Industry Proposed Responses to NRC Initial Comments on NEI 14-09, Guidance on Part 21 Evaluation and Reporting

Industry proposed changes to NEI 14-09, Guidance on Part 21 Evaluation and Reporting, in response to NRC comments at a public meeting on October 16, 2015 are provided below. Proposed changes are also discussed for two clarifications identified by industry.

Changes to guidance text are formatted as additions marked by underlined text and ~~deletions marked by strikethrough.~~ Section and page numbers for the location of changes refers to the original version.

NRC Comment #1 (slide #4)

Guidance geared toward a reactor licensee perspective. Minimal guidance provided to vendors or third party dedication entities.

Industry Response

Added a statement in the introduction to highlight certain topics to the vendors.

Section 1.3 page 3 (add after the last paragraph)

> Suppliers and sub-suppliers of safety-related items should pay particular attention to the following areas of the guidance:
>
> - Nexus between licensee evaluation report and Part 21 obligations (Section 5.2)
> - Responsibility to establish procedures (Section 6.1)
> - Maintaining Part 21 evaluations that do not result in reports to the NRC (Section 6.2)
> - Significance of specifying Part 21 requirements in procurement documents (Section 6.5)
> - Benefits of maintaining open dialog between licensee and vendor on a potential Part 21 evaluation (Section 8.2)

NRC Comment #2 (slide #4)

Does not address purchaser taking responsibility when dealing with overseas suppliers

Industry Response

Added a new paragraph to describe expectations for U.S. Purchasers that contract with non-U.S. Suppliers.

Section 3.3, new last paragraph

> U.S. Purchasers that contract with non-U.S. Suppliers are responsible for contractually requiring the Supplier to meet the requirements of Part 21, even if the NRC does not have jurisdiction to enforce the requirements. Suppliers that are U.S. subsidiaries of non-U.S. entities maintain full responsibility to comply with Part 21 requirements, even for work sub-contracted to other business units of the non-U.S. entity.

NRC Comment #3 (slide #4, and slide #5 second bullet)

Lack of discussion on entities that provide safety-related software

Responsibilities of vendors supplying safety-related software

Industry Response

Clarified that software is considered to be a basic component.

Section 2.2, Page 5 (paragraph following the definition from 10 CFR Part 21)

> Basic components include safety related equipment, software, and services, such as design, analysis, inspection, testing, and consulting activities. Basic components are obtained 1) by being supplied as such under a quality assurance program pursuant to 10 CFR Part 50, Appendix B, or 2) as commercial grade items subject to the dedication process defined in 10 CFR Part 21.

Section 3, Page 11 (first paragraph)

> Entities which operate or construct facilities, or supply basic components to these facilities are subject to 10 CFR Part 21. As defined in Part 21, the terms "constructing," "operating," and "basic component" are used to include safety-related equipment, software, and services, such as design, analysis, inspection, testing, and consulting activities ~~design, inspection, testing and consulting services~~ associated with construction, operation and basic components ~~that are important to safety~~. The thrust of the regulations goes beyond those entities licensed or previously regulated by the Commission to all entities which engage in the activities described in Part 21.

Section 3.1, Page 13 (added new bullet)

- Software used to perform safety related analyses (e.g., analyses that substantiate the design of a basic component or determine whether an item can perform its safety function), which produces results that are not independently verified (such as by hand calculation or testing) for each safety related application of the software.

NRC Comment #4 (slide #5, first bullet)

Vendors would benefit from licensee knowledge of: Significance of specifying Part 21 in the procurement documents

Industry Response

Added statement for non-U.S. suppliers, in addition to the changes in response to NRC Comment #1.

Section 3.3 page 15 (first paragraph)

> Suppliers, located outside of the US, of basic components or their subcomponent parts for use in facilities in the U.S. subject to NRC regulations may, under certain circumstances be subject to 10 CFR Part 21. 10 CFR 21.2(a)(2) states that 10 CFR Part 21 applies to each individual, corporation, partnership or other entity doing business within the United States which supplies basic components for a facility or activity licensed other than for export under Parts 50 and 52. Although the phrase "Doing business within the United States" is not defined in the regulation, similar terminology has been interpreted in other contexts to include a foreign manufacturer who contracts to sell their product to a United States purchaser. The rule does not prohibit purchases from non-US suppliers of basic components. The applicability of Part 21 should be specified in the procurement document as described in Section 6.5 of this guidance.

NRC Comment #5 (slide #5, third bullet)

Vendors would benefit from licensee knowledge of: Record keeping requirements distinction between Part 21 and 50.55(e)

Industry Response

A statement characterizing the differences in Record Retention requirements with be made for Part 21 compared to 10CFR50.55(e). A statement will also be made indicating that 50.55(e) record retention rates only apply directly to Licensees and the agents working on their behalf (i.e. EPC contractors).

Section 5.3, 2nd Paragraph, pg. 26

> 10 CFR Part 21 is applicable to all entities (licensees and suppliers) that perform activities related to nuclear safety-related applications, whereas 10 CFR 50.55(e) reporting requirements do not apply to suppliers. The requirements of 10 CFR 50.55(e) only applies directly to Licensees and agents working on their behalf (i.e. engineering, procurement and construction (EPC) contractors). Additionally, 10 CFR 50.55(e) was revised in 1991 to provide that the definitions of terms in 10 CFR 21.3 apply to 10 CFR 50.55(e).

Section 5.3, last (new) paragraph, pg. 27

> The record retention requirements for 10 CFR 21 are different than those specified for 10 CFR 50.55(e). This delta is that the requirements of 10 CFR 50.55(e)(9) specify that the retention of records of evaluations of all deviations and failures to comply is for ten (10) years from the date of evaluation while the record retention requirements for 10 CFR 21.51(1) only specifies the record retention length of time for completed evaluations of deviations and failures to comply for a length of time is five (5) years. Note that this difference in the requirements is only extended to organizations to which the requirements of 10 CFR 50.55(e) apply. The requirements of 10 CFR 50.55(e) do not apply to vendors except only in cases where vendors

are working for a Licensee as agents on their behalf (i.e. engineering, procurement and construction (EPC) contractors).

NRC Comment #6 (slide #5, fourth bullet

Vendors would benefit from licensee knowledge of: Maintaining negative Part 21 evaluations

Industry Response

Include additional detail from 10 CFR 21.51, in addition to the changes in response to NRC Comment #1.

Revised Section 6.2, pages 29 and 30

The maintenance of records related to 10 CFR Part 21 evaluations of deviations and failures to comply, and notifications sent to purchasers and affected licensees shall be maintained in accordance with 10 CFR 21.51. ~~The time limits for the maintenance of records are established in 10 CFR 21.51(a).~~

Related records as described in 10 CFR 21.51 can be maintained in accordance with an entity's internal procedures provided the procedures comply with the retention requirements ~~in 21.51~~ specified below.

1. *Retain evaluations of all deviations and failures to comply for a minimum of five years after the date of the evaluation;*
2. *Suppliers of basic components must retain any notifications sent to purchasers and affected licensees for a minimum of five years after the date of the notification.*
3. *Suppliers of basic components must retain a record of the purchasers of basic components for 10 years after delivery of the basic component or service associated with a basic component.*
4. *Applicants for standard design certification under subpart B of part 52 of this chapter and others providing a design which is the subject of a design certification, during and following Commission adoption of a final design certification rule for that design, shall retain any notifications sent to purchasers and affected licensees for a minimum of 5 years after the date of the notification, and retain a record of the purchasers for 15 years after delivery of design which is the subject of the design certification rule or service associated with the design.*
5. *Applicants for or holders of a standard design approval under subpart E of part 52 of this chapter and others providing a design which is the subject of a design approval shall retain any notifications sent to purchasers and affected licensees for a minimum of 5 years after the date of the notification, and retain a record of the purchasers for 15 years after delivery of the design which is the subject of the design approval or service associated with the design.*

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

NRC Comment #7 (slide #5, fifth bullet)

Vendors would benefit from licensee knowledge of: Benefits of maintaining open dialog between licensee and vendor on a potential Part 21 evaluation

Industry Response

Added statements that reinforce the benefits of open communications, in addition to the changes in response to NRC Comment #1.

Section 3, page 12 (last paragraph)

A subcontractor becomes subject to 10 CFR Part 21 when supplying a basic component. Generally a procurement document specifies the purchase of a basic component and invokes Part 21 and Appendix B QA requirements. Suppliers must evaluate deviations and failures to comply that are potentially associated with a substantial safety hazard, and, if ~~it~~ a defect or failure to comply that could create a substantial safety hazard, if it were to go uncorrected, is discovered~~s a defect~~, must notify ~~report or inform~~ the NRC and purchaser ~~if it is one of a tier of suppliers supplying components to a reactor licensed by the Commission pursuant to 10 CFR Part 50 or Part 52~~.

The nature of the notification depends upon the ability of the supplier to evaluate whether a defect or failure to comply could create a substantial safety hazard. Suppliers should communicate closely with purchasers as these notifications are being considered to take advantage of the collective experience of both the supplier and purchaser and to avoid potentially confusing notifications or missed notifications due to inaccurate assumptions regarding who has the capability to evaluate and is responsible.

Section 5.2, page 25 (add a new paragraph at the end of the example's response)

This is another opportunity for close coordination between a supplier and purchaser/licensee. Suppliers may have evaluation and reporting obligations under 10 CFR Part 21 that could be satisfied by licensee reports pursuant to 50.72 and 50.73. Care must be exercised when taking credit for a license report to be sure that it accurately reflects the nature of the Part 21 issue before taking credit for such a report.

Section 6.5, page 36 (add a new paragraph before the last paragraph before the example)

As a best practice, purchasers and suppliers should work together to be sure the procurement document is explicit with regards to the basic component being procured. A blanket statement in

the procurement that Part 21 and Appendix B apply may create confusion if only a small aspect of the procurement is actually safety related and a basic component.

NRC Comment #8 (slide #5, sixth bullet)

Vendors would benefit from licensee knowledge of: Nexus between licensee evaluation and Part 21 obligations

Industry Response

Included a statement about the identification of Part 21 reportable defects when they are reported under 10 CFR 50.72 and 50.73, in addition to the changes in response to NRC Comment #1.

Section 5.2, page 25 (add to last paragraph before example)

10 CFR 21.2(c) states that the evaluation of deviations and appropriate reporting of defects under 10 CFR 50.72, and 10 CFR 50.73 satisfies each person's evaluation, notification and reporting obligation to report defects under 10 CFR Part 21. The statements of consideration for the 1991 rulemaking to revise 10 CFR Part 21 (56FR36081) clarifies 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. It further clarifies that the licensee's evaluation and reporting responsibilities under 10 CFR Part 21 are satisfied by evaluating deviations of basic components, and reporting if necessary, under 10 CFR 50.72, and 10 CFR 50.73. Thus, for events evaluated under 10 CFR 50.72 and/or 50.73 a separate evaluation or report under 10 CFR Part 21 is not necessary. Additionally, a part on the shelf is considered a delivered component applicable to 10 CFR Part 21.

In the event that 10 CFR Part 21 is found applicable in the review of a 50.72 and 50.73 review, a licensee should identify that Part 21 is applicable on the Licensee Event Report form. Although not required, a licensee should ensure that the information required by 10 CFR 21.21(d)(4) is contained in the Licensee Event Report, to the best of their abilities.

NRC Comment #9 (slide #6)

Definition of failure to comply, and consistency with NRC enforcement manual and 2008 Q&A

Industry Response

Simplified the definition of failure to comply.

Section 2.9, Page 10 (definition of failure to comply)

Failure to comply means a noncompliance ~~the manufacture, construction or operation of a licensed facility or activity, a basic component supplied for such facility or activity, or a design certification or design approval under 10 CFR Part 52; which is not in compliance~~

with the Atomic Energy Act of 1954, as amended, any applicable rule, order, or license issued by the NRC.

Section 7.2, Page 38 (first paragraph)

Failure to comply means that the facility or activity regulated by the NRC, or basic component of such facility or activity, does not comply with the Atomic Energy Act of 1954, as amended, or any applicable rule, order, or license of the ~~commission~~ NRC ~~and is potentially associated with a substantial safety hazard~~.

In the context of 10 CFR Part 21, a failure to comply exists if:

- The manufacture, construction, or operation of a licensed facility or activity,
- A basic component supplied for such facility or activity, or
- A design certification or design approval under 10 CFR Part 52,

is not in compliance with:

- The Atomic Energy Act of 1954, as amended, or
- Any applicable rule, regulation of 10 CFR, order, or license issued by the Commission, or
- A standard design approval under 10 CFR Part 52.

~~and it is potentially associated with a substantial safety hazard.~~

NRC Comment #10 (slide #8)

Definition of basic component, and misconception that it only exists once delivered

Industry Response

Clarified that basic components can exist before they are delivered.

Section 2.2, page 5 (first paragraph after definition of basic component from 10 CFR Part 21)

Basic components include safety related equipment, software, and services, such as design, analysis, inspection, testing, and consulting activities. Basic components are either ~~obtained~~ 1) ~~by being~~ supplied as such under a quality assurance program pursuant to 10 CFR Part 50, Appendix B, or 2) ~~as~~ commercial grade items ~~subject to~~ that have successfully completed the dedication process defined in 10 CFR Part 21. 10 CFR Part 21 evaluation and reporting requirements apply to basic components ~~only after they are delivered~~. 10 CFR Part 21 evaluation and reporting requirements do not apply to ~~the supply of~~ commercial grade items that have not successfully completed the dedication process, because those items are not basic components ~~until they are dedicated and delivered~~. 10 CFR Part 21 evaluation and reporting responsibilities for the entity that dedicate~~d~~ the ~~basic component~~ commercial grade item do not begin until the item is ~~dedicated, delivered and~~ accepted for use as a basic component. Refer to section 7.3 (Deviation in a Delivered Basic Component) for a discussion of delivery.

Section 7.3, page 40 (second paragraph after item #2)

In determining whether a basic component has been delivered, the fundamental element is when the purchaser has taken control over the item. Normally, this would occur when the purchaser or its agent (e.g., a shipper) receives the component. However, the purchaser may be entitled, either through contractual provision or ordinary commercial practice, to conduct a receiving inspection before taking final acceptance of the component. In that case, "delivery" would not occur and therefore no notification to NRC by the purchaser would be required where the purchaser conducts the authorized receipt inspection and rejects and returns the component to the supplier within a reasonable period of time after receipt of the component. In this same situation, the supplier who receives the rejected component would be required to evaluate the deviation and report an identified defect if they had delivered components with similar deviations to other facilities or activities subject to Part 21. Suppliers should be cognizant that they may have shipped other items with the same deviation and therefore must consider the applicability of Part 21 evaluation and reporting requirements.

NRC Comment #11 (slides #9 and 10, and slide #12, second bullet)

Point of discovery; Sections 2.8 and 7 are confusing when compared, and no clear distinction between discovery and evaluation

A/E's responsibility when contracted to do Part 21 evaluation

Industry Response

Updated Sections 2.8, 7, and 8 to clarify the distinction between discovery and evaluation and to be more consistent with each other and the Appendix A flowchart. See the track-changes version of NEI 14-09 in these locations:

Section 2.8, Page 9 (paragraph after the definition of Discovery from 10 CFR Part 21)

The Point of Discovery occurs when a deviation (or failure to comply potentially associated with a substantial safety hazard) is clearly identified and documented as required by the procedure(s) established to implement 10 CFR Part 21 requirements. This Point of Discovery marks the beginning of the 60-day period permitted for completing an evaluation to determine whether the deviation or failure to comply, left uncorrected, could create a substantial safety hazard.

The Point of Discovery may differ from the date an issue was first documented (e.g., in the nonconformance or corrective action process). ~~However, "discovery" does not occur solely when it is determined that a deviation or failure to comply exists; that is but one of three elements in the discovery. Those elements are: completion of the documentation first identifying (1), the existence of a deviation or failure to comply (2) that is potentially associated with a substantial safety hazard (3). In order for discovery to occur, some investigation and analysis is often necessary.~~ This was acknowledged by the NRC in SECY 91-150, which stated, "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. Further, the discovery process is intended to be included in the procedures necessary to comply with Part 21 or §50.55(e)."

The issue may need to be reviewed by personnel familiar with 10 CFR Part 21 (as opposed to the person that reported the issue). In some instances, an initial investigation (e.g., inspections or tests) may be necessary to determine whether a deviation or failure to comply exists. In all cases, determination and documentation of whether a deviation or failure to comply exists should be timely. As described above, the 60-day clock for completing a 10 CFR Part 21 evaluation begins at the Point of Discovery. Implementing procedures should avoid specifying time periods for completing initial investigations that could cause unnecessary delays in documenting the Point of Discovery and starting the 60-day clock.

Section 7, Page 36 (intro)

10 CFR 21.2(a)(1) requires the evaluation of deviations and failures to comply in order to identify whether they could result in a substantial safety hazard, if they were to remain uncorrected. Prior to an evaluation, it first must be determined that a deviation or failure to comply exists; which is called discovery. Discovery is a process that concludes by determining whether an evaluation is required. ~~If it is determined that there is a deviation or failure to comply, then the point at which this is documented marks the Point of Discovery, and an evaluation must be performed, as described in Section 8.~~

~~Discovery is not solely when it is determined that a deviation or failure to comply exists, that is but one of three elements in the discovery. Those elements are: 1) completion of the documentation first identifying, 2) the existence of a deviation or failure to comply, and 3) it is potentially associated with a substantial safety hazard. In order for discovery to occur, some investigation and analysis is often necessary. This was acknowledged by the NRC in SECY 91-150, which stated, *"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. Further, the discovery process is intended to be included in the procedures necessary to comply with Part 21 or §50.55(e)."*~~

New Section, Page 36 (new section on issue identification)

7.1 Issue Identification

In many cases, issues are first identified and documented within a ~~licensee's corrective action process~~ Problem Identification and Resolution Program (e.g., the nonconformance and corrective action processes). ~~At this point there may not be enough information to recognize it as a Part 21 issue, and only when the issue is clearly identified as a potential Part 21 issue is the Point of Discovery established. Thus, discovery is a process that takes time and may not occur immediately when an issue is first documented in the corrective action process. It is expected that the investigation/screening of the issue to determine potential Part 21 applicability should~~

~~be timely. A delayed investigation should not be used as a means to delay evaluation and could be considered a violation of 10 CFR Part 21.~~

~~Issues that are identified and documented within the nonconformance and corrective action processes may need to be considered for evaluation and notification in accordance with 10 CFR Part 21.~~ Depending on the size of the entity and nature of the business, ~~these~~ Problem Identification and Resolution Program ~~processes~~ can generate a significant number of reports (e.g., condition reports, corrective action reports, and nonconformance reports). Only a subset of these reports identify issues that require additional actions to address 10 CFR Part 21 concerns~~, but the total number of reports can present a significant challenge in considering the applicability of 10 CFR Part 21 for each one~~.[3] ~~Prior to entering an issue into the Part 21 discovery process, the entity will need to identify whether an issue entered into a problem identification and resolution program (e.g., corrective action program) needs to be considered for Part 21 applicability.~~

Issues reported in the Problem Identification and Resolution Program should be reviewed to determine whether there is a nonconformance or condition adverse to quality relating to an NRC regulated facility, activity, or basic component. If an issue is determined to meet these conditions, then it needs to be considered for Part 21 applicability starting with the discovery process.

Footnote 3:

Issues identified in the corrective action program that are not associated with a nonconforming condition or condition adverse to quality, and thus would clearly not require a Part 21 evaluation or notification, (e.g., a condition report indicating that there is a trip hazard in an office hallway) need not be entered in the Part 21 program.

Section 7.1, Page 37 (revised section on Discovery process)

The Discovery Process is the process implemented to determine whether an issue entered in the Part 21 program, requires an evaluation in accordance with 10 CFR Part 21. The Discovery Process culminates in either the Point of Discovery (for deviations and failures to comply that require evaluation), or the determination that the issue does not require a Part 21 evaluation.

~~The main consideration is whether the issue is a nonconforming condition or condition adverse to quality relating to a facility, activity or basic component. If an issue is determined to meet these conditions, then it needs to be considered for Part 21 applicability and is entered into the Part 21 program, starting with the discovery process.~~

~~A screening is one approach to formalize the process of discovery that determines whether the issue is associated with a deviation or a failure to comply with a regulation. The screening process is a review performed to determine whether a given nonconforming condition or~~

~~condition adverse to quality[1] represents a deviation or failure to comply that is potentially associated with a substantial safety hazard, and if so, to document this determination. The screening that culminates in the point of discovery should be timely, and without undue delay in determining whether a Part 21 evaluation is warranted.~~

The Point of Discovery occurs when a deviation (or failure to comply potentially associated with a substantial safety hazard) is clearly identified and documented as required by the procedure(s) established to implement 10 CFR Part 21 requirements. The Point of Discovery marks the beginning of the 60-day period permitted for completing an evaluation as described in Section 8. In all cases, the determination and documentation of whether a deviation or failure to comply exists (i.e., document the Point of Discovery) should be timely.

~~In many cases,~~ The time appropriate for determining~~ation of~~ whether a Part 21 evaluation is necessary depends upon the unique conditions of the issue and upon what is known about the issue. Therefore, the amount of time that is reasonable to complete ~~a screening (i.e.~~ the discovery process~~)~~ is not fixed, but rather depends on the complexity of the issue being investigated. The Point of Discovery should coincide with the date of entry in the Part 21 program, if it is known that a deviation or failure to comply exists at that time. When more information is needed to determine whether a deviation or failure to comply exists, an investigation (e.g., inspections or tests) should be timely to make this determination. A delayed investigation should not be used as a means to delay evaluation. If the investigation determines a deviation or failure to comply exists, the Point of Discovery should coincide with the date the investigation results were obtained.

~~The screening process culminates in the point of discovery for deviations and failures to comply that require evaluation, or the determination that the issue does not require a Part 21 evaluation. The evaluation starts at the point of discovery and determines whether there is a defect or failure to comply that could create a substantial safety hazard and must be reported to the NRC in accordance with 10 CFR Part 21. In most cases, a deviation or failure to comply can only be identified through additional investigation performed as part of the discovery process. However, in some cases there may be enough information in the original problem identification/corrective action report to determine whether the issue is a deviation or failure to comply. In these situations, the point of discovery should be established as the first report containing sufficient information to make this determination.~~

~~If there is sufficient information from the screening process to determine whether or not the issue must be reported, then the properly documented results of the screening process may be credited as the 10 CFR Part 21 evaluation.~~

The ~~screening~~ discovery process is implemented by personnel that have knowledge of the pertinent regulatory and technical requirements. The ~~screening~~ process may be conducted by a single person or by a designated group, such as a regulatory compliance team or material

[1] Issues identified in the corrective action program that are not associated with a nonconforming condition or condition adverse to quality, and thus would clearly not require a Part 21 evaluation or notification, (e.g., a condition report indicating that there is a trip hazard in an office hallway) need not be screened.

review board. The results of the ~~screening~~ discovery process conducted by a single person should be reviewed separately by another individual with knowledge of the regulatory/technical requirements to ensure that the conclusions are sound and sufficiently substantiated by the objective evidence.

The ~~screening~~ process could be led by personnel in a variety of departments, e.g. Quality Assurance, Engineering, Operations. Personnel from other departments may also be included in the ~~screening~~ process, or receive actions resulting from the ~~screening~~ process. The personnel implementing the ~~screening~~ discovery process should be guided by a procedure or checklist to ensure the appropriate factors are considered and the results of the ~~screening~~ process are properly documented.

~~The supplier's screening process should consider whether they have the capability to perform an evaluation, if one is determined to be necessary. If it is obvious that the supplier does not have the capability to perform an evaluation, then the screening process should result in an action to inform purchasers and affected licensees accordingly.~~

The ~~screening~~ discovery process considers several factors in determining whether an issue requires a Part 21 evaluation. The specific factors to be considered ~~by an entity~~ may vary somewhat depending on the nature of the business, but are focused on the determination of whether a deviation or failure to comply exists, as described in Sections 7.3~~2~~ and 7.4~~3~~.

Section 7.2, Page 39 (after last paragraph)

Once the Discovery Process determines a failure to comply is potentially associated with a substantial safety hazard, the Point of Discovery is documented promptly to start the 60-day clock for completing the Part 21 evaluation as described in Section 8.

Section 7.3, Page 40 (starting after questions #2 on delivery)

The ~~evaluation~~ reporting requirements of 10 CFR Part 21 only apply to a deviation ~~of~~ in a basic component if that basic component has been delivered. (see the definition of Defect in Section 2.5)

In determining whether a basic component has been delivered, the fundamental ~~element~~ consideration is ~~when~~ whether the purchaser has taken control ~~over~~ of the item. Normally, this would occur when the purchaser or its agent (e.g., a shipper) receives the component. However, the purchaser may be entitled, either through contractual provision or ordinary commercial practice, to conduct a receiving inspection before taking final acceptance of the component. In that case, "delivery" would not occur and therefore no notification to NRC by the purchaser would be required where the purchaser conducts the authorized receipt inspection and rejects and returns the component to the supplier within a reasonable period of time after receipt of the component. In this same situation, the supplier who receives the rejected component would be required to evaluate the deviation and report an identified defect if they had delivered components with similar deviations to other facilities or activities subject to Part 21. Suppliers should be cognizant that they may have shipped other items with the same

deviation and therefore must consider the applicability of Part 21 evaluation and reporting requirements.

A basic component is considered delivered when the purchaser has taken control of the component or service ~~as a basic component~~ following the completion of the acceptance process (~~i.~~e.g., receipt inspection and in some cases acceptance/functional testing). ~~At that point, the control and ownership of the component transfers to the purchaser, including 10 CFR Part 21 responsibilities for reporting.~~ At any time prior to the owner accepting and taking control of the basic component, a deviation ~~any departure from a technical requirement included in a procurement document~~ is not required to be evaluated under Part 21 by the purchaser or the supplier because no substantial safety hazard can be created by a basic component.

However, the supplier retains full 10 CFR Part 21 responsibilities if the basic component was delivered to another purchaser. It is expected that the purchaser enter the issue and the basis for rejection into the corrective action process with documentation of the contact information with the supplier/manufacturer also included in the corrective action process. For purchasers, the rejection of a basic component prior to completing the acceptance process, for example during a receipt inspection, would result in the basic component not being delivered. Thus, the purchaser does not need to perform a Part 21 evaluation. The purchaser should promptly communicate the rejection to the supplier.~~, so that the supplier can determine the extent of condition and~~ A supplier who receives a rejected item should determine whether the basic component with similar deviations was delivered to ~~an~~other ~~purchaser~~ facilities or activities subject to 10 CFR Part 21 ~~with the deviation~~. If the supplier identifies a deviation in basic components delivered to other facilities or activities subject to Part 21, then the supplier should notify the other purchasers, and evaluate and report the defect pursuant to 10 CFR Part 21. However, the supplier is not required to perform a Part 21 evaluation for the item that was rejected, because the item was never delivered.

With respect to design, Part 21 is only applicable when such design (or consultation) can result in the creation of a substantial safety hazard. During the activities of design and consultation, there may be stages of conceptual design in regard to feasibility. Conceptual designs are not subject to Part 21. However, a "defect" in a design which is used in a procurement document is reportable under Part 21. Therefore, a design document, consultation or other software should be considered "delivered" for purposes of ~~reporting defects~~ evaluating deviations under Part 21 when it has been communicated to a purchaser which will use it in activities such as design, installation or manufacturing ~~or in preparing a document for the manufacturing of any~~ a basic component ~~document~~.

The concept of "delivered" is not addressed specifically when the basic component is turned over from one corporation or separate entity to another corporation or entity or delivered within a single corporation. The rule makes no distinction between inter and intra organization delivery of components as long as the transaction occurs pursuant to a procurement document. In determining whether a basic component has been delivered, the fundamental element is when the purchaser has taken control over the item. For example, if the fabricator of the component is

also the licensee of the reactor, the point of delivery is when the organization authorized to use it as a basic component has taken control over the item.

~~For purchasers, the rejection of a basic component prior to completing the acceptance process, for example during a receipt inspection, would result in the basic component not being delivered. Thus, the purchaser does not need to perform a Part 21 evaluation.~~

~~For suppliers, the response to this question, in the case of a basic component being rejected before completing the acceptance process may depend upon some investigation of the extent of condition. For example, if the supplier determines that the basic component with a deviation has not been delivered to the purchaser for the issue in question, then they should also investigate whether the basic component has been delivered to other purchasers with a deviation. Once the supplier identifies that the basic component with a deviation has been delivered to at least one purchaser, then the investigation of the extent of condition is not necessary to determine if an evaluation is necessary; however, further investigation of the extent of condition may be necessary in order to notify affected purchasers.~~

Section 7.3, Page 42 (before clarification for Part 52 design certifications)

Once the discovery process determines a basic component with a deviation has been delivered the Point of Discovery is documented to start the 60-day clock for completing the Part 21 evaluation, ~~If the basic component with a deviation has been delivered, then an evaluation is necessary and should be performed~~ as described in Section 8.

Section 7.4, Page 45 (first paragraph of Example #1)

Relay Model XY-01, a basic component, supplied for the Low Pressure Coolant Injection System was accepted by the licensee but not installed. During startup testing on May 1st, it was identified that the relay contacts were ~~deficient and~~ not closing properly. This issue was immediately entered into the corrective action program but Part 21 applicability was not readily apparent because other potential mechanisms such as setpoint drift could be the cause of the problem. There was no information that indicated the issue was due to a deviation or failure to comply.

Sections 8.1, Page 48 (last paragraph)

The results of the evaluation must be documented and should be reviewed separately by another individual with sufficient knowledge to ensure that the conclusions are sound and sufficiently substantiated by the objective evidence. ~~However, the level of effort needed to conduct and document a given evaluation may vary significantly based on the complexity of the issue and the difficulties encountered in obtaining the information needed to complete the evaluation. In some instances, for example when there is obvious need to report the defect or failure to comply, the results of a screening process, as described in Section 7, can satisfy the requirement for an evaluation.~~

Sections 8.3, Page 52 (last paragraph)

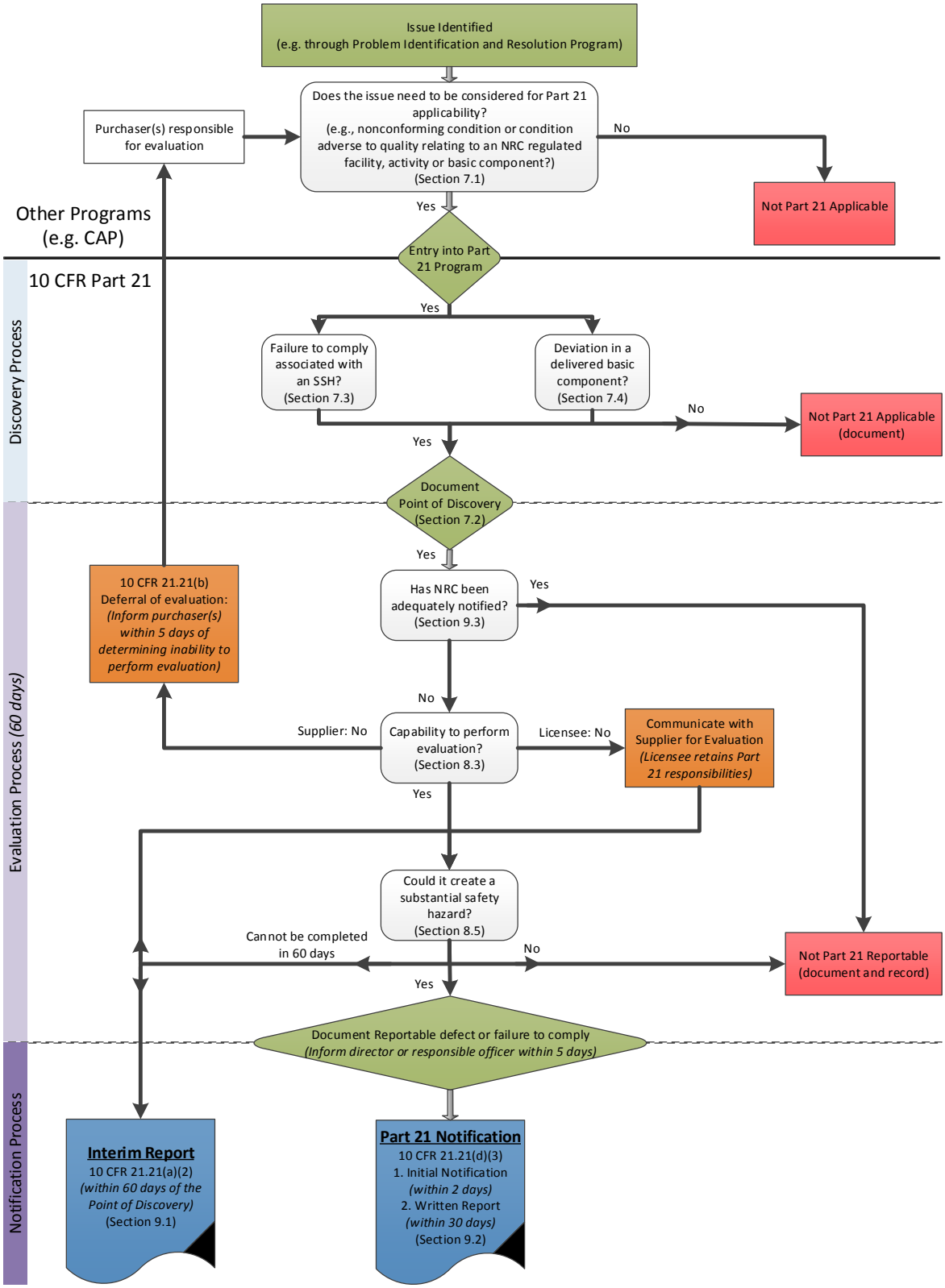
10 CFR 21.21(b) allows the transfer of responsibility for evaluation and reporting to the purchaser. This may continue up the supply chain all the way to the licensee. Supplier Part 21 programs should not contain a default conclusion that they do not have the capability to perform an evaluation and automatically transfer the Part 21 responsibility. Suppliers should make a good faith effort to lead the evaluation of deviations and failures to comply, communicating with purchasers when additional information is needed. The ~~is~~ transfer of evaluation responsibilities up the supply chain should only be exercised on a case-by-case basis once ~~when~~ the supplier ~~does not have the~~ determines its capability or ~~sufficient~~ knowledge is insufficient to determine if the defect or failure to comply could result in a substantial safety hazard were it to remain uncorrected. These conditions may exist for a supplier of basic Components for a number of reasons. If the supplier determines that it does not have the capability to perform an evaluation and determines whether there is a reportable defect or failure to comply per 10 CFR 21.21(a) then the supplier must notify, within five (5) working days of that determination, all potentially affected purchasers of this determination, that the responsibility for performing the evaluation and reporting is being transferred to them, pursuant to 10 CFR 21.21.

Sections 8.4, Page 54 (first paragraph)

Evaluations are performed to determine whether a deviation or failure to comply could create a substantial safety hazard, if it were to remain uncorrected. The level of effort needed to conduct and document a given evaluation varies significantly based on the complexity of the issue and the difficulties encountered in obtaining the information needed to complete the evaluation. Not all deviations or failures to comply need a detailed evaluation or significant level of effort to determine whether they could create a substantial safety hazard. In some instances the information needed to document the evaluation is known at the Point of Discovery. In these instances, the work to perform the evaluation is completed, and the results of the evaluation are documented in a simple fashion. ~~In order to avoid performing unnecessary detailed evaluations of deviations and failures to comply, when it can be quickly determined that they clearly cannot create a substantial safety hazard, the evaluation process begins with an initial filtering of issues.~~

~~In the initial filtering of the evaluation process, it is determined whether the deviation or failure to comply affects the ability of the facility, activity or basic component from performing a safety function. This initial filtering is at a low level of significance, as compared to substantial safety hazard, and can quickly identify those deviations and failures to comply that clearly could not result in a substantial safety hazard. If a deviation or failure to comply does not meet the initial filtering criteria, then it is not reportable under 10 CFR Part 21 and a more detailed evaluation is not necessary. If the deviation or failure to comply does meet the criteria, then a more detailed evaluation is necessary.~~

Appendix A, Page 63 (Figure A-1)



NRC Comment #12 (slide #11)

Notification and reporting; notification alone does not mean a written report not needed

Notification and reporting; need to include responsibility to ensure reporting timeliness requirements included in Part 21 procedure

Industry Response

Added statements to clarify that written notification is necessary, even if a telephonic notification has been provided.

Added guidance on addressing reporting timeliness in Part 21 procedures.

Section 2.10 (paragraphs following the definition of Notification from 10 CFR Part 21)

> The terms *notification* and *reporting* in 10 CFR Part 21 are very similar. In most cases the terms mean the same thing, with a few minor differences. Whereas the term "notification" includes both the telephonic communication and written transmittals of information to the NRC, the term "reporting" is used to mean only written notifications to the NRC in the form of a report. In all cases a written report transmitted to the NRC is required to communicate the attributes of a Reportable condition pursuant to 10CFR 21.21(d) (where a deviation or failure to comply could create a substantial safety hazard, if it were to remain uncorrected) or a 60-Day Interim Notification pursuant to 10CFR21.21(a)(2) (where the evaluation continues past the 60 days from the Point of Discovery). Additionally a written report must be submitted to the NRC upon completion of the extended evaluation period granted by the 10CFR21.21(a)(2) notification. It is also noted that all potentially affected purchasers are to be notified by the seller, in writing, when either a 10CFR 21.21(d) or 10CFR21.21(a)(2) report is transmitted to the NRC; concurrent with the transmittal to the NRC.
>
> Notifications may take the form of a telephonic communication or Facsimile to the NRC. ~~includes the initial and written notification to the NRC of a reportable defect or failure to~~ comply. The written notification is also called a report. All telephonic communications shall be followed by a written report.
>
> ~~Reporting includes the interim report of a deviation or failure to comply for which the evaluation continues past the 60 days from the Point of Discovery, and the report submitted to the NRC of~~ a defect or failure to ~~comply that could create a substantial safety hazard, if it were to remain uncorrected (written notification). The interim report and report of a defect or failure to comply must be written and submitted to the NRC.~~
>
> ~~The term "reportable defect or failure to comply" means a deviation or failure to comply that, on the basis of an evaluation, could create a substantial safety hazard if it were to remain uncorrected.~~

Section 6.1 (add to the list of bullets of content to include in the procedures), page 28

- Describe the reporting timeliness requirements in 10 CFR 21.21.

New section, page 36 (following Section 6.5)

6.6 10CFR Part 21 Reporting and Notification Time Requirements

All notifications and reporting associated with the resolution of a 10 CFR Part 21 evaluation is predicated on the completion of the evaluation. There are four resolutions possible for the completion of an evaluation by the Supplier, 1) There is no reportable condition, 2) There is a Reportable Condition (10 CFR 21.21(d)), 3) The Supplier does not have sufficient information or knowledge to make a determination of reportability and must transfer ownership of the evaluation to the Purchaser (10 CFR 21.21(b)), or 4) The Supplier can, or believes they can, complete the evaluation but requires more than 60 days from the Date of Discovery to complete the evaluation (10 CFR 21.21(a)(2)). All procedures governing the compliance to 10 CFR Part 21 should describe the reporting timeliness requirements.

1 - Not Reportable - Any evaluation that is completed and determines that there is no Reportable Condition requires no reporting to the NRC or any Purchaser of the basic component being evaluated.

2 – 10 CFR 21.21(d) - Once a determination of Reportable Condition (a Defect) is made by the Director or Responsible Office of evaluating entity, that entity, pursuant to 10 CFR 21.21(d), must notify the NRC Operations Center via facsimile (preferred method) within 2 days of notification by the Director or Responsible Office that a Reportable condition exists. A written notification is required within 30 days of notification by the Director or Responsible Office that a Reportable condition exists.

3 – 10 CFR 21.21(b) - An evaluation that ends in the Supplier being unable to complete the evaluation and unable to make a determination of Reportability requires no communication (either written or telephonic) to the NRC. All 10 CFR 21.21(b) communications are between the Seller and the Purchaser. Once the Seller has determined that they cannot complete an evaluation a 10 CFR 21.21(b) "Transfer of Information" is communicated to all identified potentially affected Purchasers within five (5) working days of that decision.

4 – 10 CFR 21.21(a)(2) - Once it has been determined that an evaluation can be completed, but not within 60 days from the Date of Discovery, a 10 CFR 21.21(a)(2) 60-Day Interim Notification shall be submitted to the NRC and any potentially affected purchasers. The 60-Day Interim Notification must be submitted within 60 days from the Date of Discovery. Following the issuance of a 60-Day Interim Notice and subsequent to the completion of the evaluation the resolution of the 10 CFR Part 21 evaluation must be communicated to the NRC, the Purchasers identified on the 10 CFR 21.21(a)(2) notification and any additional potentially affected purchasers identified during the completion of the evaluation. The report of the evaluation must be issued no later than the date of closure listed in the 10 CFR 21.21(a)(2) notification.

NRC Comment #13 (slide #12, first bullet)

Training for Engineering performing Part 21 evaluation

Industry Response

Added a best practice for assisting personnel performing Part 21 evaluations.

Section 6.4 (Training), page 32 (first paragraph)

> 10 CFR Part 21 does not establish requirements for training of personnel involved in 10 CFR Part 21 activities. However, as a good practice, appropriate familiarization and training in the requirements of 10 CFR Part 21 should be provided initially, and, as appropriate, on an ongoing basis, as necessary. As another good practice, an organization should designate individuals capable of assisting the staff in Part 21 evaluation, reporting requirements, and training requirements. Training may be in the form of classroom, computer based, read and sign, review of pertinent operating experience, or ongoing work experience. The important aspect is that individuals involved in activities associated with 10 CFR Part 21 compliance remain cognizant of the entity's responsibilities under this regulation, and their individual role in satisfying Part 21 requirements. This only includes individuals that perform 10 CFR Part 21 activities; it does not include general employees that do not perform activities subject to 10 CFR Part 21.

NRC Comment #14 (slide #12, third bullet)

No description of how to include Part 21 into the CAP

Industry Response

Added a best practice related to the CAP.

Section 6.1, page 28 (bulleted list of contents for Part 21 procedures)

> The primary objective of the evaluation and notification requirements of 10 CFR Part 21 is to ensure that issues associated with delivered basic components that are potentially associated with a substantial safety hazard, are identified, evaluated, documented, and reported to the NRC and all potentially affected purchasers, if necessary. To achieve this objective, the procedures should:
>
> - Describe how deviations and failures to comply are identified and documented,
> - Identify who has the responsibility for performing the evaluation,
> - Describe the purpose of the evaluation,
> - Provide instructions to perform 10 CFR Part 21 evaluations,
> - Provide guidance for performing and documenting the evaluation,
> - Include requirements to inform a Director or Responsible Officer of 10 CFR Part 21 reportable conditions,
> - Provide instructions to perform 10 CFR Part 21 notifications of reportable conditions, and

- Describe how deviations and failures to comply are identified and entered into the Part 21 program. As a best practice, the Corrective Action Program is often the best, although not only, means to identify issues that need to be entered into the Part 21 program.

NRC Comment #15 (slide #13, third bullet)

Part of the regulations cited inadequately: Important to safety vs. safety-related (p.11), and 21.21(b)(3) and 21.21(b)(4) no longer exist (p. 19)

Industry Response

Revise the text to change "important to safety" to "safety-related", and revise the text to change "21.21(b)(3)(vi)" to "21.21(d)(4)(vi)" and "21.21(b)(4)" to "21.21(d)(5)":

Section 3, page 11 of NEI 14-09 (two locations)

> Entities which operate or construct facilities, or supply basic components to these facilities are subject to 10 CFR Part 21. As defined in Part 21, the terms "constructing," "operating," and "basic component" are used to include safety-related equipment, software, and services, such as design, analysis, inspection, testing, and consulting activities ~~design, inspection, testing and consulting services~~ associated with construction, operation and basic components ~~that are important to safety~~. The thrust of the regulations goes beyond those entities licensed or previously regulated by the Commission to all entities which engage in the activities described in Part 21.
>
> The regulation explicitly addresses Part 21 obligations of entities that own, construct, operate, and supply basic components for NRC licensed reactors. The terms "constructing" and "supplying" are defined in 10 CFR 21.3. Specifically, the Commission has interpreted the term "constructing" to include the safety-related design, manufacture, fabrication, inspection, or testing of a facility or activity which is subject to 10 CFR Part 21, and safety-related consulting services related to the facility or activity ~~that are important to safety~~.

Section 3.1, page 12:

> The term "activity" used in 10 CFR Part 21.1(a) means any activity, except those specifically exempted, which is licensed or otherwise regulated pursuant to the Atomic Energy Act of 1954, as amended, or the Energy Reorganization Act of 1974, as amended. These include activities regulated by the NRC, and activities specifically included by 10 CFR 21.3 definition for basic component. The definition of basic component includes safety-related design, analysis, inspection, testing, fabrication, replacement of parts, or consulting services ~~important to safety~~ that are associated with component hardware, design certification, design approval, or information in support of an early site permit. Part 21 applies to any defects and noncompliance which could create a substantial safety hazard in activities that are within the regulatory authority of the NRC; therefore only those items which are safety related are within the scope of 10 CFR Part 21.

Section 4.2, page 19 of NEI 14-09 (second paragraph, second sentence)

10 CFR 21.21~~(b)(3)~~(d)(4)(vi)states " In the case of a basic component which contains a defect or fails to comply, the "number and location" of all such components in use at, supplied for, or being supplied for one or more facilities or activities subject to the regulations in this part."

Section 4.2, page 19 of NEI 14-09 (fifth paragraph, second sentence)

Specifically, if a director or responsible officer authorizes a person to make notifications for them pursuant to 10 CFR 21.21~~(b)(4)~~(d)(5), such authorization does not relieve the director or responsible officer of their responsibility to notify the Commission.

New Item Identified by Industry #1

Guidance does not discuss interface with 50.69 risk categorization.

Industry Proposal

Add a section discussing the interface of 10 CFR 50.69 with 10 CFR Part 21.

Section 5.5 (new)

5.5. 50.69

The statements of consideration for the final 10 CFR 50.69 rule (Federal Register Volume 69, page 68008) provides clarity on the risk categorizations which are as follows:

- Risk-Informed Safety Class (RISC)–1 structures, systems, and components (SSCs) means safety-related SSCs that perform safety significant functions.
- Risk-Informed Safety Class (RISC)–2 structures, systems and components (SSCs) means nonsafety-related SSCs that perform safety significant functions.
- Risk-Informed Safety Class (RISC)–3 structures, systems and components (SSCs) means safety-related SSCs that perform low safety significant functions.
- Risk-Informed Safety Class (RISC)–4 structures, systems and components (SSCs) means nonsafety-related SSCs that perform low safety significant functions.

In the statements of consideration, page 68023 (14 of pdf) middle column, the NRC makes it clear that Part 21 is only applicable to RISC-1, as quoted below. Therefore, parts that were originally purchased safety related and later re-categorized as RISC-3 would no longer need to be evaluated or reported pursuant to 10 CFR Part 21.

"The Commission concludes that Part 21 reporting requirements extend only to RISC–1 SSCs because they are important in ensuring public health and safety. RISC–2 SSCs are not subject to reporting because they play a lesser role than RISC–1 SSCs in protection of public health and safety and with the significant changes in treatment allowed under § 50.69, no regulatory purpose would be served by Part 21 reporting (as previously discussed). Individually, RISC–3 and RISC–4 SSCs have little or no risk significance and no regulatory purpose would be served

by subjecting RISC–3 and RISC–4 SSCs to Part 21 and § 50.55(e). The Commission does not believe that any changes to Part 21 or § 50.55(e) are necessary to accomplish its conclusions with respect to RISC–2 and RISC–3 SSCs.

The Commission believes this is consistent with the statutory requirements in Section 206 of the ERA. Section 206 does not contain any definition of "substantial safety hazard," but contains a direction to the Commission to define this term by regulation. Nothing in the legislative history suggests that Congress had in mind a fixed and unchanging concept of "substantial safety hazard" or that the term was limited to deterministic regulatory principles. Hence, the Commission has broad discretion and authority to determine the appropriate scope of reporting under Section 206. The Commission believes that the current definition of "substantial safety hazard" in § 21.3 is broadly written to permit the Commission to interpret it as applying, in the context of a risk-informed regulatory approach, only to RISC–1 SSCs."

New Item Identified by Industry #2

Guidance does not address its applicability before its creation.

Industry Proposal

Added a statement to the Foreword

Foreword, page i

This guidance is intended to aid in the application of 10 CFR Part 21 requirements and to provide good practices for the implementation of this rule. This guidance document is intended for use going forward, and is not intended to be applied retroactively (i.e., contracts, purchase orders, or other Part 21 documentation created before the guidance was issued).