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

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CONTENTS

CHAPTER 1 - INTRODUCTION

The U.S. Nuclear Regulatory Commission's (NRC) rulemaking process begins with the development of a regulatory basis. The regulatory basis is intended to identify a regulatory problem, consider what regulatory options are available to solve the problem, and to recommend a solution to that problem. If the recommended solution is to amend the NRC's regulations, then the staff develops a proposed rule. A proposed rule is published in the *Federal Register* along with a request for public comments on the proposal. The staff addresses these public comments in its final rule and publishes the final rule in the *Federal Register*. Any necessary regulatory guidance documents in support of the rulemaking will also be published 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 generic communications or voluntary initiatives, the final content of those solutions will similarly be informed by public and stakeholder interactions.

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 recommendations in this regulatory basis, if pursued, would simplify and clarify the rule language in Part 21, provide consolidated regulatory guidance, and would enhance regulatory stability and predictability for the entities to which Part 21 applies. Throughout this document, the terms "vendors" and "suppliers" are used interchangeably.

The NRC is providing this version of the regulatory basis as a draft to promote early stakeholder feedback. The NRC is committed to keeping its stakeholders informed and involved, and the agency plans to host public meetings to discuss this draft regulatory basis. Documents associated with this regulatory basis and (if pursued) associated rulemaking can be found on the NRC public Web Site and on the Federal Government's regulations Web Site at http://www.regulations.gov by searching for "NRC-2012-0012."

BACKGROUND

The purpose 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 which 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 assure that safety-related defects and noncompliance are brought to the attention of their responsible officers and directors (or their designees) and, in turn, are required to notify the Commission by filing a written report regarding the defect or noncompliance.

Since its inception in 1977, Part 21 has presented compliance challenges to licensees, vendors, and the NRC staff. The NRC staff has documented repetitive inspection findings related to Part 21, including commercial grade dedication findings, despite the staff's attempts to clarify requirements through generic communications and extensive outreach efforts. Recently approved Part 21 exemption requests for nonreactor facilities further underscore the need to

reexamine Part 21. The exemption requests reinforce the limitations of Part 21, as the current regulation cannot be logically applied to some nonreactor facilities.

NRC findings related to failures to report in accordance with Part 21 are important. The NRC considers the safety and security implications of noncompliances that may affect the NRC's ability to carry out its statutory mission. Many of the surveillance, quality control, and auditing systems on which both the NRC and its licensees rely in order 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 the NRC's 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: (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). The OIG's audits provided 15 recommendations, most of which were related to clarifying Part 21.

In response to OIG's recommendations, the staff accelerated ongoing initiatives to clarify Part 21. On September 29, 2011, the 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 informed the Commission of the NRC staff's plan to develop a regulatory basis to clarify Part 21. It addressed the need and priority for rulemaking, guidance (i.e., regulatory guides), and outreach efforts.

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.

The staff engaged stakeholders on the need for rulemaking in public meetings, as well as providing presentations during various meetings, such as the Regulatory Information Conference, the Nuclear Procurement Issues Committee annual vendor workshop, the annual Fuel Cycle Information Exchange, and the biannual NRC workshop on vendor oversight for new reactor construction. The staff hosted public meetings on August 1, 2011, and January 26, 2012, to provide early stakeholder outreach and solicit feedback in these areas. The public meetings helped inform SECY-11-0135 and provided additional areas for improvement.

The staff did not consider risk-informing Part 21 or substantially changing the scope of Part 21. Consistent with SECY-11-0135, the staff developed this regulatory basis with the intent of providing necessary clarity to Part 21 and its associated guidance.

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 rule language changes, guidance documents, generic communications, voluntary 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.

HISTORY OF PART 21

The NRC published the final rule for Part 21 in the *Federal Register* on June 6, 1977 (42 FR 28893), 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).

In that final rule, the NRC acknowledged that promulgating a detailed regulation at that time was not practical. Furthermore, the NRC staff anticipated making clarifying changes and developing guidance after gaining experience with Part 21. The final rule states the following:

> The Commission intends to examine closely the implementation of new Part 21 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 regulatory framework for dedication has remained largely unchanged since the issuance of this 1978 amendment.

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

- In 1991, the NRC amended Part 21 (56 FR 36081) as a result of the Commission's efforts to apply the experience gained from the Three Mile Island accident and to reflect the Commission's experience to date with the existing regulations. The NRC intended

the changes to reduce duplicate reporting, clarify the criteria for reporting of defects, and establish uniform time periods for reporting and uniform report content requirements.

- In 1995, the NRC amended Part 21 (60 FR 48373) to provide added flexibility in the ability of nuclear power plant licensees to procure commercial grade items for safety-related services. The NRC intended the action to provide the requirements for the procurement of parts and services, which are procured as commercial grade items and subsequently dedicated for safety-related service, in a manner that avoids unnecessary delay and expense while maintaining an adequate level of safety.

The increase in procurement activity associated with the construction of new reactors presents the ideal opportunity to clarify the requirements under Part 21 and initiate rulemaking.

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. Many vendors have indicated that NRC guidance would be helpful. 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 through July 26, 1977, in support of the initial promulgation of Part 21. However, that NUREG does not provide comprehensive NRC approved guidance, is outdated in many areas, and lacks sufficient detail to be useful today.

b. Definition of Regulatory Problem

The applicability of Part 21 is broader than most NRC regulations. This regulation applies to individuals, partnerships, corporations, and all entities holding or applying for an NRC license. In addition, Part 21 applies to licensees and vendors across different disciplines, adding further breadth to the scope of what must be considered for evaluation.

While all reactor licensees and certain nonreactor 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. This is evident in how vendors identify and resolve problems in their corrective action and nonconformance programs. These programs are some of the most important aspects of a QA program. 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.

Part 21 does not contain the detail necessary to address all of the scenarios that licensees and vendors face. The level of regulatory detail needed to describe an acceptable method for complying with the requirements is more appropriately located in guidance documents. However, adequate contemporary guidance for Part 21 does not exist, and stakeholders are often left to interpret the regulations according to their unique scenarios. As a result, NRC inspections often find inconsistencies and deficiencies in Part 21 evaluating and reporting.

When Part 21 was initially promulgated, the NRC hosted conferences and public meetings to introduce the regulation and to communicate expectations. NUREG-0302 captures many of the remarks, questions, and answers discussed at that time. The NRC noted the following in the opening keynote address of NUREG-0302:

It is no secret that it has been one of the most controversial rules ever promulgated by the Commission and it has potentially significant implications for all members of the nuclear community, from power plant operator, nuclear steam suppliers, architect engineers and constructors to consultants and component vendors.

Despite this, the NRC has never issued formal guidance to provide an approach acceptable to the staff for complying with the evaluating and reporting requirements of Part 21.

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.

- Guidance Development

  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 of Part 21. The NRC's regulatory guides typically provide guidance to stakeholders on implementing 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.

  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) DG-1291, "Evaluating Deviations and Reporting Defects and Noncompliance." The Nuclear Energy Institute (NEI) has expressed interest in forming a working group to support the development of this guidance.

- Generic Communications

  Guidance can be provided through generic communications. However, the staff does not consider generic communications to be the right instrument to adequately communicate its expectations for Part 21 evaluating and reporting requirements. The staff has issued various generic communications in the past, including generic letters and information notices. However, the narrow scope of previous generic communications and the lack of consolidated guidance have proven to be ineffective in reaching some vendors. Furthermore, not all vendors receive generic communications, nor is there a communications tool to reach all vendors. A consolidated approach to the problem is needed, which generic communications cannot provide.

- Voluntary Programs

  As noted above, the regulatory problem stems from a lack of NRC-endorsed guidance. In addition, the staff is unaware of any voluntary programs that would be appropriate for NRC endorsement. Furthermore, the nature of a voluntary program does not address the problem of lack of regulatory guidance. Therefore, the use of voluntary programs is not appropriate for this regulatory problem.

- No Action

  Taking no action would result in continued confusion and lack of clarity on implementing Part 21. The many repetitive problems with licensees and vendors implementing Part 21 identified during inspections and stakeholder interactions are significant enough to warrant action. Therefore, the staff does not consider this to be a viable option.

2. Quality Requirements in Procurement Documents

a. Existing Regulatory Framework

The provisions of 10 CFR 21.31, "Procurement Documents," state the following:

> 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 reactor facilities, compliance with Appendix B, "Quality Assurance Criteria for Nuclear Power Plants and Fuel Reprocessing Plants," to 10 CFR Part 50, "Domestic Licensing of Production and Utilization Facilities" (Appendix B), is a regulatory requirement. For vendors supplying to reactor facilities, Appendix B is contractually imposed by the purchaser. 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 of 10 CFR Part 71, "Quality Assurance," etc.), are required. The following focuses on Appendix B requirements; however, the discussion is equally applicable to nonreactor facilities.

Criterion IV, "Procurement Document Control," of Appendix B states the following:

> Measures shall be established to assure that applicable regulatory requirements, design bases, and other requirements which are necessary to assure adequate quality are suitably included or referenced in the documents for procurement of material, equipment, and services, whether purchased by the applicant or by its contractors or subcontractors. To the extent necessary, procurement documents shall require contractors or subcontractors to provide a quality assurance program consistent with the pertinent provisions of this appendix.

To procure a basic component, a purchaser must invoke Part 21. The regulations in 10 CFR 21.31 require that procurement documents invoke Part 21. For reactor facilities, a purchaser must also invoke Appendix B, which is required because a basic component for reactor facilities must be designed and manufactured under an Appendix B program.

b. Definition of Regulatory Problem

The requirements to invoke Part 21 and QA requirements (e.g., Appendix B for reactor facilities) in procurement documents are located in different regulations. As required by 10 CFR 21.31, procurement documents for basic components must specify that the provisions of Part 21 apply, but this regulation does not require that procurement documents specify applicable quality requirements, such as Appendix B for reactor facilities. NRC inspections have noted that some vendors misunderstand the regulatory requirements that must be imposed upon safety-related items and services (i.e., basic components).

NRC vendor inspections have noted findings for failures to invoke Appendix B with Part 21, and vice versa. In similar cases, purchasers have only invoked quality standards, such as American Society of Mechanical Engineers (ASME) NQA-1. When asked whether the parts were safety-related, some vendors were unable to provide a definitive answer.

The delineation of safety-related parts and services (i.e., basic components) is essential in ensuring that the parts and services meet the proper technical and quality requirements. The NRC regulations require licensees and applicants to clearly define what is safety-related. However, vendors do not always benefit from a clear determination of what is safety-related from their purchasers, especially as items are procured from multiple tiers down the supply chain.

A basic component must perform its intended safety function. The regulatory structure currently in place is intended to carry the requirements forward to vendors. However, purchasers have, in some instances, omitted the necessary requirements from their purchase specifications and this has been observed by NRC inspectors.

c. Options To Resolve Regulatory Problem

- Proposed Changes to NRC Regulations

  The staff could change Part 21 to require that appropriate QA requirements be imposed in procurement documents. For entities subject to Appendix B, procurement documents would be required to impose Appendix B. Appendix B already requires that safety-related orders invoke its provisions. However, requiring Appendix B in Part 21 would further strengthen the link between Part 21 and the QA program. For nonreactor applicants and licensees, the appropriate QA requirements (e.g., Appendix B, management measures, Subpart H of 10 CFR Part 71, etc.) would be required to be imposed in procurement documents.

  Adding this requirement would not impact applicants, licensees, and vendors with compliant programs. A compliant procurement document already includes the appropriate quality requirements, and the change in regulation would not require any changes in compliant QA programs.

This change would clearly identify which procurements are safety-related and reinforce that quality requirements and Part 21 are inseparable. Clear definition of safety-related procurements would help ensure that vendors are aware of the safety significance of their work. This would help keep defects, which could be harmful to public health and safety, out of safety-related structures, systems, and components. Under this change, the omission of quality requirements in procurement documents would be a violation of Part 21 as opposed to a nonconformance to contractual obligations.

The staff is considering the following additions (*in italics*) and deletions (~~in strikethrough~~) to 10 CFR 21.31:

> Each individual, corporation, partnership, dedicating entity, or other entity subject to the regulations in this part shall ensure that ~~each~~ *its* procurement ~~document~~ *documents* for a facility, or a basic component issued ~~by him, her or it~~ on or after January 6, 1978, ~~specifies~~ *specify*, when applicable, that the provisions of 10 CFR Part 21 *and appropriate quality requirements (e.g. Appendix B to 10 CFR part 50 for facilities licensed pursuant to 10 CFR part 50 or 52)* apply.

- Guidance Development

  Regulatory guides reflect one acceptable way of complying with regulations and do not constitute regulatory requirements. Thus, providing guidance alone is not anticipated to bring about the change necessary to address this problem. However, appropriate regulatory guidance could be developed to address the fundamental concept of the link between the quality requirements and Part 21. The staff plans to include this topic in DG-1291. Developing regulatory guidance in this area would contribute to the clarification of the staff's expectations for Part 21, as well as for the procurement of safety-related items and services.

- Generic Communications

  As noted above, generic communications are not the right instrument to adequately communicate NRC staff expectations for Part 21 evaluating and reporting. Generic communications would not provide a consolidated approach to guidance.

- Voluntary Programs

  The development of a voluntary program that spans the range of entities that must address Part 21 could enhance the industry's performance in terms of this problem and could reduce recurrence of findings in this area. However, the staff is unaware of any industry initiatives in this area.

- No Action

  Taking no action in this area does not address the problem of purchasers procuring safety-related items and services without clearly imposing appropriate

QA requirements. The implication of not meeting quality requirements for basic components is that substandard parts and services can find their way into NRC-licensed facilities, threaten the functioning of safety systems, and ultimately pose a risk to public health and safety. Therefore, taking no action is not a viable option.

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

a. Existing Regulatory Framework

The definition of a basic component in 10 CFR 21.3, "Definitions," as it applies to nonreactor facilities and activities, is as follows:

> 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 NRC has approved exemptions to the above definition for certain nonreactor facilities, as noted in the following letters:

- NRC letter, "Approval of Louisiana Energy Services Part 21 Exemption Request and Amendment 13 to License," dated February 11, 2009 (ADAMS Accession No. ML083400454)

- NRC letter, "Approval of the Mixed Oxide Project Quality Assurance Plan, Revision 6, Change 1," dated November 13, 2008 (ADAMS Accession No. ML082320259)

- NRC letter, "Partial Approval of Changes to the Mixed Oxide Project Quality Assurance Program, Revision 10," dated June 17, 2011 (ADAMS Accession No. ML111600016)

One example of a definition that has been approved, in the exemptions noted above, for a uranium enrichment and fuel fabrication facility licensed under 10 CFR Part 70, "Domestic Licensing of Special Nuclear Material," reads in part as follows:

> basic component means a structure, system, or component, or part thereof that affects their IROFS [items relied upon 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 the

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

For facilities licensed under 10 CFR Part 70, the staff applied existing regulatory guidance to establish a correlation between the performance requirements of 10 CFR 70.61, "Performance Requirements," and the delineation of structures, systems, and components whose failure could create a substantial safety hazard and should be identified as basic components. NUREG-0302 provided some examples of substantial safety hazards and provided reference to the Commission's Policy Statement for Abnormal Occurrence Reports (42 FR 10950) and Appendix A to NUREG-0090, "Report to Congress on Abnormal Occurrences" (prepared annually) for criteria consistent with problems that may be considered to be substantial safety hazards. The Commission's Policy Statement for Abnormal Occurrence Reports, updated most recently in 2006 (71 FR 60198), 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.

Specific examples of significant events included in NUREG-0302 include unintended radiation exposure to an adult of 25 rem and exposure of 0.5 rem to an individual outside the controlled area. 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." These criteria are consistent with the high and intermediate consequences defined in 10 CFR 70.61, meaning that those items relied upon for safety that are necessary to ensure compliance with the performance requirements of 10 CFR 70.61 are in place to prevent or mitigate the consequences of substantial safety hazards, as defined in NUREG-0302, Appendix A to NUREG-0090, and the Commission's Policy Statement for Abnormal Occurrence Reports, and are thus basic components. The staff notes that 10 CFR Part 70 also includes performance requirements related to criticality and chemical exposure, which are concerns unique to the nature of these facilities.

b. Definition of Regulatory Problem

The definition of a basic component for nonreactor licensees is vague. Furthermore, the list of applicable facilities identified in the definition does not include Part 76 facilities. The definition, as written, does not provide the necessary specificity for nonreactor facilities to consistently identify their basic components. In contrast, the reactor facility definition for a basic component is specific to reactor terminology and consequences (i.e., the definition of basic component in Part 21 references maintaining integrity of the reactor coolant 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, the NRC has granted exemptions to multiple enrichment and fuel fabrication facilities to the basic component definition so that a definition that uses terminology

applicable to 10 CFR Part 70 may be used. These modified definitions enhance the clarity, effectiveness, and ease of implementation of the Part 21 regulations and should be considered for implementation in the rule.

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 10 CFR Part 70 licensees because of the number of exemptions requested and approved for construction of such new facilities. This definition change is important because of the wide array of interpretations among licensees as to which items are basic components. While most facilities licensed after the addition of Subpart H, "Additional Requirements for Certain Licensees Authorized To Possess a Critical Mass of Special Nuclear Material," of 10 CFR Part 70 have adopted the position that all items relied upon for safety are basic components, facilities licensed before implementation of Subpart H have adopted definitions as written in Part 21, including the use of basic components. As described above, the lack of clarity in these definitions has led to inconsistent interpretation of their meaning; for instance, one incorrect interpretation of how to apply the definition of "basic components" to fuel cycle facilities is that only defects in completed fuel assemblies, which are supplied to reactors as basic components, meet the substantial safety hazard threshold. Interpreting the definition in such a manner excludes many aspects of the fuel cycle facility, such as enrichment and process tanks, whose failure may also create a substantial safety hazard.

Based on the history of the approved exemption requests and on the regulatory guidance related to substantial safety hazards, as described above, the staff is considering the following additions (*in italics*) and deletions (~~in strikethrough~~) to the definition of "basic component" in 10 CFR 21.3:

> (3) *When applied to other facilities and other activities licensed under 10 CFR Part 70 of this chapter, basic component means a structure, system, or component (SSC), or any part thereof that affects the SSC's safety function, that has been designated as an item relied on for safety in accordance with § 70.4 and whose failure would result in a condition in which no diverse SSCs are available to assure:*
>
> *(A) that under normal and credible abnormal conditions, all nuclear processes are subcritical; or*
>
> *(B) the capability to prevent or mitigate the consequences of potential accidents that could result in consequences that could exceed those referred to in § 70.61(b) or (c) of this chapter.*
>
> *(4)* 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, *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.

(5) In all cases…

For 10 CFR Part 70 licensees, the staff is considering implementing the proposed regulation and requiring implementation by all licensees within 12 months following the effective date of the rule. This would allow licensees sufficient time to change procedures as needed, conduct staff training, and establish procurement measures for basic components consistent with the rule text. The staff notes that for existing facilities and activities, basic components purchased before the implementation date of the revised rule would not be subject to the revised definition; licensees would only be expected to apply the definition to the purchase of new and replacement items for use as basic components in their facilities and activities. The staff also notes that it is not the expectation that all SSCs designated as IROFS would meet the criteria above to be designated as basic components; rather, only the subset of IROFS whose failure would result in no other diverse SSCs being available to prevent or mitigate an accident in which the performance requirements of § 70.61 are not met.

Because no such problems have been encountered with other licensees (under 10 CFR Parts 30, 40, 50 (other than nuclear power plants), 60, 61, 63, 71, and 72) using the existing definition, the staff recommends leaving the definition unchanged for those licensees. The staff also recommends including 10 CFR Part 76, "Certification of Gaseous Diffusion Plants," as an applicable regulation in the amended definition of basic component as explained in Section ii of Chapter 4 below.

- Guidance Development

  Regulatory guidance could be developed to address the definition of basic component for nonreactor facilities. The staff plans to include this topic in DG-1291. Developing regulatory guidance in this area would contribute to the clarification of the staff's expectations for Part 21.

- Generic Communications

  As noted above, generic communications are not the right instrument to adequately communicate NRC staff expectations for Part 21 evaluating and reporting. Generic communications would not provide a consolidated approach to guidance.

- Voluntary Programs

  The use of a voluntary program is not appropriate for this regulatory problem because it is related to a definition in the regulation. Allowing optional use of alternative definitions would not be appropriate.

- No Action

  Taking no action on this problem is not appropriate because confusion on the definition of a basic component has safety implications.

4. Clarification of Point of Discovery

a. Existing Regulatory Framework

The definition of discovery in 10 CFR 21.3 states the following:

> 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).

Multiple requirements for evaluation and reporting in 10 CFR 21.21, "Notification of Failure To Comply or Existence of a Defect and Its Evaluation," rely on that date of discovery, such as 10 CFR 21.21(a)(1), which states the following:

> 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…

b. Definition of Regulatory Problem

The definition of discovery explicitly describes the start of the Part 21 timeline. However, NRC vendor inspectors have noted various interpretations of discovery among vendors and have cited violations for resulting incorrect Part 21 timeliness. In some cases, this has led to delays in the reporting of substantial safety hazards. Substantial safety hazards are losses of safety function to the extent that there is a major reduction in the degree of protection provided to public health and safety. Any delay in reporting substantial safety hazards hinders the NRC's ability to take action necessary to help protect public health and safety.

The current definition notes that discovery occurs at the completion of the documentation first identifying the existence of a deviation or failure to comply. The phrase, "associated with a substantial safety hazard within the evaluation procedures discussed in § 21.21(a)," has been one source of misunderstanding. It has led some to believe that discovery cannot occur until the documented problem has been determined to be a deviation and a Part 21 evaluation is underway. However, discovery occurs when a corrective action, nonconformance, or similar report is initiated. Furthermore, the current definition does not make a clear nexus to the corrective action, nonconformance, or problem identification process when there clearly must be such a link for deviations to be discovered.

c. Options To Resolve Regulatory Problem

- Proposed Changes to NRC Regulations

  The staff is considering revising the definition of discovery. A revised definition would provide a clear connection to the programs that identify deviations (i.e., corrective action and nonconformance programs). In addition, the definition

would clarify the documentation that first starts a Part 21 timeline. This 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.

Modifying the definition as noted above would not impact applicants, licensees, and vendors who currently comply with Part 21. However, it would clarify that deviations must be identified as part of a QA program (e.g., Appendix B for reactor applicants and licensees and certain nonreactor licensees, management measures for uranium enrichment and fuel fabrication facilities, etc.). In addition, it would help ensure that applicants, licensees, and vendors are timely in the completion of Part 21 evaluations, and the reporting of substantial safety hazards, and failures to comply. As noted above, this 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.

The staff is considering the following additions (*in italics*) and deletions (~~in strikethrough~~) to the definition of discovery:

> Discovery means the ~~completion~~ *initiation of the problem identification and resolution* ~~of the~~ documentation first identifying the existence of a deviation or failure to comply *(e.g., pursuant to the corrective action or nonconformance programs required by Appendix B to 10 CFR Part 50 for Part 50 or 52 applicants or licensees)* ~~potentially associated with a substantial safety hazard within the evaluation procedures discussed in § 21.21(a)~~.

In addition, the staff is considering adding a provision in Part 21 (potentially in 10 CFR 21.21(a)) to require that all conditions adverse to quality be screened for Part 21 applicability (i.e., screened for deviations). This is current practice for entities that are subject to the requirements of Appendix B because Criterion XVI, "Corrective Action," of Appendix B requires that measures be established to ensure that conditions adverse to quality, such as deviations, are promptly identified and corrected.

- Guidance Development

  The definition of discovery should also be addressed through regulatory guidance. The staff plans to include this topic in DG-1291. This will enhance the clarity of the staff's expectations for Part 21. The staff plans to develop the regulatory guide to provide detailed examples.

- Generic Communications

  Generic communications are not the right format to adequately clarify the definition of discovery. In addition, generic communications would not provide a consolidated approach to guidance or the level of detail that can be provided by a regulatory guide.

- Voluntary Programs

  The use of a voluntary program is not appropriate to adequately clarify this regulatory problem because it is related to a lack of clarity in the definition of the point of discovery.

- No Action

  Taking no action in this area does not address the problem of an unclear definition. This would result in the continued potential that Part 21 timeliness requirements would not be met, which hinders the NRC's ability to take appropriate action. Therefore, taking no action is not a viable option.

5. Clarification of Deviation and Delivery

a. Existing Regulatory Framework

The definition of deviation in 10 CFR 21.3 states the following:

> 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 concept of delivery is presented in the definition of defect. The definition of defect in 10 CFR 21.3 states the following:

> 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.

Criterion VII, "Control of Purchased Material, Equipment, and Services," of Appendix B, states in part the following:

> Measures shall be established to assure that purchased material,

> equipment, and services, whether purchased directly or through contractors and subcontractors, conform to the procurement documents. These measures shall include provisions, as appropriate, for source evaluation and selection, objective evidence of quality furnished by the contractor or subcontractor, inspection at the contractor or subcontractor source, and examination of products upon delivery.

Section 500, "Acceptance of Item or Service," of Requirement 7, "Control of Purchased Items and Services," of Part I, "Requirements for Quality Assurance Programs for Nuclear Facilities," of ASME NQA-1-2008, "Quality Assurance Requirements for Nuclear Facility Applications," contains the requirements for acceptance of items and services. Paragraph 502, "Methods of Acceptance," of that section states the following:

> Purchaser methods used to accept an item or service from a Supplier shall be a Supplier Certificate of Conformance, source verification, receiving inspection, or post installation test at the nuclear facility site, or a combination of these methods.

Section 500, "Receiving," of Subpart 2.2, "Quality Assurance Requirements for Packaging, Shipping, Receiving, Storage, and Handling of Items for Nuclear Power Plants," of ASME NQA-1-2008, lists the detailed requirements for receiving inspections.

b. Definition of Regulatory Problem

The concept of delivery, which is critical to Part 21 reporting timeliness, is inadequately defined. This has resulted in repeated misinterpretations of the point of delivery and, in some cases, for evaluations to take longer than the 60 days allowed by Part 21. In these cases, the NRC has cited vendors for violations of Part 21. As noted above, any delay in reporting a substantial safety hazards poses a risk to public health and safety, as it hinders the NRC's ability to respond.

The definition of defect screens out "delivered" basic components. The definition of deviation includes all departures included in a procurement document regardless of whether the item has been delivered. As such, verbatim compliance would dictate that all deviations (including in-process nonconformances and problems during manufacturing) be evaluated under the formal Part 21 program. However, current accepted practice is that only delivered deviations need a Part 21 evaluation.

The disparity between the definitions and actual practice provides for potential confusion and adds the burden of evaluations for in-process problems that, by definition, cannot be defects.

Furthermore, Part 21 does not describe the related concepts of receipt and acceptance. For entities subject to the requirements of Appendix B, the regulation, as expanded upon by ASME NQA-1, requires examination of items and services upon delivery. Therefore, an item is delivered when the purchaser has accepted the item following the completion of a receiving inspection. In other words, completion of receipt inspection marks acceptance and the point of delivery.

c. Options To Resolve Regulatory Problem

- Proposed Changes to NRC Regulations

  The staff is considering modifying the definitions of deviation and defect to remove the distinction of delivery. The requirements in Part 21 for evaluating deviations will be modified to include the distinction of delivery.

  The staff is considering the following additions (*in italics*) and deletions (~~in strikethrough~~) to 10 CFR 21.3:

  > Defect means:
  >
  > (1) A deviation in a basic component *that* ~~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;…

  In the revised section on evaluating and reporting, the staff would require that all deviations in basic components that have been delivered and accepted be identified and evaluated to determine whether they are defects. The staff considered defining the term "receiving inspection" in the regulation. However, the controls of Appendix B and other NRC-promulgated QA requirements coupled with industry standards, such as ASME NQA-1, adequately address receipt inspection. Furthermore, the NRC has not noted receipt inspection to be a repetitive vendor inspection problem.

- Guidance Development

  As part of the overall rulemaking effort, the staff recommends adding a detailed description to clarify delivery in DG-1291. This addition will explain that delivery occurs when there is acceptance following a receiving inspection. It will also include references to ASME NQA-1-2008 regarding receiving inspections.

- Generic Communications

  The staff is not proposing generic communication in this area. The staff does not consider generic communications to be the right instrument to adequately clarify problems with definitions. In addition, generic communications would not provide a consolidated approach to guidance or the level of detail that can be provided in a regulatory guide.

- Voluntary Programs

  The use of a voluntary program is not appropriate for this regulatory problem because it is related to a lack of clarity of the definitions in the regulations.

- No Action

  Taking no action in this area does not address the problem of unclear definitions.

In addition, taking no action does not provide clarity to a problem that has caused industry misunderstanding. Therefore, taking no action is not a viable option.

6. Evaluating and Reporting Responsibility

a. Existing Regulatory Framework

The regulations in 10 CFR 21.21 describe the evaluating and reporting requirements for entities subject to Part 21.

b. Definition of Regulatory Problem

Part 21 does not delineate the responsibilities of multiple entities involved in a Part 21 issue. Yet the regulation, by definition, involves at least two entities: a vendor and a customer. The requirements in Part 21 are specific to each entity, yet fall short when there is a disagreement between entities. Furthermore, Part 21 does not describe the communications required between non-NRC entities, except in the cases of deferral of evaluation (10 CFR 21.21(b)).

NRC inspectors have noted instances in which the lack of formal protocol between vendor and customer has led to disagreement on whether a Part 21 report should be issued. In some cases, the two entities may not agree on the technical details, creating a potential for failing to report under Part 21. Conversely, the NRC has noted instances of licensees conservatively reporting under Part 21 when reporting would not otherwise be necessary. Clarity is necessary to assure that the NRC's requirements for reporting are adequately explained, and that vendors comply with the corresponding regulations. This is necessary to ensure that the NRC can carry out its statutory mission.

Similarly, the Part 21 process presents a potential loophole in the communication chain as illustrated by the following scenario: A licensee identifies a deviation in a basic component and evaluates the deviation as it relates to the licensee's particular application of the part, as required under Part 21. If the licensee's evaluation determines that the deviation could not cause a substantial safety hazard, the licensee has satisfied Part 21. However, the part in question may also be in use in other applications in the nuclear industry, where it could potentially cause a substantial safety hazard. While it is good practice for the licensee to communicate the existence of the deviation to the supplier, there is no requirement to do so. Without such notification from the licensee of the deviation, a vendor will not know to perform an extent of condition analysis of the part to determine whether similar deviations require Part 21 evaluation for other purchasers.

Section 206 of the Energy Reorganization Act was intended to ensure that all potential defects were reported to the NRC. Yet the scenario described above could allow potential defects to go unreported. A failure to report a substantial safety hazard poses a risk to public health and safety, as it hinders the NRC's ability to respond.

c. Options To Resolve Regulatory Problem

- Proposed Changes to NRC Regulations

  The staff is considering revising the regulation to require purchasers to communicate the existence of deviations to their suppliers. However, codifying the requirement would likely cause additional burden with minimal safety gains. As noted below, a more viable solution would be for the staff to encourage notification of deviations back through the supply chain as a good practice.

- Guidance Development

  As part of the overall rulemaking effort, the staff could add a detailed description of the process for evaluating and reporting responsibility in DG-1291. The staff would delineate the responsibilities of all parties involved and 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.

- Generic Communications

  Generic communications are not the right format to adequately clarify responsibilities for evaluating and reporting. In addition, generic communications would not provide a consolidated approach to guidance or the level of detail that can be provided in a regulatory guide.

- Voluntary Programs

  The use of a voluntary program is not appropriate to adequately clarify this regulatory problem because it is related to a lack of clarity in the evaluating and reporting process described by the regulations.

- No Action

  Taking no action in this area would potentially result in substantial safety hazards not being reported to the NRC. Therefore, taking no action is not a viable option.

7. Deferral of Evaluation—10 CFR 21.21(b)

a. Existing Regulatory Framework

Part 21 allows vendors 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). The regulation states the following:

> 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).

b. Definition of Regulatory Problem

The requirements in 10 CFR 21.21(b) do not specify communication between a vendor and a purchaser to (1) clearly document and identify purchaser responsibility to perform an evaluation once the vendor identifies its inability to perform an evaluation and (2) clearly document information that a vendor should supply to a purchaser to adequately evaluate whether a defect exists.

NRC inspectors have noted instances of vendors inadequately informing their purchasers of deviations under 10 CFR 21.21(b). In some cases, vendors informed their purchasers of departures from technical requirements included in a procurement document by e-mail, but did not explicitly call out the existence of a deviation. Additionally, NRC inspectors have noted examples in which the vendors failed to identify these issues as deviations.

The regulations in 10 CFR 21.21(b) do not state what information the vendor should or must supply to its purchaser in the case of a 10 CFR 21.21(b) determination. In addition, the regulation does not require any level of involvement by the vendor once it has informed its customer of its inability to perform an evaluation.

Clarity is necessary to assure that the NRC's regulations for reporting are adequately explained, and that vendors comply with the corresponding regulations. This is necessary to ensure that the NRC can carry out its statutory mission. A failure to report a substantial safety hazard poses a risk to public health and safety, as it hinders the NRC's ability to respond.

c. Options To Resolve Regulatory Problem

- Proposed Changes to NRC Regulations

  The staff is considering formalizing the requirements of informing a purchaser of an inability to perform an evaluation. This could include requiring the supplier to provide a formal notification to its purchaser of a 10 CFR 21.21(b) determination, which would include information similar to what is required for a Part 21 report. In addition, the staff is considering requiring the supplier to maintain some level of responsibility until the problem has been resolved (i.e., reported or determined to not need a report) in 10 CFR 21.21(b).

  These additional requirements have been observed as good practices. Implementation would provide purchasers with the necessary information to perform Part 21 evaluations and would not represent a significant additional burden to suppliers.

  The staff is considering the following additions (*in italics*) and deletions (~~in strikethrough~~) to 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 *in writing* within five working days of this determination *stating* ~~so~~ that the purchasers or affected licensees *must* ~~may~~ evaluate the deviation or failure to comply, pursuant to § 21.21(a). *The written notification 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 supplier and contact information for responsible individual or individuals.
(ii) Identification of the facility, the activity, or the basic component supplied for such facility or such activity within the United States that contains a deviation or failure to comply.
(iii) Identification of the firm constructing the facility or supplying the basic component that contains a deviation or failure to comply.
(iv) Nature of the deviation or failure to comply and the potential safety hazard that is created or could be created by such deviation or failure to comply.
(v) The date on which the information of such deviation or failure to comply was obtained.
(vi) 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) If necessary, the corrective action that 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 deviation 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.

- Guidance Development

  As part of the overall rulemaking effort, the staff could include a detailed description of the process of deferring an evaluation in DG-1291. The staff would delineate the responsibilities of all parties involved and highlight the value of open communication throughout the process.

- Generic Communications

  Generic communications are not the right instrument to adequately clarify responsibilities for evaluating and reporting. Generic communications would not provide a consolidated approach to guidance or the level of detail that can be provided in a regulatory guide.

- Voluntary Programs

  The use of a voluntary program is not appropriate to adequately clarify this regulatory problem because it is related to a lack of clarity and specificity in the evaluating and reporting process described by the regulations.

- No Action

  Taking no action in this area does not address the problem of 10 CFR 21.21(b) being inadequately implemented. This would result in the continued potential that substantial safety hazards are not being reported to the NRC, which hinders the NRC's ability to take appropriate action. Therefore, taking no action is not a viable option.

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

a. Existing Regulatory Framework

The regulations in 10 CFR 21.2(c) state the following:

> 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. Definition of Regulatory Problem

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 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 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. This is because, in accordance with Section 206 of the Energy Reorganization Act, licensees must evaluate any deviation to determine whether that deviation could create a substantial safety hazard.

However, information provided in the Statements of Consideration for the final rule complicated this original staff intention. At 36,084, the Statements of Consideration states, "If the event is determined not to be reportable under §§ 50.72 or 50.73, then the obligations of part 21 are met by the evaluation." Consequently, licensees have expressed confusion over whether only an evaluation or an evaluation and a reporting of a potential defect under 10 CFR Part 50 will discharge the licensee's Part 21 evaluation and reporting obligations.

c. Options To Resolve Regulatory Problem

- Proposed Changes to NRC Regulations

  The staff is considering correcting the regulatory ambiguity by amending its regulations through the following additions (*in italics*) and deletions (~~in strikethrough~~) to 10 CFR 21.2(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.

- 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 the following:

  > 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.

  As part of the Part 21 rulemaking effort, the staff could revise the associated guidance documents. The staff would ensure that the revised guidance documents include the above clarification.

- Generic Communications

  Generic communications are not the right instrument to adequately clarify responsibilities for evaluating and reporting. In addition, generic communications would not provide a consolidated approach to guidance or the level of detail that can be provided in a regulatory guide.

- Voluntary Programs

  The use of a voluntary program is not appropriate to adequately clarify this regulatory problem because it is related to a lack of clarity in the evaluating and reporting requirements of Part 21.

- No Action

  Taking no action in this area does not address the problem of ensuring that Part 21 reports are made to the NRC in certain scenarios. This would result in the continued potential that substantial safety hazards are not being reported to the NRC, which hinders the NRC's ability to take appropriate action. Therefore, taking no action is not a viable option.

9. Acceptable Forms of Written Notification under 10 CFR 21.21(d)(2)

a. Existing Regulatory Framework

The regulations in 10 CFR 21.21(d)(2) state the following:

> 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.

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.

b. Definition of Regulatory Problem

The regulation does not set forth any expectations for the format or content of written notifications used by licensees, in accordance with 10 CFR 21.21(d)(2), to ensure that the notification requirements of Part 21 are satisfied. The NRC has no formal guidance for the implementation of 10 CFR 21.21(d)(2).

The NRC staff has noted instances in which licensees have incorrectly considered event reports, such as those required by Appendix A, "Reportable Safety Events," to 10 CFR Part 70, to satisfy reporting under Part 21. However, such reports often only indicate the reportable safety event (e.g., radiological or chemical exposure, unavailability of items relied upon for safety, etc.) and a minimal description of the cause. 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 is considering 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).

The staff is considering the following additions (*in italics*) to 10 CFR 21.21(d)(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 *and that such writing makes reference to 10 CFR Part 21 and contains the information required by § 21.21(d)(4)*.

- Guidance Development

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

- Generic Communications

  Generic communications are not the right instrument to adequately clarify acceptable forms of written notification under 10 CFR 21.21(d)(2) for nonreactor facilities. In addition, generic communications would not provide a consolidated approach to guidance or the level of detail that can be provided in a regulatory guide.

- Voluntary Programs

  A voluntary program would not address the need to clarify the evaluation and reporting requirements of Part 21. Therefore, the use of a voluntary program is not appropriate to adequately clarify this regulatory problem.

- No Action

  Taking no action in this area does not ensure that substantial safety hazards are being clearly identified to the NRC. Therefore, taking no action is not a viable option.

10. 10 CFR 50.55(e) Redundancy

a. Existing Regulatory Framework

Part 21 and 10 CFR 50.55(e) contain the regulatory framework 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.

The NRC published the final rule for 10 CFR 50.55(e) on March 30, 1972 (37 FR 6460). The Statements of Consideration included with the final rule stated in part the following:

> It is not the intent of the Commission to require reporting of trivial matters.

> Notification is required, however, of significant deficiencies in design and construction. The holder of a permit for construction of a nuclear powerplant is required to notify the Commission of each deficiency found in the processes of design, manufacture, fabrication, installation, construction, testing, and inspection which, were it to have remained uncorrected, could have affected adversely the safety of operations of the nuclear powerplant at any time throughout the expected lifetime of the plant, and which represents either (1) a significant breakdown in any portion of the quality assurance program, (2) a significant deficiency in final designs approved and released for construction, (3) a significant deficiency in the construction of or significant damage to a structure, system, or component requiring corrective action involving extensive effort, or (4) a significant deviation from performance specifications requiring corrective action involving extensive effort.

Because of its similar purpose to Part 21, 10 CFR 50.55(e) has evolved to mirror Part 21. In the August 28, 2007, rulemaking associated with 10 CFR Part 52, the NRC changed 10 CFR 50.55(e) to parallel Part 21 (72 FR 49352). All of the current requirements of 10 CFR 50.55(e) can be found in Part 21 with the exception of the following two more stringent requirements:

- The regulations in 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 to 10 CFR Part 50 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.

- The regulations in 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 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. Definition of Regulatory Problem

The requirements of 10 CFR 50.55(e) are largely redundant with Part 21. The existence of two near-identical reporting regulations can cause confusion. The NRC staff has noted that combined operating license applicants, licensees, and their vendors have been challenged by the applicability of 10 CFR 50.55(e) through the supply chain. Specifically, the staff has noted that the regulations and associated Statements of Consideration 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.

A combined licensee recently invoked 10 CFR 50.55(e) upon its engineering procurement and construction contractor. That contractor, in turn, invoked the requirements upon the nuclear steam supply company and its other suppliers. NRC vendor inspectors have noted during inspections that the requirements of 10 CFR 50.55(e) need not apply to vendors for regulatory compliance. However, those vendors still may be under contractual obligations. The inspectors have noted that suppliers of new reactor basic components should have requirements equal to those of suppliers to operating reactors. The staff has noted that the requirements of Part 21 should capture defects and failures to comply for vendors to meet the intent of Section 206 of the Energy Reorganization Act.

c. Options To Resolve Regulatory Problem

- Proposed Changes to NRC Regulations

  The staff is considering moving the unique requirements of 10 CFR 50.55(e) to Part 21, defining the scope of the applicability of these requirements, and deleting 10 CFR 50.55(e). The staff is also considering whether vendors should need to report QA breakdowns.

- Guidance Development

  As part of the overall rulemaking effort, the staff could add a detailed description of the process for reporting QA breakdowns to DG-1291. In addition, the staff would include guidance and examples of reportable QA breakdowns, as described in the NRC Enforcement Policy.

- Generic Communications

  The staff is not considering generic communication in this area. Generic communications are not the right instrument to adequately address redundancy in the regulations.

- Voluntary Programs

  The use of a voluntary program is not appropriate to adequately clarify this regulatory problem because it is related to redundancy and a lack of clarity in the NRC's regulations.

- No Action

  Taking no action will likely not result in a significant regulatory problem. However, taking no action does not address the confusion caused by duplicate requirements, and therefore is not a preferable option.

11. 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 states the following:

> 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 NRC. 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. Definition of Regulatory Problem

As evidenced by SECY-11-0154, the NRC is putting additional emphasis on keeping CFSI from entering the nuclear supply chain. The NRC does not have a formal reporting mechanism specifically for 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 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.

- Guidance Development

  As part of the overall rulemaking effort, the staff could add a detailed description regarding CFSI to DG-1291.

- Generic Communications

  The staff is not considering generic communication as part of the Part 21 rulemaking effort in this area. Generic communications are not the right instrument to adequately communicate the staff's expectations regarding evaluating CFSI under Part 21.

- Voluntary Programs

  The focus of this topic area is to provide additional guidance regarding evaluation of CFSI. While the nuclear industry is implementing voluntary programs related to CFSI, these programs do not address this area for improvement. The use of voluntary programs is not appropriate for this regulatory problem because it is related to the NRC's guidance on evaluating CFSI.

- No Action

  Taking no action will likely not result in a significant regulatory problem. However, taking no action would not take advantage of the opportunity to provide clarity on evaluating CFSI.

12. Contemporary Posting Requirements

a. Existing Regulatory Framework

The regulations in 10 CFR 21.6, "Posting Requirements," state in part the following:

> 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, as amended (42 U.S.C. 5846) states in part the following:

> 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. Definition of Regulatory Problem

The posting requirements in 10 CFR 21.6 and the Energy Reorganization Act do not specifically address and allow for digital posting of requirements. These posting requirements were written when posting physical paper copies was the most effective and logical, if not the only, means of communicating the regulation. Part 21 and the Energy Reorganization Act do not preclude the use of contemporary posting or other

communication methods, such as the use of digital media. However, absent explicit approval from the NRC, entities may be unwilling to take advantage of improved communication methods for fear of violating NRC requirements.

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 regulations are statutory and can be interpreted to allow modern communication methods to be employed to meet the regulation.

- Guidance Development

  As part of the overall rulemaking effort, the staff could describe acceptable ways to meet the posting requirements of Part 21 and the Energy Reorganization Act in DG-1291. The staff would clarify that contemporary posting methods, such as the use of digital media, meet these posting 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 10 CFR Part 20; 10 CFR Part 19, "Notices, Instructions and Reports to Workers; Inspection and Investigations"; and 10 CFR 50.7, "Employee Protection."

- Generic Communications

  The staff is not considering generic communication in this area. This problem does not meet the threshold for generic communications.

- Voluntary Programs

  Voluntary programs could clarify acceptable means of posting, in accordance with 10 CFR 21.6, however they would lack NRC endorsement. The staff is unaware of any industry initiatives in this area.

- No Action

  Current posting requirements do not preclude contemporary posting methods. However, taking no action would fail to take advantage of the opportunity to provide clarity on posting requirements and methods. The safety significance of not taking action is minimal.

13. Training

a. Existing Regulatory Framework

Part 21 does not explicitly address training of personnel. For reactor facilities, training requirements can be found in Criterion II, "Quality Assurance Program," of Appendix B. That regulation states in part the following:

> The program shall take into account the need for special controls, processes, test equipment, tools, and skills to attain the required quality, and the need for verification of quality by inspection and test. 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 set forth in the respective part of the *Code of Federal Regulations* (e.g., management measures are required for facilities licensed under 10 CFR Part 70; Subpart G, "Quality Assurance," of 10 CFR Part 72 sets forth QA requirements for facilities licensed under 10 CFR Part 72, etc.).

b. Definition of Regulatory Problem

NRC vendor inspectors have noted training deficiencies in personnel who are expected to maintain compliance with Part 21.

c. Options To Resolve Regulatory Problem

- Proposed Changes to NRC Regulations

  The staff is not considering changes to Part 21 to address this area.

- Guidance Development

  As part of the overall rulemaking effort, the staff could reinforce the training requirements in the relevant QA requirements in DG-1291. The staff would note that Part 21 activities affect quality and, therefore, personnel performing Part 21 activities must receive adequate training.

- Generic Communications

  The staff is not considering generic communication in this area. This problem does not meet the threshold for generic communications.

- Voluntary Programs

  Voluntary programs could clarify training requirements associated with Part 21. However, the staff is unaware of any industry initiatives in this area.

- No Action

  Taking no action would fail to take advantage of the opportunity to provide clarity on training requirements. The safety significance of not taking action is minimal.

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," NUREG-0302, Revision 1, October 1977.

U.S. Nuclear Regulatory Commission, "Event Reporting Guidelines: 10 CFR 50.72 and 50.73," NUREG-1022, Revisions 1 (January 1998) and 2 (October 2000), Supplement 1, and Draft Revision 3 (September 2011).

U.S. Nuclear Regulatory Commission, Inspection Manual Part 9900: 10 CFR Guidance, "10 CFR 50.55(e) Construction Deficiency Reporting," 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, 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, Note to Commissioners' Assistants, "Clarification of Staff Position on Part 21 Reporting Requirements," 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.

"Questions Asked at the 2011 Fuel Cycle Information Exchange Related to Title 10 of the Code of Federal Regulations Part 21," July 19, 2011, ADAMS Accession No. ML111880130.

CHAPTER 3 – COMMERCIAL GRADE DEDICATION

A. Lack of Regulatory Guidance

a. Existing Regulatory Framework

Dedication is a key regulatory process, since it allows the use of commercial parts and services in safety-related applications.

Dedication is defined in 10 CFR 21.3, for reactor facilities and activities, in part, as follows:

> 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 an Appendix B, quality assurance program.

Dedication is further defined in 10 CFR 21.3, for nonreactor facilities and activities, in part, as follows:

> 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 Electric Power Research Institute (EPRI) NP-5652, "Guideline for the Utilization of Commercial Grade Items in Nuclear Safety Related Applications (NCIG-07)," issued June 1988, in Generic Letter 89-02, "Actions to Improve the Detection of Counterfeit and Fraudulently Marketed Products," dated March 21, 1989. EPRI NP-5652 is still considered the essential roadmap to the dedication process.

Generic Letter 91-05, "Licensee Commercial-Grade Procurement and Dedication Programs," dated April 9, 1991, identified 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 regarding commercial grade procurement and dedication programs that would provide acceptable methods to meet regulatory requirements.

More recently, Information Notice 2011-01, "Commercial-Grade Dedication Issues Identified during NRC Inspections," dated February 15, 2011, summarized the staff's observations and findings in the area of commercial grade dedication.

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

b. Definition of Regulatory Problem

The regulatory framework for dedication currently resides solely in 10 CFR 21.3 and is not discussed in the body of the regulation. Stakeholders do not have contemporary and consolidated guidance to help ensure that dedication is performed properly. As such, the regulation is difficult to apply. This is evident by repetitive inspection findings, which illustrate inadequate licensee and vendor interpretation of the dedication process.

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. Repetitive inspection findings and the lack of contemporary guidance, paired with an increasing use of commercial grade dedication for nuclear components, illustrate the need to clarify and consolidate guidance.

Licensee programs must assure 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 use of potentially substandard items and services in safety systems is safety significant.

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.

- Guidance Development

  The staff could develop a regulatory guide on commercial grade dedication to accompany the Part 21 rulemaking. The NRC's regulatory guides provide guidance to stakeholders on implementing 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.

  A regulatory guide to address commercial grade dedication would be essential in providing clear expectations to Part 21 stakeholders. The staff has begun developing DG-1292, "Dedication of Commercial Grade Items." The draft guide is expected to endorse and consolidate industry guidance. For instance, the staff expects to endorse an updated version of EPRI NP-5652 to provide guidance on implementation of the dedication process. The staff also expects to review and endorse industry guidance on sampling in dedication. As noted below, EPRI plans to issue a revision to EPRI TR-017218-R1, "Guideline for Sampling in the

Commercial-Grade Item Acceptance Process," issued January 1999.

Through the regulatory guide, the staff expects to point to other NRC guidance in technical areas related to dedication, such as the use of commercial calibration and testing laboratories, and software dedication. As noted below, the staff plans to provide guidance on these areas before completion of the rulemaking effort.

- Generic Communications

  With the absence of regulatory guides, the most significant guidance provided by the staff has been through its generic communications. As noted in the existing regulatory framework section above, Generic Letters 89-02 and 91-05 have provided the staff's most comprehensive guidance on dedication. However, the narrow scope of previous generic communications and the lack of consolidated guidance have proven to be ineffective in reaching some vendors.

  Generic communications are not the right instrument to adequately communicate the staff's expectations for commercial grade dedication requirements. Furthermore, generic communications do not provide a consolidated approach to the problem of the lack of guidance.

- Voluntary Programs

  The industry is developing revised commercial grade dedication guidance. EPRI has developed guidance on software dedication and is working on revisions to EPRI NP-5652 and TR-102260, "Supplemental Guidance for the Application of EPRI Report NP-5652 on the Utilization of Commercial Grade Items," issued March 1994. The industry has also expressed an interest in revising EPRI TR-017218 for sampling, as well as other guides relevant to dedication.

  These voluntary efforts will provide the staff with guidance that can be endorsed through a regulatory guide. NRC endorsement of industry guidance through a regulatory guide would provide a comprehensive solution to the lack of current guidance.

- No Action

  Taking no action would result in the continuance of the Part 21 problems discussed above. The many repetitive problems with Part 21 are significant enough to warrant action. Therefore, taking no action is not a viable option.

B. Proper Place for Commercial Grade Dedication Requirements

a. Existing Regulatory Framework

As noted in areas A and C, dedication is defined 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 process. 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. The NRC's regulations contain no other substantive requirements for commercial grade dedication.

b. Definition of Regulatory Problem

The regulatory framework for dedication resides primarily in the definition of dedication found in 10 CFR 21.3 and is not discussed in the body of the regulation. As such, the regulation is difficult to apply in today's industry as evidenced by inadequate licensee and vendor interpretation of the dedication process.

In 1978, licensees typically performed dedication activities for a small number of basic components that were unavailable from suppliers under Appendix B. The supply chain for nuclear power reactors has greatly evolved since the initial issuance of Part 21. The number of nuclear industry suppliers implementing an Appendix B QA program has declined. This evolution has prompted an increased reliance by nuclear power reactor licensees on commercial grade dedication.

c. Options To Resolve Regulatory Problem

- Proposed Changes to NRC Regulations

  The staff is considering restructuring Part 21 to separate evaluation and reporting requirements from commercial grade dedication requirements. This would provide a contemporary and proper regulatory framework for dedication. The staff is considering the addition of 10 CFR 21.71, "Commercial Grade Dedication Requirements," to include the implementation details that are removed from the definitions. As an alternative, the staff is considering the benefits of moving dedication to an appendix to Part 21 or creating a new regulation (e.g., Part 22).

- Guidance Development

  While guidance development is a large part of the overall rulemaking effort, as recommended in Section A above, this regulatory problem stems from a lack of clarity and structure in the rule language. Guidance cannot address this area for improvement.

- Generic Communications

  The staff is not considering generic communication in this area. Generic communications are not the right instrument to adequately clarify and structure the regulatory framework of dedication.

- Voluntary Programs

  The use of a voluntary program is not appropriate for this regulatory problem because it is related to the structure of the rule language.

- No Action

  Taking no action in this area does not address the problem of a lack of a proper regulatory framework for dedication. This would contribute to continued misinterpretation of the regulation and result in continuance of the Part 21 problems noted above. The many repetitive findings, and the corresponding potential for substandard parts and services to be used in safety systems are significant enough to warrant action. Therefore, taking no action is not a viable option.

C. Definition of Dedication

a. Existing Regulatory Framework

The definition of dedication in 10 CFR 21.3 states the following:

> (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.

The NRC has approved exemption requests for some 10 CFR Part 70 licensees from the dedication definition. These exemptions incorporate many elements of the reactor definition (e.g., identifying critical characteristics, verifying their acceptability), as well as elements of 10 CFR Part 70. One example is as follows (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. Definition of Regulatory Problem

The current definition of dedication provides potentially confusing information and is not consistent with EPRI NP-5652. EPRI NP-5652 is the only industry guide that the NRC has endorsed. The staff conditionally endorsed EPRI NP-5652 in Generic Letter 89-02. It is the most widely used industry guide on dedication.

As noted above in Sections A and B, the Part 21 definitions currently encompass the regulatory framework for dedication. The definition of dedication describes implementation details, which go beyond the fundamental intent of dedication. The definitions section is not an ideal fit for such details. Furthermore, the details in the definition are inconsistent with the methods described in EPRI NP-5652, which currently provides the most comprehensive guidance on commercial grade dedication. The implementation details in Part 21 are not extensive enough to provide comprehensive guidance on how to dedicate, yet are not aligned with EPRI NP-5652.

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

Many vendor inspections findings are related to a lack of recognition that the dedicating entity is actually performing dedication. The only two ways to create a basic component are to design and manufacture it under an appropriate QA program (e.g., Appendix B for reactor facilities) or to dedicate it.

In addition, nonreactor licensees are presented with conflicting requirements for dedication. Dedication is defined separately for facilities and activities other than nuclear power plants. That definition does not provide the same level of specificity for the process as that provided for reactor facilities.

Since 2008, the NRC has approved a number of exemption requests by materials applicants and nonreactor licensees. These exemptions have sought to address challenges caused by Part 21 for design and construction of new enrichment and fuel fabrication facilities. The exempted definitions mirror those for reactor facilities.

c. Options To Resolve Regulatory Problem

- Proposed Changes to NRC Regulations

  In conjunction with the efforts noted in Sections A and B above, the staff is considering restructuring Part 21, including the definitions of dedication. The fundamental principle of dedication should be kept in the definitions. This emphasizes 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. This is consistent with the proposed changes recommended in Section B above.

For nonreactor facilities, the approved exemptions highlight the need for improved commercial grade dedication requirements. Revising the definition of dedication is a critical element of this activity. Revising the definition would help to alleviate the level of subjectivity associated with implementing the existing definition. This would also reduce the need for future exemptions.

For nonreactor licensees, the revised definition may require program enhancements, and present additional requirements. Therefore, the staff plans to propose a 12 month grace period for implementation of the new requirements following the effective date of the final rule. This would allow licensees time to revise procedures, conduct staff training, and establish dedication programs consistent with the revised rule. The staff notes that commercial grade items purchased and dedicated before the implementation date of the revised rule would not be subject to the revised definition.

The staff is considering the following additions (*in italics*) and deletions (~~in strikethrough~~) to the definition of dedication in 10 CFR 21.3:

> ~~(1) When applied to nuclear power plants licensed pursuant to 10 CFR Part 30, 40, 50, 60, dedication~~*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 *an appropriate quality assurance program (e.g., 10 CFR Part 50, Appendix B, quality assurance program for nuclear power plants licensed pursuant to 10 CFR Part 50 or Part 52).* ~~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.~~

The staff is considering the additions *in italics* and deletions ~~in strikethrough~~ to the definition of dedicating entity in 10 CFR 21.3 “Definitions”:

> ~~When applied to nuclear power plants licensed pursuant to 10 CFR Part 50,~~ ~~d~~*D*edicating 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.~~

The staff is considering the addition of the new section 10 CFR 21.71 to include the implementation details that are removed from the definitions. In the event that the subject of dedication is moved to a separate appendix or a new part of 10 CFR, as noted above in Section B, the implementation details would be moved accordingly.

- Guidance Development

  As noted above, regulatory guidance will be essential in providing clear expectations to Part 21 stakeholders. The staff has begun developing DG-1292, which will focus on the dedication process.

  However, guidance alone cannot remedy potential confusion in the definitions. Therefore, guidance would be developed in parallel with a change in the rule language to take advantage of the opportunity to provide clear regulations and associated guidance.

- Generic Communications

  The staff is not considering generic communication in this area. Generic communications are not the right instrument to adequately clarify the definition of dedication.

- Voluntary Programs

  The use of a voluntary program is not appropriate for this regulatory problem because it stems from a lack of clarity in the rule language.

- No Action

  Taking no action in this area would result in continued misinterpretations of the intent of dedication. For materials and nonreactor facilities and activities, the current regulations and guidance would remain inadequate in describing the NRC’s expectations for dedication and could result in additional future exemption requests. The many repetitive problems with commercial grade dedication are significant enough to warrant action. Therefore, taking no action is not a viable option.

D. Definition of Commercial Grade Item

a. Existing Regulatory Framework

The definition of commercial grade item in 10 CFR 21.3 states the following:

> (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).

An October 19, 1978, amendment to the regulation (43 FR 48621) first defined commercial grade items in Part 21. In the Statements of Consideration for that rulemaking, the NRC noted the need to limit the types of items included in the scope for reporting of defects and noncompliance.

In September 19, 1995 (60 FR 48369), in response to an industry petition, the NRC stated the following:

> 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.

The NRC further stated the following:

> With the development of increased confidence in licensee implementation of dedication activities through NRC inspection and experience, and because the availability of basic components has further declined, the NRC believes that the current definition of commercial grade items has become unnecessarily restrictive.

Despite this, the NRC noted that the definition of commercial grade items should be somehow limited, since certain items cannot be dedicated. The NRC stated the following:

The petitioner proposed that a commercial grade item be defined as any item that has not been dedicated for use as a basic component. Thus, any commercial grade item could be subject to a dedication process to verify its qualification as a basic component. The Commission maintains that not all commercial grade items can be properly dedicated for safety-related use after the manufacturing process is completed. In fact several commenters agreed that there is a limited category of components for which quality assurance is an integral part of the manufacturing process and that their critical characteristics cannot be attested to after-the-fact. The Commission believes that if the design or manufacturing process of an item is such that dedication cannot reasonably assure the absence of a defect that could affect one or more critical characteristics of the item, the item must be designed and manufactured as a basic component in accordance with 10 CFR Part 50, Appendix B requirements. There are components in this limited category that generally have requirements and applications in which the design and manufacturing processes require in-process inspections and verifications to ensure that defects and failures to comply are identified and corrected. Thus, the NRC believes that commercial grade items cannot encompass the full spectrum of items envisioned by the petitioner.

b. Definition of Regulatory Problem

The definition of commercial grade item in 10 CFR 21.3 is not consistent with contemporary uses of dedication. This arises from the evolution of the definition and the fact that dedication was initially a last-resort process when Appendix B suppliers were unavailable. The definition of a commercial grade item contains the concept that certain items cannot be dedicated. The staff noted in the Statement of Considerations to the 1995 amendments that in some cases QA is integral to the design or manufacture of an item. Therefore, the staff added the second sentence to the definition of commercial grade item, which states that commercial grade items do not include items for which the design and manufacture 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).

As noted above, this was the staff's attempt to restrict certain items from being dedicated. However, in practice, a dedicating entity may not know whether it can dedicate an item until it has undertaken the dedication process. For instance, through its analysis it may be revealed that a proprietary manufacturing process is critical in ensuring that an item will perform its safety function. If the dedicating entity has no way to evaluate that proprietary process, then that item cannot be dedicated.

In the example above, the item could not be designated as a commercial grade item. A more logical approach would be to designate all items not designed and manufactured as basic components as commercial grade items. In the example, the item described would be a commercial grade item that cannot be dedicated.

The staff has noted similar regulatory problems for nonreactor facilities. 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 proposed changes to 10 CFR Part 21 regulatory requirements for nonreactor licensees were being considered. However, the staff has not yet initiated any such changes.

Since 2008, the NRC has approved a number of exemption requests that have been submitted to the agency by materials applicants and nonreactor licensees because of the 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 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 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. The definition of a commercial grade item should be clarified for nonreactor licensees, and the NRC should consider changes comparable to those provided for reactor facilities.

c. Options To Resolve Regulatory Problem

- Proposed Changes to NRC Regulations

  The staff is considering revising the definition of commercial grade items to provide a simple contemporary definition. This would make the definition consistent with a common understanding of commercial items. The staff is considering moving the second sentence, which restricts what can be dedicated, to the proposed new section, part, or appendix on dedication discussed above.

  In addition, the staff is considering making the definition of commercial grade item consistent for reactor and nonreactor facilities. This could be accomplished by deleting all references to specific regulations.

  Under this proposal, all items not designed and manufactured under an appropriate QA program would be considered commercial grade items. The description of the dedication process would still restrict certain items from being dedicated.

  The staff is considering the following additions (*in italics*) and deletions (~~in strikethrough~~) to the definition of commercial grade item in 10 CFR 21.3:

  > ~~(1) When applied to nuclear power plants licensed pursuant to 10 CFR part 50, c~~*C*ommercial 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).~~

The deleted concepts from the current definition would be moved to the new section, part, or appendix on dedication, as recommended in Section B above.

- Guidance Development

  The NRC's development of a regulatory guide on dedication will be essential in providing clear expectations to Part 21 stakeholders. The staff has begun developing DG-1292. The industry has expressed interest in the development of an NEI working group to support guidance development.

  However, the use of guidance alone will not address the fundamental flaws of the definition of commercial grade items.

- Generic Communications

  The staff is not considering generic communication in this area. Generic communications are not the right instrument to adequately clarify the definition of a commercial grade item.

- Voluntary Programs

  The use of a voluntary program is not appropriate for this regulatory problem because it stems from a lack of clarity in the rule language.

- No Action

  The definition for a commercial grade item, as stated in Part 21, has required various 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.

  Taking no action in this area does not address the problem of a lack of a proper regulatory framework for dedication. This would contribute to continued misinterpretation of the regulation and result in continuance of the Part 21 problems noted above. Therefore, taking no action is not a viable option.

E. Clarification of Dedication as a Safety-Related Activity for Reactor Facilities

a. Existing Regulatory Framework

The definition of dedication for reactor facilities in 10 CFR 21.3 states in part the following:

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

The definition of a basic component in 10 CFR 21.3, as it applies to reactor facilities, states in part 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:
>
> (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.

The definition of safety-related structures, systems, and components for reactor facilities in 10 CFR 50.2, “Definitions,” states 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:
>
> (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.

b. Definition of Regulatory Problem

For reactor facilities, NRC vendor inspections have noted many instances of dedication being performed without adequate QA controls. Specifically, inspections have found that many dedication activities are performed improperly, without being in accordance with applicable provisions of Appendix B. A common example is dedication performed without adequate documentation, as required by Criterion V, “Instructions, Procedures, and Drawings,” of Appendix B.

c. Options To Resolve Regulatory Problem

- Proposed Changes to NRC Regulations

  As noted above, the staff is considering changes to the structure of Part 21, to include revising the definition of dedication. The staff is considering moving the following sentence from the definitions to the new section, part, or appendix on dedication:

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

- 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 discuss dedication as a safety-related activity. The guide is expected to endorse industry guidance, such as a new revision to EPRI NP-5652.

- Generic Communications

  The staff is not considering generic communication in this area. Generic communications are not the right instrument to adequately clarify that dedication is a safety-related activity.

- Voluntary Programs

  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 can be endorsed through a regulatory guide. However, the use of a voluntary program alone would not provide NRC-approved guidance to licensees or vendors, and therefore is not an appropriate standalone solution.

- No Action

  Taking no action in this area would result in the continued performance of inadequate commercial grade dedication. 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. Dedication Plans and the Importance of Safety Function

a. Existing Regulatory Framework

Dedication plans and safety function are not explicitly linked in Part 21. However, the definition of dedicating entity in 10 CFR 21.3 states in part the following:

> 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.

EPRI NP-5652 discusses safety function and the use of dedication plans. Regarding safety function, Section 2.1, "Determining Safety Function of Item," of EPRI NP-5652 states in part the following:

> The first step is to perform an evaluation to determine if an item is safety-related based on its function.

Throughout the discussion in EPRI NP-5652 regarding the use of the four methods of dedication, the document notes the following:

> critical characteristics should be verified by developing a documented plan or checklist.

In addition, Generic Letter 91-05 addresses the importance of technical evaluations to identify critical characteristics, acceptance criteria, and the methods to be used for verification. Dedication plans and the importance of safety function are also in ASME NQA-1. The NRC endorsed ASME NQA-1-2008 and the NQA-1a-2009 Addenda in Revision 4 of Regulatory Guide 1.28.

b. Definition of Regulatory Problem

Similar to the problems noted above, dedication requirements are currently embedded in the definitions contained in Part 21. For example, the definition of dedicating entity notes that records must be kept for dedication.

NRC vendor inspections have noted many findings of inadequate commercial grade dedication because of a lack of documentation in a dedication plan and inadequate knowledge of the safety function of the item being dedicated.

In certain cases, licensees did not provide dedicating entities with sufficient information on an item's end use for the entity to develop a set of critical characteristics. In other cases, dedicating entities were verifying critical characteristics without documenting why the tests were adequate to make the item a basic component.

As emphasized in Section E above, dedication is a safety-related activity. For entities subject to Appendix B, Criterion V requires that dedication, which is an activity affecting quality, be "prescribed by documented instructions, procedures, or drawings, of a type appropriate to the circumstances and shall be accomplished in accordance with these instructions, procedures, or drawings." Non-reactor facilities are subject to requirements similar to Appendix B for safety-related activities (e.g., fuel cycle and enrichment facilities are required to have records as part of the facilities' management measures, which are in place to ensure availability and reliability of items relied on for safety).

As offered in EPRI NP-5652, plans and checklists are critical for the planning of the verification of critical characteristics. The use of dedication plans offers clear justification of the engineering judgment applied to the process. The NRC considers auditable

records crucial to providing adequate evidence that dedication was appropriately accomplished with applicable QA requirements (e.g., Appendix B for reactor facilities).

Dedication is defined as the acceptance process undertaken to provide reasonable assurance that a commercial grade item will perform its intended safety function. Therefore, knowledge of the item's safety function appears to be an essential component of dedication. However, many items are dedicated without the safety function being identified. This practice may be acceptable in certain circumstances. For example, raw materials can be dedicated for use in a variety of applications, yet it is not necessary to know the end use of the raw materials. However, the regulations and available guidance do not provide clear expectations regarding safety function.

c. Options To Resolve Regulatory Problem

- Proposed Changes to NRC Regulations

  The staff is considering moving details in the definition of dedicating entity from the definitions section to the proposed new section, part, or appendix on dedication.

  The staff is considering explicitly requiring dedication plans in Part 21. Documentation is currently required via the definition of dedicating entity. Reactor facilities are required to document via Criterion V of Appendix B and nonreactor facilities via QA requirements such as Part 70's management measures. Formalizing the requirement in Part 21 would ensure that dedicating entities clearly understand the requirement to properly document dedication. In addition, creating a requirement to use dedication plans would provide clear enforceable regulations.

- 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 would include a discussion on dedication plans and safety function. The guide is expected to endorse industry guidance, such as a revision to EPRI NP-5652.

- Generic Communications

  The staff is not considering generic communication in this area. Generic communications are not the right instrument to adequately emphasize the importance of using dedication plans and knowing the safety function of the item or service being dedicated.

- Voluntary Programs

  The industry is revising the commercial grade dedication guidance in EPRI NP-5652, which is the most prevalently used guide. A revised version of EPRI NP-5652 would be the ideal vehicle for detailing the implementation of dedication plans and the knowledge and use of safety function in the dedication process. These voluntary efforts will provide the staff with guidance that can be endorsed through a regulatory guide.

- No Action

  Taking no action in this area would result in continued performance of inadequate commercial grade dedication. The many repetitive problems with inadequate performance and documentation in dedication are significant enough to warrant action. Therefore, taking no action in this area is not a viable option

G. Sampling Requirements

a. Existing Regulatory Framework

Part 21 does not explicitly address the acceptance of sampling in dedication. However, many of the industry standards that the NRC has approved for compliance with Appendix B provide guidance on sampling. For example, Section 7.3.2, "Receiving Inspection," of American National Standards Institute (ANSI) N45.2.13-1976, "Quality Assurance Requirements for Control of Procurement of Items and Services for Nuclear Power Plants," states in part: "Sampling may be utilized during receiving inspection when conducted in accordance with established procedures or recognized standards."

NRC Inspection Procedure (IP) 38703, "Commercial-Grade Dedication," and IP 43004, "Inspection of Commercial-Grade Dedication Programs," describe sampling in dedication and the selection of sampling plans. These NRC inspection procedures emphasize the importance of documenting the basis for the selection of the sample plan. This documentation should address the factors that were considered before selecting a sampling plan. Documentation should also present the technical justification for sampling.

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 following:

> 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 conditionally endorsed, states in part: "The test and inspections may be performed utilizing a sampling plan when appropriate."

EPRI TR-017218, which the NRC has not approved, provides detailed guidance on the use of sampling in dedication.

b. Definition of Regulatory Problem

NRC inspectors found cases during recent vendor inspections in which vendor procedures did not provide adequate guidance for the development of sampling plans consistent with staff guidance and industry standards. Also, inspections 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 as a result of sampling being improperly conducted.

Sampling of commercial grade items during dedication should provide reasonable assurance that items inspected and tested conform to specification requirements. Sampling of items for dedication can be controlled by establishing heat traceability of metallic material or establishing lot/batch controls on the items. When neither can be verified, documented sampling plans need to be established on an individual, item specific basis to provide a high level of assurance of the item's suitability.

The NRC has not promulgated specific requirements relative to the development of sampling practices as part of commercial grade dedication. However, the NRC has not endorsed a guide as comprehensive as EPRI TR-017218. The EPRI guide is the standard most used by vendors to dedicate, and the NRC staff presentations have recommended this guide as an excellent starting point. With some modification, the EPRI guide could be endorsed by an NRC regulatory guide.

c. Options To Resolve Regulatory Problem

- Proposed Changes to NRC Regulations

  The staff is considering amendments to Part 21 to ensure consistent and effective dedication of commercial grade items. These amendments will clearly define sampling requirements as part of dedication. Specifically, the staff is considering briefly defining sampling in the revised regulation. The proposed rule language will be consistent with current industry practice for sampling. However, implementation details regarding sampling should remain in guidance documents, as noted below.

- 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 would include implementation guidance on sampling. The guide is expected to endorse industry guidance, such as potential new revisions to EPRI NP-5652 and EPRI TR-017218. For NRC endorsement, the current version of EPRI TR-017218 would require a description of a format for documenting the sampling justification, among other potential modifications.

Licensees' and suppliers' use of this guidance will 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.

- Generic Communications

  The staff is not considering generic communication in this area. Generic communications are not the right instrument to endorse industry guidance on sampling requirements in the commercial grade dedication process.

- Voluntary Programs

  The industry commonly uses the current version of EPRI TR-017218, which contains guidance on the use of sampling in dedication. However, the guide requires modification to be endorsed by the NRC without conditions. The industry is planning to revise EPRI TR-017218 to support this rulemaking. This industry guide can be endorsed through a regulatory guide. However, the use of voluntary programs alone will not provide NRC-approved guidance to licensees or vendors, and is therefore not an appropriate standalone solution in this area.

- No Action

  Taking no action in this area would result in continued performance of inadequate commercial grade dedication. 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 viable option.

H. Use of Commercial Calibration and Testing Laboratories—International Laboratory Accreditation Cooperation Process

a. Existing Regulatory Framework

Criterion VII, "Control of Purchased Material, Equipment and Services," of Appendix B states in part the following:

> The effectiveness of the control of quality by contractors and subcontractors shall be assessed by the applicant or designee at intervals consistent with the importance, complexity, and quantity of the product or services.

Criterion XII, "Control of Measuring and Test Equipment," of Appendix B states the following:

> Measures shall be established to assure that tools, gages, instruments, and other measuring and testing devices used in activities affecting quality are properly controlled, calibrated, and adjusted at specified periods to maintain accuracy within necessary limits.

On September 28, 2005, the NRC approved a request from Arizona Public Service Company (APS) that proposed a change to the Quality Assurance Program (QAP) for

the Palo Verde Nuclear Generating Station. The proposed change provided for the use of accreditation of commercial grade calibration services by a nationally recognized accrediting body (AB) in lieu of a commercial grade survey or in-process surveillance. In its proposed change to the QAP, APS stated that nationally recognized ABs include the National Voluntary Laboratory Accreditation Program (NVLAP) and others recognized by NVLAP through a mutual recognition arrangement (MRA). The NRC staff understood this statement to include other U.S.-based ABs accepted as signatories (full members) to the International Accreditation Cooperation Process (ILAC) MRA.

The NRC staff approved APS's request based on the review of the NVLAP and American Association of Laboratory Accreditation (A2LA) programs recognized through the ILAC MRA with the following conditions:

- NRC review and approval is limited to NVLAP and A2LA.
- The QA program description documents the alternative method.
- Accreditation is to International Standard Organization/International Electrotechnical Commission (ISO/IEC) 17025, "General Requirements for the Competence of Testing and Calibration Laboratories."
- The scope of accreditation covers the contracted services.
- Purchase documents should (1) impose additional technical and administrative requirements, (2) require reporting as-found calibration data, and (3) require identification of the laboratory equipment and standards used.

To use commercial grade calibration services, licensees and suppliers would be required to dedicate the services, which should include surveys or in-process surveillances. Through the APS Safety Evaluation Report (SER), the NRC recognized the accreditation provided by six U.S. ABs as an alternative to performing commercial grade surveys or in-process surveillances as part of the dedication process.

The process described above can only be applied to the dedication of commercial grade calibration services and is not applicable for the procurement of calibration services as basic components. In other words, this dedication process may not be used to place a commercial entity on an approved suppliers list. To procure any items or services as basic components, licensees and vendors are required to perform an audit.

b. Definition of Regulatory Problem

NRC vendor inspections identified multiple instances of vendors improperly dedicating commercial grade calibration services. In many instances, vendors have improperly used accreditation by ABs as the justification for placing the laboratories on approved suppliers' lists and purchasing the services as safety-related.

The APS SER noted above focused on the APS program. The SER did not discuss the broad application to the nuclear industry of the alternatives. For instance, the SER did not emphasize that any commercial grade service must be dedicated for it to be considered safety-related. The focus of the SER has proven to be too narrow to provide

clear guidance to the broad spectrum of all nuclear vendors. The SER is frequently taken out of context and misinterpreted.

c. Options To Resolve Regulatory Problem

- Proposed Changes to NRC Regulations

  The staff is not considering changes to Part 21 to address this area.

- 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 discuss the use of commercial grade calibration and testing laboratories.

  As noted below, the nuclear industry plans to request NRC endorsement of a methodology for dedicating commercial grade calibration and testing services. If acceptable, the staff plans to endorse this proposal using an SER and issue generic communications. The overall guidance on dedication will include these documents and will provide clear and consolidated guidance on how to dedicate these services.

- Generic Communications

  As noted above, the staff anticipates that the planned industry submittal and corresponding SER will provide clear and consolidated guidance. The staff plans to issue generic communications following completion of the SER outside of the Part 21 rulemaking effort.

- Voluntary Programs

  The NEI submitted a letter to the NRC dated September 16, 2011, describing a proposal for expanded use of internationally accredited calibration and testing laboratories (ADAMS Accession No. ML112700589). On October 4, 2011, the NRC responded to the NEI letter and described the NRC's general support of NEI's approach (ADAMS Accession No. ML112710405).

  The staff anticipates that the planned industry submittal and corresponding SER will provide clear and consolidated guidance. The regulatory guide on dedication can refer to this guidance.

- No Action

  The actions described above are being undertaken independent of the Part 21 rulemaking effort. The rulemaking effort, which potentially includes publication of regulatory guidance, is the ideal vehicle to consolidate the available guidance on the use of commercial calibration and testing laboratories. Therefore, taking no action in this area is not a viable option.

I. Software Dedication

a. Existing Regulatory Framework

The definition of basic component in 10 CFR 21.3 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 10 CFR Part 52, whether these services are performed by the component supplier or others.

The NRC endorsed ASME NQA-1-2008 and the 2009 Addenda in Regulatory Guide 1.28. Subpart 2.7, "Quality Assurance Requirements for Computer Software for Nuclear Facility Applications," of ASME NQA-1 includes requirements for software.

b. Definition of Regulatory Problem

Safety-related software use has increased since the genesis of Part 21. Part 21 and the philosophy of dedication apply to all safety-related items and services, including software. However, Part 21 and its associated guidance do not provide contemporary requirements for software dedication.

While the staff notes that software can be safety-related and can be dedicated, some stakeholders have interpreted Part 21 to the contrary. Part 21 provides an area for potential improvement in defining the requirements for software dedication.

c. Options To Resolve Regulatory Problem

- Proposed Changes to NRC Regulations

  As part of the overall rulemaking effort, the staff is considering revising the definitions for simplicity and clarity. For example, the revised definition of commercial grade item, as proposed in Section D above, would unequivocally include software. The staff is considering ensuring that Part 21 does not exclude software and software dedication.

- 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 would include implementation guidance for software. The guide will consolidate the NRC-approved guidance described below.

  The staff is reviewing EPRI guide "Plant Engineering: Guideline for the Acceptance of Commercial-Grade Design and Analysis Computer Programs Used in Nuclear Safety-Related Applications 1025243." The staff is considering endorsing this guide through a separate regulatory guide outside of the Part 21 rulemaking effort, or the staff may include it in its final publication of DG-1292, depending on project schedules.

- Generic Communications

  The staff is not considering generic communication in this area. Generic communications are not the right instrument to provide comprehensive guidance on software dedication.

- Voluntary Programs

  The staff plans to review and potentially endorse industry guidance outside of the rulemaking process. The staff can include additional guidance as part of these efforts as necessary, with the overall goal of providing clear and contemporary guidance.

- No Action

  The actions described above are being undertaken independent of the Part 21 rulemaking effort. The rulemaking effort, which potentially includes publication of regulatory guidance, is the ideal vehicle to consolidate the available guidance on software dedication. Therefore, taking no action in this area is not a viable option.

References

U.S. Nuclear Regulatory Commission, "Sampling Plans Used for Dedicating Simple Metallic Commercial Grade Items for Use in Nuclear Power Plants," Draft Regulatory Guide DG-1070, November 24, 1999.

U.S. Nuclear Regulatory Commission, "Closure of User Needs Request-1998-030," March 22, 2002. Prepared for the Office of Research review of the EPRI sampling guideline EPRI TR-017218-R1, "Guideline for Sampling in the Commercial-Grade Item Acceptance Process."

U.S. Nuclear Regulatory Commission, "Quality Assurance Program Criteria (Design and Constriction)," Regulatory Guide 1.28, Revision 4, June 2010.

U.S. Nuclear Regulatory Commission, "Design, Inspection, and Testing Criteria for Air Filtration and Adsorption Units of Post-Accident Engineered-Safety-Feature Atmosphere Cleanup Systems in Light-Water-Cooled Nuclear Power Plants," Regulatory Guide 1.152, Revision 3, July 2011.

U.S. Nuclear Regulatory Commission, "Review of EPRI TR-106439," July 17, 1997, ADAMS Accession No. ML092190664.

U.S. Nuclear Regulatory Commission, "Final Safety Evaluation for EPRI TR-107330," July 30, 1998, ADAMS Accession No. ML12205A265.

U.S. Nuclear Regulatory Commission, "Final Safety Evaluation for Technical Report NEI 06-14, Revision 9," July 13, 2010, ADAMS Accession No. ML101800497.

U.S. Nuclear Regulatory Commission, "Guidance on Software Reviews for Digital Computer-based Instrumentation and Control Systems," Branch Technical Position 7-14, Revision 5, NUREG-0800, "Standard Review Plan for the Review of Safety Analysis Reports for Nuclear Power Plants: LWR Edition," March 2007.

U.S. Code of Federal Regulations, "Domestic Licensing of Production and Utilization Facilities," Part 50, Chapter I, Title 10, "Energy."

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

American Society of Mechanical Engineers, "Quality Assurance Requirements for Nuclear Facility Applications," ASME NQA-1-2008, New York, NY.

American Society of Mechanical Engineers, "Quality Assurance Requirements for Nuclear Facility Applications," ASME NQA-1a-2009 Addenda to ASME NQA-1-2008, New York, NY.

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.”

Electric Power Research Institute, “Guideline for the Utilization of Commercial Grade Items in Nuclear Safety Related Applications (NCIG-07),” EPRI NP-5652, June 1988.

Electric Power Research Institute, “Supplemental Guidance for the Application of EPRI Report NP-5652 on the Utilization of Commercial Grade Items,” EPRI TR-102260, March 1994.

Electric Power Research Institute, “Guideline for the Utilization of Sampling Plans for Commercial-Grade Item Acceptance (NCIG-19),” EPRI NP-7218.

Electric Power Research Institute, “Guideline for Sampling in the Commercial-Grade Item Acceptance Process,” EPRI TR-017218-R1, June 1999.

Electric Power Research Institute, “Guideline on Evaluation and Acceptance of Commercial Grade Digital Equipment for Nuclear Safety Applications,” EPRI TR-106439, October 1996.

Electric Power Research Institute, “Generic Requirements Specification for Qualifying a Commercially Available PLC for Safety-Related Applications in Nuclear Power Plants,” EPRI TR-107330, December 1996.

Electric Power Research Institute, “Evaluating Commercial Digital Equipment for High Integrity Applications,” EPRI TR-107339, December 1997.

Institute of Electrical and Electronics Engineers, “Standard Criteria for Digital Computers in Safety Systems of Nuclear Power Generating Stations,” IEEE 7-4.3.2-2003, December 19, 2003.

Nuclear Energy Institute, “Quality Assurance Program Description,” NEI 06-14A, Revision 7, August 2010.

U.S. Nuclear Regulatory Commission, “Actions to Improve the Detection of Counterfeit and Fraudulently Marketed Products,” Generic Letter 89-02, March 21, 1989.

U.S. Nuclear Regulatory Commission, “Licensee Commercial-Grade Procurement and Dedication Programs,” Generic Letter 91-05, April 9, 1991.

U.S. Nuclear Regulatory Commission, *Federal Register,* Volume 43, October 19, 1978, p. 48622.

U.S. Nuclear Regulatory Commission, *Federal Register,* Volume 60, September 19, 1995, p. 48369.

U.S. Nuclear Regulatory Commission, “Request for an Exemption from 10 CFR Part 21.3 Commercial Grade Item, MOX Services,” 2008, ADAMS Accession No. ML0800303932.

U.S. Nuclear Regulatory Commission, “Approval of Louisiana Energy Services Part 21 Exemption Request and Amendment 13 to License,” 2009, ADAMS Accession

No. ML110140698.

U.S. Nuclear Regulatory Commission, “Approval of Areva Enrichment Services Part 21 Exemption Request,” 2010, ADAMS Accession No. ML110140636.

International Standard Organization/International Electrotechnical Commission, “General Requirements for the Competence of Testing and Calibration Laboratories,” ISO/IEC 17025.

CHAPTER 4 - ADMINISTRATIVE CHANGES

The following potential changes to the rule language are administrative in nature. The changes aim to correct omissions and typographical errors. These changes are not assessed as those in Chapters 2 and 3 of this regulatory basis. They are proposed as administrative corrections to the regulations under Part 21.

i. Addition of "10 CFR part 52" to Applicable Definitions

On August 28, 2007, the NRC revised Part 21 to address the applicability of 10 CFR Part 52 (72 FR 49486). The staff revised 10 CFR 21.3, but unintentionally omitted "10 CFR part 52" from the definitions of commercial grade item, critical characteristics, dedicating entity, and dedication.

The staff is considering simplifying the definitions of commercial grade item, dedicating entity and dedication in Sections D, C, and C above, respectively. The proposals delete applicability statements to specific parts of Title 10 of the *Code of Federal Regulations*, since the definitions will be applied universally. The staff is considering extending this approach to the definition of critical characteristics.

The staff is considering the following additions (*in italics*) and deletions (~~in strikethrough~~) to the definition of critical characteristics in 10 CFR 21.3:

> ~~When applied to nuclear power plants licensed pursuant to 10 CFR part 50,~~ ~~c~~*C*ritical 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.

If the proposals in Sections C and D are not pursued, the staff will consider adding a reference to 10 CFR Part 52 in the definitions, where applicable.

ii. Definitions of 10 CFR Part 76 Facilities (Basic Component and Substantial Safety Hazard)

Part 21 does not provide definitions of basic component, commercial grade item, critical characteristics, dedicating entity, dedication, or substantial safety hazard as they apply to facilities regulated under 10 CFR Part 76, "Certification of Gaseous Diffusion Plants." The staff is considering simplifying the definitions of these terms, with the exception of substantial safety hazard, in Sections 3, D, i, C, and C above, respectively.

The staff is considering the following additions (*in italics*) and deletions (~~in strikethrough~~) to include 10 CFR Part 76 in the definition of substantial safety hazard in 10 CFR 21.3:

> 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.

If areas for improvement 3, C, D, and i are not pursued, the staff is considering adding reference to 10 CFR Part 76 where applicable.

iii. Definition of Critical Characteristics and Dedicating Entity for Nonreactor Facilities

The terms critical characteristics and dedicating entity are only defined for nuclear power plants licensed pursuant to 10 CFR Part 50. Nonreactor licensees also perform commercial grade dedication; however, the lack of relevant definitions and guidance for nonreactor licensees fails to provide adequate infrastructure for nonreactor stakeholders performing dedication. The limited scope of the definitions of critical characteristics and dedicating entity needs to be expanded to include nonreactor licensees in order to ensure robust and consistent implementation of the rule.

The staff is considering simplifying the definitions of critical characteristics and dedicating entity in Sections i and C, above, respectively. The proposals delete applicability statements to specific parts of Title 10 of the *Code of Federal Regulations*, since the definitions will be applied universally.

iv. Incorrect Numbering in 10 CFR 50.55(e)(4)

The regulations in 10 CFR 50.55(e)(4) state the following:

> Notification. (i) The holder of a facility construction permit subject to this part, combined license (until the Commission makes the finding under 10 CFR 52.103(g)), and manufacturing license who obtains information reasonably indicating that the facility fails to comply with the AEA, as amended, or any applicable regulation, order, or license of the Commission relating to a substantial safety hazard must notify the Commission of the failure to comply through a director or responsible officer or designated person as discussed in paragraph **(e)(10) of this section**. **(Emphasis added.)**

However, paragraph (e)(10) does not exist. When the NRC promulgated rulemaking in 2007 to update 10 CFR Part 52, this paragraph of the regulation was revised and this reference was incorrectly cited. The reference should instead be to paragraph (e)(4)(v).

The staff is considering moving the relevant unique requirements of 10 CFR 50.55(e) to Part 21 and remove 10 CFR 50.55(e). The staff will correct the reference when moved to Part 21. If the staff does not pursue moving the unique requirements of 10 CFR 50.55(e), then it will correct 10 CFR 50.55(e)(4) by replacing its reference to “(e)(10)” with “(e)(4)(v).”

References

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

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

U.S. Nuclear Regulatory Commission, "Request for an Exemption from 10 CFR Part 21.3 Commercial Grade Item, MOX Services," 2008, ADAMS Accession No. ML0800303932.

U.S. Nuclear Regulatory Commission, "Approval of Louisiana Energy Services Part 21 Exemption Request and Amendment 13 to License," 2009, ADAMS Accession No. ML1101406980.

U.S. Nuclear Regulatory Commission, "Approval of Areva Enrichment Services Part 21 Exemption Request," 2010, ADAMS Accession No. ML1101406360.

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," July 19, 2011, ADAMS Accession No. ML111880130.

CHAPTER 5 - IMPACT

Backfit Rule Applicability

The NRC staff has not prepared a backfit analysis for this draft regulatory basis. As described above, the purpose of the recommended rule amendments and guidance documents is to clarify the requirements of Part 21. None of these recommendations would result in the modification of or addition to systems, structures, components, or design of a facility; or the design approval or manufacturing license for a facility; or the procedures or organization required to design, construct or operate a facility pursuant to the definition of backfitting in 10 CFR 50.109(a)(1). Nonetheless, the direct and indirect costs of implementing these recommendations are justified in view of the public health and safety requirement of Section 206 of the Energy Reorganization Act that the NRC be immediately notified of information that a facility, activity, or basic component "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 contains a defect which could create a substantial safety hazard." A full backfit analysis will be developed, as necessary, as part of any rule proposed as a result of this draft regulatory basis.

Safety Goal Applicability

The recommendations of this draft regulatory basis include amendments to Part 21 and the issuance of Part 21 guidance documents. The purpose of these recommendations is to clarify the requirements of Part 21. Regulatory clarity supports the NRC goal of ensuring adequate protection of the public health and safety.

Environmental Analysis Applicability

The recommendations of this draft regulatory basis provide regulatory clarity; they would not impact the environment.

Information Requirements Applicability

The recommendations of this draft regulatory basis would not require entities subject to Part 21 to submit additional information to the NRC or change the frequency or burden associated with current information collection requirements. These recommendations clarify those information collection requirements already required by NRC regulations.

Impact of Proposed Rule

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

Impact on State, Local, or Tribal Governments

The recommendations of this draft regulatory basis would likely have little, if any, impact on State, local, and Tribal governments. Nonetheless, the NRC staff will notify Agreement States of these recommendations. The NRC will also host public meetings and discussions on these recommendations that will be broadcast on the NRC's Web site. Any rule proposed as a result of these recommendations will be fully subject to public notice and comment.

Impact on the NRC

The NRC expects the rulemaking recommended by this draft 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 not require any additional budget to review updated Part 21 programs. However, the NRC will need to promulgate the recommended rulemaking and the associated regulatory guides and 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 rulemaking is pursued as a result of this draft regulatory basis, the working group established for this rulemaking effort will develop a more detailed assessment of the impact on the agency.

CHAPTER 6 - SCHEDULE

If rulemaking is pursued as a result of this draft regulatory basis, the NRC would implement its recommendations through a proposed rule scheduled for completion in 2014, resolution of public comments, and a final rule scheduled for completion in 2015. After completion of the proposed rule's regulatory basis in 2013, 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 - DRAFT RULE LANGUAGE

Forthcoming.