expectations on the concept of delivery under Part 21.

- Voluntary Industry Initiatives

  The staff believes that a rule text is necessary to clearly establish and apply the definition of discovery to ensure appropriate, consistent and enforceable application of the term and to provide regulatory stability within 10 CFR Part 21. In the absence of definitive rule text, the staff anticipates that vendors and licensees will continue to misinterpret the concept of delivery, which could result in Part 21 evaluations taking longer than the 60 days allowed by Part 21. For these reasons, the staff does not believe that industry guidance is the most effective tool to resolve problems associated with definition of delivery.

  However, it should be noted that NEI has recently developed guidance on the concept of delivery. That guidance, contained in NEI 14-09, "Guidelines for Implementation of 10 CFR Part 21 Reporting of Defects and Noncompliance, Revision 0," dated August 2014 (ADAMS Accession No. ML14245A415) is currently under review by the NRC staff.

- No Action

  Under this alternative, the NRC staff would rely on existing regulations and guidance documents. Taking no action on this regulatory problem is not appropriate because confusion concerning the concept of delivery as it relates to the definition of defect has safety implications. The "no action" alternative would not meet the intent of clarifying the concept of delivery, and is therefore not a preferred option.

7. Delineation of Evaluation and Reporting Responsibilities between Purchasers and Suppliers

a. Existing Regulatory Framework

Part 21 evaluation and reporting requirements are described under 10 CFR 21.21, "Notification of Failure to Comply or Existence of a Defect and Its Evaluation."

10 CFR 21.21(a) requires those entities subject to the regulations under Part 21 to evaluate deviations and failures to comply to identify defects and failures to comply associated with substantial safety hazards as soon as practicable in order to identify reportable Part 21 defects.

10 CFR 21.21(b) allows the transfer of responsibility for evaluation and reporting from the supplier to the purchaser. Specifically, if a supplier discovers a deviation or failure to comply and the supplier determines that it does not have the capability or sufficient knowledge to determine if the deviation or failure to comply could result in a substantial safety hazard, the supplier is required to notify the purchaser or affected licensees so that the purchasers or affected licensees can perform the Part 21 evaluation.

b. Description of Regulatory Problem

1. Communications between Purchasers and Suppliers:

Except in the cases of deferral of evaluation (10 CFR 21.21(b)), the Part 21 regulations do not describe the communications requirements between non-NRC entities when a deviation or failure to comply is identified.

When a potential Part 21 defect is identified, communications and information sharing between purchasers and suppliers is prudent. Information sharing between purchasers and suppliers is important to facilitate the collection of necessary information to perform an efficient Part 21 evaluation. Once a deviation or failure to comply is identified, the entity that identified the condition should be proactive in communicating the issue to others in their supply chain for the affected basic component.

NRC inspections have identified that suppliers may not fully understand the intended end-use of a basic component supplied to a purchaser, and therefore may need additional information from the purchaser in order to determine the safety significance of the deviation or failure to comply. Conversely, purchasers may not be fully aware of the design attributes of the supplier's product, and these details could have a significant effect on the determination of whether the deviation or failure to comply could create a substantial safety hazard.

2. Delineation of Evaluating and Reporting Responsibility Between Purchaser and Supplier:

NRC inspectors have noted that in instances in which a deviation or failure to comply was identified, there existed confusion between purchasers and suppliers as to whom was responsible for performing Part 21 evaluation and reporting.

Following the discovery of a deviation or failure to comply, it has been the NRC staff's position that the delineation in the evaluation and reporting responsibility (purchaser vs. supplier) lies with the delivery of a basic component.[11] Prior to delivery, the supplier bears the Part 21 evaluation responsibility. The concept of delivery is discussed in Section 6 of this chapter. After a basic component has been delivered to the purchaser, the purchaser bears the responsibility for the evaluation and reporting under Part 21.

Clarity is necessary to ensure that the NRC's requirements for reporting are adequately explained, and that purchasers and suppliers comply with the corresponding regulations so that defects do not go unreported. The benefit of notification of affected entities is to establish communications and information sharing that may be helpful to perform the Part 21 evaluation and determination of whether a report to the NRC is necessary.

[11] Staff position was discussed in NUREG-0302, "Remarks Presented (Questions Answered/Discussed) at Public Regional Meetings to Discuss Regulations (10 CFR Part 21) for Reporting of Defects and Noncompliance," Revision 1, dated July 12-26, 1977.

c. Options To Resolve Regulatory Problem

- Proposed Changes to NRC Regulations

  The staff considered revising the regulations to require communications between the purchaser and supplier when a deviation or failure to comply associated with a basic component was identified. However, the staff determined that prescribing communications requirements between purchasers and suppliers would be difficult to codify, and cumbersome to implement in relation to the potential safety gains realized from any new regulations to address these particular issues.

- NRC Guidance Development

  The staff intends to detail the existing responsibilities and expectations for communication between purchasers and suppliers in DG-1291. The staff would delineate the responsibilities of all parties involved and would highlight the value of open communication throughout the process. The staff would encourage notification of deviations back through the supply chain as a good practice.

  Voluntary Industry Initiatives

  Because there are no current regulations requiring the information sharing between purchasers and suppliers when a deviation in a basic component or failure to comply is identified (with the exception of deferral of evaluation under 10 CFR 21.21(b)), voluntary initiative programs may be a viable alternative to proposing new regulations. NEI has recently developed guidance on communication between suppliers and purchasers during the evaluation and notification process. That guidance, contained in NEI 14-09, "Guidelines for Implementation of 10 CFR Part 21 Reporting of Defects and Noncompliance, Revision 0," dated August 28, 2014 (ADAMS Accession No. ML14245A415) is currently under review by the NRC staff.

- No Action

  Under this alternative, the NRC staff would rely on existing regulations and guidance documents. No changes to regulatory language would be proposed. Taking no action would likely result in continuing communication shortcomings between purchasers and suppliers, therefore increasing the potential that defects in basic components go unreported. Therefore, the "no action" alternative is not a preferred option.

8. Transfer of Evaluation and Reporting Responsibilities under 10 CFR 21.21(b) – Deferral of Evaluation

a. Existing Regulatory Framework

Part 21 allows a vendor to defer the evaluation of a deviation if it determines that it does not have the capability to determine whether a defect exists under 10 CFR 21.21(b):

If the deviation or failure to comply is discovered by a supplier of basic components, or services associated with basic components, and the supplier determines that it does not have the capability to perform the evaluation to determine if a defect exists, then the supplier must inform the purchasers or affected licensees within five working days of this determination so that the purchasers or affected licensees may evaluate the deviation or failure to comply, pursuant to 10 CFR 21.21(a).

b. Description of Regulatory Problem

When deferring an evaluation under 10 CFR 21.21(b), current regulations do not specify (1) that the vendor must formally notify the purchaser of the deferral of evaluation; and (2) the type of specific and detailed information pertaining to the deviation or failure to comply that a vendor should supply to the purchaser.

NRC inspectors have noted instances of vendors inadequately informing their purchasers of deviations under 10 CFR 21.21(b). For example, in some cases, vendors informed their purchasers of departures from technical requirements included in a procurement document by e-mail; however, they did not explicitly call out the existence of a deviation.

The regulations at 10 CFR 21.21(b) do not state the type of information the vendor must supply to its purchaser in the case of a determination under 10 CFR 21.21(b). Specifically, the regulations do not require that the vendor identify the basic component or activity that contains a deviation or fails to comply, the nature of the deviation, the date on which the information of such deviation was obtained, and any advice related to the deviation about the activity or basic component that may be given to the purchaser.

c. Options To Resolve Regulatory Problem

- Proposed Changes to NRC Regulations

  The staff considered codifying additional requirements of a supplier informing a purchaser of its inability to perform an evaluation. However, based on discussions during public meetings, the staff determined that codifying these requirements would likely cause additional burden with minimal safety gains. Therefore, the staff is not proposing a change to the regulations.

- NRC Guidance Development

  Appropriate regulatory guidance could be developed to address the deferral of evaluation under 10 CFR 21.21(b). The staff intends to detail the process of deferring an evaluation in DG-1291. The staff would delineate the responsibilities of all parties involved and would highlight the value of open communication throughout the process.

- Voluntary Industry Initiatives

  NEI recently developed guidance on deferral of evaluation under 10 CFR 21.21(b). That guidance, contained in NEI 14-09, "Guidelines for Implementation of 10 CFR Part 21 Reporting of Defects and Noncompliance, Revision 0," dated August 28, 2014 (ADAMS Accession No. ML14245A415), is currently under review by the NRC staff.

- No Action

  Taking no action in this area does not address the problem of the inadequate implementation of 10 CFR 21.21(b.) This issue would result in the continued potential that vendors are not adequately informing their purchasers of deviations under 10 CFR 21.21(b), thus hindering the purchasers' ability to take appropriate action. Therefore, the "no action" alternative is not a preferred option.

9. Use of Licensee Event Reporting (10 CFR 50.72 and 10 CFR 50.73)

a. Existing Regulatory Framework

10 CFR 21.1 requires any individual director or responsible officer to immediately notify the Commission of a defect that could create a substantial safety hazard, or failure to comply relating to a substantial safety hazard "unless he has actual knowledge that the Commission has been adequately informed of such defect or failure to comply."

Part 21 allows a power reactor licensee to satisfy Part 21 reporting responsibilities under sections 50.72, 50.73 or 73.71 to avoid duplicate reporting. 10 CFR 21.2(c) states:

> For persons licensed to operate a nuclear power plant under part 50 or part 52 of this chapter, evaluation of potential defects and appropriate reporting of defects under §§ 50.72, 50.73, or § 73.71 of this chapter, satisfies each person's evaluation, notification, and reporting obligation to report defects under this part, and the responsibility of individual directors and responsible officers of these licensees to report defects under Section 206 of the Energy Reorganization Act of 1974.

b. Description of Regulatory Problem

Power reactor licensees are inconsistent in their approach over whether only an evaluation or an evaluation and a reporting of a potential defect under Part 50 will discharge their Part 21 evaluation and reporting obligations.

On July 31, 1991, the Commission published a final rule amending its Part 21 reporting requirements entitled, "Criteria and Procedures for the Reporting of Defects and Conditions of Construction Permits" (56 FR 36081). With this amendment, the staff intended to relieve the licensee of its obligation to submit a separate Part 21 report if a defect in an installed component caused a reportable event and if a report was issued to the Commission using the criteria of 10 CFR 50.72, "Immediate Notification Requirements for Operating Nuclear Power Reactors," and 10 CFR 50.73, "License Event Report System." The NRC staff did not intend to relieve the licensee of

the obligation to evaluate and report a failure to comply or a defect that could cause a significant safety hazard. The intent was simply to reduce duplicative reporting.

The staff, however, did not issue guidance to clarify the intentions of the rule when it was amended in 1991. Lack of guidance has led to licensee confusion over reporting responsibilities under 10 CFR 50.72 or 50.73 and whether only an evaluation or an evaluation and a reporting of a potential defect under 10 CFR Part 50.72 or 50.73 will discharge their Part 21 evaluation and reporting obligations.

In response to NEI's letter dated July 8, 2014 (ADAMS Accession No. ML14189A169) the NRC staff provided to stakeholders examples of licensee event reports (LERs) in which the criteria for 10 CFR 50.72 and 50.73 are met. However, identification of potential Part 21 issues is not satisfied (ADAMS Accession No. ML14232A816). The examples provide LERs that do not identify potential Part 21 defects and noncompliances and inconsistency of the reporting process between licensees. The NRC staff plans to hold discussions in public meetings to inform the next steps for this area.

In addition, Office of the Inspector General (OIG) Audit OIG-A-08 (ADAMS Accession No. ML110910047) provided several examples of LERs considered to contain potential 10 CFR Part 21 reportable defects that were not identified as such in the report. The OIG sampled the LER database during the performance of the audit in order to identify examples of apparent unreported defective components that could cause a substantial safety hazard but were not reported under Part 21.

Both the NRC staff's and OIG's sets of examples provided illustrate that the reports submitted by licensees pursuant to 10 CFR 50.72 or 50.73[12] are not applied consistently to satisfy the reporting requirements of 10 CFR Part 21.

c. Options To Resolve Regulatory Problem

- Proposed Changes to NRC Regulations

  The NRC staff is considering correcting the regulatory ambiguity by clarifying the statement in 10 CFR 21.2(c), that the report of defects under 10 CFR 50.72, 50.73, or 73.71 of this chapter, satisfies each entity's evaluation, notification, and reporting obligation under this part. The staff is not proposing the modification of any of the current requirements of 10 CFR 50.72 or 50.73.

- NRC Guidance Development

  The staff notified the Commission of the staff's position in a Note to Commissioners' Assistants and provided interim guidance. The Note to Commissioners' Assistants stated, in part:

[12] NRC guidance on how to meet 10 CFR 50.72 and 50.73 requirements is currently found in NUREG-1022, Revision 3 (ADAMS Accession No. ML13032A220) and its Supplement 1 (ADAMS Accession No. ML14267A447). Rulemaking efforts associated with Part 21 are not intended to revise or modify regulatory requirements or guidance associated with these sections.

> If the evaluation of a deviation in basic component under the guidance for §§ 50.72 and 50.73 results in a report, the obligations under Part 21 for evaluation and reporting have been met. In the event, the evaluation of a deviation under the guidance for §§ 50.72 and 50.73 does not result in a report, licensees must ensure that the evaluation also meets Part 21 and its associated guidance to ensure Part 21 reporting is completely satisfied.

The staff intends to explain with greater clarity and in more detail the NRC's expectations on the use of 10 CFR 50.72, 50.73 or 73.71 reports to satisfy Part 21 reporting responsibilities in DG-1291.

- Voluntary Industry Initiatives

  NEI has recently developed guidance on the use of the 10 CFR 50.72, 50.73 and 73.71 evaluating and reporting processes to satisfy Part 21 reporting requirements. That guidance, contained in NEI 14-09, "Guidelines for Implementation of 10 CFR Part 21 Reporting of Defects and Noncompliance, Revision 0," dated August 2014 (ADAMS Accession No. ML14245A415) is currently under review by the NRC staff. If the industry chooses to draft guidance in this area consistent with the staff's position, the staff could endorse this guidance through a regulatory guide.

- No Action

  Under this alternative, the NRC staff would rely on existing regulations and guidance documents. No changes to regulatory language would be proposed. As no accepted guidance currently exists, taking no action would likely result in continuing lack of clarity in reporting responsibility. Therefore, the "no action" alternative is not a preferred option.

10. Notifications That Satisfy 10 CFR 21.21(d)(2)

a. Existing Regulatory Framework

10 CFR 21.21(d)(2) provides provisions related to Commission notification of defects and failures to comply. 10 CFR 21.21(d)(2) states:

> The notification to NRC of a failure to comply or of a defect under paragraph (d)(1) of this section and the evaluation of a failure to comply or a defect under paragraphs (a)(1) and (a)(2) of this section, are not required if the director or responsible officer has actual knowledge that the Commission has been notified in writing of the defect or the failure to comply.

10 CFR 21.21(d)(4) identifies the information that must be contained in reports made under Part 21. The regulation allows directors and responsible officers to be relieved of duplicate reporting under Part 21 when they have actual knowledge that the Commission has already been notified, in writing, of a defect or failure to comply as follows:

(4) The written report required by this paragraph shall include, but need not be limited to, the following information, to the extent known:

(i) Name and address of the individual or individuals informing the Commission.

(ii) Identification of the facility, the activity, or the basic component supplied for such facility or such activity within the United States which fails to comply or contains a defect.

(iii) Identification of the firm constructing the facility or supplying the basic component which fails to comply or contains a defect.

(iv) The nature of the defect or failure to comply and the safety hazard which is created or could be created by such defect or failure to comply.

(v) The date on which the information of such defect or failure to comply was obtained.

(vi) In the case of a basic component which contains a defect or fails to comply, the number and location of these components in use at, supplied for, being supplied for, or may be supplied for, manufactured, or being manufactured for one or more facilities or activities subject to the regulations in this part.

(vii) The corrective action which has been, is being, or will be taken; the name of the individual or organization responsible for the action; and the length of time that has been or will be taken to complete the action.

(viii) Any advice related to the defect or failure to comply about the facility, activity, or basic component that has been, is being, or will be given to purchasers or licensees.

(ix) In the case of an early site permit, the entities to whom an early site permit was transferred.

b. Description of Regulatory Problem

The NRC has no formal guidance for the implementation of 10 CFR 21.21. While the regulation relieves entities from further reporting under Part 21 if the Commission has been notified in writing of a defect or failure to comply, the NRC has not issued guidance to communicate the expectations for written notifications used by licensees, in accordance with 10 CFR 21.21(d)(2), to ensure that the notification requirements in Part 21 are satisfied.

The NRC staff has noted instances in which licensees have inappropriately considered event reports, such as those required by Appendix A to Part 70 (“Reportable Safety Events”) or 50.72/50.73, to satisfy reporting under Part 21 when such reports do not provide the necessary information to inform the Commission of a defect or failure to comply required by 10 CFR 21.21(d)(4). For example, such reports often only indicate the reportable safety event (e.g., radiological or chemical exposure, failure of equipment to function and unavailability of items relied upon for safety, etc.) and provide a minimal

description of the cause. In some cases, the reports do not indicate the applicability of Part 21, identify information related to the manufacturer or supplier, or provide other information required by 10 CFR 21.21(d)(4).

c. Options To Resolve Regulatory Problem

- Proposed Changes to NRC Regulations

  The staff considered amending its regulations to ensure that reports made under other reporting requirements make reference to Part 21 and contain the requisite information necessary to satisfy the Part 21 reporting requirements of 10 CFR 21.21(d)(4). However, based on discussions during public meetings, the staff determined that codifying these requirements would likely cause additional burden with minimal safety gains. Therefore, the staff is not proposing a change to the regulations.

- NRC Guidance Development

  As part of the overall rulemaking effort, the staff could provide regulatory guidance that includes a detailed description in DG-1291 of the process for reporting Part 21 issues under other reporting mechanisms.

- Voluntary Industry Initiatives

  NEI recently developed guidance on notifications made to the NRC under 10 CFR 21.21(d)(2). That guidance, contained in NEI 14-09, "Guidelines for Implementation of 10 CFR Part 21 Reporting of Defects and Noncompliance, Revision 0," dated August 28, 2014 (ADAMS Accession No. ML14245A415) is currently under review by the NRC staff.

  No Action

  Under this alternative, the NRC staff would rely on existing regulations and guidance documents. Lack of clarification in the regulations would likely result in the continuation of inadequate reporting by licensees that attempt to credit other reports as meeting the provisions of 21.21(d)(2) when they do not provide the requisite information specified in 21.21(d)(4). Therefore, the "no action" alternative is not a preferred option.

11. Division of Part 21 and 10 CFR 50.55(e) Requirements

a. Existing Regulatory Framework

The current Part 21 and 10 CFR 50.55(e) provides nearly identical regulatory requirements for reporting defects and failures to comply that would constitute a substantial safety hazard. Both regulations establish the requirements for implementing Section 206 of the Energy Reorganization Act of 1974.

The similar reporting purposes are only distinguished by the responsible entity and two additional requirements in 10 CFR 50.55(e) as follows:

(1) The regulations at 10 CFR 50.55(e) require the reporting of "any significant breakdown in any portion of the quality assurance program conducted under the requirements of Appendix B that could have produced a defect in a basic component. These breakdowns in the quality assurance program are reportable whether or not the breakdown actually resulted in a defect in a design approved and released for construction, installation, or manufacture." Section 6.5, "Facility Construction (10 CFR Part 50 and 52 Licensees and Fuel Cycle Facilities)," of the NRC Enforcement Policy, dated July 7, 2012, contains descriptions of reportable programmatic breakdowns in a QA program.

(2) The regulations at 10 CFR 50.55(e) include longer record retention requirements for suppliers of basic components. Specifically, suppliers of basic components must retain records of all notifications sent to affected licensees or purchasers for a minimum of 10 years following the date of notification (Part 21 requires only 5 years) and must retain records of the facilities or other purchasers to whom basic components or associated services were supplied for a minimum of 15 years after delivery (Part 21 requires 10 years). This increase of 5 years reflects the assumption that the typical construction period will be 5 years; 10 CFR 50.55(e) applies to licensees engaged in construction as evidenced by the following statement in 10 CFR 50.55, "Conditions of Construction Permits, Early Site Permits, Combined Licenses, and Manufacturing Licenses":

> Each construction permit is subject to the following terms and conditions; …each manufacturing license is subject to the terms and conditions in paragraphs (e) and (f) of this section; and each combined license is subject to the terms and conditions in paragraphs (e) and (f) of this section until the date that the Commission makes the finding under §52.103(g) of this chapter…

b. Description of Regulatory Problem

The subdivision of requirements being nearly identical in Part 21 and 10 CFR 50.55(e) has led to misinterpretation of the regulatory requirements in proper implementation by affected parties.

Requirements in 10 CFR 50.55(e) are largely the same as Part 21. The two regulations currently differ only in terms of (1) the entities to whom the requirements are imposed upon, (2) length of record retention, and (3) reporting of a significant breakdown in the quality program. The existence of two near-identical regulations has resulted in confusion as to which regulation is applicable. The NRC staff has noted that combined license applicants, licensees, and their vendors have been challenged by the applicability of 10 CFR 50.55(e) throughout the supply chain. Additionally, the NRC staff has noted that the regulations are unclear as to when vendors are required to report significant breakdowns in any portion of the QA program that could have produced a defect in a basic component.

On April 10, 2013, NEI submitted a white paper to the NRC that concluded that the safety benefits provided by 10 CFR 50.55(e) no longer justify the regulatory costs of implementing the essentially duplicative rule (ADAMS Accession No. ML13107B496).

NEI made the following conclusion:

> As described above, 10 CFR 50.55(e) and Part 21 are nearly identical; the existing rule is ambiguous and difficult to implement resulting in inappropriate levels of resources devoted to its implementation which diverts licensee and vendor resources from more important nuclear safety issues; and the underlying purpose of 10 CFR 50.55(e) is achieved through the implementation of 10 CFR Part 21 and other regulatory processes. Therefore, 10 CFR 50.55(e) should be deleted as part of the Part 21 rulemaking, and this can be done without any reduction to the health and safety of the public.

c. Options To Resolve Regulatory Problem

- Proposed Changes to NRC Regulations

  The NRC staff is considering: (1) removal of 10 CFR 50.55(e) and the corresponding definitions in 10 CFR 50.2; and (2) adoption of analogous requirements in Part 21. The adoption of analogous requirements will include retaining the regulatory language that requires the reporting of a significant quality assurance program breakdown. The staff believes that the regulatory approach of treating the requirements of 10 CFR 50.55(e) as a license condition does not adversely affect the NRC's regulatory capability to ensure compliance with the substantive requirements.

- NRC Guidance Development

  Regulatory guidance could be developed to address the duplication of the regulations in 10 CFR Part 21 and 10 CFR 50.55(e); however, because of the complications that the implementation of both rules has caused entities subject to the rules, the staff does not believe that guidance alone is the most appropriate solution to resolve this regulatory problem.

  However, as part of the proposed rule change, the staff intends to add a detailed description in DG-1291 of the process for reporting QA breakdowns, as failures to comply that could create a substantial safety hazard. In addition, the staff would include guidance and examples of reportable QA breakdowns, as described in the NRC Enforcement Policy.

- Voluntary Industry Initiatives

  Voluntary initiative programs are not an acceptable substitute to address existing regulatory requirements to notify the NRC. Similar to the case of issuing NRC guidance on this topic, the staff believes that further guidance would simply complicate the interpretation of the regulations. It should be noted, however, that NEI has recently developed guidance on the implementation of 50.55(e). That guidance, contained in NEI 14-09, "Guidelines for Implementation of 10 CFR 21 Reporting of Defects and Noncompliance, Revision 0, dated August 2014 (ADAMS Accession No. ML14245A415) is currently under review by the NRC staff.

- No Action

  Under this alternative, the NRC staff would rely on the existing regulations. No changes to regulatory language would be proposed. Taking no action would not address the subdivision of requirements being nearly identical in Part 21 and 10 CFR 50.55(e), which has led to the misinterpretation of the regulatory requirements in proper implementation by affected parties. Therefore, the "no action" alternative is not a preferred option.

12. Evaluation of Counterfeit, Fraudulent, and Suspect Items

a. Existing Regulatory Framework

Part 21 does not specifically address counterfeit, fraudulent, and suspect items (CFSI). However, the definition of "deviation" in 10 CFR 21.3 implicitly includes CFSI, due to CFSI constituting a departure from procurement document requirements:

> Deviation means a departure from the technical requirements included in a procurement document, or specified in early site permit information, a standard design certification or standard design approval.

The provisions of 10 CFR 21.21 contain the requirements for evaluating and reporting deviations.

The NRC developed an agencywide task force to identify and implement proactive strategies to detect and prevent the introduction of CFSI into equipment, components, systems, and structures regulated by the agency. SECY-11-0154, "An Agencywide Approach to Counterfeit, Fraudulent, and Suspect Items," dated October 28, 2011 (ADAMS Accession No. ML112200150), documents the results of the task force.

b. Description of Regulatory Problem

The NRC does not have a formal reporting mechanism that specifically addresses CFSI. Part 21 was never intended to be a reporting mechanism for CFSI and would make a poor instrument for the reporting of all CFSI. However, Part 21 is appropriate for reporting substantial safety hazards, of which CFSI within the scope of NRC's regulatory jurisdiction can be a subset.

Therefore, it would be beneficial to clarify that basic components found to be CFSI are deviations (and, therefore, conditions adverse to quality) that must be evaluated under Part 21 for substantial safety hazards.

c. Options To Resolve Regulatory Problem

- Proposed Changes to NRC Regulations

  The staff is not considering changes to Part 21 to address this area because the current definition of deviation includes CFSI within the scope of NRC's regulatory purview.

- NRC Guidance Development

  The staff issued draft Regulatory Issue Summary (RIS) 2014-xx, "Oversight of Counterfeit, Fraudulent, and Suspect Items in the Nuclear Industry," for public comment on October 2, 2014. The RIS was issued to heighten awareness of the existing NRC regulations and how they apply to CFSI within the scope of NRC's regulatory jurisdiction.

  Appropriate regulatory guidance could be developed to address evaluation and reporting of CFSI under Part 21. The staff intends to add a detailed description on evaluating and reporting of deviations associated with CFSI within the scope of the NRC's regulatory purview in DG-1291.

- Voluntary Industry Initiatives

  Although the nuclear industry is implementing voluntary programs related to CFSI, these programs do not address reporting CFSI to the NRC. Thus, voluntary initiative programs are not an acceptable substitute to address the issue of formal reporting of CFSI. It should be noted, however, that Electric Power Research Institute (EPRI) has recently updated guidance on prevention, detection, and control of CFSI. That guidance, contained in EPRI Report 1019163, "Plant Support Engineering: Counterfeit and Fraudulent Items – Mitigating the Increasing Risk," Revision 1, was issued in July 2014 and is publicly available.

- No Action

  Under this alternative, the NRC staff would rely on existing regulations and guidance documents. No changes to regulatory language would be proposed. However, as noted above, the agency has already taken action to address CFSI in the form of a RIS.

13. Contemporary Posting Requirements

a. Existing Regulatory Framework

All entities subject to 10 CFR Part 21 are required to post copies of Section 206 of the Energy Reorganization Act of 1974 and associated implementing procedures.

10 CFR 21.6, "Posting Requirements," states, in part, that current copies of 10 CFR 21, Section 206 of the Energy Reorganization Act of 1974, and adopted procedures, are to be posted by the entity on its premises:

> …documents must be posted in a conspicuous position on any premises within the United States where the activities subject to this part are conducted.

Section 206, "Noncompliance," of the Energy Reorganization Act of 1974, states, in part:

The requirements of this section shall be prominently posted on the premises of any facility licensed or otherwise regulated pursuant to the Atomic Energy Act of 1954, as amended.

b. Description of Regulatory Problem

The posting requirements in 10 CFR 21.6 and the Energy Reorganization Act of 1974 do not specifically address nor allow for electronic postings in a location accessible to employees. These posting requirements were written when posting physical paper copies was the most effective, logical, and only means of communicating the regulation. Part 21 and the Energy Reorganization Act of 1974 do not preclude the use of contemporary posting methods, such as the use of online web site posting. However, in the absence of explicit approval from the NRC, entities may be unwilling to take advantage of online web site posting, for fear of violating NRC requirements.

c. Options To Resolve Regulatory Problem

- Proposed Changes to NRC Regulations

  The NRC staff is not proposing changes to the regulations. The staff is not considering changes to Part 21 to address this area because the current regulation can be interpreted to allow the use of online web site posting to meet the regulation.

- NRC Guidance Development

  The staff intends to describe the acceptable ways to meet the posting requirements in Part 21 and the Energy Reorganization Act of 1974, in DG-1291. The staff would clarify that contemporary posting methods, such as the use of online web site posting, meet these regulatory requirements. The staff could also develop an NRC-approved posting, similar to the NRC's Form 3, "Notice to Employees," which outlines the NRC's regulations in Part 20; 10 CFR Part 19, "Notices, Instructions and Reports to Workers; Inspection and Investigations"; and 10 CFR 50.7, "Employee Protection."

- Voluntary Industry Initiatives

  NEI recently developed guidance on posting requirements. That guidance, contained in NEI 14-09, "Guidelines for Implementation of 10 CFR Part 21 Reporting of Defects and Noncompliance, Revision 0," dated August 28, 2014 (ADAMS Accession No. ML14245A415) is currently under review by the NRC staff.

- No Action

  Under this alternative, the NRC staff would rely on existing regulations and guidance documents. No changes to regulatory language would be proposed. Taking no action would likely result in continuing lack of clarity with regard to the use of online web site posting methods as a means of meeting

the requirements of 10 CFR 21.6. Therefore, the "no action" alternative is not a preferred option.

14. Training

a. Existing Regulatory Framework

10 CFR Part 21 does not explicitly require training of personnel on the requirements of Part 21 and implementation of Part 21 programs.

b. Description of Regulatory Problem

Part 21 regulations do not describe training requirements for personnel performing activities under 10 CFR Part 21. Certain activities performed under Part 21, such as evaluation of deviations and failures to comply, would have a similar impact on basic components as those activities performed under regulations elsewhere in 10 CFR providing quality assurance requirements. For example, for power reactor facilities and fuel cycle facilities, training requirements for matters within the scope of Appendix B to 10 CFR Part 50 quality assurance requirements, are found in Criterion II, "Quality Assurance Program." That regulation states, in part:

> The program shall provide for indoctrination and training of personnel performing activities affecting quality as necessary to assure that suitable proficiency is achieved and maintained.

For nonreactor facilities that are not required to comply with Appendix B, similar training requirements are typically part of the QA requirements established in the respective part of the *Code of Federal Regulations* (e.g., management measures are required for facilities subject to the requirements of Subpart H of 10 CFR Part 70, "Domestic Licensing of Special Nuclear Material"; Subpart G, "Quality Assurance," of 10 CFR Part 72 sets forth QA requirements for facilities licensed under 10 CFR Part 72, etc.).

NRC inspectors have noted instances where QA Managers and other responsible personnel who are expected to maintain compliance with Part 21 lack understanding of the process requirements, due to inadequate or insufficient training.

c. Options To Resolve Regulatory Problem

- Proposed Changes to NRC Regulations

  The staff considered revising regulations to require that personnel performing activities affecting quality under 10 CFR Part 21 receive indoctrination and training as necessary, to assure that suitable proficiency is achieved and maintained. However, because the training of personnel performing activities affecting quality is already covered under Appendix B to 10 CFR Part 50, the staff determined the potential safety gains achievable from any additional requirements would not be significant enough to justify proposing changes to the current regulations at this time.

- NRC Guidance Development

  The staff intends to describe its expectations regarding training requirements for personnel performing activities under Part 21 in DG-1291. The staff would note that Part 21 activities affect quality and, therefore, personnel performing Part 21 activities must receive adequate training.

- Voluntary Industry Initiatives

  Voluntary Industry Initiatives could clarify training requirements associated with Part 21. NEI recently developed guidance on training of personnel involved in 10 CFR Part 21 activities. That guidance, contained in NEI 14-09, "Guidelines for Implementation of 10 CFR Part 21 Reporting of Defects and Noncompliance, Revision 0," dated August 28, 2014 (ADAMS Accession No. ML14245A415) is currently under review by the NRC staff.

- No Action

  Under this alternative, the NRC staff would rely on existing regulations and guidance documents. No changes to regulatory language would be proposed. Taking no action would likely result in continuing lack of clarity with regard to the need for training of personnel performing activities under Part 21. Therefore, the "no action" alternative is not a preferred option.

15. Lack of Clarity in Evaluating and Reporting Requirements for Part 70 Licensees

a. Existing Regulatory Framework

10 CFR 21.21 describes the evaluating and reporting requirements for entities subject to Part 21. Specifically, 10 CFR 21.21(a) states:

> Each individual, corporation, partnership, dedicating entity, or other entity subject to the regulations in this part shall adopt appropriate procedures to --
> (1) Evaluate deviations and failures to comply to identify defects and failures to comply associated with substantial safety hazards as soon as practicable, and, except as provided in paragraph (a)(2) of this section, in all cases within 60 days of discovery, in order to identify a reportable defect or failure to comply that could create a substantial safety hazard, were it to remain uncorrected.

In 2000, the NRC amended Part 70 to incorporate new requirements for the development of an ISA for fuel cycle facilities authorized to possess greater than a critical mass of special nuclear material. The Commission's action was in response to the Petition for Rulemaking (Docket No. PRM 707) that the NEI filed on November 26, 1996 (61 FR 60057). Subpart H, "Additional Requirements for Certain Licensees Authorized to Possess a Critical Mass of Special Nuclear Material," of Part 70 includes the majority of the petitioner-proposed revisions to Part 70. These revisions were proposed to increase confidence in the margin of safety at the facilities affected by the rule.

The Statement of Considerations published with the issuance of Subpart H of Part 70 on September 18, 2000 (65 FR 56211) states that, in developing the proposed rule, the Commission sought to achieve its objectives through a risk informed and performance based regulatory approach that included (1) the identification of performance requirements for the prevention of accidents or the mitigation of their consequences, (2) the performance of an ISA to identify potential accidents at the facility and the IROFS, (3) the implementation of measures to ensure that IROFS are available and reliable to perform their function when needed, (4) the maintenance of the safety bases, including the reporting of changes to the NRC, and (5) the allowance for licensees to make certain changes to their safety program and facilities without prior NRC approval.

The regulations at 10 CFR 70.62, "Safety Program and Integrated Safety Analysis," address the need for a safety program and ISA, as follows:

> (a) Safety program. (1) Each licensee or applicant shall establish and maintain a safety program that demonstrates compliance with the performance requirements of § 70.61. The safety program may be graded such that management measures applied are graded commensurate with the reduction of the risk attributable to that item. Three elements of this safety program; namely, process safety information, integrated safety analysis, and management measures, are described in paragraphs (b) through (d) of this section.
>
> (2) Each licensee or applicant shall establish and maintain records that demonstrate compliance with the requirements of paragraphs (b) through (d) of this section.
>
> (3) Each licensee or applicant shall maintain records of failures readily retrievable and available for NRC inspection, documenting each discovery that an item relied on for safety or management measure has failed to perform its function upon demand or has degraded such that the performance requirements of § 70.61 are not satisfied. These records must identify the item relied on for safety or management measure that has failed and the safety function affected, the date of discovery, date (or estimated date) of the failure, duration (or estimated duration) of the time that the item was unable to perform its function, any other affected items relied on for safety or management measures and their safety function, affected processes, cause of the failure, whether the failure was in the context of the performance requirements or upon demand or both, and any corrective or compensatory action that was taken. A failure must be recorded at the time of discovery and the record of that failure updated promptly upon the conclusion of each failure investigation of an item relied on for safety or management measure.
>
> (d) Management measures. Each applicant or licensee shall establish management measures to ensure compliance with the performance requirements of § 70.61. The measures applied to a particular engineered or administrative control or control system may be graded commensurate with the reduction of the risk attributable to that control or control system. The management measures shall ensure that engineered and administrative controls and control systems that are identified as items relied on for safety

pursuant to § 70.61(e) of this subpart are designed, implemented, and maintained, as necessary, to ensure they are available and reliable to perform their function when needed, to comply with the performance requirements of § 70.61 of this subpart.

b. Description of Regulatory Problem

It is unclear if the implementation of 10 CFR 21.21 enables consideration of risk-informed and performance-based approaches such as those which were integrated to ensure safety at fuel cycle facilities with the issuance of Subpart H.

With the issuance of Subpart H to Part 70 in 2000, licensees were able to apply a system of engineered and administrative (i.e., human or procedural) controls to maintain an acceptable level of risk for their facilities. Although this rule change encouraged the adoption of risk-informed and performance-based practices, an assessment was not performed to determine the need for conforming changes to Part 21 at that time or to consider the need for clarified implementation guidance for Part 21. As a result, it is unclear if the implementation of 10 CFR 21.21, which simply directs entities subject to the rule to establish procedures to evaluate deviations and failures to comply to identify defects and failures to comply associated with substantial safety hazards, enables consideration of risk-informed and performance-based approaches such as those which were integrated to ensure safety at fuel cycle facilities with the issuance of Subpart H. Further, there is very limited guidance available for evaluating and reporting, leaving applicants and licensees without a comprehensive understanding of NRC expectations for applying 10 CFR 21.21. The result is that applicants and licensees may perform evaluations differently, even if given the same information, because there is a lack of clarity regarding what factors may be credited as part of the evaluation process. This can lead to inconsistencies in reporting, which decreases the effectiveness of the Part 21 rule.

Part 70 requires applicants and licensees to perform an ISA, and it allows the use of administrative controls in conjunction with engineered controls to prevent or mitigate the consequences of events that could cause the performance requirements in 10 CFR 70.61 to be exceeded. NUREG-1520, “Standard Review Plan for the Review of a License Application for a Fuel Cycle Facility,” Revision 1, “Final Report,” issued May 2010, acknowledges the use of passive engineered controls, active engineered controls, administrative controls, and enhanced administrative controls (or a combination of these) to maintain safe process conditions at a fuel cycle facility. Part 70 licensee ISAs use combinations of various controls and management measures to ensure that IROFS are reliable and that they will perform their functions when needed. Part 21 does not presently acknowledge the use of administrative controls, as addressed in the ISAs required by Part 70. As a result, the fuel cycle industry has expressed concerns that Part 21 does not acknowledge the unique nature of their regulatory structure, which may result in unnecessary cost and resource implications when implementing Part 21 programs. The staff believes that consistency should be established between the provisions for evaluation and reporting under Part 21 and the overarching regulatory requirements in Part 70 that ensure safety at fuel cycle facilities. This will ensure that the safety benefit of Part 21 evaluation and reporting is balanced with the risk and consequence analysis methodology in Part 70, resulting in reporting of only those defects and failures to comply that could reasonably be expected to create a substantial

safety hazard (and exclusion of those that have extensive defense-in-depth provided by features such as administrative controls).

c. Options To Resolve Regulatory Problem

- Proposed Changes to NRC Regulations

  Regulations in 10 CFR 21.21 require entities subject to Part 21 to establish procedures to evaluate deviations and failures to comply to identify defects and failures to comply associated with substantial safety hazards as soon as practicable…in order to identify a reportable defect or failure to comply that could create a substantial safety hazard, were it to remain uncorrected. There are numerous considerations that factor into determination of whether a deviation or failure to comply could create a substantial safety hazard, only one of which is the presence or availability of other controls or protective features to prevent or mitigate such a hazard. While revising 10 CFR 21.21 to outline factors for consideration in the evaluation process would provide a high degree of regulatory certainty, it also could result in an overly-prescriptive rule. It could also result in unintended consequences by forcing applicants and licensees to revise procedures when such changes should be at the discretion of the applicant or licensee as such provisions are intended to allow a more risk-informed, performance-based approach to evaluating and reporting rather than a rigid expectation of how to implement 10 CFR 21.21. For these reasons, rule changes to address this issue are not recommended.

- NRC Guidance Development

  There is very limited guidance available for evaluating and reporting under Part 21, leaving applicants and licensees without a comprehensive understanding of NRC expectations for applying 10 CFR 21.21. Regulatory guidance is an appropriate tool for providing guidance to licensees and applicants on implementing specific parts of the NRC's regulations. As such, the staff recommends providing regulatory guidance to describe evaluation and reporting requirements for Part 70 fuel cycle facilities. The clarifications could provide guidance related to the evaluation of deviations and failures to comply in light of the combination of engineered and administrative controls applied to prevent or mitigate facility hazards in the ISA process defined by Part 70.[13] For example, guidance could describe Part 21 evaluation and reporting considerations for fuel cycle facilities as follows:

  i. A Part 21 evaluation is required for a deviation identified in:

     a. an IROFS (or part thereof that affects its safety function) such that, if it failed, no other controls (engineered or administrative)

[13] ISAs performed in accordance with Part 70 requirements identify potential accident sequences in fuel facility operations, designate IROFS to either prevent such accidents or mitigate their consequences, and describe management measures to provide reasonable assurance that IROFS are available and reliable to perform their function when needed. IROFS may include a combination of engineered and administrative (i.e., human or procedural) controls to prevent or mitigate the consequences of accidents analyzed in the ISA.

would remain to prevent or mitigate an accident sequence that could result in high or intermediate consequences, as defined in 10 CFR 70.61 (e.g., a sole IROFS).

b. an IROFS (or part thereof that affects its safety function) such that, if all effectively identical components or parts in the facility were to fail to perform their function, no controls (engineered or administrative) would remain to prevent or mitigate an accident sequence that could result in high or intermediate consequences, as defined in 10 CFR 70.61.

c. an IROFS (or part thereof that affects its safety function) such that, if it failed, only administrative controls remain to prevent or mitigate an accident sequence that could result in high or intermediate consequences, as defined in 10 CFR 70.61.

d. Any systems, structures, components, or controls that are not designated as IROFS but are used to prevent or mitigate accident sequences that could result in high or intermediate consequences as defined in 10 CFR 70.61. Such controls may include components or equipment for nuclear criticality and alarm systems that are necessary for compliance with the requirements in 10 CFR 70.24, “Criticality Accident Requirements.”

ii. For all scenarios, the evaluation process should take into account that deviations in IROFS are <u>not</u> reportable if administrative IROFS were available and would have prevented or mitigated the effects of an accident sequence that could result in the Part 70 performance requirements being exceeded. The Part 21 evaluation must identify the administrative control(s) that would have prevented the Part 70 performance requirements from being exceeded and confirm that the administrative control was available and reliable when the deviation was identified.

- <u>Voluntary Industry Initiatives</u>

  The use of a voluntary program is not preferred for this regulatory problem because it is related to a lack of clarity related to the reporting requirements in the regulations. Further, to date, industry has not expressed interest in development of voluntary initiatives for this topic.

- <u>No Action</u>

  Taking no action in this area does not address the problem of regulatory uncertainty with respect to if the implementation of Part 21.21 enables consideration of risk informed and performance based approaches. Therefore, taking no action is not a preferred option.

References

U.S. Nuclear Regulatory Commission, "Remarks Presented (Questions/Answers Discussed) at Public Regional Meetings To Discuss Regulations (10 CFR Part 21) for Reporting of Defects and Noncompliance: July 12–26, 1977," NUREG-0302, Revision 1, Washington, DC, October 1977.

U.S. Nuclear Regulatory Commission, "Event Reporting Guidelines: 10 CFR 50.72 and 50.73," NUREG-1022, Rev. 1 (January 1998); Rev. 2 (October 2000); and Rev. 3, Supplement 1 (September 2014), Washington, DC.

U.S. Nuclear Regulatory Commission, "10 CFR 50.55(e) Construction Deficiency Reporting," Inspection Manual Part 9900, 10 CFR Guidance, Washington, DC, January 31, 1989.

U.S. Nuclear Regulatory Commission, "Improving Quality and Assurance of Quality in the Design and Construction of Nuclear Power Plants: A Report to Congress," NUREG-1055, Washington, DC, May 1984.

U.S. Code of Federal Regulations, "Reporting of Defects and Noncompliance," Part 21, Chapter I, Title 10, "Energy."

U.S. Nuclear Regulatory Commission's Note to Commissioners' Assistants entitled, "Clarification of Staff Position on Part 21 Reporting Requirements," U.S. Nuclear Regulatory Commission, Washington, DC, September 8, 2011.

U.S. Nuclear Regulatory Commission, *Federal Register*, Volume 37, March 30, 1972, p. 6460.

U.S. Nuclear Regulatory Commission, *Federal Register*, Volume 42, February 24, 1977, p. 10950.

U.S. Nuclear Regulatory Commission, *Federal Register*, Volume 56, July 31, 1991, p. 36081.

U.S. Nuclear Regulatory Commission, *Federal Register*, Volume 71, October 12, 2006, p. 60198.

U.S. Nuclear Regulatory Commission, *Federal Register*, Volume 72, August 28, 2007, p. 49352.

U.S. Nuclear Regulatory Commission report entitled, "Questions Asked at the 2011 Fuel Cycle Information Exchange Related to Title 10 of the *Code of Federal Regulations* Part 21," July 19, 2011, U.S. Nuclear Regulatory Commission, Washington, DC (Agencywide Documents Access Management System (ADAMS) Accession No. ML11259A039).

CHAPTER 3
COMMERCIAL GRADE DEDICATION

Background of NRC Commercial Grade Dedication

Commercial-grade dedication is a process by which a commercial-grade item is designated for use as a basic component. This acceptance process is 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. Licensees subject to Part 21 are required to ensure the suitability of commercially procured and dedicated equipment intended for use in safety-related applications.

Why the Current Regulatory Framework for Commercial Grade Dedication is Inadequate

The nuclear supply chain has evolved since the promulgation of Part 21 in 1978, prompting greater reliance by nuclear power plant licensees on commercial grade dedication. NRC inspection findings have repeatedly identified programmatic deficiencies in the area of dedication. The inspection findings, however, have been difficult to convey, as the methodology for dedication is prescribed in definitions. Therefore, staff believes that the current regulatory framework for dedication is inadequate, both from the standpoint of licensee implementation and NRC enforcement.

Current commercial grade dedication requirements are primarily prescribed in the definition of dedication in 10 CFR 21.3. The staff believes that the description of dedication in the definition under 10 CFR 21.3 does not provide an adequate basis to capture basic elements of the commercial grade dedication process, such as the necessary steps and sequence that need to be performed to properly dedicate a commercial grade item.

The current regulatory framework for commercial grade dedication also provides challenges for nonreactor licensees because of a lack of clarity. The current definition for dedication for nonreactors neither provides a clear delineation of the purpose and outcome of dedication process, nor does it prescribe requirements of *how* the process must be conducted. This lack of clarity has resulted in uncertainty of among nonreactor licensees on when dedication is required and how to implement the process.

Necessity to Clarify Commercial Grade Dedication Requirements

As such, the regulation is difficult to apply in today's industry, as evidenced by inadequate licensee and vendor interpretation of the dedication process. The increasing use of commercial grade dedication due to a decline in nuclear industry suppliers implementing Appendix B QA programs underscored a need to rectify the current regulatory framework for dedication.

In light of the NRC findings in the area of commercial grade dedication, the staff believes that it is imperative for the staff to make clarifying revisions to the current regulatory framework which would include: defining dedication using clear and enforceable regulatory language, establishing a proper framework for the dedication process within Part 21 to enhance clarity, and administering consolidated guidance that addresses commercial grade dedication.

The following sections (A thorough I) describe the relevant policy and implementation aspects associated with proposed rulemaking in the area of commercial grade dedication, as well as the NRC guidance that would need to be issued and/or revised.

Definition of Dedication

a. Existing Regulatory Framework

"Dedication" is currently defined in 10 CFR 21.3 as follows:

> (1) When applied to nuclear power plants licensed pursuant to 10 CFR Part 30, 40, 50, 60, dedication is 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. This assurance is achieved by identifying the critical characteristics of the item and verifying their acceptability by inspections, tests, or analyses performed by the purchaser or third-party dedicating entity after delivery, supplemented as necessary by one or more of the following: commercial grade surveys; product inspections or witness at hold points at the manufacturer's facility, and analysis of historical records for acceptable performance. In all cases, the dedication process must be conducted in accordance with the applicable provisions of 10 CFR Part 50, appendix B. The process is considered complete when the item is designated for use as a basic component.
>
> (2) When applied to facilities and activities licensed pursuant to 10 CFR Parts 30, 40, 50 (other than nuclear power plants), 60, 61, 63, 70, 71, or 72, dedication occurs after receipt when that item is designated for use as a basic component.

The NRC has approved exemption requests for some licensees under Part 70 from the dedication definition. These exemptions incorporate many elements of the power reactor definition (*e.g.*, identifying critical characteristics and verifying their acceptability) and elements of Part 70. The following is one example (ADAMS Accession No. ML110140636):

> Dedication is an acceptance process undertaken to provide reasonable assurance that a Commercial Grade Item to be used as a Basic Component will perform its intended IROFS function and, in this respect, is deemed equivalent to an item designed and manufactured under QA Level 1 or QA Level 2 or QA Level [Fire Protection] requirements in accordance with the [facility] QAPD. This assurance is achieved by identifying the critical characteristics of the item and verifying their acceptability by inspections, tests, or analyses performed by the purchaser or third-party Dedicating Entity after delivery, supplemented, as necessary, by one or more of the following: commercial grade surveys; product inspections or witness at hold points at the manufacturer's facility; and analysis of historical records for acceptable performance. In all cases, the applicable provisions of the [facility] QAPD will be used to conduct the dedication process. The process is considered complete when the item is designated for use as a Basic Component.

b. Description of Regulatory Problem

The current definition of dedication in 10 CFR 21.3 is complex and has led to confusion in the industry, as it attempts to prescribe the regulatory requirements to implement the dedication process.

The lack of simplicity in the definition detracts from the basic concept of dedication. Dedication is an acceptance process undertaken to provide reasonable assurance that a commercial grade item will perform its intended safety function.

The NRC staff has noted through inspections that entities conducting dedication lack a thorough understanding of the implementation of the dedication process due to lack of substantive regulatory requirements. The definition of dedication is inadequate for the current state of dedication involving complex items.

There are currently two ways to create a basic component: (1) design and manufacture it under an appropriate QA program, or (2) dedicate a commercial grade item in accordance with the dedication process. As it applies to nonreactor licensees, the definition of dedication lacks clarity. Dedication is defined separately for facilities and activities other than nuclear power plants and does not provide a clear delineation of the purpose and outcome of dedication processes. Specifically, because the rule simply states that "dedication occurs after receipt when that item is designated for use as a basic component," there is a large degree of uncertainty in the expectations for applying commercial grade dedication for nonreactor facilities.

As part of a series of licensing and exemption requests made by fuel cycle applicants and licensees since 2008, the fuel cycle industry has sought to achieve clarity in applying the dedication process to the design and construction of new enrichment and fuel fabrication facilities. Exempted definitions requested by these licensees and approved by the NRC have provided more detail to describe commercial grade dedication for these facilities and have clearly defined that dedication is a process used to ensure that a commercial grade item to be used as a basic component will perform its safety function. The recognition of the importance of dedication in ensuring that a commercial grade item will perform its safety function when used as a basic component is critical to the application of the dedication process, but is currently lacking in the rule as written for nonreactor facilities.

c. Options To Resolve Regulatory Problem

- Proposed Changes to NRC Regulations

  The staff is proposing to revise the definition of "dedication" in 10 CFR 21.3. The revision will involve simplifying the definition by removing the discussion of how dedication should be conducted. The fundamental concept of dedication should be kept in the definition to emphasize that dedicating entities are creating safety-related items from commercial products that do not have the QA pedigree of a basic component. The implementing details should be moved to a separate section and expanded, as necessary to provide a proper regulatory framework for the dedication process. The restructuring of Part 21 to separate evaluation

and reporting requirements from commercial grade dedication requirements is discussed in Section B, "Proper Place for Commercial Grade Dedication Requirements," of this chapter.

A possible approach to the revision of the definition of "dedication" under 10 CFR 21.3 is included in Appendix A of this document.

- NRC Guidance Development

  The staff believes that a definitive rule text is necessary to prescribe the requirements of commercial grade dedication to ensure consistent and enforceable application of the process and to provide regulatory consistency within 10 CFR Part 21. Absent of a rule change, the staff does not believe that guidance alone is the most effective solution to resolve problems associated with the commercial grade dedication requirements. However, as part of any change to the regulations affecting the commercial grade dedication process, the staff intends to provide additional guidance in regulatory guide DG-1292, "Dedication of Commercial Grade Items," to accompany the Part 21 rulemaking.

- Voluntary Industry Initiatives

  The staff believes that voluntary initiatives are not appropriate to address this issue because this regulatory problem stems from an inadequacy in the current regulatory framework. It should be noted, however, that industry has recently developed revised commercial grade dedication guidance. That guidance, contained in EPRI 3002002982, "Plant Engineering: Guideline for the Acceptance of Commercial-Grade Items in Nuclear Safety-Related Applications, Revision 1 to EPRI NP-5652 and TR-102260," dated September 2014 (ADAMS Accession No. ML14265A198) is currently under review by the NRC staff.

- No Action

  Under this alternative, the NRC staff would rely on existing regulations and guidance documents. It is the staff's position that taking no action in this area does not address the problem of a lack of a proper regulatory framework for the dedication process. Taking no action in this area would result in continued misinterpretations of the requirements on the dedication process. For materials and nonreactor facilities and activities, the current regulations and guidance would remain inadequate in describing the NRC's requirements for dedication and could result in additional future licensing and exemption requests. The many repetitive problems with commercial grade dedication provide sufficient evidence that some type of regulatory action is needed to minimize these recurrent compliance problems.

A. Proper Place for Commercial Grade Dedication Requirements

a. Existing Regulatory Framework

The description of the commercial grade dedication process is contained in the definition of dedication in 10 CFR 21.3. The NRC amended Part 21 on October 19, 1978

(43 FR 48621), providing the first definition of the commercial grade dedication. The amendment exempted commercial grade items from the requirements in Part 21 until those items were dedicated for safety-related use in a nuclear facility. The regulatory framework for dedication has remained largely unchanged since the issuance of this 1978 amendment.

b. Description of Regulatory Problem

The regulatory framework for dedication resides primarily in the definition of dedication found in 10 CFR 21.3. Substantive regulatory requirements should not reside solely in definitions. The lack of descriptive regulatory requirements has resulted in difficulty developing and implementing a comprehensive commercial grade dedication process. As such, the regulation is difficult to apply in today's industry as evidenced by inadequate licensee and vendor interpretation of the dedication process.

The description of dedication in the definition under 10 CFR 21.3 does not provide an adequate basis to capture basic elements of the commercial grade dedication process such as the necessary steps and sequence that need to be performed to properly dedicate a commercial grade item. Such elements would include documenting a technical evaluation and determining safety function. Also, certain limitations to the commercial grade dedication process are not addressed. For example, one such limitation that is imposed in practice, but not currently addressed, would include restrictions on the use of Method 4, "Acceptable Supplier/Item Performance Record," in Generic Letter 89-02 (ADAMS Accession No ML031140060)[14], as the sole acceptance method, and that if any critical characteristic cannot be verified, then the item shall not be declared a basic component.

c. Options To Resolve Regulatory Problem

- Proposed Changes to NRC Regulations

  The staff is proposing to restructure Part 21 to separate evaluation and reporting requirements from commercial grade dedication requirements. This change would provide a proper regulatory framework for the dedication process. The proposed changes would include the addition of 10 CFR 21.71, "Commercial Grade Dedication Requirements," to include a description of the commercial grade dedication process. The staff's proposal for the description of the commercial grade dedication process would include the basic steps in dedication, the necessity for documenting the technical evaluation, and the importance of conducting dedication in accordance with the requirements of Appendix B to 10 CFR Part 50.

  The staff has been conducting meetings and working groups on the dedication process to understand the issues resulting in the misinterpretation of the regulatory requirements. Both industry experts and knowledgeable NRC staff have collaborated on areas for improvement, which are noted in Appendix A.

[14] Generic Letter 89-02, "Actions to Improve the Detection of Counterfeit and Fraudulently Marketed Products," endorsed several methods for verifying the critical characteristics of commercial grade items intended for safety-related applications.

The staff considered moving the commercial grade dedication requirements outside of Part 21 to a separate regulation. However, due to possible implications on a number of vendors affected, the staff is not proposing such a solution at this time.

- NRC Guidance Development

  Although guidance development is a large part of the overall rulemaking effort, this regulatory problem also stems from a lack of clarity due to the current regulatory framework of the regulation. It is the staff's position that the current regulatory framework is insufficient for the adequate implementation of the commercial grade dedication process, and that guidance alone is not the most appropriate solution to address this issue. However, as part of any change to the regulations affecting the commercial grade dedication process, the staff intends to provide additional guidance in regulatory guide, DG-1292, "Dedication of Commercial Grade Items" to accompany the Part 21 rulemaking.

  Voluntary Industry Initiatives

  The staff believes that a definitive rule text is necessary to prescribe the requirements of commercial grade dedication requirements to ensure consistent and enforceable application of the process and to provide regulatory consistency within 10 CFR Part 21. Absent of a rule change, the staff does not believe that industry guidance alone is the most effective solution to resolve problems associated with the commercial grade dedication requirements.

  It should be noted, however, that EPRI has recently developed guidance on the commercial grade dedication process. That guidance, contained in EPRI 3002002982, "Plant Engineering: Guideline for the Acceptance of Commercial-Grade Items in Nuclear Safety-Related Applications, Revision 1 to EPRI NP-5652 and TR-102260," dated September 2014 (ADAMS Accession No. ML14265A198) is currently under review by the NRC staff.

  No Action

  Under this alternative, the NRC staff would rely on existing regulations and guidance documents. It is the staff's position that taking no action in this area does not address the problem of a lack of a proper regulatory framework for the dedication process. Taking no action would contribute to continued inadequate licensee and vendor interpretation of the dedication process which increases the potential for the use of substandard parts and services in safety systems and therefore significant enough to warrant action. Therefore, the "no action" alternative is not a preferred option.

B. Definition of Dedicating Entity

a. Existing Regulatory Framework

10 CFR 21.3 defines "dedicating entity" as the following:

When applied to nuclear power plants licensed pursuant to 10 CFR Part 50, dedicating entity means the organization that performs the dedication process. Dedication may be performed by the manufacturer of the item, a third-party dedicating entity, or the licensee itself. The dedicating entity, pursuant to § 21.21(c) of this part, is responsible for identifying and evaluating deviations, reporting defects and failures to comply for the dedicated item, and maintaining auditable records of the dedication process.

b. Definition of Regulatory Problem

The definition of dedicating entity in 10 CFR 21.3 does not apply to nonreactor licensees, nonpower reactors, or nuclear power plants licensed pursuant to 10 CFR Part 52.

The term "dedicating entity" is only defined for nuclear power plants licensed under to 10 CFR Part 50. When the NRC revised Part 21 to address the applicability of 10 CFR Part 52 (72 FR 49486; August 28, 2007), the stuff unintentionally omitted 10 CFR Part 52 from the definition of dedicating entity under Part 21 (the conforming amendments to 10 CFR 50.55 do address Part 52 entities and regulatory approvals, but rely on the definitions in 10 CFR 21.3). Further, the revision did not consider the applicability of the definition to licensees under Part 70. Nonreactor licensees also perform commercial grade dedication; however, the definition of dedicating entity in the regulation does not apply to them.

Since 2008, the NRC has approved a number of exemption requests that have been submitted to the agency by fuel cycle facility applicants and licensees because of their inability to effectively design and construct new enrichment and fuel fabrication facilities under the current provisions of Part 21. These exemptions have sought to address challenges caused by Part 21 for the design and construction of new enrichment and fuel fabrication facilities.

c. Options To Resolve Regulatory Problem

- Proposed Changes to NRC Regulations

  The staff is proposing to revise the definition of dedicating entity. The staff is considering simplifying the definition by removing the reference to nuclear power plants licensed under Part 50. With this simplification in place, the definition will apply to all reactor and nonreactor facilities.

- NRC Guidance Development

  Because this problem is due to and inadequacy of the language in the current regulations, the staff does not believe that guidance is the most effective solution for addressing this problem.

- Voluntary Industry Initiatives

  The staff believes that voluntary initiatives are not an appropriate means of addressing this issue because this regulatory problem stems from an inadequacy in the current regulatory framework. It should be noted, however, that industry has recently developed revised commercial grade dedication guidance. That guidance, contained in EPRI 3002002982, "Plant Engineering: Guideline for the Acceptance of Commercial-Grade Items in Nuclear Safety-Related Applications, Revision 1 to EPRI NP-5652 and TR-102260," dated September 2014 (ADAMS Accession No. ML14265A198) is currently under review by the NRC staff.

- No Action

  Under this alternative, the NRC staff would rely on existing regulations and guidance documents. No changes to regulatory language would be proposed. Taking no action would likely result in continuing lack of clarity with regard to the regulatory requirements for a dedicating entity with respect to power reactor licensees under Part 52, nonpower reactors, and nonreactor facilities. Taking no action is not a preferred option.

C. Definition of Commercial Grade Item

a. Existing Regulatory Framework

Part 21 distinguishes a commercial grade item from a basic component.

For power reactors, "commercial grade item" is currently defined in 10 CFR 21.3 as follows:

> When applied to nuclear power plants licensed pursuant to 10 CFR Part 50, commercial grade item means a structure, system, or component, or part thereof that affects its safety function, that was not designed and manufactured as a basic component. *Commercial grade items do not include items where the design and manufacturing process require in-process inspections and verifications to ensure that defects or failures to comply are identified and corrected (i.e., one or more critical characteristics of the item cannot be verified) [emphasis added].*

For nonpower reactor and nonreactor facilities and activities, "commercial grade item" is currently defined in 10 CFR 21.3 as follows:

> When applied to facilities and activities licensed pursuant to 10 CFR Parts 30, 40, 50 (other than nuclear power plants), 60, 61, 63, 70, 71, or 72, *commercial grade item means an item that is:*
>
> *(i) Not subject to design or specification requirements that are unique to those facilities or activities;*
>
> *(ii) Used in applications other than those facilities or activities; and*

(iii) To be ordered from the manufacturer/supplier on the basis of specifications set forth in the manufacturer's published product description (for example, a catalog) [emphasis added].

The purpose of distinguishing a commercial grade item from a basic component for power reactors, nonpower reactors, and nonreactor facilities and activities was to clearly specify the characteristics of commercial grade items which are not subject to the reporting requirements of Part 21.

On September 19, 1995 (60 FR 48369), the NRC adopted a final rule which responded to a petition for rulemaking, PRM-21-2, submitted by NUMARC, notice of docketing in 58 FR 52159 (October 14, 1993). The NRC response stated:

> The NRC examined the issue of how far down the procurement chain Part 21 should be applicable and on October 19, 1978 (43 FR 4862), amended Part 21 to exempt commercial grade items from the reporting requirements of Part 21 until the items were dedicated for use as a basic component.

b. Description of Regulatory Problem

1. The current definition for power reactor licensees has been incorrectly interpreted by industry to mean that a specific design or manufacturing critical characteristic can only be verified through in-process inspection.

Inspections are just one verification method available under the dedication process. A commercial grade item may still be capable of being dedicated by verifying in-process design and manufacturing critical characteristics through testing.

The purpose of the dedication process is to provide reasonable assurance an item can perform its safety function. If a dedicating entity provides justification through an alternate means of the dedication process other than inspection, then the goal of dedication is achieved.

2. The current definition for commercial grade item for nonpower reactors and nonreactor licensees restricts the use of commercial grade items to items that are generic in nature, thereby prohibiting the use of dedication to obtain a basic component that is unique to its application.

As part of the 1995 amendments to Part 21, the staff received a comment that the proposed new definitions and changes should not be limited to power plant licensees under 10 CFR Part 50 and their vendors. The NRC responded that it was considering proposed changes to 10 CFR Part 21 regulatory requirements for nonpower reactors and nonreactor licensees. However, the staff has not yet initiated any such changes.

Since 2008, the NRC has approved a number of licensing and exemption requests that have been submitted to the agency by fuel cycle facility applicants and licensees because of their inability to effectively design and construct new enrichment and fuel fabrication facilities under the current provisions of Part 21.

The current definition for commercial grade item for nonpower reactors and nonreactor licensees restricts the use of commercial grade items to items that are generic in nature, thereby prohibiting the use of dedication to obtain a basic component that is unique to its application. As stated by the licensing and exemption requests, the definition has statements that might complicate and, in some cases, prohibit necessary procurement of certain components to support the design, construction, and safe operation of nonreactor facilities.

c. Options To Resolve Regulatory Problem

- Proposed Changes to NRC Regulations

  The staff is proposing to revise the definition of commercial grade item to clarify that it is simply an item that is not a basic component. With this definition, the dedication process in 10 CFR 21.71 would appropriately determine if the commercial grade item could be dedicated and therefore be designated as a basic component.

  In addition, the staff is considering making the definition of commercial grade item equivalent for reactor and nonreactor facilities. Under this proposal, all items not designed and manufactured under an appropriate QA program would be considered commercial grade items. One of those requirements that would be maintained in the dedication process description would prohibit dedication if any critical characteristic of the item cannot be verified as acceptable.

  A possible approach to the revision of definition of commercial grade item in 10 CFR 21.3 is included in Appendix A of this document.

- NRC Guidance Development

  The NRC staff has engaged in extensive interaction with industry and understands that the definition of commercial grade dedication, as written, is subject to misinterpretation and is thus being implemented inconsistently and, in some cases, incorrectly among those entities subject to the Part 21 regulations. As discussed above, dedicating entities have struggled with the concept that the definition limits and delineates the dedication process. For this reason, the staff does not regard guidance alone to be the most appropriate solution to resolve the current issues with the definition of a commercial grade item. However, as part of any change to the definition of commercial grade item, the staff intends to provide additional information on the NRC's expectations with regard to a commercial grade item in DG-1292 to enhance the clarity of the staff's expectations of the dedication process.

- Voluntary Industry Initiatives

  The staff believes that voluntary initiatives are not appropriate to address this issue because this regulatory problem is directly associated with an inadequacy in the current regulatory framework. It should be noted, however, that industry has recently developed revised commercial grade dedication guidance. That

guidance, contained in EPRI NP-5652 and TR-102260, "Supplemental Guidance for the Application of EPRI Report NP-5652 on the Utilization of Commercial Grade Items," dated September 17, 2014 (ADAMS Accession No. ML14265A198) is currently under review by the NRC staff.

- No Action

  Under this alternative, the NRC staff would rely on existing regulations and guidance documents. The definition of a commercial grade item, as stated in Part 21, has required various licensing and exemption requests so that licensees and applicants could procure safety significant items that were needed for the design, construction, and safe operation of their facilities. The staff believes this would contribute to continued misinterpretation of the regulation and would result in future exemption requests and the continuance of the Part 21 problems noted above. Therefore, a "no action" alternative is not a preferred option.

D. Clarification of 'Basic Component' as Equivalent to 'Safety-Related' Nuclear Power Plants

a. Existing Regulatory Framework

The definitions of basic component and safety-related, which are intended to refer to the same set of structures, systems, and components, vary slightly.

10 CFR 21.3 defines basic component, as it applies to power reactor facilities, as the following:

> When applied to nuclear power plants licensed under 10 CFR Part 50 or Part 52 of this chapter, basic component means a structure, system, or component, or part thereof that *affects its safety function necessary to assure [emphasis added]:*
>
> A. The integrity of the reactor coolant pressure boundary;
> B. The capability to shut down the reactor and maintain it in a safe shutdown condition; or
> C. The capability to prevent or mitigate the consequences of accidents which could result in potential offsite exposures comparable to those referred to in *§ 50.34(a)(1), § 50.67(b)(2), or § 100.11* of this chapter, as applicable *[emphasis added].*

10 CFR 50.2, "Definitions," defines safety-related SSCs for reactor facilities as the following:

> *Safety-related structures,* systems and components means those structures, systems and components that are *relied upon to remain functional during and following design basis events to assure* [emphasis added]:
>
> (1) The integrity of the reactor coolant pressure boundary

(2) The capability to shut down the reactor and maintain it in a safe shutdown condition; or
(3) The capability to prevent or mitigate the consequences of accidents which could result in potential offsite exposures comparable to the applicable guideline exposures set forth in *§ 50.34(a)(1) or § 100.11* of this chapter, as applicable *[emphasis added].*

b. Definition of Regulatory Problem

The definitions for "basic component" and "safety-related" do not align. Specifically, the use of the terms "affects its safety function" in the definition of basic component is less specific than that provided in the definition of "safety-related," and has led to inadequate application of QA controls to basic components by vendors and licensees.

c. Options To Resolve Regulatory Problem

- Proposed Changes to NRC Regulations

  The staff is considering revising the definition of basic component to align with safety-related. In the preliminary draft rule language this new definition would more closely match that of safety-related, as defined in 10 CFR 50.2, without changing its meaning.

  The NRC staff does not intend to differentiate between "basic component" and "safety-related" or apply separate criteria to determining which SSCs are basic components or safety-related.

  An approach to the revised definition of basic is included in Appendix A of this document.

- NRC Guidance Development

  Because the regulatory inconsistency is associated with definitions of terms contained in 10 CFR Part 21 and 10 CFR Part 50, the use of guidance alone does not represent the most direct and effective mechanism to align the definitions.

  For this reason, the staff does not believe that guidance is the most appropriate solution to resolve the issues associated with the differences between the definitions of basic component and safety-related. However, guidance can be used in conjunction with changes to NRC regulations to add further clarity to the correlation between the terms basic component and safety-related.

- Voluntary Industry Initiatives

  The staff holds the position that voluntary initiatives are not appropriate to address this issue because this regulatory problem stems from an inadequacy in the current regulatory framework. It should be noted, however, that industry has recently developed revised guidance for evaluating and reporting and

commercial grade dedication. The guidance is currently under review by the NRC staff and may aid in clarifying the correlation between the terms basic component and safety-related. As stated above, however, the staff does not believe that guidance alone can adequately address this inconsistency.

- No Action

  Under this alternative, the NRC staff would rely on existing regulations and guidance documents. A "no action" alternative is not preferred because the staff believes that in order to achieve a clear, comprehensive rule in Part 21, the terminology and requirements used in the rule must be in agreement internally as well as with other NRC regulations. Taking no action would not support the goal of increasing regulatory stability and would represent a weakness in the overall clarity of the rule.

E. Clarification of Quality Assurance Requirements for the Conduct of Dedication for Facilities Subject to Appendix B

a. Existing Regulatory Framework

10 CFR 21.3 includes in the definition for dedication as applied to power reactor licensees the following substantive requirement:

> In all cases, the dedication process must be conducted in accordance with the applicable provisions of 10 CFR Part 50, Appendix B.

There are no similar statements to identify the QA requirements applicable to dedication activities for other facilities subject to the requirements of Part 21.

b. Definition of Regulatory Problem

1. The regulatory framework for dedication, which includes the application of necessary QA controls, resides primarily in the definition of dedication found in 10 CFR 21.3. Substantive regulatory requirements should not reside solely in definitions.

Specifically, NRC inspections of power reactor licensees have found that many dedication activities are performed improperly, without being in accordance with applicable provisions of Appendix B to 10 CFR Part 50. A common example is dedication performed without adequate documentation, as required by Criterion V, "Instructions, Procedures, and Drawings," of Appendix B.

2. For nonpower reactors and nonreactor facilities, there is no description within Part 21 or any existing guidance associated with Part 21 to describe QA controls that should be applied to dedication activities.

Part 70 fuel fabrication facilities that process plutonium are required in 10 CFR 70.22(f) to describe a quality assurance program that meets criteria in Appendix B of 10 CFR Part 50, whereas other facilities licensed under Part 70 apply a system of management measures as defined in 70.62(d). These factors affect the expectations for a dedication

program; however, this is not clearly addressed by the rule as written, or any associated guidance. Fuel cycle facilities that have Appendix B QA programs currently conduct dedication in accordance with these requirements; however, Part 21 does not make it clear that such licensees should apply their Appendix B QA programs to the dedication process.

c. Options To Resolve Regulatory Problem

- Proposed Changes to NRC Regulations

  The staff is considering adding an express requirement as part of a new section on commercial grade dedication that identifies that dedication must be conducted in accordance with Appendix B for those entities subject to the requirements of Appendix B. This will provide clear regulatory infrastructure to communicate dedication requirements. For power reactor licensees, moving the requirement from the definition of dedication to a new section on dedication will support a better understanding of the requirements since they will all be contained in one consolidated section. For nonreactor licensees, providing the link between Appendix B compliance and applying Appendix B to dedication activities will provide increased clarity in the rule and aid in enhancing the specificity of the rule for materials licensees.

- NRC Guidance Development

  A regulatory guide to address commercial grade dedication will be essential in providing clear expectations to Part 21 stakeholders. The staff has begun developing DG-1292, which will emphasize that commercial grade dedication should be performed in accordance with the prevailing QA requirements applicable to the licensee or activity (i.e., if a licensee if required to comply with Appendix B, it should perform dedication activities in accordance with Appendix B). The guidance will also discuss dedication as a safety-related activity for power reactors (see section on “Clarification of ‘Basic Component’ as Equivalent to ‘Safety-Related’ for Facilities Subject to Appendix B”). Through the guide, the NRC also expects to endorse industry guidance, such as a new revision to EPRI NP-5652, which will provide detailed guidance on the conduct of dedication activities.

- Voluntary Industry Initiatives

  The industry is revising the commercial grade dedication guidance in EPRI NP-5652, which is the most prevalently used guide. These voluntary efforts will provide the staff with guidance that the staff can review and endorse through a regulatory guide, if deemed acceptable. However, the use of a voluntary program alone would not provide comprehensive guidance to all affected licensees (power reactors and nonreactors) and vendors, and therefore is not an appropriate standalone solution. Pairing voluntary industry initiatives with NRC guidance development and rule changes are the most appropriate means to ensure that adequate clarity is achieved for power reactor, nonpower reactors, and nonreactor stakeholders performing dedication activities.

- No Action

  Taking no action for this problem would prevent much-needed clarification of the applicability of QA requirements to dedication activities for both reactor and nonreactor licensees and vendors. This clarification is needed to ensure regulatory stability and ensure consistent implementation of Part 21 for all users. Furthermore, taking no action in this area would result in the continued performance of inadequate commercial grade dedication among power reactor licensees. The many repetitive problems with Part 21 are significant enough to warrant action. Therefore, taking no action in this area is not a viable option.

F. Sampling Requirements

a. Existing Regulatory Framework

Dedication is defined in 10 CFR 21.3, in part, as:

> When applied to nuclear power plants licensed pursuant to 10 CFR Part 30, 40, 50, 60, dedication is 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. *This assurance is achieved by identifying the critical characteristics of the item and verifying their acceptability by inspections, tests, or analyses performed by the purchaser or third-party dedicating entity after delivery, supplemented as necessary by one or more of the following: commercial grade surveys; product inspections or witness at holdpoints at the manufacturer's facility, and analysis of historical records for acceptable performance [emphasis added].*

Paragraph 601, "Special Test(s), Inspection(s), and/or Analyses," of Section 600, "Methods of Accepting Commercial Grade Items," of Subpart 2.14, "Quality Assurance Requirements for Commercial Grade Items and Services," of ASME NQA-1-2008 states, in part:

> The special test(s), inspection(s), and/or analyses may include post-installation testing and may be performed utilizing a sampling plan, when appropriate. …Sampling plans utilized to select items for special test(s), inspection(s), and/or analysis shall have an adequate technical basis based on established standards that consider lot traceability, homogeneity, and the complexity of the item.

EPRI NP-5652, which Generic Letter 89-02 found to be acceptable with certain conditions, states in part: "The test and inspections may be performed utilizing a sampling plan when appropriate."

b. Definition of Regulatory Problem

The current Part 21 regulatory framework is silent with respect to the usage of sampling.

The NRC has not issued formal guidance (e.g., a regulatory guide) on the acceptable use of sampling in the dedication process under Part 21; however, the NRC recognizes that sampling may be used appropriately in dedication, consistent with the industry standards. To that end, the NRC has approved a number of industry standards as an acceptable means of complying with the quality assurance requirements in 10 CFR Part 50, Appendix B.

The industry has interpreted the definition of dedication under 10 CFR 21.3 in conjunction with the NRC's accepted use of national standards such as ANSI N45.2.13-76 and ASME NQA-1-2008 to mean that it is acceptable for tests and inspections for dedication of commercial grade items to be performed utilizing a sampling plan, when appropriate.

During recent vendor inspections, NRC inspectors identified instances where vendor procedures did not provide adequate guidance for the development of sampling plans consistent with the staff's position and industry standards. In addition, inspectors identified that vendor procedures did not provide adequate guidance for the development of sampling criteria to include qualitative factors, such as the safety significance of the item; adequacy of supplier controls; complexity of the item; and performance history to ensure adequate selection, documentation, and implementation of sampling plans. Consequently, the NRC has issued many findings for inadequate dedication due to improper sampling.

c. Options To Resolve Regulatory Problem

- Proposed Changes to NRC Regulations

  The staff is not considering changes to Part 21 to address this area as a regulation can be interpreted to allow the use of sampling for dedication of commercial grade items. The staff believes that implementation details on sampling should remain in guidance documents. The current EPRI sampling guide, EPRI TR-017218-R1, "Guidelines for Sampling in the Commercial-Grade Dedication Process, dated January 1999, is the standard most used by vendors to dedicate items, and the NRC staff presentations have recommended this guide as a viable starting point. With some modification, the NRC could review and find acceptable the EPRI sampling guide through the regulatory guide process.

- NRC Guidance Development

  A regulatory guide to address sampling for commercial grade dedication will be essential in providing clear expectations to Part 21 stakeholders. The staff has begun developing DG-1292, which would include implementation guidance on sampling. Through the guide, the NRC could review for acceptance industry guidance in EPRI TR-017218-R1, "Guidelines for Sampling in the Commercial-

Grade Dedication Process." If implemented appropriately, licensees' and suppliers' use of this guidance should result in a more uniform application of sampling, improve overall confidence in the industry's sampling process for the dedication of commercial grade items, and provide reasonable assurance that a dedicated item will perform its intended safety function.

- Voluntary Industry Initiatives

  The industry revised the commercial grade dedication guidance in EPRI 3002002982, "Plant Engineering: Guideline for the Acceptance of Commercial-Grade Items in Nuclear Safety-Related Applications, Revision 1 to EPRI NP-5652 and TR-102260," dated September 2014 (ADAMS Accession No. ML14265A198). That guidance, which discusses the use of sampling in commercial grade dedication, is currently under review by the NRC staff.

  The industry also commonly uses the current version of EPRI TR-017218-R1, which provides guidance on the use of sampling in dedication. However, the staff anticipates that the guide will require modification before the NRC can accept it without conditions. The industry has not made the NRC aware of any intent to revise EPRI TR-017218-R1 to support this rulemaking.

- No Action

  Under this alternative, the NRC staff would rely on existing regulations and guidance documents. Taking no action in this area would result in continued performance of inadequate sampling during commercial grade dedication. The staff believes that the many repetitive problems with the use of sampling in dedication are significant enough to warrant action. Therefore, taking no action in this area is not a preferred option.

H. Software Dedication

a. Existing Regulatory Framework

Part 21 does not expressly identify software within its purview, nor do the regulations clearly address the dedication of software.

Commercial grade item is defined in 10 CFR 21.3 as:

(1) When applied to nuclear power plants licensed pursuant to 10 CFR Part 50, commercial grade item means a structure, system, or component, or part thereof that affects its safety function, that was not designed and manufactured as a basic component. Commercial grade items do not include items where the design and manufacturing process require in-process inspections and verifications to ensure that defects or failures to comply are identified and corrected (i.e., one or more critical characteristics of the item cannot be verified).

(2) When applied to facilities and activities licensed pursuant to 10 CFR Parts 30, 40, 50 (other than nuclear power plants), 60, 61, 63, 70, 71, or 72, commercial grade item means an item that is:

(i) Not subject to design or specification requirements that are unique to those facilities or activities;

(ii) Used in applications other than those facilities or activities; and

(iii) To be ordered from the manufacturer/supplier on the basis of specifications set forth in the manufacturer's published product description (for example, a catalog).

Basic component is defined in 10 CFR 21.3, in part, as:

> In all cases, basic component includes safety-related design, analysis, inspection, testing, fabrication, replacement of parts, or consulting services that are associated with the component hardware, design certification, design approval, or information in support of an early site permit application under part 52 of this chapter, whether these services are performed by the component supplier or others.

NUREG-0302, "Remarks Presented (Questions/Answers Discussed) at Public Regional Meetings To Discuss Regulations (10 CFR Part 21) for Reporting of Defects and Noncompliance: July 12–26, 1977," identified examples of safety-related services and software which could, if they contained defects, create a substantial safety hazard.

b. Description of Regulatory Problem

The existing regulatory framework of Part 21 does not expressly identify software as a commercial grade item or basic component. The regulations do not set forth a specific dedication approach for software.

In NUREG-0302, "Remarks Presented (Questions/Answers Discussed) at Public Regional Meetings To Discuss Regulations (10 CFR Part 21) for Reporting of Defects and Noncompliance: July 12–26, 1977," issued October 1977, the staff included software under the purview of safety-related equipment and services which could, if they contained defects, create a substantial safety hazard.

Safety-related software use has increased since the NRC's initial adoption of Part 21 and 50.55(e). Reporting of defects and failures to comply, as well as the process of dedication apply to all safety related items and services, including software. Nonetheless, some stakeholders have interpreted Part 21 to the contrary. Moreover, Part 21 does not provide a regulatory framework for software dedication. This can be a problem, because the dedication of software offers special concerns and issues not present in the dedication of hardware and services.

Use of commercial grade design and analysis software is common in the nuclear industry, but control processes for the program vary. Current industry dedication

guidance[15] was developed in the late 1980's and only focused on components, before the common use of complex computer programs. Although still applicable to computer programs from a process perspective, the guidance does not specifically consider the unique failure modes and characteristics of computer programs, nor the evaluation and testing challenges of off-the-shelf commercial computer programs procured for safety-related end-use application.

c. Options To Resolve Regulatory Problem

- Proposed Changes to NRC Regulations

  The staff is not considering changes to Part 21 to address this area because the regulation can be interpreted to define software as a commercial grade item or basic component, thus subject to the regulations.

- NRC Guidance Development

  The staff believes that the issues associated with software dedication can be resolved through guidance. Independent of the Part 21 rulemaking effort, the staff is developing DG-1305, "Design and Analysis Computer Program Commercial Grade-Dedication Requirements" to address software dedication. In tandem with the Part 21 rulemaking effort, the staff has begun developing DG-1292, which will complement the NRC's guidance on software implementation.

  In addition, as noted below, the staff is currently reviewing an industry guidance document on software dedication. If this guidance is acceptable, the staff will consider whether to approve for use this industry guidance document through NRC guidance such as a regulatory guide.

- Voluntary Industry Initiatives

  EPRI submitted guidance on software dedication through Technical Report 1025243, "Plant Engineering: Guideline for the Acceptance of Commercial-Grade Design and Analysis Computer Programs Used in Nuclear Safety-Related Applications, Revision 1," issued December 2013 (ADAMS Accession No. ML14085A084). That guidance is currently under review by the staff.

- No Action

  Because there is industry demand for the use of commercial grade software in safety-related applications and the agency currently has no guidance to address software dedication, a "no-action" alternative is not a preferred option.

[15] EPRI NP-5652, "Guideline for the Utilization of Commercial-Grade Items in Nuclear Safety Related Applications (NCIG-07)," Electric Power Research Institute, Palo Alto, CA, June 1988.

I. Lack of Regulatory Guidance

a. Existing Regulatory Framework

Dedication is a regulatory process allowing the use of commercial parts and services as basic components.

Dedication is defined in 10 CFR 21.3, for power reactor facilities, in part, as:

> is 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 an Appendix B, quality assurance program.

Although 10 CFR 21.3(2) contains a "definition" of dedication for facilities other than nuclear power plants, it does not actually define the process for such facilities but is limited to delineating when dedication occurs:

> dedication occurs after receipt when that item is designated for use as a basic component.

The NRC's guidance on commercial grade dedication can be found in an array of generic communications, guidance documents, and other communications. Most notably, the NRC conditionally endorsed EPRI NP-5652, "Guideline for the Utilization of Commercial Grade Items in Nuclear Safety Related Applications (NCIG-07)," issued June 1988 (ADAMS Accession No. ML14239A523), and in Generic Letter 89-02, "Actions to Improve the Detection of Counterfeit and Fraudulently Marketed Products," dated March 21, 1989 (ADAMS Accession No. ML031140060). EPRI NP-5652 is still considered the essential roadmap by the industry for the NRC dedication process.

Generic Letter 91-05, "Licensee Commercial-Grade Procurement and Dedication Programs," dated April 9, 1991 (ADAMS Accession No. ML031140508) identifies a number of failures in licensees' commercial grade dedication programs. It notified the industry of the staff's pause in conducting procurement inspection and enforcement activities to allow licensees sufficient time to fully understand and implement guidance developed by industry to improve procurement and commercial grade dedication programs. The letter expresses staff positions on commercial grade procurement and dedication programs that would provide acceptable methods to meet regulatory requirements.

In addition, the NRC approved ASME NQA-1-2008 and the ASME NQA-1a-2009 Addenda in Revision 4 to Regulatory Guide 1.28, "Quality Assurance Program Criteria (Design and Construction)," issued June 2010.[16] Subpart 2.14 of ASME NQA-1-2008 offers programmatic requirements for a compliant dedication program. Stakeholders have expressed interest in updating and consolidating NRC guidance on dedication.

[16] ASME NQA-1-2008 and ASME NQA-1a-20009 are not available through the NRC. These standards are the property of the American Society of Mechanical Engineers, and are available for a fee.

b. Description of Regulatory Problem

There is currently no NRC-issued consolidated guidance for an acceptable form of dedicating commercial grade items, in particular for nonpower reactors, and nonreactor facilities and activities. Because of this, stakeholders do not have consolidated guidance to help ensure that dedication is performed properly.

The NRC has never issued a regulatory guide on commercial grade dedication. Current guidance is scattered throughout various documents partly because dedication has evolved since it was first conceived in 1978. At that time, licensees typically performed dedication activities for a small number of basic components that were unavailable from suppliers under Appendix B to 10 CFR Part 50. Since the initial issuance of Part 21, the supply chain for the nuclear power industry has greatly evolved. The number of nuclear industry suppliers implementing an Appendix B QA program has declined. This evolution has prompted an increased reliance by nuclear power licensees on commercial grade dedication. Repetitive inspection findings in the implementation of the dedication process due to the lack of consolidated guidance, in conjunction with an increasing use of commercial grade dedication for nuclear components, illustrate the need to clarify and consolidate guidance.

Further, there is a lack of guidance for commercial grade dedication as it applies to nonpower reactors, and nonreactor facilities, in particular fuel cycle facilities. When the staff added Subpart H to Part 70 in 2000, it included requirements for licensees to implement a system of management measures in the revised rule. For plutonium processing and fuel fabrication plants facilities, licensees were also required to comply with 10 CFR Part 50, Appendix B.[17] The staff did not evaluate the implications of these new requirements to determine if conforming changes to Part 21 or associated guidance were appropriate.

Licensees subject to Part 21 must ensure the suitability of commercially procured and dedicated equipment for its intended safety-related application. Basic components that have been improperly dedicated do not meet the NRC's regulatory requirements, and, therefore, are not suitable for use in safety-related applications. The staff has described dedication issues in IN 2014-11, "Recent Issues Related to the Qualification and Commercial Grade Dedication of Safety-Related Components," issued September 19, 2014 (ADAMS Accession No. ML14149A520) and IN 2011-01, "Commercial-Grade Dedication Issues Identified during NRC Inspections," issued February 15, 2011 (ADAMS Accession No. ML103220180).

c. Options To Resolve Regulatory Problem

- Proposed Changes to NRC Regulations

  Changes to NRC regulations would not address the problem of lack of regulatory guidance related to the commercial grade dedication process for power reactors.

[17] Part 70 fuel fabrication facilities that process plutonium are required in § 70.22(f) to describe a quality assurance program that meets criteria in Appendix B of 10 CFR Part 50.

Fuel cycle facilities regulated under Subpart H (except those subject to the requirements of Appendix B to 10 CFR Part 50) perform measures to ensure the availability and reliability of IROFS as part of their management measures programs. Because the NRC staff does not expect licensees to implement any measures to ensure the availability and reliability of commercially-procured IROFS beyond those already required by 10 CFR Part 70, any change to the regulations in Part 21 for dedication as it applies to these facilities would only refer to the requirements of Part 70 and would thus be redundant and unnecessary.

For fuel cycle facilities regulated under Subpart H and subject to the requirements of Appendix B to 10 CFR Part 50 (e.g., facilities that process plutonium), proposed rule changes described in this chapter will clarify the applicability of Appendix B QA controls to dedication activities (Section G of this chapter, "Clarification of Quality Assurance Requirements for the Conduct of Dedication for Facilities Subject to Appendix B").

- <u>NRC Guidance Development</u>

The Commission has directed the staff to develop guidance needed for providing implementing guidance on new or revised rules as part of the rulemaking process. To date, the NRC has not issued consolidated guidance on the commercial grade dedication process. The most significant guidance that the NRC has issued on commercial grade dedication has been through Generic Letters 89-02 and 91-05. However, these generic communications have not resolved the lack of consolidated guidance. The staff intends to develop consolidated guidance in the form of a regulatory guide to address commercial grade dedication. That regulatory guide, DG-1292, "Dedication of Commercial Grade Items" will supplement the Part 21 rulemaking. A regulatory guide to address commercial grade dedication is essential to providing clear expectations to Part 21 stakeholders.

For fuel cycle facilities, the staff expects to provide guidance such that licensees may satisfy the requirements of commercial grade dedication by implementing existing management measures programs under Part 70. This guidance is necessary because, to date, there has been no guidance offered to describe NRC expectations for commercial grade dedication for entities outside the scope of power reactor licensees and vendors.

Existing regulatory requirements require licensees to ensure the availability and reliability of Items Relied On for Safety (IROFS). To verify item quality and functionality in service, licensees may apply a graded approach to elements of procurement, such as supplier evaluation and selection, and inspections and tests. Grading of these practices is permitted in accordance with 10 CFR Part 70.62(d), which states that:

> "The measures applied to a particular engineered or administrative control or control system may be graded commensurate with the reduction of the risk attributable to that control or control system. The management measures shall ensure that engineered and

administrative controls and control systems that are identified as items relied on for safety pursuant to § 70.61(e) of this subpart are designed, implemented, and maintained, as necessary, to ensure they are available and reliable to perform their function when needed, to comply with the performance requirements of § 70.61 of this subpart."

The NRC reviews and approves licensee programs for management measures, as part of the licensing process for fuel cycle facilities. The NRC also conducts periodic inspections to assess licensee compliance with license commitments. The application of management measures programs ensures the availability and reliability of IROFS at fuel cycle facilities. Therefore, guidance in this area will describe how these program elements fulfill the expectations for commercial grade dedication under Part 21.

Part 70 fuel fabrication facilities that process plutonium are required to comply with the requirements of Appendix B to 10 CFR Part 50. Section G of this chapter, "Clarification of Quality Assurance Requirements for the Conduct of Dedication for Facilities Subject to Appendix B," provides guidance for the application of QA controls to commercial grade dedication for those facilities.

Through the issuance of regulatory guide DG-1292, the staff expects to provide the guidance to address commercial grade dedication as it applies to power reactors and nonreactors, and also point to other NRC guidance in technical areas related to dedication, such as the use of commercial calibration and testing laboratories and software dedication.

- Voluntary Industry Initiatives

  The industry has recently developed revised commercial grade dedication guidance. That guidance, contained in EPRI 3002002982, "Plant Engineering: Guideline for the Acceptance of Commercial-Grade Items in Nuclear Safety-Related Applications, Revision 1 to EPRI NP-5652 and TR-102260," dated September 2014 (ADAMS Accession No. ML14265A198) is currently under review, for the potential approval for use, by the NRC staff.

- No Action

  Under this alternative, the NRC staff would rely on existing regulations and guidance documents. No changes to regulatory language would be proposed. The staff believes that to take no action would result in the continuance of the Part 21 problems and lack of clarity discussed above which are significant enough to warrant action. Therefore, the "no action" alternative is not a preferred option.

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NQA-1-2008, Part II, Subpart 2.14, “Sampling Plans Utilized To Select Items for Special Test(s), Inspection(s), and/or Analysis Shall Have an Adequate Technical Basis Based on Established Standards That Consider Lot Traceability, Homogeneity, and the Complexity of the Item.”

NQA-1a-2009, Part II, Subpart 2.14, “Sampling Plans Utilized To Select Items for Special Test(s), Inspection(s) and/or Analyses Shall Be Based Upon Standard Statistical Methods with Supporting Engineering Justification and Shall Consider Lot/Batch Traceability, Homogeneity, and the Complexity of the Item.”

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U.S. Nuclear Regulatory Commission, "Approval of AREVA Enrichment Services Part 21 Exemption Request," July 28, 2010 (ADAMS Accession No. ML110140636).

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CHAPTER 4
ADMINISTRATIVE CHANGES

The following potential change to the rule language would correct an omission error in the current language of Part 21. It may be made as part of this rulemaking or as part of the occasional rulemakings that the NRC conducts to address such matters.[18]

i. Addition of Reference to 10 CFR Part 76 Facilities to the Definition of Substantial Safety Hazard

Substantial safety hazard is defined in 10 CFR 21.3 as follows:

> Substantial safety hazard means a loss of safety function to the extent that there is a major reduction in the degree of protection provided to public health and safety for any facility or activity licensed or otherwise approved or regulated by the NRC, other than for export, under Parts 30, 40, 50, 52, 60, 61, 63, 70, 71, or 72 of this chapter.

The definition omits facilities regulated under 10 CFR Part 76, "Certification of Gaseous Diffusion Plants." To address this omission, the staff is considering the addition of reference to Part 76 facilities to the definition of substantial safety hazard, to provide regulatory clarity and consistency.

[18] An example of such a rulemaking would be the Miscellaneous Corrections rulemaking published on December 12, 2013 (78 FR 75449).

References

U.S. Nuclear Regulatory Commission, *Federal Register,* Vol. 60, September 19, 1995, p. 48373.

U.S. Nuclear Regulatory Commission, *Federal Register,* Vol. 72, August 28, 2007, p. 49486.

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U.S. Nuclear Regulatory Commission, "Questions Asked at the 2011 Fuel Cycle Information Exchange Related to Title 10 of the *Code of Federal Regulations* Part 21" (ADAMS Accession No. ML11259A039).

CHAPTER 5

BACKFITTING AND ISSUE FINALITY, SAFETY GOAL EVALUATION, COMPLIANCE WITH NEPA, REGULATORY FLEXIBILITY ANALYSIS, INFORMATION COLLECTION REQUIREMENTS APPLICABILITY, COST/IMPACT CONSIDERATIONS, AND NEED FOR PEER REVIEW

This chapter presents the staff's preliminary evaluations on a variety of subjects that must be addressed in rulemaking. The staff developed the preliminary evaluations for two reasons: (i) development of the preliminary evaluation helped the staff identify appropriate alternatives for addressing the staff-identified issues; and (ii) publication of the draft preliminary evaluations for public comment (as part of this draft Regulatory Basis document) allowed the staff to obtain the benefit of early external stakeholder input on these subjects, to help finalize this Regulatory Basis document.

The preliminary evaluations in this chapter are not final, and will be further refined by the staff if the Part 21 rulemaking proceeds through to the development of a proposed rule. If a proposed Part 21 rule is published in the *Federal Register* for public comment, then that Federal Register notice of proposed rulemaking will include the NRC's formal proposed positions on these subjects. All external stakeholders will then have an opportunity to comment on the NRC's proposed positions on these subjects.

Backfitting and Issue Finality

This regulatory basis describes proposed changes to the current Part 21 regulatory structure via rulemaking in two main subject areas. First, updating the requirements for evaluation and reporting of defects and noncompliance, as discussed in this regulatory basis, would entail:

- Adding a definition for basic component that is specific to Part 70 licensees;
- Revising the definition of discovery, to expressly address the time allowed for discovery and more clearly delineate what matters are subject to the discovery process;
- Revising the definition of defect, to simplify the verbiage;
- Revising the definition of delivery, to minimize misinterpretation and clarify the delineation of evaluating and reporting responsibility between purchaser and supplier;
- Revising 10 CFR 21.21(c), to clarify that reports of defects under 10 CFR 50.72, 10 CFR 50.73, or 10 CFR 73.71 satisfy the evaluation, notification, and reporting obligations under this part;
- Removing 10 CFR 50.55(e) and corresponding definitions in 10 CFR 50.2 and adopting analogous requirements in Part 21;

In a number of areas where rule changes are not proposed, the regulatory basis recommends providing regulatory guidance on an acceptable approach for compliance with evaluating and reporting requirements; guidance addressing the concept of the link between the quality assurance requirements and Part 21; guidance on the responsibilities for communication between purchasers and suppliers; guidance on deferral of evaluation under 10 CFR 21.21(b); guidance on the process for reporting Part 21 issues under reporting mechanisms other than 10 CFR 21.21(d)(4); guidance addressing evaluation and reporting of CFSI under Part 21; guidance on the use of contemporary posting methods; guidance on the training requirements

for personnel performing activities under Part 21; and guidance for Part 21 evaluation and reporting requirements for Part 70 fuel cycle facilities.

Second, updating and clarifying the text of Part 21 would clarify the requirements for the commercial grade dedication process, as discussed in this document, would entail:

- Restructuring Part 21 to separate evaluation and reporting requirements from commercial grade dedication requirements. This change would include the addition of 10 CFR 21.71, "Commercial Grade Dedication Requirements";
- Revising the definition of dedication, by simplifying the definition and moving the implementing details to a separate section;
- Revising the definition of dedicating entity, by simplifying the definition so that it would apply to all reactor and nonreactor facilities;
- Revising the definition of commercial grade item, to clarify the definition and make it equivalent for reactor and nonreactor facilities;
- Revising the definition of basic component, to align it with the definition of safety-related for reactor facilities;

In addition, this regulatory basis recommends providing guidance in the following three areas: dedication of commercial grade items, including (1) clarifying the applicability of quality assurance requirements for facilities subject to Appendix B of 10 CFR Part 50 and (2) describing how fuel cycle facilities may satisfy the requirements of commercial grade dedication by implementing existing management measures programs under Part 70; use of sampling in commercial grade dedication; and dedication of software.

Entities That Are Provided With Backfitting Protection

Part 21 currently applies to all production and utilization facilities licensed under Parts 50 and 52, all fuel cycle facilities licensed under Part 70, independent spent fuel storage installations (ISFSI) or monitored retrievable storage (MRS) installations licensed under Part 72, gaseous diffusion plants that seek or hold a certificate of compliance from the NRC under Part 76, geologic repositories for the disposal of high-level radioactive waste under Part 60 or 63, and suppliers of basic components for facilities or activities licensed, other than for export, under Parts 30, 40, 50, 52, 60, 61, 63, 70, 71, and 76. Of these entities, only power reactors licensed under Part 50, fuel cycle facilities licensed under Part 70, ISFSI and MRS licensees under Part 72, and gaseous diffusion plants under Part 76[19] are accorded backfitting protection. In addition, licensees, Design Certification Rule applicants, and design approval holders under Part 52 are covered by issue finality provisions in 10 CFR 52.39, 52.63, 52.98, 52.145, and 52.171.

Administrative Change That Is Not Subject to Backfitting Considerations

Addition of reference to Part 76 facilities to the definition of substantial safety hazard in 10 CFR 21.3 does not result in new provisions in the Commission rules or the imposition of a regulatory staff position interpreting the Commission rules that is either new or different from a previous NRC staff position. Therefore, it is not subject to backfitting considerations.

[19] Part 76 was promulgated with exclusive applicability to Portsmouth and Paducah Gaseous Diffusion Plants, both of which have ceased to operate and have been decertified.

Information Collection and Reporting

This regulatory basis document describes proposed changes to existing information collection and reporting requirements in Part 21. Information collection and reporting requirements, the primary purpose of which is to support NRC regulatory oversight, rather than achievement of substantive regulatory objectives (such as radiological health and safety and common defense and security), are not subject to backfitting consideration and issue finality regulations. The rationale underlying this interpretation is that information collection and reporting requirements would be difficult to characterize as involving adequate protection, and they usually do not result in improvements to radiological health and safety and common defense and security. The staff's determination that certain evaluation and reporting requirements in Part 21 are information collection requirements not subject to backfitting and issue finality regulations is consistent with past rulemakings published in the Federal Register (e.g., 56 FR 55991 published on October 31, 1991, 67 FR 78130 published on December 23, 2002; and 73 FR 32453 published on June 9, 2008).

The staff has determined that the proposed rulemaking in the following areas falls within the category of information collection and reporting requirements: clarification of discovery; clarification of defect; use of licensee event reporting under Parts 72 and 73; notifications made under 10 CFR 21.21(d)(2); and evaluation of counterfeit, fraudulent, and suspect items.

Proposed Guidance and Clarification of Existing Requirements Not Subject to Backfitting

This regulatory basis document proposes rulemaking to clarify the concept of delivery. Although delivery is not currently defined in the regulations, the staff does not consider this proposed change to be backfitting because the existing staff position with regard to delivery was documented in NUREG-0302.

The staff is also considering rule change to remove 10 CFR 50.55(e) requirements and the corresponding definitions in 10 CFR 50.2 and adoption of analogous requirements in Part 21. The staff does not consider this change to be backfitting because the requirements in 10 CFR 50.55(e) are largely the same as Part 21 and the relocation of requirements would not change any underlying substantive regulatory requirement. Therefore, this change is not subject to backfitting considerations.

In addition to proposing rule changes, this regulatory basis document proposes issuance of guidance on the inclusion of quality requirements in procurement documents, which is intended to further clarify existing staff's position and provide an acceptable approach for compliance with Part 21 requirements. The staff does not consider providing such guidance to be backfitting.

Commercial Grade Dedication for Power Reactor Licensees

Provisions in the proposed rulemaking addressing commercial grade dedication for power reactor licensees would not constitute a new requirement or changed position within the definition of backfitting in the backfitting provisions in Part 50 and would not be inconsistent with the issue finality provisions in Part 52.

In NRC Generic Letter (GL) 89-02, "Action to Improve the Detection of Counterfeit and Fraudulently Marked Products," the staff described its perspective on good practices in procurement and dedication and provided the NRC's conditional endorsement of industry-developed guidelines on methods of commercial grade dedication. The NRC

conducted inspections at licensee facilities, which identified several programmatic deficiencies in the control of licensee dedication processes.

In response to the findings of these inspections, the staff developed and published an Advance Notice of Proposed Rulemaking (ANPR), "Acceptance of Products Purchased for Use in Nuclear Plant Structures, Systems, and Components" in the Federal Register (54 FR 9229; March 6, 1989). The ANPR solicited public comments on the need for regulatory actions to effect improvements for procurement, receipt inspection, and testing, and dedication programs.

The NRC also issued GL 91-05, "Licensee Commercial-Grade Procurement and Dedication Programs." The GL outlined staff positions regarding commercial grade procurement and dedication programs which would provide acceptable methods to meet regulatory requirements and identified a number of failures in licensees' commercial grade dedication programs identified during inspections performed by the staff during 1986 through 1989.

From February 1991 to June 1992, the NRC conducted eight assessments and five pilot inspections of licensee procurement and dedication programs. Although weaknesses in the implementation of licensees' procurement and dedication programs still existed, the staff noted that, generally, licensees' dedication programs had improved. In November 1994, the staff forwarded to the Commission SECY-94-277, "Withdrawal of Advance Notice of Proposed Rulemaking, 'Acceptance of Products Purchased For Use in Nuclear Power Plant Structures, Systems, and Components'," by which the staff requested Commissions' approval to withdraw the ANPR. The staff's request for withdrawal of the ANPR was based on the conclusion that the nuclear industry had made significant progress toward improving its procurement and commercial grade dedication programs. The conclusion was drawn from the requested public comment, discussions with industry and staff, and the findings of inspections and assessments.

Recently, with the revival of the vendor inspection program, the staff resumed inspection of dedicating entities. During these inspections, the staff identified several programmatic deficiencies in the control of dedication processes. The staff determined that the effectiveness of commercial grade dedication programs has decreased, and once again, is considering the need for rulemaking in this area.

In conclusion, the staff finds that the expectations for commercial grade procurement and dedication programs have been previously outlined in generic communications published in 1989 and 1991. Therefore, the staff believes that no new requirements or expectations with regard to commercial grade dedication are being introduced in this rulemaking.

Commercial Grade Dedication for Nonreactor Facilities

Provisions in the proposed rulemaking addressing certain elements of commercial grade dedication for nonreactor facilities would not constitute a new requirement or changed position within the definition of backfitting in the backfitting provisions in 10 CFR 70.76.

Fuel cycle facility licensees that are required to comply with Subpart H to 10 CFR Part 70 but not Appendix B to 10 CFR Part 50

The issuance of guidance in conjunction with the rulemaking effort will seek to clarify that the implementation of management measures programs for fuel cycle facilities that are not subject to Appendix B satisfies the elements of commercial grade dedication. Issuance of this guidance is consistent with current licensee practices and aligns with the existing text in Part 21

related to dedication for nonreactors. Because the staff is not introducing new requirements or expectations with regard to commercial grade dedication for nonreactor facilities (namely fuel cycle facilities that are not subject to Appendix B) in this rulemaking or the proposed guidance associated with the rulemaking, the guidance proposed for this subject is not a backfit.

Fuel cycle facility licensees that are required to comply with Subpart H to 10 CFR Part 70 and Appendix B to 10 CFR Part 50

The scope of fuel cycle facilities that are subject to the requirements of Appendix B to 10 CFR Part 50 by regulation is limited to fuel fabrication facilities that process plutonium. Only one such facility currently exists, and that facility performs commercial grade dedication using methodology that is consistent with the guidance in EPRI NP-5652 and comparable to the dedication process performed at power reactor facilities.

The rulemaking will seek to align the basic commercial grade dedication requirements for fuel cycle facilities subject to the requirements of Appendix B to 10 CFR Part 50 with the commercial grade dedication requirements for power reactors since both entities perform the same basic elements of commercial grade dedication (i.e., identification of critical characteristics, designation of acceptance criteria, and verification that an item meets the acceptance criteria for each critical characteristic). For both power reactors and fuel cycle facilities subject to the requirements of Appendix B to 10 CFR Part 50, dedication is performed in accordance with the requirements of Appendix B to 10 CFR Part 50.

The staff notes that it has approved a graded quality assurance program for this plutonium processing facility that applies QA elements consistent with the risk reduction attributable to an IROFS (ADAMS Accession No. ML13127A456).

For both IROFS of high and low safety significance, the basic principles of the dedication practice described above are performed. Further, the applicability of Appendix B to the dedication process and Part 21 to the item designated as a basic component upon completion of the dedication process is maintained. As such, the delineation of dedication requirements applicable to fuel cycle facilities that are subject to Appendix B as part of a new section in the Part 21 rule does not represent the introduction of new requirements or expectations for dedication for this facility. Nor does this proposed change alter the applicability of existing license provisions for this licensee. For these reasons, the staff does not believe that the description of commercial grade dedication requirements as part of a new section of Part 21 rule text constitutes a backfit.

<u>Requirements Not Falling Into Any of the Categories of Backfitting Rationales</u>

For the proposed regulatory revisions that do not fall into any of the above categories of backfitting rationales, the NRC staff would need to develop the information necessary to address applicable backfitting and issue finality requirements, in developing the proposed rule. In some cases, one of the exceptions from the requirement to conduct a backfit analysis may apply. In other cases, the staff would need to perform a backfit analysis, to determine whether the applicable option would result in substantial increase in the overall protection of the public health and safety and the common defense and security, and determine that the costs of implementing that option would be justified, in view of this increased protection.

Safety Goal Evaluation

Safety goal evaluations are applicable to regulatory initiatives considered to be generic enhancement backfits subject to the substantial additional protection standard at 10 CFR 50.109(a)(3).[20] The proposed regulatory changes addressed in this regulatory basis may potentially include generic enhancement backfitting, for which a safety goal evaluation must be prepared under NUREG/BR-0058.

Typically, a safety goal evaluation requires a quantitative determination of risk for a proposed action. For this Part 21 rulemaking, however, the staff may be unable to quantify the change in risk due to the proposed rule changes. This is because of the large variety of items that are manufactured as basic components and commercial grade items that are dedicated to become basic components. The data available to conduct a quantitative evaluation is insufficient and has too much uncertainty. Thus, given a variety of components and their applications, the staff would not be able to make reasonable assumptions to prepare well-informed estimates of changes to core damage frequency. Therefore, a quantitative safety goal evaluation cannot be performed.

A qualitative safety goal evaluation of Part 21 rulemaking will be undertaken during the proposed rule stage. The safety goal evaluation will discuss the safety benefits provided by the proposed rulemaking, which will include the following considerations:

- For proposed rule changes related to accurate and timely reporting of defects under Part 21, the increased level of safety is provided by the reduced probability of failure in a basic component while it is performing a safety function;

- For proposed rule changes related to Part 21 commercial grade dedication, the safety gain is provided by reducing the likelihood of improper dedication of commercial-grade items and reducing the adverse impact of dedicated items where they cannot perform their safety functions.

[20] NUREG-BR-0058, "Regulatory Analysis Guidelines of the U.S. Nuclear Regulatory Commission," Revision 4 (ADAMS Accession No. ML042820192).

Compliance with NEPA

A rulemaking to clarify Part 21 would not be a major Federal action significantly affecting the quality of human environment and, therefore, an environmental impact statement would not be required. The NRC developed regulations that implement the National Environmental Policy Act in 10 CFR Part 51, "Environmental Protection Regulations for Domestic Licensing and Related Regulatory Functions." During the proposed rule phase, the proposed rule language will be analyzed for its potential adverse effects on the environment. The recommendations of this regulatory basis provide regulatory clarity and the NRC doesn't foresee the amendments to Part 21 having any adverse impact on the environment, because better identification, evaluation, and reporting of defects and failures to comply in basic components may reduce the possibility and severity of accidents. An environmental assessment likely would conclude that such reductions would constitute a positive environmental impact, when compared against current conditions under the existing Part 21 and 10 CFR 50.55(e) requirements.

Regulatory Flexibility Analysis

The Regulatory Flexibility Act,[21] enacted in September 1980, requires agencies to consider the impact of their regulatory proposals on small entities, analyze alternatives that minimize small entity impacts, and make their analyses available for public comment.

There are approximately 2,000 licensees and other organizations subject to Part 21. The exact number entities subject to Part 21 that fall within the definition of "small entities" set forth in the size standards established by the NRC in 10 CFR 2.810 is not known. However, the staff believes that small entities subject to the reporting requirements of 10 CFR Part 21 would be most likely involved in supplying basic components or services associated with basic components to licensees. Part 21 permits a supplier of basic components, for example, a small entity, to reduce the burden associated with evaluation and reporting of defects and noncompliance by transferring that responsibility to the purchaser. Therefore, such a rulemaking would not have a significant economic impact on small entities.

Information Collection Requirements Applicability

The recommendations of this regulatory basis would not require entities subject to Part 21 to submit additional information to the NRC or to change the frequency or burden associated with current information collection requirements. These recommendations clarify those information collection requirements already required by NRC regulations. A more detailed analysis of information collections requirements will be performed during the proposed rule phase.

Impact of Proposed Rule

The recommendations of this regulatory basis, if pursued, may impact certain entities listed in the scope of 10 CFR 21.2, "Scope." For example, licensees would be required to update their procedures to reflect the clarifications suggested by this regulatory basis. Further, the suggestions of this regulatory basis would provide some flexibility in posting requirements that may be considered regulatory relief for some entities. The staff will develop a more detailed impact statement, as necessary, as part of any rule proposed as a result of this regulatory basis.

[21] Regulatory Flexibility Act, Pub. L. No. 96-354, 94 Stat. 1164 (codified at 5 U.S.C § 601).

Impact on State, Local, or Tribal Governments

The proposed changes are unlikely to affect State and local government resources. Part 21 regulations are designated as non-essential for Agreement States Agreement State authorities would not be required to adopt a similar requirement for their licensees. As a result, State and local resource needs would be minimal.

Impact on the NRC

The NRC expects the rulemaking recommended by this regulatory basis to have a minimal impact in terms of one-time expenditures by the agency. The NRC expects to continue to perform Part 21 inspections on a sampling basis with the same frequency as is currently employed and to require no additional budget for the review of updated Part 21 programs. However, the NRC will need to issue the recommended rulemaking and the associated regulatory guides and to revise the implementation guidelines and inspection procedures. These activities would result in a one-time cost to the NRC of approximately 10 full time equivalents. However, after that, the NRC does not expect that the recommended rulemaking will result in a substantial increase in annual expenditures of agency resources. If the NRC pursues rulemaking as a result of this regulatory basis, the working group established for this rulemaking effort will develop a more detailed assessment of the impact on the agency.

Need for Peer Review of the Regulatory Basis

The Office of Management and Budget's (OMB's) "Final Information Quality Bulletin for Peer Review"[22] requires each Federal agency to subject "influential scientific information" to peer review, prior to dissemination. The OMB defines "influential scientific information" as "scientific information the agency reasonably can determine will have or does have a clear and substantial impact on important public policies or private sector decisions." This regulatory basis document does not contain "influential scientific information." Therefore, a peer review of this regulatory basis is not required.

[22] Office of Management and Budget, "Final Information Quality Bulletin for Peer Review," dated December 16, 2004.

CHAPTER 6
SCHEDULE

If the NRC pursues rulemaking as a result of this regulatory basis, the agency would implement its recommendations through a proposed rule scheduled for completion in 2016, resolution of public comments, and a final rule scheduled for completion in 2018. After completion of the proposed rule's regulatory basis in 2015, a working group established for the rulemaking effort would develop a more detailed schedule for the proposed and final rule and its associated guidance documents.

APPENDIX A
PRELIMINARY DRAFT RULE LANGUAGE

NOTE:

This preliminary draft rule language was issued by the NRC staff to to facilitate NRC interactions with the public on this regulatory basis document, which the NRC staff developed to support possible rulemaking on Part 21. This preliminary rule language has not been reviewed or approved by the Commission, and does not constitute either a formal NRC proposal or staff recommendation.

PART 21 — REPORTING OF DEFECTS AND NONCOMPLIANCE

GENERAL PROVISION

Sec.
21.1 Purpose.
21.2 Scope.
21.3 Definitions.
21.4 Interpretations.
21.5 Communications.
21.6 Posting requirements.
21.7 Exemptions.
21.8 Information collection requirements: OMB approval.

NOTIFICATION

21.21 Notification of failure to comply or existence of a defect and its evaluation.

PROCUREMENT DOCUMENTS

21.31 Procurement documents.

INSPECTIONS, RECORDS

21.41 Inspections.
21.51 Maintenance and inspection of records.

ENFORCEMENT

21.61 Failure to notify.
21.62 Criminal penalties.

COMMERCIAL GRADE DEDICATION

21.71 Commercial grade dedication requirements.

Authority: Atomic Energy Act secs. 161, 223, 234, 1701 (42 U.S.C. 2201, 2273, 2282, 2297f); Energy Reorganization Act secs. 201, 206 (42 U.S.C. 5841, 5846); Government Paperwork Elimination Act sec. 1704 (44 U.S.C. 3504 note).

Section 21.2 also issued under Nuclear Waste Policy Act secs. 135 and 141 (42 U.S.C. 10155, 10161).

GENERAL PROVISIONS

§ 21.1 Purpose.

The regulations in this part establish procedures and requirements for implementation of section 206 of the Energy Reorganization Act of 1974. That section requires any individual director or responsible officer of a firm constructing, owning, operating or supplying the components of any facility or activity which is licensed or otherwise regulated pursuant to the Atomic Energy Act of 1954, as amended, or the Energy Reorganization Act of 1974, who obtains information reasonably indicating: (a) That the facility, activity or basic component supplied to such facility or activity fails to comply with the Atomic Energy Act of 1954, as amended, or any applicable rule, regulation, order, or license of the Commission relating to substantial safety hazards or (b) that the facility, activity, or basic component supplied to such facility or activity contains defects, which could create a substantial safety hazard, to immediately notify the Commission of such failure to comply or such defect, unless he has actual knowledge that the Commission has been adequately informed of such defect or failure to comply.

§ 21.2 Scope.

(a) The regulations in this part apply, except as specifically provided otherwise in parts 31, 34, 35, 39, 40, 60, 61, 63, 70, or Part 72 of this chapter, to each individual, partnership, corporation, dedicating entity, or other entity doing business within the United States, and each director and responsible officer of such an organization, that:

(1) Applies for or holds a license or permit under the regulations in this chapter to possess, use, or transfer within the United States source material, byproduct material, special nuclear material, and/or spent fuel and high-level radioactive waste, or to construct, manufacture, possess, own, operate, or transfer within the United States, any production or utilization facility or independent spent fuel storage installation (ISFSI) or monitored retrievable storage installation (MRS);

(2) Constructs a production or utilization facility licensed for manufacture, construction, or operation under parts 50 or 52 of this chapter, an ISFSI for the storage of spent fuel licensed under Part 72 of this chapter, an MRS for the storage of spent fuel or high-level radioactive waste under Part 72 of this chapter, or a geologic repository for the disposal of high-level radioactive waste under parts 60 or 63 of this chapter;

(3) Applies for a design certification rule under Part 52 of this chapter;

(4) Applies for or holds a standard design approval under Part 52 of this chapter;

(5) Supplies basic components for a facility or activity licensed under parts 30, 40, 50, 52, 60, 61, 63, 70, 71, or part 72 of this chapter, other than for export;

(b) Reporting of defects under §§ 50.72, 50.73, or § 73.71 of this chapter, satisfies each person's evaluation, notification, and reporting obligation to report defects under this part, and the responsibility of individual directors and responsible officers of these licensees to report defects under Section 206 of the Energy Reorganization Act of 1974. However, in the event, the evaluation of a deviation under the guidance for §§ 50.72, 50.73, or § 73.71 does not result in a report, each individual, partnership, corporation, dedicating entity, or other entity doing business within the United States, and each director and responsible officer of such an organization must ensure that the evaluation also meets Part 21 and its associated guidance to ensure Part 21 reporting is completely satisfied.

(c) Nothing in these regulations should be deemed to preclude either an individual, a manufacturer, or a supplier of a commercial grade item (as defined in § 21.3) not subject to the regulations in this part from reporting to the Commission, a known or suspected defect or failure to comply and, as authorized by law, the identity of anyone so reporting will be withheld from disclosure. NRC regional offices and headquarters will accept collect telephone calls from individuals who wish to speak to NRC representatives concerning nuclear safety-related problems. The location and telephone numbers of the four regions (answered during regular working hours), are listed in appendix D to part 20 of this chapter. The telephone number of the NRC Operations Center (answered 24 hours a day—including holidays) is (301) 816-5100.

(d) The regulations in this part apply in accordance with 10 CFR 76.60 to each individual, partnership, corporation, or other entity required to obtain a certificate of compliance or an approved compliance plan under Part 76 of this chapter.

§ 21.3 Definitions.

As used in this part:

Basic component. (1)(i) When applied to nuclear power plants licensed under 10 CFR Part 50 or Part 52 of this chapter, a basic component means a structure, system, component, or part thereof relied upon to remain functional during and following design basis events to assure:

(A) The integrity of the reactor coolant pressure boundary;

(B) The capability to shut down the reactor and maintain it in a safe shutdown condition; or

(C) The capability to prevent or mitigate the consequences of accidents which could result in potential offsite exposures comparable to those referred to in § 50.34(a)(1), § 50.67(b)(2), or § 100.11 of this chapter.

(ii) Basic components are controlled under a quality assurance program complying with Appendix B to Part 50 of this chapter.

(2) When applied to facilities and activities licensed under 10 CFR Part 70 of this chapter and subject to the requirements of Subpart H of Part 70, basic component means a structure, system, or component (SSC), or any part thereof that affects the SSC's safety function, that is designated as an item relied on for safety in accordance with § 70.61, is directly procured by the licensee, and in which a defect or failure to comply with any applicable regulation in this chapter, order, or license issued by the Commission could cause the performance requirements of § 70.61 to be exceeded. The SSC is not a basic component if diverse SSCs (but not redundant SSCs) exist whose independent action could prevent the performance requirements of § 70.61 from being exceeded.

(3) When applied to facilities and activities licensed under 10 CFR Parts 30, 40, 50 (other than nuclear power plants), 60, 61, 63, 70 (other than facilities subject to the requirements of Subpart H of Part 70), 71, 72, or 76 of this chapter, basic component means a structure, system, or component, or part thereof, that affects their safety function, that is directly procured by the licensee of a facility or activity subject to the regulations in this part and in which a defect or failure to comply with any applicable regulation in this chapter, order, or license issued by the Commission could create a substantial safety hazard.

(4) Basic components include all activities affecting the safety-related functions of those structures, systems, and components, including, design, analysis, inspection, testing, fabrication, replacement of parts, services, software, or

information within the scope of a design certification or early site permit under part 52 of this chapter.

Commercial grade item means an item that is not a basic component.

Commission means the Nuclear Regulatory Commission or its duly authorized representatives.

Constructing or construction means the analysis, design, manufacture, fabrication, placement, erection, installation, modification, inspection, or testing of a facility or activity which is subject to the regulations in this part and services related to the facility or activity that are safety related.

Critical characteristics are those important design, material, and performance characteristics of a commercial grade item that, once verified, will provide reasonable assurance that the item will perform its intended safety function.

Dedicating entity means the organization that performs the dedication process.

Dedication is 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.

Defect means a deviation in a basic component delivered to a purchaser that could create a substantial safety hazard.

Delivery means acceptance of a basic component through a formal process (i.e. receipt inspection). Once a basic component has accepted by a purchaser, the purchaser bears the responsibility for the evaluation and reporting, pursuant to § 21.21(a).

Deviation means a departure from the technical requirements included in a procurement document, or specified in early site permit information, a standard design certification or standard design approval.

Director means an individual, appointed or elected according to law, who is authorized to manage and direct the affairs of a corporation, partnership or other entity. In the case of an individual proprietorship, director means the individual.

Discovery means the documentation that identifies the existence of a deviation or failure to comply through a problem identification program (e.g., in accordance with the corrective action program required by appendix B to part 50 of this chapter, for entities subject to part 50 or 52).

Failure to comply means any failure to comply with the Atomic Energy Act of 1954, as amended or any applicable rule, regulation, order, or license of the Commission.

Evaluation means the process of determining whether a deviation or failure to comply could create a substantial safety hazard.

Notification means the telephonic communication to the NRC Operations Center or written transmittal of information to the NRC Document Control Desk.

Operating or operation means the operation of a facility or the conduct of a licensed activity which is subject to the regulations in this part and consulting services related to operations that are safety-related.

Procurement document means a contract that defines the requirements which facilities or basic components must meet in order to be considered acceptable by the purchaser.

Responsible officer means the president, vice-president or other individual in the organization of a corporation, partnership, or other entity who is vested with executive authority over activities subject to this part.

Substantial safety hazard means a loss of safety function to the extent that there is a major reduction in the degree of protection provided to public health and safety for any facility or activity licensed or otherwise approved or regulated by the NRC, other

than for export, under parts 30, 40, 50, 52, 60, 61, 63, 70, 71, 72, or 76 of this chapter.

Supplying or supplies means contractually responsible for a basic component used or to be used in a facility or activity which is subject to the regulations in this part.

[42 FR 28893, June 6, 1977; 42 FR 36803, July 18, 1977, as amended at 43 FR 48622, Oct. 19, 1978; 46 FR 58283, Dec. 1, 1981; 47 FR 57480, Dec. 27, 1982; 56 FR 36089, July 31, 1991; 59 FR 5519, Feb. 7, 1994; 60 FR 48373, Sept. 19, 1995; 61 FR 65171, Dec. 11, 1996; 64 FR 72000, Dec. 23, 1999; 66 FR 55790, Nov. 2, 2001; 72 FR 49486, Aug. 28, 2007]

§ 21.4 Interpretations.

Except as specifically authorized by the Commission in writing, no interpretation of the meaning of the regulations in this part by any officer or employee of the Commission other than a written interpretation by the General Counsel will be recognized to be binding upon the Commission.

§ 21.5 Communications.

Except where otherwise specified in this part, written communications and reports concerning the regulations in this part must be addressed to the NRC's Document Control Desk, and sent by mail to the U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001; by hand delivery to the NRC's offices at 11555 Rockville Pike, Rockville, Maryland; or, where practicable, by electronic submission, for example, Electronic Information Exchange, or CD–ROM. Electronic submissions must be made in a manner that enables the NRC to receive, read, authenticate, distribute, and archive the submission, and process and retrieve it a single page at a time. Detailed guidance on making electronic submissions can be obtained by visiting the NRC's Web site at http://www.nrc.gov/site-help/e-submittals.html; by e-mail to MSHD.Resource@nrc.gov; or by writing the Office of Information Services, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001. The guidance discusses, among other topics, the formats the NRC can accept, the use of electronic signatures, and the treatment of nonpublic information. In the case of a licensee or permit holder, a copy of the communication must also be sent to the appropriate Regional Administrator at the address specified in appendix D to part 20 of this chapter.

[56 FR 36089, July 31, 1991 as amended at 68 FR 58802, Oct. 10, 2003; 70 FR 69421, Nov. 16, 2005; 72 FR 33386, Jun. 18, 2007; 72 FR 49487, Aug. 28, 2007; 74 FR 62680, Dec. 1, 2009]

§ 21.6 Posting requirements.

(a)(1) Each entity subject to the regulations in this part shall post current copies of—

(i) The regulations in this part;

(ii) Section 206 of the Energy Reorganization Act of 1974; and

(iii) Procedures adopted pursuant to the regulations in this part.

(2) These documents must be posted in a conspicuous position on any premises within the United States where the activities subject to this part are conducted.

(b) If posting of the regulations in this part or the procedures adopted pursuant to the regulations in this part is not practicable, the licensee or firm subject to the regulations in this part may, in addition to posting section 206, post a notice which describes the regulations/procedures, including the name of the individual to whom reports may be made, and states where they may be examined.

[42 FR 28893, June 6, 1977, as amended at 60 FR 48374, Sept. 19, 1995]

§ 21.7 Exemptions.

The Commission may, upon application of any interested person or upon its own initiative, grant such exemptions from the requirements of the regulations in this part as it determines are authorized by law and will not endanger life or property or the common defense and security and are otherwise in the public interest.

[42 FR 28893, June 6, 1977, as amended at 43 FR 48622, Oct. 19, 1978]

§ 21.8 Information collection requirements: OMB approval.

(a) The Nuclear Regulatory Commission has submitted the information collection requirements contained in this part to the Office of Management and Budget (OMB) for approval as required by the Paperwork Reduction Act (44 U.S.C. 3501 et seq.). The NRC may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. OMB has approved the information collection requirements contained in this part under control number 3150-0035.

(b) The approved information collection requirements contained in this part appear in §§ 21.7, 21.21, and 21.51.

[62 FR 52185, Oct. 6, 1997]

NOTIFICATION

§ 21.21 Notification of failure to comply or existence of a defect and its evaluation.

(a) Each entity subject to the regulations in this part shall—

(1) Adopt procedures to ensure that the requirements of paragraphs (a)(2) through (c)(3) of this section are met.

(2) Identify failures to comply, and deviations in basic components that have been delivered and accepted.

(3) Evaluate deviations to identify defects as soon as practicable, and, in all cases within 60 days of discovery, except as provided in paragraph (c)(1) of this section.

(4) Evaluate failures to comply to identify those that could create a substantial safety hazard as soon as practicable, and, in all cases within 60 days of discovery, except as provided in paragraph (c)(1) of this section.

(5) Inform a director or responsible officer as soon as practicable but no later than 5 working days after completion of any evaluation that identifies a defect or failure to comply that could create a substantial safety hazard.

(b) If a supplier determines that it does not have the capability to perform an evaluation, then the supplier must inform the purchasers or affected licensees within five working days of this determination. The purchasers or affected licensees must evaluate the deviation or failure to comply, pursuant to § 21.21(a). The date of discovery for the purchasers or affected licensees shall be the date of the supplier's communication.

(c) A director or responsible officer subject to the regulations of this part or a person designated under § 21.21(f) shall:

(1) Submit a written interim report to the Commission if an evaluation cannot be completed within 60 days from discovery. The interim report shall describe the deviation or failure to comply and shall state when the evaluation will be completed.

(2) Notify the Commission of any evaluation that identifies a defect or failure to comply that could create a substantial safety hazard. Notification must be made as follows—

(i) Initial notification by facsimile, which is the preferred method of notification, to the NRC Operations Center at (301) 816 - 5151 or by telephone at (301) 816 - 5100 within two days following receipt by the director or responsible officer of information on the identification of a defect or a failure to comply that could create a substantial safety hazard. Verification that the facsimile has been received should be made by calling the NRC Operations Center.

(ii) Written notification to the NRC at the address specified in § 21.5 within 30 days following receipt by the director or responsible officer of information on the identification of a defect or a failure to comply that could create a substantial safety hazard.

(3) A written report required by this paragraph shall include, but need not be limited to, the following information, to the extent known:

(i) Name and address of the individual or individuals informing the Commission.

(ii) Identification of the facility, the activity, or the basic component supplied for such facility or such activity within the United States which fails to comply or contains a defect.

(iii) Identification of the firm constructing the facility or supplying the basic component which fails to comply or contains a defect.

(iv) Nature of the defect or failure to comply and the safety hazard which is created or could be created by such defect or failure to comply.

(v) The date on which the information of such defect or failure to comply was obtained.

(vi) In the case of a basic component which contains a defect or fails to comply, the number and location of these components in use at, supplied for, being supplied for, or may be supplied for, manufactured, or being manufactured for one or more facilities or activities subject to the regulations in this part.

(vii) The corrective action which has been, is being, or will be taken; the name of the individual or organization responsible for the action; and the length of time that has been or will be taken to complete the action.

(viii) Any advice related to the defect or failure to comply about the facility, activity, or basic component that has been, is being, or will be given to purchasers or licensees.

(ix) In the case of an early site permit, the entities to whom an early site permit was transferred.

(d) Evaluation, notification, and reporting are not required if the director or responsible officer has knowledge that the Commission has been notified in writing of the defect or the failure to comply that could create a substantial safety hazard.

(e) Reporting of defects under §§ 50.72, 50.73, or § 73.71 of this chapter, satisfies each entity's evaluation, notification, and reporting obligation under this part.

(f) The director or responsible officer may authorize an individual to provide the notification required by this paragraph, provided that this shall not relieve the director or responsible officer of his or her responsibility under this paragraph.

(g) Individuals subject to this part may be required by the Commission to supply additional information related to a defect or failure to comply. Commission action to obtain additional information may be based on reports of defects from other reporting entities.

[42 FR 28893, June 6, 1977, as amended at 46 FR 58283, Dec. 1, 1981; 47 FR 57480, Dec. 27, 1982; 52 FR 31611, Aug. 21, 1987; 56 FR 36089, July 31, 1991; 59 FR 14086, Mar. 25, 1994;

60 FR 48374, Sept. 19, 1995; 66 FR 55790, Nov. 2, 2001; 67 FR 77652, Dec. 19, 2002; 72 FR 49487, Aug. 28, 2007]

PROCUREMENT DOCUMENTS

§ 21.31 Procurement documents.

Each entity subject to the regulations in this part shall specify that the provisions of 10 CFR Part 21 apply when issuing a procurement document for a basic component.

[60 FR 48374, Sept. 19, 1995]

INSPECTIONS, RECORDS

§ 21.41 Inspections.

Each entity subject to the regulations in this part shall permit the Commission to inspect records, premises, activities, and basic components as necessary to accomplish the purposes of this part.

[60 FR 48374, Sept. 19, 1995]

§ 21.51 Preparation, maintenance and inspection of records.

(a) Each entity subject to the regulations in this part shall prepare and maintain records necessary to accomplish the purposes of this part, specifically-

(b) Retain evaluations of all deviations and failures to comply for a minimum of ~~five~~ ten years after the date of the evaluation

(c) Suppliers of basic components must retain:

(1) Any notifications sent to purchasers and affected licensees for a minimum of ten years after the date of the notification.

(2) A record of the purchasers of basic components for 10 years after delivery of the basic component or service associated with a basic component.

(d) Applicants for standard design certification under subpart B of part 52 of this chapter and others providing a design which is the subject of a design certification, during and following Commission adoption of a final design certification rule for that design, shall retain any notifications sent to purchasers and affected licensees for a minimum of 5 years after the date of the notification, and retain a record of the purchasers for 15 years after delivery of design which is the subject of the design certification rule or service associated with the design.

(e) Applicants for or holders of a standard design approval under subpart E of part 52 of this chapter and others providing a design which is the subject of a design approval shall retain any notifications sent to purchasers and affected licensees for a minimum of 5 years after the date of the notification, and retain a record of the purchasers for 15 years after delivery of the design which is the subject of the design approval or service associated with the design.

(f) The holder of a construction permit, combined license, and manufacturing license must prepare and maintain records necessary to accomplish the purposes of this section, specifically—

(1) Retain procurement documents, which define the requirements that facilities or basic components must meet in order to be considered acceptable, for the lifetime of the facility or basic component.
(2) Retain records of evaluations of all deviations and failures to comply for the longest of:
(i) 10 years from the date of the evaluation;
(ii) Five years from the date that an early site permit is referenced in an application for a combined license; or
(iii) Five years from the date of delivery of a manufactured reactor.

[56 FR 36090, July 31, 1991, as amended at 60 FR 48374, Sept. 19, 1995; 72 FR 49488, Aug. 28, 2007]

ENFORCEMENT

§ 21.61 Failure to notify.

(a) Any director or responsible officer of an entity that is not otherwise subject to the deliberate misconduct provisions of this chapter but is subject to the regulations in this part who knowingly and consciously fails to provide the notice required as by § 21.21 shall be subject to a civil penalty equal to the amount provided by section 234 of the Atomic Energy Act of 1954, as amended.
(b) Any entity subject to the regulations in this part who fails to provide the notice required by § 21.21, or otherwise fails to comply with the applicable requirements of this part shall be subject to a civil penalty as provided by Section 234 of the Atomic Energy Act of 1954, as amended.
(c) NRC enforcement action can be taken for failure to identify and evaluate deviations, failure to report defects and failures to comply, or failure to maintain auditable records.

[60 FR 48374, Sept. 19, 1995; 72 FR 49488, Aug. 28, 2007]

§ 21.62 Criminal penalties.

Section 223 of the Atomic Energy Act of 1954, as amended, provides for criminal sanctions for willful violation of, attempted violation of, or conspiracy to violate, any regulation issued under sections 161b, 161i, or 161o of the Act. For purposes of section 223, all the regulations in part 21 are issued under one or more of sections 161b, 161i, or 161o, except for §§ 21.1, 21.2, 21.3, 21.4 21.5, 21.7, 21.8, 21.61, 21.62, and 21.71.

[57 FR 55071, Nov. 24, 1992]

COMMERCIAL GRADE DEDICATION

§ 21.71 Commercial grade dedication

(a)(1) When applied to nuclear power plants licensed under 10 CFR Part 50 or Part 52 of this chapter and fuel fabrication plants licensed under 10 CFR part 70 that engage in plutonium processing, dedication ensures that a commercial grade item is controlled

under a quality assurance program complying with appendix B to Part 50 of this chapter, and is therefore acceptable for use as a basic component. To dedicate an item, a dedicating entity must:

(i) Perform a technical evaluation that identifies the item's critical characteristics.

(ii) Identify acceptance criteria for each critical characteristic.

(iii) Verify that the item meets the acceptance criteria for each critical characteristic using one or more of the following acceptance methods:

(A) Method 1: Special tests and inspections

(B) Method 2: Survey of a commercial grade supplier

(C) Method 3: Source verification (e.g., Product inspections or witness holdpoints)

(D) Method 4: Supplier/Item history (e.g., Historical records for acceptable performance). Method 4 must be based on industry-wide performance data applicable to the item's critical characteristic. Method 4 shall not be used as the sole method of acceptance for all of the item's critical characteristics.

(2) Dedication is complete when all of the item's critical characteristics have been verified and documented.

(3) Dedication must be conducted in accordance with the provisions of 10 CFR Part 50, appendix B.

(4) If any critical characteristic of the item cannot be verified acceptable, that item cannot be dedicated.

(b) When applied to facilities and activities licensed pursuant to 10 CFR Parts 30, 40, 50 (other than nuclear power plants), 60, 61, 63, 70 (other than plutonium processing and fuel fabrication plants), 71, 72, or 76, dedication occurs after receipt when that item is designated for use as a basic component.

§ 50.55 Conditions of construction permits, early site permits, combined licenses, and manufacturing licenses.

Each construction permit is subject to the following terms and conditions; each early site permit is subject to the terms and condition in paragraph (f) of this section; each manufacturing license is subject to the terms and conditions in paragraph (f) of this section; and each combined license is subject to the terms and condition in paragraph (f) of this section until the date that the Commission makes the finding under § 50.52.103(g) of this chapter:

(a) through (d) No Change.

(e) Deleted.

(f) No Change.

APPENDIX B
REDLINE/STRIKEOUT SHOWING DIFFERENCES BETWEEN CURRENT PART 21 AND PRELIMINARY DRAFT RULE LANGUAGE

This Appendix shows the differences between the current language of Part 21 and the NRC staff's preliminary rule language revising Part 21.

The preliminary draft rule language is being issued to facilitate NRC interactions with the public on the regulatory basis which the NRC staff is developing to support possible rulemaking on Part 21. This preliminary rule language has not been reviewed nor approved by the Commission, and does not constitute either formal NRC approval or staff recommendation.

PART 21 — REPORTING OF DEFECTS AND NONCOMPLIANCE

GENERAL PROVISION

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21.61 Failure to notify.
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COMMERCIAL GRADE DEDICATION

21.71 Commercial grade dedication requirements.

Authority: Atomic Energy Act secs. 161, 223, 234, 1701 (42 U.S.C. 2201, 2273, 2282, 2297f); Energy Reorganization Act secs. 201, 206 (42 U.S.C. 5841, 5846); Government Paperwork Elimination Act sec. 1704 (44 U.S.C. 3504 note).

Section 21.2 also issued under Nuclear Waste Policy Act secs. 135 and 141 (42 U.S.C. 10155, 10161).

SOURCE: 42 FR 28893, June 6, 1977, unless otherwise noted.

[77 FR 39905, Jul. 6, 2012]

§ 21.1 Purpose.

The regulations in this part establish procedures and requirements for implementation of section 206 of the Energy Reorganization Act of 1974. That section requires any individual director or responsible officer of a firm constructing, owning, operating or supplying the components of any facility or activity which is licensed or otherwise regulated pursuant to the Atomic Energy Act of 1954, as amended, or the Energy Reorganization Act of 1974, who obtains information reasonably indicating: (a) That the facility, activity or basic component supplied to such facility or activity fails to comply with the Atomic Energy Act of 1954, as amended, or any applicable rule, regulation, order, or license of the Commission relating to substantial safety hazards or (b) that the facility, activity, or basic component supplied to such facility or activity contains defects, which could create a substantial safety hazard, to immediately notify the Commission of such failure to comply or such defect, unless he has actual knowledge that the Commission has been adequately informed of such defect or failure to comply.

§ 21.2 Scope.

(a) The regulations in this part apply, except as specifically provided otherwise in parts 31, 34, 35, 39, 40, 60, 61, 63, 70, or part 72 of this chapter, to~~:~~

~~(1) Each~~ each individual, partnership, corporation, dedicating entity, or other entity doing business within the United States, and each director and responsible officer of such an organization, that:

(1)~~applying~~ Applies for or ~~holding~~ holds a license or permit under the regulations in this chapter to possess, use, or transfer within the United States source material, byproduct material, special nuclear material, and/or spent fuel and high-level radioactive waste, or to construct, manufacture, possess, own, operate, or transfer within the United States, any production or utilization facility or independent spent fuel storage installation (ISFSI) or monitored retrievable storage installation (MRS);~~ and each director and responsible officer of such a licensee;~~

(2) ~~Each individual, corporation, partnership, or other entity doing business within the United States, and each director and responsible officer of such an organization, that constructs~~Constructs a production or utilization facility licensed for manufacture, construction, or operation under parts 50 or 52 of this chapter, an ISFSI for the storage of spent fuel licensed under part 72 of this chapter, an MRS for the storage of spent fuel or high-level radioactive waste under part 72 of this chapter, or a geologic repository for the disposal of high-level radioactive waste under part 60 or 63 of this chapter;~~ or supplies basic components for a facility or activity licensed, other than for export, under parts 30, 40, 50, 52, 60, 61, 63, 70, 71, or part 72 of this chapter;~~

(3) ~~Each individual, corporation, partnership, or other entity doing business within the United States, and each director and responsible officer of such an organization, applying~~Applies for a design certification rule under part 52 of this chapter;~~ or supplying basic components with respect to that design certification, and each individual, corporation, partnership, or other entity doing business within the United States, and each director and responsible officer of such an organization, whose application for design certification has been granted under part 52 of this chapter, or who has supplied or is supplying basic components with respect to that design certification;~~

(4) ~~Each individual, corporation, partnership, or other entity doing business within the United States, and each director and responsible officer of such an organization, applying~~Applies for or ~~holding~~ holds a standard design approval under part 52 of this chapter;

~~or supplying basic components with respect to a standard design approval under part 52 of this chapter;~~

(5) Supplies basic components for a facility or activity licensed under parts 30, 40, 50, 52, 60, 61, 63, 70, 71, or part 72 of this chapter, other than for export;

~~(b) For persons licensed to construct a facility under either a construction permit issued under § 50.23 of this chapter or a combined license under part 52 of this chapter (for the period of construction until the date that the Commission makes the finding under § 52.103(g) of this chapter), or to manufacture a facility under part 52 of this chapter, evaluation of potential defects and failures to comply and reporting of defects and failures to comply under § 50.55(e) of this chapter satisfies each person's evaluation, notification, and reporting obligation to report defects and failures to comply under this part and the responsibility of individual directors and responsible officers of these licensees to report defects under Section 206 of the Energy Reorganization Act of 1974.~~

~~(c) For persons licensed to operate a nuclear power plant under part 50 or part 52 of this chapter, evaluation of potential defects and appropriate reporting of defects under §§ 50.72, 50.73, or § 73.71 of this chapter, satisfies each person's evaluation, notification, and reporting obligation to report defects under this part, and the responsibility of individual directors and responsible officers of these licensees to report defects under Section 206 of the Energy Reorganization Act of 1974.~~

(b) Reporting of defects under §§ 50.72, 50.73, or § 73.71 of this chapter, satisfies each person's evaluation, notification, and reporting obligation to report defects under this part, and the responsibility of individual directors and responsible officers of these licensees to report defects under Section 206 of the Energy Reorganization Act of 1974. However, in the event, the evaluation of a deviation under the guidance for §§ 50.72, 50.73, or § 73.71 does not result in a report, each individual, partnership, corporation, dedicating entity, or other entity doing business within the United States, and each director and responsible officer of such an organization must ensure that the evaluation also meets Part 21 and its associated guidance to ensure Part 21 reporting is completely satisfied.

(~~d~~c) Nothing in these regulations should be deemed to preclude either an individual, a manufacturer, or a supplier of a commercial grade item (as defined in § 21.3) not subject to the regulations in this part from reporting to the Commission, a known or suspected defect or failure to comply and, as authorized by law, the identity of anyone so reporting will be withheld from disclosure. NRC regional offices and headquarters will accept collect telephone calls from individuals who wish to speak to NRC representatives concerning nuclear safety-related problems. The location and telephone numbers of the four regions (answered during regular working hours), are listed in appendix D to part 20 of this chapter. The telephone number of the NRC Operations Center (answered 24 hours a day—including holidays) is (301) 816-5100.

(~~e~~d) The regulations in this part apply in accordance with 10 CFR 76.60 to each individual, partnership, corporation, or other entity required to obtain a certificate of compliance or an approved compliance plan under part 76 of this chapter.

[56 FR 36089, July 31, 1991, as amended at 59 FR 14086, Mar. 25, 1994; 59 FR 48959, Sept. 23, 1994; 60 FR 48373, Sept. 19, 1995; 66 FR 55790, Nov. 2, 2001; 72 FR 49486, Aug. 28, 2007]

§ 21.3 Definitions.

As used in this part:

Basic component. (1)(i) When applied to nuclear power plants licensed under 10 CFR Part 50 or Part 52 of this chapter, a basic component means a structure, system, ~~or~~ component,

or part thereof relied upon to remain functional during and following design basis events~~that affects its safety function necessary~~ to assure:

(A) The integrity of the reactor coolant pressure boundary;

(B) The capability to shut down the reactor and maintain it in a safe shutdown condition; or

(C) The capability to prevent or mitigate the consequences of accidents which could result in potential offsite exposures comparable to those referred to in § 50.34(a)(1), § 50.67(b)(2), or § 100.11 of this chapter~~, as applicable~~.

(ii) Basic components are ~~items designed and manufactured~~controlled under a quality assurance program complying with appendix B to part 50 of this chapter~~, or commercial grade items which have successfully completed the dedication process~~.

(2)~~ When applied to standard design certifications under subpart C of part 52 of this chapter and standard design approvals under part 52 of this chapter, basic component means the design or procurement information approved or to be approved within the scope of the design certification or approval for a structure, system, or component, or part thereof, that affects its safety function necessary to assure:~~

~~(i) The integrity of the reactor coolant pressure boundary;~~

~~(ii) The capability to shut down the reactor and maintain it in a safeshutdown condition; or~~

~~(iii) The capability to prevent or mitigate the consequences of accidents which could result in potential offsite exposures comparable to those referred to in §§ 50.34(a)(1), 50.67(b)(2), or 100.11 of this chapter, as applicable.~~ When applied to facilities and activities licensed under 10 CFR Part 70 of this chapter and subject to the requirements of Subpart H of Part 70, basic component means a structure, system, or component (SSC), or any part thereof that affects the SSC's safety function, that is designated as an item relied on for safety in accordance with § 70.61, is directly procured by the licensee, and in which a defect or failure to comply with any applicable regulation in this chapter, order, or license issued by the Commission could cause the performance requirements of § 70.61 to be exceeded. The SSC is not a basic component if diverse SSCs (but not redundant SSCs) exist whose independent action could prevent the performance requirements of § 70.61 from being exceeded.

(3) When applied to ~~other~~ facilities and ~~other~~ activities licensed under 10 CFR parts 30, 40, 50 (other than nuclear power plants), 60, 61, 63, 70 (other than facilities subject to the requirements of Subpart H of Part 70), 71, 72, or ~~72~~ 76 of this chapter, basic component means a structure, system, or component, or part thereof, that affects their safety function, that is directly procured by the licensee of a facility or activity subject to the regulations in this part and in which a defect or failure to comply with any applicable regulation in this chapter, order, or license issued by the Commission could create a substantial safety hazard.

(4) ~~In all cases, basic~~Basic component~~s~~ include~~s~~ all activities affecting the safety-related functions of those structures, systems, and components, including, ~~safety-related~~ design, analysis, inspection, testing, fabrication, replacement of parts, ~~or consulting~~ services, software, or information within the scope of a design certification or early site permit under part 52 of this chapter~~ that are associated with the component hardware, design certification, design approval, or information in support of an early site permit application under part 52 of this chapter, whether these services are performed by the component supplier or others~~.

Commercial grade item~~. (1) When applied to nuclear power plants licensed pursuant to 10 CFR Part 50, commercial grade item means a structure, system, or component, or part thereof that affects its safety function, that was not designed and manufactured as a basic component. Commercial grade items do not include items where the design and manufacturing process require in-process inspections and verifications to ensure that defects or failures to~~

~~comply are identified and corrected (i.e., one or more critical characteristics of the item cannot be verified).~~

~~(2) When applied to facilities and activities licensed pursuant to 10 CFR Parts 30, 40, 50 (other than nuclear power plants), 60, 61, 63, 70, 71, or 72, commercial grade item means an item that is:~~

~~(i) Not subject to design or specification requirements that are unique to those facilities or activities;~~

~~(ii) Used in applications other than those facilities or activities; and~~

~~(iii) To be ordered from the manufacturer/supplier on the basis of specifications set forth in the manufacturer's published product description (for example, a catalog)~~ means an item that is not a basic component.

Commission means the Nuclear Regulatory Commission or its duly authorized representatives.

Constructing or construction means the analysis, design, manufacture, fabrication, placement, erection, installation, modification, inspection, or testing of a facility or activity which is subject to the regulations in this part and ~~consulting~~ services related to the facility or activity that are safety related.

Critical characteristics~~. When applied to nuclear power plants licensed pursuant to 10 CFR Part 50, critical characteristics~~ are those important design, material, and performance characteristics of a commercial grade item that, once verified, will provide reasonable assurance that the item will perform its intended safety function.

Dedicating entity~~. When applied to nuclear power plants licensed pursuant to 10 CFR Part 50, dedicating entity~~ means the organization that performs the dedication process. ~~Dedication may be performed by the manufacturer of the item, a third-party dedicating entity, or the licensee itself. The dedicating entity, pursuant to § 21.21(c) of this part, is responsible for identifying and evaluating deviations, reporting defects and failures to comply for the dedicated item, and maintaining auditable records of the dedication process.~~

Dedication~~. (1) When applied to nuclear power plants licensed pursuant to 10 CFR Part 30, 40, 50, 60, dedication~~ is 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. This assurance is achieved by identifying the critical characteristics of the item and verifying their acceptability by inspections, tests, or analyses performed by the purchaser or third-party dedicating entity after delivery, supplemented as necessary by one or more of the following: commercial grade surveys; product inspections or witness at holdpoints at the manufacturer's facility, and analysis of historical records for acceptable performance. In all cases, the dedication process must be conducted in accordance with the applicable provisions of 10 CFR Part 50, appendix B. The process is considered complete when the item is designated for use as a basic component.~~

~~(2) When applied to facilities and activities licensed pursuant to 10 CFR Parts 30, 40, 50 (other than nuclear power plants), 60, 61, 63, 70, 71, or 72, dedication occurs after receipt when that item is designated for use as a basic component~~.

Defect means ~~:~~

~~(1) A~~a deviation in a basic component delivered to a purchaser ~~for use in a facility or an activity subject to the regulations in this part if, on the basis of an evaluation, the deviation~~that could create a substantial safety hazard~~;~~

~~(2) The installation, use, or operation of a basic component containing a defect as defined in this section;~~

~~(3) A deviation in a portion of a facility subject to the early site permit, standard design certification, standard design approval, construction permit, combined license or manufacturing~~

licensing requirements of part 50 or part 52 of this chapter, provided the deviation could, on the basis of an evaluation, create a substantial safety hazard and the portion of the facility containing the deviation has been offered to the purchaser for acceptance;

(4) A condition or circumstance involving a basic component that could contribute to the exceeding of a safety limit, as defined in the technical specifications of a license for operation issued under part 50 or part 52 of this chapter; or

(5) An error, omission or other circumstance in a design certification, or standard design approval that, on the basis of an evaluation, could create a substantial safety hazard.

Delivery means acceptance of a basic component through a formal process (i.e. receipt inspection). Once a basic component has accepted by a purchaser, the purchaser bears the responsibility for the evaluation and reporting, pursuant to § 21.21(a).

Deviation means a departure from the technical requirements included in a procurement document, or specified in early site permit information, a standard design certification or standard design approval.

Director means an individual, appointed or elected according to law, who is authorized to manage and direct the affairs of a corporation, partnership or other entity. In the case of an individual proprietorship, director means the individual.

Discovery means the completion of the documentation first that identifying identifies the existence of a deviation or failure to comply through a problem identification program potentially associated with a substantial safety hazard within the evaluation procedures discussed in § 21.21. (a)(e.g., in accordance with the corrective action program required by appendix B to part 50 of this chapter, for entities subject to part 50 or 52.).

Failure to comply means any failure to comply with the Atomic Energy Act of 1954, as amended or any applicable rule, regulation, order, or license of the Commission.

Evaluation means the process of determining whether a particular deviation or failure to comply could create a substantial safety hazard or determining whether a failure to comply is associated with a substantial safety hazard.

Notification means the telephonic communication to the NRC Operations Center or written transmittal of information to the NRC Document Control Desk.

Operating or operation means the operation of a facility or the conduct of a licensed activity which is subject to the regulations in this part and consulting services related to operations that are safety--related.

Procurement document means a contract that defines the requirements which facilities or basic components must meet in order to be considered acceptable by the purchaser.

Responsible officer means the president, vice-president or other individual in the organization of a corporation, partnership, or other entity who is vested with executive authority over activities subject to this part.

Substantial safety hazard means a loss of safety function to the extent that there is a major reduction in the degree of protection provided to public health and safety for any facility or activity licensed or otherwise approved or regulated by the NRC, other than for export, under parts 30, 40, 50, 52, 60, 61, 63, 70, 71, or 72, or 76 of this chapter.

Supplying or supplies means contractually responsible for a basic component used or to be used in a facility or activity which is subject to the regulations in this part.

[42 FR 28893, June 6, 1977; 42 FR 36803, July 18, 1977, as amended at 43 FR 48622, Oct. 19, 1978; 46 FR 58283, Dec. 1, 1981; 47 FR 57480, Dec. 27, 1982; 56 FR 36089, July 31, 1991; 59 FR 5519, Feb. 7, 1994; 60 FR 48373, Sept. 19, 1995; 61 FR 65171, Dec. 11, 1996; 64 FR 72000, Dec. 23, 1999; 66 FR 55790, Nov. 2, 2001; 72 FR 49486, Aug. 28, 2007]

§ 21.4 Interpretations.

Except as specifically authorized by the Commission in writing, no interpretation of the meaning of the regulations in this part by any officer or employee of the Commission other than a written interpretation by the General Counsel will be recognized to be binding upon the Commission.

§ 21.5 Communications.

Except where otherwise specified in this part, written communications and reports concerning the regulations in this part must be addressed to the NRC's Document Control Desk, and sent by mail to the U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001; by hand delivery to the NRC's offices at 11555 Rockville Pike, Rockville, Maryland; or, where practicable, by electronic submission, for example, Electronic Information Exchange, or CD–ROM. Electronic submissions must be made in a manner that enables the NRC to receive, read, authenticate, distribute, and archive the submission, and process and retrieve it a single page at a time. Detailed guidance on making electronic submissions can be obtained by visiting the NRC's Web site at http://www.nrc.gov/site-help/e-submittals.html; by e-mail to MSHD.Resource@nrc.gov; or by writing the Office of Information Services, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001. The guidance discusses, among other topics, the formats the NRC can accept, the use of electronic signatures, and the treatment of nonpublic information. In the case of a licensee or permit holder, a copy of the communication must also be sent to the appropriate Regional Administrator at the address specified in appendix D to part 20 of this chapter.

[56 FR 36089, July 31, 1991 as amended at 68 FR 58802, Oct. 10, 2003; 70 FR 69421, Nov. 16, 2005; 72 FR 33386, Jun. 18, 2007; 72 FR 49487, Aug. 28, 2007; 74 FR 62680, Dec. 1, 2009]

§ 21.6 Posting requirements.

(a)(1) Each ~~individual, partnership, corporation, dedicating entity, or other~~ entity subject to the regulations in this part shall post current copies of—

(i) The regulations in this part;

(ii) Section 206 of the Energy Reorganization Act of 1974; and

(iii) Procedures adopted pursuant to the regulations in this part.

(2) These documents must be posted in a conspicuous position on any premises within the United States where the activities subject to this part are conducted.

(b) If posting of the regulations in this part or the procedures adopted pursuant to the regulations in this part is not practicable, the licensee or firm subject to the regulations in this part may, in addition to posting section 206, post a notice which describes the regulations/procedures, including the name of the individual to whom reports may be made, and states where they may be examined.

~~(c) The effective date of this section has been deferred until January 6, 1978.~~

[42 FR 28893, June 6, 1977, as amended at 60 FR 48374, Sept. 19, 1995]

§ 21.7 Exemptions.

The Commission may, upon application of any interested person or upon its own initiative, grant such exemptions from the requirements of the regulations in this part as it determines are authorized by law and will not endanger life or property or the common defense and security and are otherwise in the public interest. ~~Suppliers of commercial grade items are exempt from the provisions of this part to the extent that they supply commercial grade items.~~

[42 FR 28893, June 6, 1977, as amended at 43 FR 48622, Oct. 19, 1978]

§ 21.8 Information collection requirements: OMB approval.

(a) The Nuclear Regulatory Commission has submitted the information collection requirements contained in this part to the Office of Management and Budget (OMB) for approval as required by the Paperwork Reduction Act (44 U.S.C. 3501 et seq.). The NRC may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. OMB has approved the information collection requirements contained in this part under control number 3150-0035.

(b) The approved information collection requirements contained in this part appear in §§ 21.7, 21.21, and 21.51.

[62 FR 52185, Oct. 6, 1997]

NOTIFICATION

§ 21.21 Notification of failure to comply or existence of a defect and its evaluation.

(a) Each ~~individual, corporation, partnership, dedicating entity, or other~~ entity subject to the regulations in this part shall ~~adopt appropriate procedures to~~—

(1) Adopt procedures to ensure that the requirements of paragraphs (a)(2) through (c)(3) of this section are met.

(2) Identify failures to comply, and deviations in basic components that have been delivered and accepted.

(3) Evaluate deviations to identify defects as soon as practicable, and, in all cases within 60 days of discovery, except as provided in paragraph (c)(1) of this section.

(4) Evaluate failures to comply to identify those that could create a substantial safety hazard as soon as practicable, and, in all cases within 60 days of discovery, except as provided in paragraph (c)(1) of this section.

(5) Inform a director or responsible officer as soon as practicable but no later than 5 working days after completion of any evaluation that identifies a defect or failure to comply that could create a substantial safety hazard.

(b) If a supplier determines that it does not have the capability to perform an evaluation, then the supplier must inform the purchasers or affected licensees within five working days of this determination. The purchasers or affected licensees must evaluate the deviation or failure to comply, pursuant to § 21.21(a). The date of discovery for the purchasers or affected licensees shall be the date of the supplier's communication.

(c) A director or responsible officer subject to the regulations of this part or a person designated under § 21.21(f) shall:

(1) Submit a written interim report to the Commission if an evaluation cannot be completed within 60 days from discovery. The interim report shall describe the deviation or failure to comply and shall state when the evaluation will be completed.

(2) Notify the Commission of any evaluation that identifies a defect or failure to comply that could create a substantial safety hazard. Notification must be made as follows—

(i) Initial notification by facsimile, which is the preferred method of notification, to the NRC Operations Center at (301) 816 - 5151 or by telephone at (301) 816 - 5100 within two days following receipt by the director or responsible officer of information on the identification of a defect or a failure to comply that could create a substantial safety hazard. Verification that the facsimile has been received should be made by calling the NRC Operations Center.

(ii) Written notification to the NRC at the address specified in § 21.5 within 30 days following receipt by the director or responsible officer of information on the identification of a defect or a failure to comply that could create a substantial safety hazard

(3) A written report required by this paragraph shall include, but need not be limited to, the following information, to the extent known:

(i) Name and address of the individual or individuals informing the Commission.

(ii) Identification of the facility, the activity, or the basic component supplied for such facility or such activity within the United States which fails to comply or contains a defect.

(iii) Identification of the firm constructing the facility or supplying the basic component which fails to comply or contains a defect.

(iv) Nature of the defect or failure to comply and the safety hazard which is created or could be created by such defect or failure to comply.

(v) The date on which the information of such defect or failure to comply was obtained.

(vi) In the case of a basic component which contains a defect or fails to comply, the number and location of these components in use at, supplied for, being supplied for, or may be

supplied for, manufactured, or being manufactured for one or more facilities or activities subject to the regulations in this part.

(vii) The corrective action which has been, is being, or will be taken; the name of the individual or organization responsible for the action; and the length of time that has been or will be taken to complete the action.

(viii) Any advice related to the defect or failure to comply about the facility, activity, or basic component that has been, is being, or will be given to purchasers or licensees.

(ix) In the case of an early site permit, the entities to whom an early site permit was transferred.

(d) Notification, and reporting are not required if the director or responsible officer has knowledge that the Commission has been notified in writing of the defect or the failure to comply that could create a substantial safety hazard.

(e) Reporting of defects under §§ 50.72, 50.73, or § 73.71 of this chapter, satisfies each entity's evaluation, notification, and reporting obligation under this part.~~Evaluate deviations and failures to comply to identify defects and failures to comply associated with substantial safety hazards as soon as practicable, and, except as provided in paragraph (a)(2) of this section, in all cases within 60 days of discovery, in order to identify a reportable defect or failure to comply that could create a substantial safety hazard, were it to remain uncorrected, and~~

~~(2) Ensure that if an evaluation of an identified deviation or failure to comply potentially associated with a substantial safety hazard cannot be completed within 60 days from discovery of the deviation or failure to comply, an interim report is prepared and submitted to the Commission through a director or responsible officer or designated person as discussed in § 21.21(d)(5). The interim report should describe the deviation or failure to comply that is being evaluated and should also state when the evaluation will be completed. This interim report must be submitted in writing within 60 days of discovery of the deviation or failure to comply.~~

~~(3) Ensure that a director or responsible officer subject to the regulations of this part is informed as soon as practicable, and, in all cases, within the 5 working days after completion of the evaluation described in paragraphs (a)(1) or (a)(2) of this section if the manufacture, construction, or operation of a facility or activity, a basic component supplied for such facility or activity, or the design certification or design approval under part 52 of this chapter—~~

~~(i) Fails to comply with the Atomic Energy Act of 1954, as amended, or any applicable rule, regulation, order, or license of the Commission or standard design approval under part 52 of this chapter, relating to a substantial safety hazard, or~~

~~(ii) Contains a defect.~~

~~(b) If the deviation or failure to comply is discovered by a supplier of basic components, or services associated with basic components, and the supplier determines that it does not have the capability to perform the evaluation to determine if a defect exists, then the supplier must inform the purchasers or affected licensees within five working days of this determination so that the purchasers or affected licensees may evaluate the deviation or failure to comply, pursuant to § 21.21(a).~~

~~(c) A dedicating entity is responsible for—~~

~~(1) Identifying and evaluating deviations and reporting defects and failures to comply associated with substantial safety hazards for dedicated items; and~~

~~(2) Maintaining auditable records for the dedication process.~~

~~(d)(1) A director or responsible officer subject to the regulations of this part or a person designated under § 21.21(d)(5) must notify the Commission when he or she obtains information reasonably indicating a failure to comply or a defect affecting—~~

~~(i) The manufacture, construction or operation of a facility or an activity within the United States that is subject to the licensing requirements under parts 30, 40, 50, 52, 60, 61, 63, 70, 71, or 72 of this chapter and that is within his or her organization's responsibility; or~~

(ii) A basic component that is within his or her organization's responsibility and is supplied for a facility or an activity within the United States that is subject to the licensing, design certification, or approval requirements under parts 30, 40, 50, 52, 60, 61, 63, 70, 71, or 72 of this chapter.

(2) The notification to NRC of a failure to comply or of a defect under paragraph (d)(1) of this section and the evaluation of a failure to comply or a defect under paragraphs (a)(1) and (a)(2) of this section, are not required if the director or responsible officer has actual knowledge that the Commission has been notified in writing of the defect or the failure to comply.

(3) Notification required by paragraph (d)(1) of this section must be made as follows—

(i) Initial notification by facsimile, which is the preferred method of notification, to the NRC Operations Center at (301) 816 - 5151 or by telephone at (301) 816 - 5100 within two days following receipt of information by the director or responsible corporate officer under paragraph (a)(1) of this section, on the identification of a defect or a failure to comply. Verification that the facsimile has been received should be made by calling the NRC Operations Center. This paragraph does not apply to interim reports described in § 21.21(a)(2).

(ii) Written notification to the NRC at the address specified in § 21.5 within 30 days following receipt of information by the director or responsible corporate officer under paragraph (a)(3) of this section, on the identification of a defect or a failure to comply.

(4) The written report required by this paragraph shall include, but need not be limited to, the following information, to the extent known:

(i) Name and address of the individual or individuals informing the Commission.

(ii) Identification of the facility, the activity, or the basic component supplied for such facility or such activity within the United States which fails to comply or contains a defect.

(iii) Identification of the firm constructing the facility or supplying the basic component which fails to comply or contains a defect.

(iv) Nature of the defect or failure to comply and the safety hazard which is created or could be created by such defect or failure to comply.

(v) The date on which the information of such defect or failure to comply was obtained.

(vi) In the case of a basic component which contains a defect or fails to comply, the number and location of these components in use at, supplied for, being supplied for, or may be supplied for, manufactured, or being manufactured for one or more facilities or activities subject to the regulations in this part.

(vii) The corrective action which has been, is being, or will be taken; the name of the individual or organization responsible for the action; and the length of time that has been or will be taken to complete the action.

(viii) Any advice related to the defect or failure to comply about the facility, activity, or basic component that has been, is being, or will be given to purchasers or licensees.

(ix) In the case of an early site permit, the entities to whom an early site permit was transferred.

(5f) The director or responsible officer may authorize an individual to provide the notification required by this paragraph, provided that, this shall not relieve the director or responsible officer of his or her responsibility under this paragraph.

(eg) Individuals subject to this part may be required by the Commission to supply additional information related to a defect or failure to comply. Commission action to obtain additional information may be based on reports of defects from other reporting entities.

[42 FR 28893, June 6, 1977, as amended at 46 FR 58283, Dec. 1, 1981; 47 FR 57480, Dec. 27, 1982; 52 FR 31611, Aug. 21, 1987; 56 FR 36089, July 31, 1991; 59 FR 14086, Mar. 25, 1994; 60 FR 48374, Sept. 19, 1995; 66 FR 55790, Nov. 2, 2001; 67 FR 77652, Dec. 19, 2002; 72 FR 49487, Aug. 28, 2007]

PROCUREMENT DOCUMENTS

§ 21.31 Procurement documents.

Each ~~individual, corporation, partnership, dedicating entity, or other~~ entity subject to the regulations in this part shall specify that the provisions of 10 CFR Part 21 apply when issuing ~~aensure that each~~ procurement document for a ~~facility, or a~~ basic component ~~issued by him, her or it on or after January 6, 1978, specifies, when applicable, that the provisions of 10 CFR Part 21 apply~~.

[60 FR 48374, Sept. 19, 1995]

INSPECTIONS, RECORDS

§ 21.41 Inspections.

Each ~~individual, corporation, partnership, dedicating entity, or other~~ entity subject to the regulations in this part shall permit the Commission to inspect records, premises, activities, and basic components as necessary to accomplish the purposes of this part.

[60 FR 48374, Sept. 19, 1995]

§ 21.51 Maintenance and inspection of records.

(a) 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—

(b) Retain evaluations of all deviations and failures to comply for a minimum of ~~five~~ ten years after the date of the evaluation

~~(1) Retain evaluations of all deviations and failures to comply for a minimum of five years after the date of the evaluation;~~

(~~2~~c) Suppliers of basic components must retain:

(1) ~~any~~ Any notifications sent to purchasers and affected licensees for a minimum of ~~five~~ ten years after the date of the notification.

(~~3~~2) ~~Suppliers of basic components must retain a~~A record of the purchasers of basic components for 10 years after delivery of the basic component or service associated with a basic component.

(4d) Applicants for standard design certification under subpart B of part 52 of this chapter and others providing a design which is the subject of a design certification, during and following Commission adoption of a final design certification rule for that design, shall retain any notifications sent to purchasers and affected licensees for a minimum of 5 years after the date of the notification, and retain a record of the purchasers for 15 years after delivery of design which is the subject of the design certification rule or service associated with the design.

(~~5~~e) Applicants for or holders of a standard design approval under subpart E of part 52 of this chapter and others providing a design which is the subject of a design approval shall retain any notifications sent to purchasers and affected licensees for a minimum of 5 years after the date of the notification, and retain a record of the purchasers for 15 years after delivery of the design which is the subject of the design approval or service associated with the design.

(f) The holder of a construction permit, combined license, and manufacturing license must prepare and maintain records necessary to accomplish the purposes of this section, specifically—

(1) Retain procurement documents, which define the requirements that facilities or basic components must meet in order to be considered acceptable, for the lifetime of the facility or basic component.

(2) Retain records of evaluations of all deviations and failures to comply for the longest of:

(i) 10 years from the date of the evaluation;

(ii) Five years from the date that an early site permit is referenced in an application for a combined license; or

(iii) Five years from the date of delivery of a manufactured reactor.

~~(b) Each individual, corporation, partnership, dedicating entity, or other entity subject to the regulations in this part shall permit the Commission the opportunity to inspect records pertaining to basic components that relate to the identification and evaluation of deviations, and the reporting of defects and failures to comply, including (but not limited to) any advice given to purchasers or licensees on the placement, erection, installation, operation, maintenance, modification, or inspection of a basic component.~~

[56 FR 36090, July 31, 1991, as amended at 60 FR 48374, Sept. 19, 1995; 72 FR 49488, Aug. 28, 2007]

ENFORCEMENT

§ 21.61 Failure to notify.

(a) Any director or responsible officer of an entity ~~(including dedicating entity)~~ that is not otherwise subject to the deliberate misconduct provisions of this chapter but is subject to the regulations in this part who knowingly and consciously fails to provide the notice required as by § 21.21 shall be subject to a civil penalty equal to the amount provided by section 234 of the Atomic Energy Act of 1954, as amended.

(b) Any ~~NRC licensee or applicant for a license (including an applicant for, or holder of, a permit), applicant for a design certification under part 52 of this chapter during the pendency of its application, applicant for a design certification after Commission adoption of a final design certification rule for that design, or applicant for or holder of a standard design approval under part 52 of this chapter~~entity subject to the regulations in this part who fails to provide the notice required by § 21.21, or otherwise fails to comply with the applicable requirements of this part shall be subject to a civil penalty as provided by Section 234 of the Atomic Energy Act of 1954, as amended.

(c) ~~The dedicating entity, pursuant to § 21.21(c) of this part, is responsible for identifying and evaluating deviations, reporting defects and failures to comply for the dedicated item, and maintaining auditable records of the dedication process.~~ NRC enforcement action can be taken for failure to identify and evaluate deviations, failure to report defects and failures to comply, or failure to maintain auditable records.

[60 FR 48374, Sept. 19, 1995; 72 FR 49488, Aug. 28, 2007]

§ 21.62 Criminal penalties.

~~(a)~~ Section 223 of the Atomic Energy Act of 1954, as amended, provides for criminal sanctions for willful violation of, attempted violation of, or conspiracy to violate, any regulation issued under sections 161b, 161i, or 161o of the Act. For purposes of section 223, all the regulations in part 21 are issued under one or more of sections 161b, 161i, or 161o, except for ~~the sections listed in paragraph (b) of this section.~~

~~(b) The regulations in part 21 that are not issued under sections 161b, 161i, or 161o for the purposes of section 223 are as follows:~~ §§ 21.1, 21.2, 21.3, 21.4 21.5, 21.7, 21.8, 21.61, ~~and~~ 21.62, and 21.71.

[57 FR 55071, Nov. 24, 1992]

COMMERCIAL GRADE DEDICATION

§ 21.71 Commercial grade dedication requirements

(a)(1) When applied to nuclear power plants licensed under 10 CFR part 50 or part 52 of this chapter and fuel fabrication plants licensed under 10 CFR part 70 that engage in plutonium processing, dedication ensures that a commercial grade item is controlled under a quality assurance program complying with appendix B to part 50 of this chapter, and is therefore acceptable for use as a basic component. To dedicate an item, a dedicating entity must:

(i) Perform a technical evaluation that identifies the item's critical characteristics.

(ii) Identify acceptance criteria for each critical characteristic.

(iii) Verify that the item meets the acceptance criteria for each critical characteristic using one or more of the following acceptance methods:

(A) Method 1: Special tests and inspections

(B) Method 2: Survey of a commercial grade supplier

(C) Method 3: Source verification (e.g., Product inspections or witness holdpoints)

(D) Method 4: Supplier/Item history (e.g., Historical records for acceptable performance). Method 4 must be based on industry-wide performance data applicable to the item's critical characteristic. Method 4 shall not be used as the sole method of acceptance for all of the item's critical characteristics.

(2) Dedication is complete when all of the item's critical characteristics have been verified and documented.

(3) Dedication must be conducted in accordance with the provisions of 10 CFR part 50, appendix B.

(4) If any critical characteristic of the item cannot be verified acceptable, that item cannot be dedicated.

(b) When applied to facilities and activities licensed pursuant to 10 CFR parts 30, 40, 50 (other than nuclear power plants), 60, 61, 63, 70 (other than plutonium processing and fuel fabrication plants), 71, ~~or~~ 72, or 76, dedication occurs after receipt when that item is designated for use as a basic component.

§ 50.55 Conditions of construction permits, early site permits, combined licenses, and manufacturing licenses.

Each construction permit is subject to the following terms and conditions; each early site permit is subject to the terms and condition in paragraph (f) of this section; each manufacturing license is subject to the terms and conditions in paragraph (f) of this section; and each combined license is subject to the terms and condition in paragraph (f) of this section until the date that the Commission makes the finding under § 50.52.103(g) of this chapter:

(a) through (d) No Change.

(e) Deleted.

(f) No Change.