## Introduction

The Nuclear Energy Institute, Inc. (NEI) appreciates the opportunity to comment on the NRC Draft Regulatory Basis to Clarify 10 CFR Part 21, "Reporting of Defects and Noncompliance" (Revision 1) (March 2015) (Docket ID: NRC-2012-0012).

NEI is concerned that the significant inconsistencies and inaccuracies in the NRC's March 2015 revised Draft Regulatory Basis ("draft Reg. Basis") undercut the validity of that document. We therefore ask the NRC to postpone issuing a Final Regulatory Basis until these deficiencies have been addressed. Under its own process, the NRC must provide an accurate and compelling regulatory basis to support initiation of rulemaking to amend 10 CFR Part 21. As discussed throughout these comments, we believe the draft Reg. Basis fails to meet that standard given the many incorrect conclusions and recommendations it contains. In turn, a rulemaking to amend 10 CFR Part 21 based on an inaccurate regulatory basis would be similarly defective.

If promulgated as proposed, the Part 21 revisions described in the draft Reg. Basis:

- Are not justified on the basis of practicality or cost-benefit, and will not improve safety;
- Will not improve the reporting of defects that warrant NRC, licensee and vendor/ manufacturer attention;
- Will create confusion in the implementation of wholly new standards after more than 38 years of experience in implementing a highly effective Part 21 reporting process;
- Will have unforeseen consequences (such as confusion or expansion of current requirements) from unanticipated inconsistencies and errors, even if intended merely as clarifications;[1]
- Will result in considerable costs to the NRC and those implementing Part 21, beyond the costs of participating in a rulemaking, to the extent that those affected parties will be forced to revise historically compliant industry programs and procedures.

NEI believes that the issuance of new regulatory guidance can effectively address the few minor clarity issues that have been experienced. As recognized by 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,"* NRC has not issued regulatory guides for either evaluating and reporting defects under 10 CFR Part 21 or the Part 21 dedication process for accepting commercial items and services for use in safety-related applications.

[1] For example, the proposed change to the language of 10 CFR 21.7 on Exemptions (p.106 of the draft Regulatory Basis) creates confusion, as it would no longer clarify that organizations supplying commercial grade items to the nuclear industry are not subject to Part 21 requirements. Other unintended consequences may not be readily apparent and could cause issues years later.

Some Revisions Proposed in the draft Reg. Basis Expand the Scope and Intent of Part 21

Several of the proposed changes to Part 21 discussed in the draft Reg. Basis expand the scope and intent of Part 21 requirements, and are inconsistent with established regulatory positions found in the NRC's regulations, statements of consideration, and policy papers (e.g., SECY 91-105). Therefore, the draft Regulatory Basis is clearly inconsistent with the NRC staff position in SECY 11-0135,[2] and no rationale is provided for this departure. (See the discussion below of the definition of Basic Component for Nonreactor Facilities and Activities, clarification of "delivery," and licensee event reporting.) Specifically, we are concerned with the NRC's portrayal of these new regulatory positions, which expand the scope and intent of existing requirements, as "clarifications." They are in fact new or changed regulatory positions to the extent they are inconsistent with established regulatory positions in NRC rules, statements of consideration, and policy papers. The NRC should therefore analyze these new regulatory positions as backfits pursuant to 10 CFR §50.109 or other applicable backfitting provisions.

The "preliminary draft proposed rule language" in Appendix A and B to the draft Reg. Basis also appears to reflect changes to the Part 21 rule that are not discussed in the draft Regulatory Basis discussion. It is unclear whether these proposed changes have been evaluated by the NRC or may reflect unintended consequences of rulemaking. In either event, many of these revisions, if promulgated as an amended rule, would modify regulatory positions and/or expand the scope or intent of Part 21. For example, the draft rule language contains a change to Section 21.51 that would expand the required retention period for evaluations from *five years to ten years*. Such examples heighten industry concern that the agency's regulatory basis for initiating rulemaking on Part 21 is incomplete and lacks transparency, because it does not include a discussion or evaluation of these unexplained rule changes.

Unintended consequences could result not only by inadvertent expansion of the scope or intent of Part 21, but also from newly created confusion resulting from revised rule language. The NRC should factor unintended consequences into the consideration of the considerations of costs and benefits of undertaking an ill-defined rulemaking.

[2] SECY 11-0135 states: "This effort will clarify the requirements in Part 21. However, the staff does not intend to expand the scope or intent of the regulation."

The Draft Regulatory Basis Incorrectly Presumes that Guidance Alone Cannot Improve Clarity

The draft Reg. Basis appears to justify the need for rulemaking simply by *assuming* that issuance of regulatory guidance alone cannot provide improved clarity to 10 CFR Part 21. No basis is provided for this important staff position--which is inconsistent with the NRC's historic common practice to use guidance to clarify agency regulations. As the staff has never issued guidance on Part 21 (see SECY 11-0135)[3], we do not understand the staff's conclusion that guidance *cannot* clarify Part 21 rule language.

In numerous instances the draft Reg. Basis asserts that, because NRC public meeting summaries (Q&A in a 2008 Workshop - ML092660129) have not been effective in reaching the broader industry, guidance would also not be effective. NEI disagrees with this illogical assertion. First, most of the clarifications described in the NRC's draft Regulatory Basis are not found in the 2008 Q&A or in the original Q&A documented in NUREG-0302. Further, the purpose and use of NRC regulatory guidance is well understood by stakeholders, unlike the 2008 Q&A that were documented in an internal memorandum that is not easily located on the NRC website. Finally, as the Staff is aware, the distribution of NRC meeting summaries is not the equivalent to the issuance of agency regulatory guidance. (For example, it is unclear whether stakeholder input was ever sought or whether any regulatory positions in the meeting summaries were subjected to a backfit evaluation.)

NRC Should promptly Review and Endorse Industry Guidance

Notably, industry guidance exists today that address all NRC-identified issues associated with clarifying the existing Part 21 requirements. The following three guidance documents were submitted for NRC review and endorsement months ago:

1. NEI 14-09 Revision 0, *Guidelines for Implementation of 10 CFR Part 21 Reporting of Defects and Noncompliance* (ML14245A415) was submitted on August 28, 2014.
2. EPRI 3002002982, Revision 1 to EPRI NP-5652 and TR-102260, *Plant Engineering: Guideline for the Acceptance of Commercial-Grade Items in Nuclear Safety-Related Applications* (ML14265A198) was submitted on September 17, 2014.
3. EPRI 3002002289, Revision 1 of EPRI-1025243 *Plant Engineering: Guideline for the Acceptance of Commercial-Grade Design and Analysis Computer Programs Used in Nuclear Safety-Related Applications*, which includes clarifications to address all of the NRC issues related to commercial grade dedication, was submitted on January 22, 2014.

We recommend that the NRC expedite completion of its review and endorsement of industry guidance on Part 21, and postpone consideration of rulemaking until after this guidance is endorsed. Moving forward promptly with the industry guidance already developed (in coordination with the NRC) is the most effective and efficient path forward. This is especially true considering that rulemaking takes significantly longer, costs considerably more, could unintentionally expand the scope or intent of the requirements, and is simply not necessary. As stated in the NRC's Principles of Good Regulation: Efficiency, "Where several effective

[3] 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" (recognizes that NRC has not issued regulatory guides for evaluating and reporting defects under Part 21 or the Part 21 dedication process for accepting commercial items and services for use in safety-related applications).

alternatives are available, the option which minimizes the use of resources should be adopted. Regulatory decisions should be made without undue delay." In the case of clarifying Part 21 requirements, guidance is the effective alternative that is most efficient and aligns with the NRC's Office of Inspector General's recommendation (ML15089A311).

The NRC should expedite review of these three industry guidance documents on a schedule that leads to their endorsement by October 31, 2015. Given that these guidance documents are consistent with the existing NRC regulations, statements of consideration for previous rulemakings, policy papers, and documented regulatory positions, and the NRC has had the guidance for over 8 months, this schedule should be realistic.

Voluntary Initiatives

In sub-part (c) for each issue area, the NRC evaluates the option for "Voluntary Industry Initiatives" and then references industry guidance; however, these are not the same. Industry guidance was submitted to the NRC for endorsement through the NRC's draft regulatory guides DG-1291 and DG-1292. Thus, discussion of NRC review and endorsement of industry guidance should be included in the option "NRC Guidance Development" as a means to develop NRC guidance. A voluntary industry initiative is something that the industry commits to on its own and has been limited to very few issues. We are not proposing industry guidance documents as industry voluntary initiatives.

## NEI Comments on Draft Reg. Basis Chapter 2 (Evaluating and Reporting)

### 1) Lack of Regulatory Guidance

The draft Reg. Basis discusses the lack of regulatory guidance on Part 21 at pp. 10-12. We agree that there is currently no comprehensive guidance on Part 21 evaluation and reporting that has been endorsed or issued by the NRC. 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* (October 1977), has been the sole source of clarifications to implementing Part 21 requirements for the past 38 years. Even at the time the original rule was promulgated, the NRC identified the need for clear guidance, but never developed such guidance. As discussed elsewhere in these comments, we urge the NRC to promptly complete review the three proposed Part 21 guidance documents submitted by the industry in 2014 and endorse that guidance for stakeholder use.

### 2) Quality Requirements in Procurement Documents

We agree with the NRC statement in the draft Reg. Basis that procurement documents for basic components must include requirements to comply with both 10 CFR Part 21, and Appendix B of 10 CFR Part 50. We also agree that changing rule language would cause additional burden without improvement to safety (see p. 13), and thus guidance is the preferred option to make this clarification.

Industry guidance, NEI 14-09 Revision 0, includes this clarification in Section 5.1, Quality Assurance Requirements, and Section 6.5, Quality Requirements in Procurement Documents. The NRC should expedite review and endorsement of industry guidance in order to improve clarity in this area.

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

See Attachment 2 to these comments for issues related to fuel cycle facilities.

## 4) Clarification of Discovery

The draft Reg. Basis identifies two distinct issues related to the definition of "Discovery."

Documentation of Discovery

The NRC's proposed changes to Part 21 (see pp. 22-23) would expand the scope and intent of Part 21 requirements, and are inconsistent with established regulatory positions in the NRC's regulations, statements of consideration, and policy papers (e.g., SECY 91-105). The new NRC position (p. 23) that "discovery is the time at which a deviation is first documented in a formal process (i.e., condition report, corrective action report) as part of a QA program" is inconsistent with SECY 91-150.[4] That SECY states: "Discovery is not complete until the documentation identifying the existence of a deviation or failure to comply is complete. Thus, in order to complete the documentation, some evaluation must take place to identify a deviation or failure to comply." What SECY 91-150 communicates in that excerpt is an acknowledgement that when issues are first identified and documented within a licensee's condition reporting process, there may not be enough information to recognize it as a Part 21 issue. The SECY further recognizes that only when the issue is clearly identified as a potential Part 21 issue is the Point of Discovery established.

SECY 91-150 has established the NRC's policy for the last 20 plus years, based upon an understanding that discovery is a process that takes time and *cannot* occur immediately. This is because the information immediately available when an issue is identified is not sufficient to identify that a deviation or failure to comply exists. The amount of time reasonably required to complete the discovery process cannot be fixed. The determination of whether a Part 21 evaluation is necessary depends on the complexity of the issue being investigated, the unique conditions applicable to the issue, and what is known about the issue when the entity is notified.

The NRC should analyze this new regulatory position as a backfit pursuant to 10 CFR 50.109 or other applicable backfitting provisions. In our assessment, the NRC proposal for a broad rulemaking is not supported by reasons of safety, practicality, or cost-benefit. The NRC's proposed expansion of Part 21 requirements would impose an additional, unnecessary burden on industry by requiring NRC licensees and suppliers to start the Part 21 clock every time an issue is documented in their corrective action program. Licensees and suppliers generate a significant number of issues, sometimes in the hundreds per day, many of which are not deviations or failures to comply, and not safety significant. The draft Reg. Basis does not show how performing a Part 21 evaluation on every issue in the corrective action program would improve safety, and it would clearly distract industry resources from other more safety significant activities.

[4] In the April 28, 2015 NRC public meeting, the NRC indicated that any proposed change to Part 21 should be consistent with the position in SECY 91-150: that discovery is a process that may take time to obtain the necessary evidence to document a determination that a deviation exists. The final Regulatory Basis should be updated to reflect this position.

The draft Reg. Basis refers to a few instances where a licensee or vendor possessed knowledge of a deviation or failure to comply, but delayed documentation of this information and thus delayed the start of the 60 day evaluation period. (See pp. 22-23) Because NRC has not provided specific detail supporting these statements, we are unable to understand whether there is a valid basis for this concern. This factual support must be included in the final regulatory basis so that stakeholders can better understand and evaluate the NRC's concerns.

Industry guidance, NEI 14-09 Revision 0, includes a clarification to address what we believe to be the NRC's concerns on this point. In NEI 14-09, Section 7.1, Discovery Process and Point of Discovery, guidance places an emphasis on timely discovery and clarifies the discovery process. The guidance specifically describes how, under some circumstances, discovery could occur at the time the issue is entered into a corrective action report, but in a way that does not require that all corrective actions be treated as potential Part 21 issues.

"Potentially Associated" with a Substantial Safety Hazard

The draft Reg. Basis states (p. 23): "the staff has found that licensees and vendors have interpreted the phrase 'potentially associated with a substantial safety hazard,' as it applies to the definition of discovery to mean that discovery cannot occur until a Part 21 evaluation under 10 CFR 21.21(a) is initiated." No supporting detail is provided.

We agree that the assessment of whether a *deviation* is potentially associated with a substantial safety hazard should occur as part of the evaluation. But NEI believes that the assessment of whether a *failure to comply* is potentially associated with a substantial safety hazard should occur as part of the discovery process. Many NRC requirements (e.g., administrative type requirements) are not associated with safety and a failure to comply with such requirements could never create a substantial safety hazard. Therefore, it is acceptable to perform the assessment for failures to comply during discovery in order to avoid unnecessary evaluations.

Industry guidance includes clarifications addressing this issue; see NEI 14-09 Revision 0, Section 7.2, Failure to Comply, and Section 7.3, Deviation of Delivered Basic Component.

## 5) Clarification of Defect

The proposed revision to the definition of defect in the draft Reg. Basis (pp. 25-27) is a substantive change to the regulations that, if implemented as proposed, will *reduce* clarity. Industry does not believe that the current definition of defect is confusing, and we know of no cases where the current definition has resulted in non-compliance with Part 21 requirements. We are concerned that the simplified definition would no longer capture the nuanced differences of how Part 21 requirements apply to different classes of licensees and their suppliers. The proposed simplified definition creates new confusion and may also inadvertently alter the scope and intent of Part 21 requirements.

For example, the requirement of "offered for use" included in definition #3 of defect (p. 25) is an important concept that is applied to early site permits, standard designs, combined licenses, etc. The NRC's simplified definition would no longer articulate this nuance for the affected licensees and suppliers. The NRC should analyze whether the proposed change creates a new or changed regulatory position, and include the appropriate backfit considerations pursuant to §50.109 or other applicable backfitting provisions. In our assessment, the NRC proposal for a broad rulemaking is neither justified on a practical basis, nor justified on a cost-benefit basis.

Additionally, NRC should provide examples to support the claims in the draft Reg. Basis that the definition of defect in 10 CFR 21.3 is "complex" and has resulted in some evaluations taking longer than 60 days. We cannot understand or evaluate the NRC's concerns because the NRC has not provided the examples needed to support rulemaking on this issue. Further, it is inaccurate for the draft Reg. Basis to imply that industry supports rulemaking on this point because this definition is "difficult to interpret."

The draft Reg. Basis is incorrect in its statement (p. 26) that the 2008 Vendor Workshop Q&A addressed confusion over the relationship of defect and delivery. There are no questions asking for clarification on the definition of defect, nor are there any expressed concerns over the definition in 10 CFR 21.3.

**6) Clarification of Delivery**

We do not agree with the NRC's assertion (p. 28) that the absence of a definition of delivery in Part 21 has resulted in entities failing to meet the evaluation and notification requirements in 10 CFR 21.21. The absence of specific examples or references in the draft Reg. Basis to support this broad claim make it impossible for stakeholders to understand or evaluate the NRC's conclusion. The final Regulatory Basis should provide such examples to support the NRC justification for rulemaking.

We agree that the concept of delivery is important, that the definition needs to be clarified, and we agree on with the NRC's proposed definition. However, clarification can be achieved by including the definition in guidance, thus there is no need to revise the rule just to include the definition in the regulations. The NRC should consider the costs and benefits of such a change in a backfit evaluation. Since the NRC's ability to be notified of Part 21 issues has been successful over the past 38 years, the NRC should not proceed with rulemaking only to include a mutually-understood definition.

Industry guidance, NEI 14-09 Revision 0, Section 2.6, Delivered, and Section 7.3, Deviation of Delivered Basic Component, includes clarifications to address the definition of delivery. The NRC should expedite review and endorsement of industry guidance in order to improve clarity in this area.

## 7) Evaluation and Reporting Responsibilities between Purchaser and Suppliers

The draft Reg. Basis identified two distinct aspects of this issue: 1) communications between purchasers and suppliers, and 2) delineation of evaluation and reporting responsibility between purchaser and supplier (pp. 30-32). The instances of confusion in these areas have been very limited and have not challenged the NRC's ability to be notified of Part 21 issues. We agree with the staff (p. 32) that Part 21 should not include requirements for the communications between suppliers and licensees, as this would be burdensome and would not have any safety benefit. We also agree that clarity on these topics in guidance would be beneficial.

Industry guidance, NEI 14-09 Revision 0, Section 8.1, Evaluation Responsibilities, and Section 8.2, Communication Between Suppliers and Purchasers During the Evaluation and Notification Process, includes clarifications to address supplier/purchaser responsibilities and communications. The NRC should expedite review and endorsement of industry guidance in order to improve clarity in this area.

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

We agree that Part 21 should not include requirements on the process for deferring evaluations, as this would be burdensome and would not have any safety benefit (p. 33). We also agree that clarity on this topic in guidance would be beneficial.

The draft Reg. Basis states that while there have been a few instances where there was confusion on the process for a supplier to defer an evaluation to the purchaser, these few instances have not challenged the NRC's ability to receive Part 21 notifications.

Industry guidance, NEI 14-09 Revision 0, Section 8.3, Transfer of Evaluation and Reporting Responsibilities, includes clarifications to address the deferral of an evaluation to the purchaser. The NRC should expedite review and endorsement of industry guidance in order to improve clarity in this area.

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

The NRC identified two distinct issues related to the use of licensee event reporting (LERs).

Duplicate Evaluation under 10 CFR 50.72/50.73 and 10 CFR Part 21

The draft Reg. Basis states (p. 34) that "licensees are inconsistent in their approach over whether only an evaluation or an evaluation and a reporting of a potential defect under Part 50 will discharge their Part 21 evaluation and reporting obligations." NRC proposes rulemaking to revise 10 CFR 21.21(c) as well as the issuance of guidance. We are concerned that the NRC's proposed change to the rule language expands the scope and intent of Part 21 requirements, and is inconsistent with established regulatory positions found in the NRC's regulations, statements of consideration, and policy papers. Moreover, the proposed change would create the need for duplicate evaluations for issues that are evaluated (but not reported) under 10 CFR 50.72 and 50.73. This is inconsistent with the NRC's statements of consideration for the 1991 rulemaking to revise 10 CFR Part 21 (56 FR 36081), which clarified that the evaluation and reporting criteria in 10 CFR Part 21 and in 10 CFR 50.72/73 are similar, and duplicate evaluation and reporting is not necessary: "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." (56 FR at 36084) (emphasis added).

The NRC's proposed revision to Section 21.21(c) reflects a new regulatory position and a substantial change to the NRC requirements. In our assessment, the NRC proposal for a broad rulemaking is not justified on either a practical or a cost-benefit basis. Requiring duplicate evaluations in these instances would impose unnecessary burden on licensees. Further, the NRC has not provided any examples where an issue that was evaluated under §50.72/50.73 and determined not to require an LER, and thus was not evaluated under Part 21, is a defect or failure to comply that could result in a substantial safety hazard that should be reported under Part 21. Additionally, the NRC should analyze this new regulatory position as a backfit pursuant to Section 50.109 or other applicable backfitting provisions.

Industry guidance, NEI 14-09 Revision 0, Section 5.2, 50.72 and 50.73 includes clarifications to address this topic. The NRC should expedite review and endorsement of industry guidance in order to improve clarity in this area.

LERs that Indicate Part 21 Applicability

We agree with the NRC that if an issue reported under 10 CFR 50.72 or 50.73 is also a Part 21 issue, then Part 21 applicability should be indicated on the LER. In the NRC letter to NEI dated July 8, 2014, the NRC provided numerous examples of LERs that are also Part 21 issues, but which did not indicate the applicability to Part 21.

Industry guidance, NEI 14-09 Revision 0, Section 5.2, 50.72 and 50.73, includes clarifications to address this topic. The NRC should expedite review and endorsement of industry guidance in order to improve clarity in this area.

## 10) Notifications that Satisfy 10 CFR 21.21(d)(2)

We agree that Part 21 should not include requirements to describe which notifications satisfy 10 CFR 21.21(d)(2), as it would be burdensome and would not have any safety benefit (p. 38). We also agree that clarity on this topic in guidance would be beneficial.

Industry guidance, NEI 14-09 Revision 0, Section 9.3, Actual Knowledge that the NRC has Been Adequately Informed, includes clarifications to address this topic. The NRC should expedite review and endorsement of industry guidance in order to improve clarity in this area.

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

We agree that Part 21 and 10 CFR 50.55(e) requirements are essentially identical and both establish the requirements to implement Section 206 of the Energy Reorganization act of 1974. Therefore, 10 CFR 50.55(e) can be deleted. We agree with the following NRC position (p. 40):

> "The staff believes that the regulatory approach of treating the requirements in of 10 CFR 50.55(e) as a license condition does not adversely affect the NRC's regulatory capability to ensure compliance with the substantive requirements. The requirement to evaluate a significant QA program breakdown can be deleted from the regulation without any reduction in regulatory requirements. Indication of a nonfunctioning QA program can be related to lack of adequacy of the item or service provided."

The existing duplication of 10 CFR 50.55(e) and Part 21 requirements causes considerable confusion. Additionally, it imposes an unnecessary burden on licensees and vendors by requiring them to devote additional time and resources. Deletion of §50.55(e) and the corresponding definitions in 10 CFR 50.2 are not related to a Part 21 rulemaking.

The regulatory effort of deleting these sections of the regulation can move forward independent of the proposed rulemaking to amend 10 CFR 21. For this reason, we request that the NRC expedite a rulemaking specific to 10 CFR 50.55(e), separate and independent from considerations of a Part 21 rulemaking.

## 12) Evaluation of Counterfeit, Fraudulent, and Suspect Items (CFSI)

We agree that "Part 21 was never intended to be a reporting mechanism for CFSI and would make a poor instrument for the reporting of all CFSI." (p. 42). We also agree that the NRC is providing adequate clarification on the applicability of regulations to CFSI in a Regulatory Issue Summary (the draft RIS 2014-xx was issued in October 2014 and is scheduled to be finalized in 2015) and SECY 15-0003. EPRI has also issued guidance *Plant Support Engineering: Counterfeit and Fraudulent Items*, Revision 1 of 1019163, which clarifies that CFSI are considered deviations. Thus the relationship of Part 21 and CFSI has already been clarified, and there is no need to add this clarification to Part 21 guidance.

## 13) Contemporary Posting Requirements

We agree that Part 21 should not include requirements for electronic posting, as this would be burdensome and would not have any safety benefit. As the draft Reg. Basis states (p. 44), the current regulation can be interpreted to allow the use of online web site posting to meet the regulation. We also agree that clarity on this topic in guidance would be beneficial.

Industry guidance, NEI 14-09 Revision 0, Section 6.3, Posting, includes clarifications to address this topic. The NRC should expedite review and endorsement of industry guidance in order to improve clarity in this area.

## 14) Training

We agree that revising regulations to require that personnel performing activities under Part 21 receive indoctrination and training are unnecessary (p. 45). Such new requirements would be burdensome and would not have any safety benefit. We also agree that clarity on this topic in guidance would be beneficial.

Industry guidance, NEI 14-09 Revision 0, Section 6.4, Training, includes clarifications to address this topic. The NRC should expedite review and endorsement of industry guidance in order to improve clarity in this area.

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

See Attachment 2 to these comments for comments related to fuel cycle facilities.

### NEI Comments on Draft Reg. Basis Chapter 3 (Commercial Grade Dedication)

### A) Lack of Regulatory Guidance

We agree that there is a need for consolidated and updated guidance on the topic of commercial grade dedication (pp. 52-56). We also agree that guidance on commercial grade dedication is found is an array of generic communications, guidance documents and other communications, and most notably the NRC conditional endorsement of EPRI NP-5652.

NEI submitted EPRI 3002002982, Revision 1 to EPRI NP-5652 and TR-102260 *Plant Engineering: Guideline for the Acceptance of Commercial-Grade Items in Nuclear Safety-Related Applications* (ML14265A198) on September 17, 2014 for NRC review and endorsement. EPRI's guidance has provided clarity for all of the issues identified by the NRC relating to commercial grade dedication, and has incorporated other lessons learned from experience gained in implementing the associated Part 21 requirements. The NRC should expedite review and endorsement of industry guidance in order to improve clarity in this area.

### B) Proper Place for Commercial Grade Dedication Requirements

We disagree with the NRC staff's description of a regulatory "problem" in this area and its unsupported conclusion in the draft Reg. Basis (pp. 56-57) that the organization of rule language in the regulations is the root cause for the very few and minor issues related to commercial grade dedication. The root cause is the lack of clear and comprehensive guidance, and an evolution of staff positions over the last 37 years. We also disagree with the NRC's assertion (p.57) that "the current regulatory framework is insufficient for the adequate implementation of the commercial grade dedication process, and that guidance alone is not the most appropriate solution to address this issue." It is industry's view that implementation of Part 21 dedication requirements has been largely successful over the past several decades. The draft Reg. Basis does not provide sufficient justification or examples to support the staff conclusions therein.

Industry guidance, EPRI 3002002982, Revision 1 to EPRI NP-5652 and TR-102260, includes clarifications to address all of the NRC issues related to commercial grade dedication. The NRC should expedite review and endorsement of industry guidance in order to improve clarity in this area.

### C) Definition of Dedication

We disagree with the assertion in the draft Reg. Basis (pp. 58-61) that the organization of rule language is the root cause of the instances of confusion related to commercial grade dedication, and that rulemaking is needed. The root cause is the lack of clear and comprehensive guidance, and an evolution of staff positions over the last 37 years.

We do agree that the definition of dedication can be wholly clarified through guidance. Industry guidance, EPRI 3002002982, Revision 1 to EPRI NP-5652 and TR-102260, includes clarifications to address all of the NRC issues related to commercial grade dedication. The NRC should expedite review and endorsement of industry guidance in order to improve clarity in this area.

## D) Definition of Dedicating Entity

See Attachment 2 to these comments for comments related to fuel cycle facilities.

## E) Definition of Commercial Grade Item

We disagree with the draft Reg. Basis conclusion (p. 64) that the existing rule language is the root cause of the few and minor instances of confusion related to commercial grade dedication. The root cause is the lack of clear and comprehensive guidance, and an evolution of staff positions over the last 37 years.

We agree that the definition of commercial grade item can be wholly clarified through guidance. Industry guidance, EPRI 3002002982, Revision 1 to EPRI NP-5652 and TR-102260, includes clarifications to address all of the NRC issues related to commercial grade dedication. The NRC should expedite review and endorsement of industry guidance in order to improve clarity in this area.

## F) Clarification of "Basic Component" as Equivalent to "Safety-Related" for Facilities Subject to Appendix B

We disagree with the NRC conclusion (p. 66) that there is a need to revise the existing rule language to clarify the equivalence of basic component to safety-related, as this clarification can be wholly achieved through guidance. Industry guidance, EPRI 3002002982, includes clarifications to address all of the NRC issues related to commercial grade dedication. The NRC should expedite review and endorsement of industry guidance in order to improve clarity in this area.

## G) Clarification of Quality Assurance Requirements for the Conduct of Dedication for Facilities Subject to Appendix B

We disagree with the draft Reg. Basis conclusion (pp. 68-69) that there is a need to revise the existing rule language to clarify the quality assurance requirements that apply to the dedication process. On the contrary, this clarification can be wholly achieved through guidance. Industry guidance, EPRI 3002002982, includes clarifications to address all of the NRC issues related to commercial grade dedication. The NRC should expedite review and endorsement of industry guidance in order to improve clarity in this area.

## H) Sampling Requirements

We agree that Part 21 should not include requirements for sampling (p. 71), as this would be burdensome and would not have any safety benefit. We also agree that clarity on this topic in guidance would be beneficial.

Industry guidance, EPRI TR-017218-R1 *Guidelines for Sampling in the Commercial-Grade Dedication Process*, dated January 1999, includes clarifications to address this topic and NRC's concerns with EPRI NP 7218. The NRC states that "with modification, the NRC could review and find acceptable the EPRI sampling guidance," however, the NRC has never made clear what modifications would be necessary in order to endorse this guidance. We request that the NRC document the concerns with the industry guidance so that we can discuss with the NRC how best to address them in industry guidance. Industry guidance, EPRI 3002002982, Revision 1 to EPRI NP-5652 and TR-102260, also includes clarifications related to sampling. The NRC should expedite review and endorsement of industry guidance in order to improve clarity in this area.

## I) Software Dedication

We agree that Part 21 should not include requirements for software dedication (p. 74), as this would be unduly burdensome for licensees and vendors and would not have any commensurate safety benefit. We also agree that clarity on this topic in guidance would be beneficial.

Industry submitted EPRI 3002002289, Revision 1 of EPRI-1025243 *Plant Engineering: Guideline for the Acceptance of Commercial-Grade Design and Analysis Computer Programs Used in Nuclear Safety-Related Applications* on January 22, 2014, which includes clarifications to address all of the NRC issues related to commercial grade dedication. In an NRC letter to NEI dated May 6, 2014, the NRC indicated their anticipation of completing review by the fall of 2014; however, the review has not yet been completed. The NRC should expedite review and endorsement of industry guidance in order to improve clarity in this area. Further, given that more than six months have passed since the original estimate to complete the review, we would appreciate the staff providing an update on the current estimate to complete the review and providing the reasons for the delay.

## Backfitting, Safety Goal Evaluation and Cost/Benefit Considerations

Backfitting "Protection:"

A section in Chapter 5 of the draft Reg. Basis, "Entities That Are Provided With Backfitting Protection," describes facilities licensed pursuant to parts of 10 C.F.R. that contain backfitting provisions as being accorded "backfitting protection." Although the backfitting and issue finality provisions in the NRC's regulations can be viewed as functioning to "protect" licensees, describing these provisions in this way mischaracterizes their primary purpose. Specifically, the primary purpose of the backfitting and issue finality provisions in 10 C.F.R. is not to "protect" licensees from regulatory action. Rather, the purpose of these provisions is to ensure that NRC and licensee resources are devoted to activities that yield significant safety benefits and are cost-justified. Thus, the backfitting process helps to ensure a safety-focused and effective regulatory framework, which is an appropriate objective for both the industry and the NRC. The NRC's backfitting and issue finality provisions also promote accountability and transparency in agency decision making, which is a central part of open government. Thus, we recommend that this section be retitled to reflect that it is describing the applicability of the various backfitting and issue finality provisions in 10 C.F.R., and that any use of the term "backfitting protection" be removed from the draft Reg. Basis.

Information Collection and Reporting:

The draft Regulatory Basis states (pp. 81-82):

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

This section goes on to identify several sections of the proposed regulations that would fall within the category of information collection and reporting requirements. While we recognize that internal staff guidance documents may support the proposition that changes reporting and recordkeeping requirements do not constitute backfitting,[5] NEI disagrees with the categorical statement that the backfitting rule and issue finality provisions of Part 52 do not apply to portions of the Part 21 rulemaking that can be categorized as "information collection and reporting requirements." Rather, the staff should apply the definition provided in 10 CFR 50.109 (or other appropriate backfitting provisions) and determine, based on that definition, whether each of the proposed revisions would constitute backfitting.

Backfitting is defined as:

> [T]he 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; any of which may result from a new or amended provision in the Commission's regulations or the imposition of a regulatory staff position interpreting the Commission's regulations that is either new or different from a previously applicable staff position after:[6]

New or amended provisions of the Part 21 regulations described in the draft Reg. Basis will modify the definitions of terms such as "discovery" and "defect;" as well as requirements governing the use of event reporting under 10 CFR Parts 72 and 73, notifications made under Section 21.21(d)(2), and the evaluation of counterfeit, fraudulent, and suspect items. Changes proposed by the NRC would require licensees and other affected entities to revise programs and procedures (that already comply with existing requirements) in order to comply with the revised rule language. Thus, applying the definition provided in 10 C.F.R. 50.109(a), these new or amended provisions of the Commission's regulations may, in fact, constitute backfitting because

[5] See MD 8.4 "Management of Facility-Specific Backfitting and Information Collection," Oct. 9, 2013, at pg. 7 of the Directive Handbook.

[6] 10 C.F.R. 50.109(a).

they result in the modification of or addition to systems, structures, components, or design of a facility; or the procedures or organization required to design, construct or operate a facility. This definition applies regardless of whether the new or amended provision causing the modification or addition happens to require the collection and reporting of information.

Nothing in NRC regulations exempts the NRC from applying the backfit rule to information collection requirements. Although changes to mere information collection requirements would not typically meet the definition of backfitting, that is only because such changes would not require modification of the SSCs, procedures, or organization required to operate a facility. By not evaluating new or amended provisions of the agency's regulations against the regulatory definition of backfitting provided in Section 50.109, the staff runs the risk of imposing unanalyzed backfits by mischaracterizing them as information collection or reporting requirements, then applying a categorical rule that excludes such requirements from further evaluation. The Commission has rejected staff proposals for rulemaking due to such mischaracterizations in the past. Specifically, in 2013 the Commission disapproved publication of proposed revisions to the material control and accounting regulations of 10 C.F.R. Part 74, in large part because the staff had mischaracterized certain provisions of that proposed rulemaking as mere information collections and failed to perform the required backfitting analysis.[7]

We acknowledge that the Commission has long distinguished information requests issued pursuant to 10 C.F.R. 50.54(f) from the backfitting requirements of Section 50.109, however the primary rationale for this distinction is that – unlike the rulemaking being considered here – information requests issued pursuant to Section 50.54(f) do not generally impose new or different requirements on licensees.[8] And, even in the case of Section 50.54(f) information requests, the agency's backfitting guidance acknowledges that backfitting analyses may be appropriate in certain circumstances.[9] It is also noteworthy that, with a few exceptions provided for in the rule, Section 50.54(f) requires the NRC to ensure that the burden associated with information requests is justified in light of the safety significance of the issue to be addressed in the requested information. Adoption of an interpretation that categorically exempts requirements that can be categorized as governing "information collection and reporting" from the backfitting rule could result in subjecting substantive requirements that are imposed via regulation to a less rigorous evaluation than information requests issued pursuant to Section 50.54(f). There is no indication in the regulatory history of 10 CFR 50.109 that the Commission intended such a result.

[7] Staff Requirements – COMSECY-12-0026 – Revisions to Proposed Rule: Amendments to Material Control and Accounting Regulations (RIN 3150-A161), May 10, 2013. See also, Staff Requirements – SECY-11-0175 – Proposed Rule: Amendments to Material Control and Accounting Regulations (RIN 3150-AI61) (a previous SRM on the same rulemaking directing the staff to "either include a more thorough discussion of how the requirements in this proposed rule satisfy one or more of the backfit exception provisions of 70.76(a)(4) or... provide a backfit analysis if the proposed rule is determined not to qualify for an exception.").

[8] See 50 Fed. Reg. 38,097, 38,102 (Sept. 20, 1985)(explaining that "[t]he amendment of § 50.54(f) should be read as indicating a strong concern on the part of the Commission that extensive information requests be carefully scrutinized by staff management prior to initiating such requests. The Commission recognizes that there may be instances where it is not clear whether a backfit will follow an information request. Those cases should be resolved in favor of analysis. In short, staff management should develop an internal review process to ensure that there is a rational basis for all information requests, even where it is not clear that a backfit will result.").

[9] "Backfitting Guidelines," NUREG-1409, July 1990, at pgs. 5-6 (explaining that a backfitting analysis is to be performed if an information request promulgates a new or revised staff position and requests that licensees state whether they will adopt the new positions in their responses).

Although no regulatory basis for the interpretation regarding "information collection and reporting requirements" is provided, the draft Reg. Basis states that this position is consistent with several past rulemakings. NRC cites three rulemakings to support this statement, all of which address material control and accounting.[10] Before examining the specific rulemakings relied upon in the draft Reg. Basis, it is important to note that the Commission has been reluctant to rely on this type of historical rationale without a careful evaluation of the specific requirements in question – particularly in the area of material control and accounting.[11] Turning to the rulemakings referenced, we note that in the 1991 rulemaking the Commission concluded:

> The Commission has determined that a backfit analysis is not required for this final amendment, because the backfit rule, 10 CFR 50.109, applies only to new requirements for power reactors. See 50 FR 38097 (September 20, 1985) (final backfit rule). However, as noted above, the Commission has prepared a regulatory analysis examining the benefits and impacts of these amendments.[12]

Both the 2002 and 2008 rulemakings include the following simple conclusion:

> NRC has determined that the backfit rule (§§ 50.109, 70.76, 72.62, or 76.76) does not apply to this final rule because this amendment does not involve any provisions that impose backfits as defined in the backfit rule. Therefore, a backfit analysis is not required.[13]

[10] "Material Control and Accounting Requirements for Uranium Enrichment Facilities Producing Special Nuclear Material of Low Strategic Significance," 56 Fed.Reg. 55,991 (Oct. 31, 1991); "Materials Control and Accounting Amendments," 67 Fed.Reg. 78,130 (Dec. 23, 2002); "Regulatory Improvements to the Nuclear Materials Management and Safeguards System," 73 Fed.Reg. 32,453 (June 9, 2008).

[11] See Commission Voting Record – COMSECY-12-0026 – Revisions to Proposed Rule: Amendments to Material Control and Accounting Regulations.

[12] 56 Fed.Reg. 55,996.

[13] 67 Fed.Reg. 78,141; 73 Fed.Reg. 32,461.

Although it is clear that the backfitting rule was not applied in any of these rulemakings, the specific basis for the positions taken in those rulemakings is not immediately apparent.[14] In addition, the basis for not applying the backfitting provisions in Section 50.109 in the 1991 rulemaking referenced in the draft Regulatory Basis seems to have been that the licensees impacted by the rule were not licensed under 10 C.F.R. Part 50 and, thus, Section 50.109 was not applicable.[15]

Another data point not discussed in the draft Reg. Basis is the 1991 rulemaking revising the Part 21 requirements, where the Commission concluded: "[T]he final rule, when effective, does not impose new safety reporting requirements on part 50 licensees. Therefore, a Backfit Analysis is not required for this final rule pursuant to § 50.109."[16] This conclusion indicates that, in the past, the Commission has not viewed Part 21 reporting requirements as being categorically excluded from the backfitting rule. While this short statement is not definitive on the point, it suggests that if the 1991 rulemaking had imposed "new safety reporting requirements" on Part 50 licensees, the Commission would have considered imposition of such new requirements to be backfitting.

Finally, the draft Regulatory Basis states that the rationale underlying this interpretation of Section 50.109 "is that information collection and reporting requirements would be difficult to characterize as involving adequate protection, and... usually do not result in improvements to radiological health and safety and common defense and security." Thus, it appears that the reason for reading the "information collection and reporting requirement" exemption into the definition of backfitting is that it would be difficult to justify new or amended "information collection and reporting requirements" if the rule were applied. This rationale is troubling because, taken to its logical conclusion, it could be used to forgo application to the backfitting rule in situations where it is most relevant and important – i.e., in circumstances where it is uncertain whether a change in the Commission's regulations will result in a substantial safety increase and can be justified in light of the associated costs.

NRC staff should apply the definition of backfitting provided in 10 CFR 50.109 to determine whether the proposed revisions to Part 21 meet the definition of backfitting, rather than applying an interpretation that reads a categorical exemption into the rule.

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[14] A preliminary review of the proposed rules and associated papers also did not shed additional light on the rationale for concluding that these requirements did not constitute backfits. See "Final Rule: Material Control and Accounting Amendments," SECY-02-0179 (Oct. 2, 2002); "Proposed Rule: Material Control and Accounting Amendments," 66 Fed. Reg. 29,251 (May 30, 2001); "Proposed Rule: Material Control and Accounting Amendments," SECY-01-0066 (April 20, 2001); "Final Rule: Regulatory Improvements to the Nuclear Materials Management and Safeguards System," SECY-07-0224 (Dec. 29, 2007); "Proposed Rule: Regulatory Improvements to the Nuclear Materials Management and Safeguards System," 72 Fed. Reg. 5,348 (Feb. 6, 2007); "Proposed Rule: Regulatory Improvements to the Nuclear Material Management and Safeguards System," SECY-07-0001 (Jan. 3, 2007).

[15] Although the backfitting rule was not applied to these rulemakings, in several instances regulatory analyses were performed. This is helpful in that the costs and benefits associated with the proposed action and alternatives are evaluated, but it does not address the applicability of the backfitting rule.

[16] "Final Rule: Criteria and Procedures for the Reporting of Defects and Conditions of Construction Permits," 56 Fed. Reg. 36,081, 36,088 (July 31, 1991).

"Clarifications:"

In Chapter 5 of the draft Reg. Basis the NRC characterizes several proposed changes as "clarifications," rather than substantive changes to existing staff positions. Thus, the staff takes the position that these proposed changes do not meet the definition of backfitting. As discussed elsewhere in this comment letter, NEI believes that several of the proposed changes to the Part 21 requirements described as "clarifications" actually represent new or changed regulatory positions whose effect is to substantially expand the scope and intent of existing requirements. Examples include, but are not limited to, proposed changes to the definition of discovery, the duplication of evaluations with 10 CFR Part 50.72 and 50.73, and the definition of basic components for fuel cycle facilities. Thus, NEI believes that the NRC should analyze these changes as backfits pursuant to Section 50.109 or other applicable backfitting provisions.

Safety Goal Evaluation:

The draft Reg. Basis states (p. 84) that:

> Safety goal evaluations are applicable to regulatory initiatives considered to be generic enhancement backfits subject to the substantial additional protection standard at 10 CFR § 50.109(a)(3). This draft regulatory basis describes potential regulatory changes that are unlikely to qualify as generic safety enhancements because they do not significantly affect the likelihood of core damage and spent fuel damage, which generally are the focus of a quantitative safety goal evaluation."

Here the staff seems to be acknowledging that the regulatory changes described in the draft Regulatory Basis will not significantly affect the likelihood of core damage or spent fuel damage, which are typically the outcomes used to perform quantitative evaluations of whether a proposed backfit will result in a "substantial increase in the overall protection of the public health and safety or the common defense and security." See 10 CFR 50.109(a)(3). The staff goes on to conclude (p. 84) that "[b]ecause the change in safety associated with a rulemaking to clarify Part 21 requirements cannot be quantified, the regulatory changes cannot be compared to NRC's safety goals." This section should be clarified to acknowledge that, prior to imposing a backfit, the NRC is required to find that a "substantial increase in the overall protection of the public health and safety or the common defense and security" will be derived from the backfit, regardless of whether the change in safety can be quantified (if quantification is impossible or impractical, a qualitative assessment should be undertaken). Further, the statements regarding the impacts on core and spent fuel damage require clarification. If the staff is, in fact, concluding that the proposed changes to Part 21 cannot meet the quantitative safety goal evaluation criteria provided in NUREG/BR-0058, then it is unlikely that they can be justified pursuant to the criteria provided in Section 50.109. However, if the staff is concluding that the safety benefit of the rule cannot be quantified, then a through explanation of why quantification is "not possible or practical" [17] should be provided and a qualitative evaluation should be undertaken.

[17] "Staff Requirements – SECY-14-0087 – Qualitative Consideration of Factors in the Development of Regulatory Analyses and Backfit Analyses," SRM-SECY-14-0087 (March 4, 2015)("To ensure that qualitative factors are used in a judicious and disciplined manner, the revised guidance should continue to encourage quantifying costs to the extent possible and use qualitative factors to inform decision making, in limited cases, when quantitative analyses are not possible or practical (i.e., due to lack of methodologies or data).")