October 5, 2009

MEMORANDUM TO: John A. Nakoski, Chief
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SUBJECT: REVISION 1 TO NRC RESPONSES TO 10 CFR PART 21 AND FUEL CYCLE FACILITY QUESTIONS RECEIVED DURING THE VENDOR WORKSHOP ON NEW REACTOR CONSTRUCTION IN DECEMBER, 2008

Enclosed please find Revision 1 to the NRC Responses to questions concerning 10 CFR Part 21 and Fuel Cycle Facility requirements received during the Workshop on Vendor Oversight for New Reactor Construction, which took place December 10 - 11, 2008 in Rockville, Maryland. This revision seeks to clarify the concept of “delivery” as it applies to basic components and applies only to Part 21 Questions 13, 14, 30, and 35 and Fuel Cycle Question 8.

Enclosures:
1. 10 CFR Part 21 and Fuel Cycle Facility Requirements, Revision 1

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10 CFR PART 21 (Revision 1)

PURPOSE AND SCOPE

Question 1:

What is the responsibility of the entity subject to 10 CFR Part 21 (Part 21)?

Answer:

In general, Part 21 requires entities subject to its regulations to 1) notify the NRC of a defect in a facility, activity, or basic component supplied to any facility licensed pursuant the Atomic Energy Act of 1954, as amended, or the Atomic Reorganization Act of 1974, that on a basis of an evaluation, the defect could create a substantial safety hazard; 2) comply with the posting requirements of §21.6; 3) evaluate deviations and failures to comply that may be associated with a substantial safety hazard in accordance with §21.21(a); 4) specify the applicability of Part 21 in procurement documents for basic components (i.e., safety-related systems, structures, and components (SSCs)); 5) permit the NRC to inspect records, premises, and activities related to Part 21; and 6) maintain records as required by §21.51.

Question 2:

Does Part 21 apply to anyone supplying parts and services or only those supplying a basic component?

Answer:

Part 21 regulations apply to each individual, corporation, partnership, or other entity, and each director and responsible officer of such an organization, that supplies basic components (i.e., safety-related SSCs) for a facility or activity licensed under the NRC regulations. As defined by § 21.3, basic component includes safety related design, analysis, inspection, testing, fabrication, replacement of parts, or consulting services that are associated with the component hardware, design, design certification, design approval, or information in support of an early site permit application, whether these services are performed by the component supplier or others.

Question 3:

Is Part 21 applicable to the procurement of non-safety-related components?

Answer:

No, Part 21 is not applicable to non-safety related SSCs. Part 21 is only applicable to basic components, as defined by § 21.3.

Question 4:

Does Part 21 apply to a third party dedicating entity?

Answer:

Yes, a dedicating entity that is supplying a basic component (i.e., safety-related SSC) is responsible for compliance with the requirements of Part 21.

Question 5:

Since Part 21 is a federal regulation, does it apply to all domestic suppliers whether or not they have an Appendix B to 10 CFR Part 50 (Appendix B) quality assurance (QA) program?

Answer:

Yes; Part 21 applies to all domestic suppliers of basic components (i.e., safety-related SSCs).

Question 6:

Can you reiterate the regulatory tie between Appendix B and Part 21? Is 10 CFR 21 invoked by Appendix B?

Answer:

Appendix B and Part 21 are separate regulations. Part 21 applies to basic components, as defined in § 21.3. Section 21.3 states, in part, that basic components are items designed and manufactured in accordance with Appendix B to 10 CFR Part 50.

Question 7:

I had a software supplier that quoted an NRC person that Part 21 did not apply since they did not supply a basic component and were not in a position to evaluate the software use. How do I convince the software supplier that Part 21 applies? Supplier stated that his program complies with Appendix B, but did not accept Part 21.

Answer:

If the supplier refuses to accept Part 21, the item cannot be supplied as a basic component (i.e., as a safety-related SSC).

Question 8:

If a basic component has been received and installed, why wouldn't the requirements of Part 21 apply? Wouldn't the supplier and the licensee have to perform an evaluation in accordance with Part 21?

Answer:

The requirements of Part 21 continue to apply to the supplier and the licensee after a basic component (i.e., safety-related SSC) is installed in the facility or used in the licensed activity. However, the Part 21 reporting obligation for the licensee may be satisfied by proper reporting under § 50.72 and/or § 50.73. It should be noted that if any licensee chooses to use the § 50.72 and/or § 50.73 reporting mechanism, the reports must contain the information required by Part 21.

PART 21 APPLICABILITY FOR NEW REACTORS

Question 9:

Is Design Certification Document (DCD) engineering work a basic component?

Answer:

Yes, DCD engineering work is a basic component because it is a safety-related design activity. As explained in the statement of considerations for the 2007 changes to Part 52 (72 FR 49352, August 28, 2007) the NRC regards the standard design certification applicant as supplying a component of an activity which is otherwise regulated by the NRC. The activity that is regulated by the NRC is the design certification rulemaking, and/or the Part 52 regulatory regime in which a design certification rule may be referenced in a subsequent licensing application.

Question 10:

Under Part 52, if engineered construction documents, purchase orders, or shop drawings are delivered to a licensee that conflict with the DCD, is this a Part 21 deviation?

Answer:

Based upon the information provided, the NRC cannot provide a definitive answer. The NRC notes that such conflicts must be placed in the licensee's corrective action program and be dispositioned. The purchase order or contract should specify if the item is safety related or a basic component. The delivery of safety-related engineered construction documents, purchase orders, or shop drawings to a licensee that conflict with the DCD may be determined to be a deviation that would need to be evaluated in accordance with § 21.21.

DEFINITIONS

Question 11:

For commercially dedicated items, if the dedicating entity is an Architect/Engineer (A/E), does it retain the reporting responsibility for the life of the plant even after his contract is completed with the licensee?

Answer:

Yes. A dedicating entity remains responsible for reporting any defects in a dedicated item which the dedicating entity has identified even after its contract is completed with the licensee.

Question 12:

Please define "failure to comply;" that is, failure to comply with what?

Answer:

A failure to comply is associated with the Atomic Energy Act of 1954, as amended, or any applicable rule, regulation, order, or license of the NRC associated with the facility, activity, or basic components purchased by a licensee that relate to substantial safety hazards.

Question 13:

The definition of defect includes the term "delivered" basic component. Delivered to whom, the licensee or any Appendix B supplier, who ordered the item or service?

Answer:

The term “delivered” applies when the basic component has been received and accepted by the purchaser, whether a licensee or vendor. As stated in NUREG-0302, “Remarks Presented (Questions Answered/Discussed) at Public Regional Meetings to Discuss Regulations (10 CFR Part 21) for Reporting of Defects and Noncompliance,” Revision 1, dated July 12-26, 1997, it is the staff’s position that a basic component (i.e., safety-related SSC) has been delivered 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, there may be instances in which delivery does not occur at the time of receipt. For instance, the purchaser may be entitled, either through contractual provision or ordinary commercial practice, to conduct a receipt inspection before taking final acceptance of the component. In such cases, delivery occurs when the purchaser finally accepts the component in accordance with the contractual provisions or provisions of commercial law governing acceptance.

Question 14:

In the Engineering, Procurement, and Construction (EPC) world, how is delivery defined?

Answer:

The definition of delivery is provided in the response to Question 13, above. For additional examples of delivery as it applies to design, construction, and analysis, please refer to Questions 10-13 of NUREG-0302 (pages 21.3(d)-5 through 21.3(d)-7).

Question 15:

(1) Are the terms "delivered" and "received" intended to be in reference to the actual licensee? (2) Do lower tier suppliers' Part 21 obligations tend to end with notification to their customer?

Answer:

(1) The terms "delivered" and "received" are reference to the entity procuring the basic component (i.e., safety-related SSC), which may or may not be the NRC licensee. (2) If the supplier cannot perform the evaluation, it must inform its customers per § 21.21(b). If the supplier is able to perform the evaluation, the supplier's Part 21 obligation would not end with notification to the customer. In this situation, the supplier would be required to perform the evaluation.

Question 16:

Are integral items within basic components which have no impact on the safety function of the component themselves considered to be basic components subject to Part 21?

Answer:

If the integral items within a basic component (i.e., safety-related SSC) have no impact on the safety function of the component, then those integral items are not considered basic components (i.e., safety-related SSCs) and are not governed by Part 21. This would also apply for the replacement of those integral items. It is the responsibility of the licensee or purchaser to identify those integral components which are or are not considered to be basic components (i.e., safety-related SSCs). All basic components (i.e., safety-related SSCs), including the overall component, are subject to Part 21.

Question 17:

A vendor has just discovered a deviation in a subcomponent within a delivered basic component.

(1) Does this qualify as an item for evaluation?

(2) The vendor determined that it was a defect, but the root cause shows it is an isolated incident. Is the vendor required to report it? This can be costly if delivered base is 50+ customers for a one-off isolated incident.

Answer:

(1) Yes, the subcomponent deviation must be evaluated to determine if there is a defect with respect to that subcomponent that may affect the ability of the basic component (i.e., safety-related SSC) to perform its safety function. (2) Yes, as required by Part 21 a notification to the NRC is required for every defect, even if the vendor determines that the incident is an isolated incident. If the incident is isolated in nature, it should be noted as such in the Part 21 report submitted to the NRC.

Question 18:

If a vendor supplies a part which is a subcomponent of a basic component, and there is a deviation (not a defect) from the purchase specification with respect to that part, how can the vendor perform the evaluation for a safety concern if that is dependent on how the purchaser or licensee uses the subcomponent?

Answer:

The procurement documents must specify if the subcomponent performs a safety-related function that is integral to the safety function of the overall basic component (i.e., safety-related SSC), which would make the subcomponent a basic component (i.e., safety-related SSC). Assuming that the subcomponent is a basic component (i.e., safety-related SSC), whether or not the subcomponent vendor has the capability to evaluate a deviation depends upon the specific situation and capabilities of the subcomponent vendor. However, the NRC notes that if a supplier determines that it does not have the capability to perform the evaluation of a deviation, § 21.21(b) allows for the supplier to notify its customer of a deviation within five working days of this determination. Once the supplier has notified its customer(s) that it does not have the capability to evaluate the deviation, the customer takes on the responsibility for conducting the evaluation.

Question 19:

If the basic component is a structure (building), are the parts on the building qualified or dedicated for 1st time use?

Answer:

If the structure is a basic component (i.e., safety-related SSC), then all parts that support the building's safety-related function – regardless of whether they are attached to ("on"), embedded within, or located in or under the building are considered basic components (i.e., safety-related SSCs) and must be manufactured under an Appendix B QA program or undergo commercial grade dedication prior to use. Parts that are attached to the building but do not support the building's safety related function would not themselves be subject to Part 21 by virtue of their location on the building. They may, however, be subject to Part 21 by virtue of that part's own safety function. It is the responsibility of the licensee to identify safety-related components that are part of, or support, a safety related structure. It is also the licensee's responsibility to assure the items are properly procured or dedicated to meet their safety related function.

Question 20:

Please give an example of a SSC which is not a basic component.

Answer:

Anything not identified by a licensee as safety related is not a basic component. This may include a potable water system, for example.

Question 21:

Are audits of basic components considered a basic component themselves under Part 21 reportability? (this refers to contract audit services)

Answer:

Yes. Part 21 requirements apply to any services that directly affect safety related components or activities.

Question 22:

Defect: if the wrong item [basic component] was delivered to a customer and the customer discovered the deviation and returned it, would this meet the definition of a defect?

Answer:

No. It is a deviation that requires an evaluation.

Question 23:

Can you please clarify what is included or considered to be procurement documentation?

Answer:

A procurement document, as defined in § 21.3, is a contract that defines the requirements which facilities or basic components must meet in order to be considered acceptable by the purchaser.

Question 24:

Is there a plan to clarify Part 21 with respect to definitions, substantial safety hazard, etc.?

Answer:

The NRC is currently evaluating the possibility of recommending rulemaking for Part 21 to the Commission. The scope of any rulemaking that may be recommended has not yet been decided.

Question 25:

What is a working day? What if a supplier only works 4 days a week?

Answer:

Although "working day" is not defined in Part 21, the NRC staff considers a working day to be any day on which Federal Government offices are open for normal business. Saturdays, Sundays, and official Federal holidays are not working days. However, in reviewing the implementation of Part 21, the staff will consider a supplier's regular, established work schedule.

POSTING REQUIREMENTS

Question 26:

What are the purpose and the value in posting a Part 21 placard for employees, especially in the new global market?

Answer:

The purpose is to ensure that companies and their employees are aware of their responsibilities as they pertain to 1) the specifics of the Part 21 regulation, 2) Section 206 of the Energy Reorganization Act of 1974, and 3) the company's approved nonconformance/defect notification program. The value is to ensure a level of company/personnel awareness of Section 206, the NRC's implementing regulations in Part 21, and specific company procedures. The application of the posting requirement as applied to the new global market is that if parts and/or components are produced for U.S. nuclear power plant use, U.S. regulations must be followed.

Question 27:

What are the posting requirements for work at home?

Answer:

Section 21.6 requires that every premise in the U.S. where activities subject to Part 21 are conducted, posts current copies of (1) the regulations in Part 21; (2) Section 206 of the Energy Reorganization Act of 1974; and (3) company procedures adopted pursuant to the regulations in Part 21 must be posted in a conspicuous location. If work subject to Part 21 is being done at a residence, then that location constitutes a premise for which the relevant notifications must be posted under § 21.6. If posting of the regulations is not practicable at the residence, then the staff considers access to Part 21, Section 206, and the company's applicable Part 21 reporting procedure, via the internet by "work at home" personnel to be adequate.

PROCEDURES

Question 28:

If a Part 21 procedure stating processes to be in accordance with § 21.21(a) is not adequate, why doesn't the regulation state as such?

Answer:

Section 21.21(a) states, in part, that each individual, corporation, partnership, dedicating entity, or other entity subject to the regulations in this part shall adopt appropriate procedures to evaluate deviations and failures to comply to identify defects and failures to comply associated with substantial safety hazards. The regulation specifically states that the vendor must have a procedure in place that governs the conduct of Part 21 evaluations. A procedure that simply references the regulations instead of providing working level guidance on how to meet the regulations does not provide reasonable assurance that Part 21 is being met. The vendor must include in its procedure adequate guidance to ensure regulatory compliance, such as a description of specific steps that will be implemented to meet the requirements of Part 21.

Question 29:

I received an audit finding for stating that "Notification time lines will be in accordance with § 21.21(d)." The auditor felt that I should have the timelines spelled out. Was that finding warranted?

Answer:

First, it should be noted that the NRC does not provide guidance or control what an auditor from a licensee or vendor deems to warrant a “finding.” The NRC believes that entities’ procedures for implementing the regulations of Part 21 must include notification time limits established by Part 21 in order to ensure compliance. Failure to make the necessary reports required by § 21.21(b) and § 21.21(d) within the time limits are considered violations and would result in the NRC taking appropriate enforcement actions. The NRC has identified occurrences where notifications were not made within the necessary time limits because the time limits were not spelled out in the entity’s procedure.

IDENTIFICATION OF DEVIATIONS

Question 30:

When does a vendor identify deviations?

Answer:

A vendor that supplies basic components may identify deviations at any time.

Question 31:

With respect to "discovery," using an example of stainless steel versus carbon steel bolts: what if during inventory check it is found that there are two extra carbon steel bolts and two missing stainless steel bolts but the vendor does not know when the discrepancy occurred. The vendor reviews records and finds (one month later) that the stainless steel bolts were shipped to Springfield Nuclear. When does the discovery clock start: when they identified the discrepancy or when they determined that the two stainless steel bolts were shipped to Springfield Nuclear?

Answer:

Discovery, as defined in § 21.3, is the completion of the documentation first identifying the existence of a deviation or failure to comply potentially associated with a substantial safety hazard. Therefore, the discovery occurs once the supplier documents that the incorrect bolts were shipped to Springfield Nuclear as basic components (i.e., safety-related SSCs).

EVALUATIONS

Question 32:

Why not notify the client/customer immediately when you discover a potential defect rather than waiting the 60 days evaluation period? The defect may cause a safety problem before the 60 day evaluation is completed and notification is made.

Answer:

Nothing in Part 21 requires an entity discovering a potential defect to wait 60 days before completing the evaluation and making the necessary notification; in fact, the NRC encourages suppliers to inform customers as soon as possible after identifying a potential defect. The 60 day period is the length of time that an entity is provided for completing its evaluation, and the NRC encourages entities to complete its evaluations before 60 days so long as the quality of the evaluation is not adversely affected. If an entity is unable to complete the evaluation within 60 days, it is required to submit an interim report to the NRC.

Question 33:

Is the NRC okay with Areva's 7 days to make a Part 21 evaluation? I am used to 24 hours.

Answer:

Part 21 regulations require evaluations to be performed within 60 days of discovery. However, the NRC does not restrict licensees or vendors from adopting more restrictive timelines as long as they are within the requirements of Part 21.

Question 34:

What is the role of the design organization with respect to evaluation of deviations and its impact on the safety function of the item?

Answer:

The staff interprets the design organization specified in the question as being the entity that is contractually responsible for the safety-related design, which is a basic component for which Part 21 is applicable. If the design organization discovers a deviation in the design, which has been offered for use, the design organization is obligated to comply with the provisions of Part 21.

Question 35:

If a deviation was found during receipt inspection and was documented as a nonconformance then dispositioned as scrap, would the deviation require an evaluation? If yes, considering that the item was not delivered to the customer, what would the evaluation involve? This question is coming from the perspective of a supplier to nuclear power plants.

Answer:

Yes. The item was "delivered" when the purchaser accepted the item. The dispositioning of the item as "scrap" is indicative that delivery and acceptance had already occurred. If acceptance had not occurred, then the purchaser would have refused the item and the supplier would retain control of the item and be responsible for its ultimate disposition.

Question 36:

What if a supplier discovered the deviation and notified the customer prior to the customer's receipt inspection and arranged replacement shipment. Would this require Part 21 reporting?

Answer:

In this case, Part 21 reporting may be required. It is the supplier's responsibility to perform an evaluation to determine if it had offered basic components with the same deviation to other customers for safety-related use.

Question 37:

If you have a component that can be used in both safety-related and non-safety related applications and you find a deviation in the non-safety related use, do you need to evaluate the deviation?

Answer:

The need for an evaluation depends upon whether the components have, in fact, been supplied as basic components (i.e., safety-related SSCs). If they have been supplied as basic components (i.e., safety-related SSCs), then the deviation (even if found in a nonsafety component) must be evaluated to determine if the deviation could result in a defect that could cause a substantial safety hazard.

PART 21 RESPONSIBILITIES UNDER DIFFERENT SITUATIONS

Question 38:

In the 1980's, the NRC informed licensees that it is the NRC's responsibility to verify implementation of Part 21 and not the supplier's responsibility. Only responsibility of the supplier is to specify Part 21 responsibilities in the procurement documents. Now, NRC is holding the supplier responsible for implementation of Part 21 by his sub-suppliers. What changed?

Answer:

Nothing has changed. The NRC does not hold suppliers responsible for the implementation of Part 21 by their sub-suppliers However, the NRC does not prohibit purchasers or other entities (e.g., NUPIC) from evaluating a supplier's Part 21 program and implementation.

Question 39:

Please identify the Part 21 requirements in the event that a licensee identifies [a] deviation instead of a supplier. What steps should the licensee take with respect to Part 21?

Answer:

If the licensee identifies the deviation, it is the licensee's responsibility to assure that a Part 21 evaluation is performed. The licensee and vendor may work together to determine if the deviation is a defect that could cause a substantial safety hazard.

Question 40:

Who will be responsible for reporting a defect if a safety problem occurred during operation – Which is the responsible entity of a Part 21 if a safety problem occurred?

Answer:

The licensee is responsible to comply with the requirements of Part 21 after a basic component (i.e., safety-related SSC) is installed in the facility or used in the licensed activity. However, the Part 21 reporting obligation may be satisfied by proper reporting under § 50.72 and/or § 50.73. It should be noted that if any licensee chooses to use the § 50.72 and/or § 50.73 reporting mechanism, the reports must contain the information required by Part 21.

Question 41:

A vendor supplies a basic component to a NSSS who in turn supplies the component within a system to an end user (licensee). The vendor discovers a deviation but cannot evaluate system impact, notifies the purchaser (NSSS) of the deviation and offers to help the purchaser in evaluation. Does the vendor need to notify the end user or the NRC? How does the vendor bring closure to the issue?

Answer:

Part 21 requires the vendor to inform the purchaser within five working days of the determination that the vendor cannot perform the evaluation. The vendor does not need to inform the end user; that would be the responsibility of the entity (in this case, the purchaser/NSSS) that supplies the final product to the end user. The vendor "closes" the issue by keeping a record of the information that was supplied to the purchaser.

Question 42:

Vendor 1 supplies a valve for use in a balance of plant (BOP) application but has not supplied this valve for use as a basic component (*i.e.*, for safety related applications). This valve is manufactured by another vendor (Vendor 2). Vendor 1 discovers a problem with the valve under certain circumstances, and thinks that the valve is used in safety related applications. What, if anything, should Vendor 1 do to comply with Part 21?

Answer:

Vendor 1 has no Part 21 obligations. However, the NRC encourages Vendor 1 to voluntarily inform its purchaser, who presumably has the information necessary to determine whether, in fact, it supplied the valve as a basic component (i.e., safety-related SSC) to other users.

Question 43:

Once a purchaser has notified its vendor of a deviation in an item it had received and rejected, does the purchaser have any further obligation to ensure that the vendor completes the Part 21 process?

Answer:

If the purchaser discovered a deviation in a basic component during receipt inspection, rejected the item, and informed the supplier, it is the supplier's responsibility to perform the evaluation to determine if the supplier offered basic components with the same deviation to other customers for safety-related use. The purchaser does not have any obligation to ensure that the supplier conducts an evaluation.

NOTIFICATIONS TO CUSTOMERS

Question 44:

If a lower tier subcontractor to a licensee identifies a deviation in a basic component but is unable to perform an evaluation, what are the obligations to the contractor and/or to the licensee?

Answer:

If the subcontractor identifies a deviation in a basic component (i.e., safety-related SSC) which was provided to a contractor or supplier of a licensee and determined that it is unable to perform the evaluation, the subcontractor must inform the contractor or supplier who purchased the basic component of the deviation within five working days of the determination so that the contractor or supplier can evaluate the deviation. The subcontractor does not have an obligation to directly inform the licensee. However, if the contractor or supplier to whom the services were supplied is no longer in business or cannot be located, then the NRC strongly encourages the subcontractor to directly contact the NRC.

Question 45:

Suppliers of calibration services and computer software may detect a deviation, but cannot determine the impact since they are not aware whether measuring and test equipment (M&TE) and software have been used. Would such a supplier satisfy the Part 21 reporting requirements by merely informing their customers within five days?

Answer:

Yes, if a supplier has determined that they cannot perform the evaluation, then the supplier fulfills its obligation under § 21.21(b) if it inform its customers within five working days of discovery of the deviation.

Question 46:

Does a supplier have 60 days before the five day clock starts to inform the customer even if the supplier knows it cannot complete an evaluation?

Answer:

No. The five working days clock starts when the supplier has determined that it is unable evaluate the deviation.

RESPONSIBLE OFFICER

Question 47:

In many small supplier organizations, the "responsible officer" may also be the "subject matter expert." Is there a regulatory conflict if the responsible officer / subject matter expert participates in the not greater than/equal to 60 day evaluation process?

Answer:

No.

NOTIFICATION TO NRC

Question 48:

If the "responsible officer" is also the "subject matter expert" and participates in the 60 day evaluation process, is the "responsible officer" notification five day clock still applicable or would the supplier be required to immediately initiate the "initial notification" within two days of completing the evaluation?

Answer:

The responsible officer clock starts after the completion of the evaluation. In this case, the two days for initial notification to the NRC would start at the end of the evaluation.

PROCUREMENT DOCUMENTS

Question 49:

Can a licensee relieve its suppliers, contractors and subcontractors of the obligation to comply with Part 21, for example, limiting to the notification of deviations but not invoking Part 21 in its procurement documents?

Answer:

If the licensee is purchasing a basic component (i.e., safety-related SSC), the supplier must comply with all provisions of Part 21.

Question 50:

Does a vendor with an Appendix B QA program who receives an order from a licensee invoking Part 21 provide: (1) a basic component, or (2) a commercial grade item that the licensee will dedicate to be a basic component?

Answer:

If the procurement document requires the item to be supplied under Appendix B and Part 21, the item would meet the regulatory requirements for being a basic component.

Question 51:

Can you invoke Part 21 on a supplier that does not have an Appendix B QA program?

Answer:

Any entity that supplies a basic component (i.e., safety-related SSC) must comply with all provisions of Part 21.

Question 52:

Please confirm that there is no regulatory requirement that Part 21 be imposed in procurement documents to suppliers of commercial grade items.

Answer:

There is no regulatory requirement that Part 21 be invoked in procurement documents to suppliers of commercial grade items, since such entities are not supplying a basic component (i.e., safety-related SSC).

Question 53:

Does an Appendix B supplier making a basic component have to invoke Part 21 on a purchase order to a non-Appendix B machine shop who supplies a subcomponent to be used in a basic component, if the machine shop has been qualified for traceability, nonconformance processing, handling, shipping, and receiving via limited scope audit and the purchase order requires reporting of any nonconformances to the supplier making the basic component?

Answer:

If the subcomponent is to be supplied as a basic component (i.e., as a safety-related SSC), the machine shop must comply with all provisions of Part 21 and applicable portions of Appendix B.

Question 54:

Should a utility require Appendix B and Part 21 for non-safety components (components that by design evaluation do not provide a safety-related function)?

Answer:

Part 21 is only required when purchasing basic components (i.e., safety-related SSCs); there is no regulatory requirement for goods and services that are not safety-related or do not meet the definition of basic component in § 21.3. If the licensee wishes to apply the requirements to non-basic components, that would be a private contractual matter between the purchaser and the supplier.

Question 55:

Is it appropriate to impose Part 21 on calibration suppliers that are accredited to ISO/IEC 17025 by a recognized accrediting body?

Answer:

It is appropriate to impose Part 21 on calibration suppliers whether or not accredited to ISO/IEC 17025 if they are supplying safety-related calibration services that meets the definition of a basic component.

Question 56:

Many 2nd and 3rd tier suppliers (heat treaters, test labs, plating houses, etc.) do not have an Appendix B QA program in place, but have a Part 21 reporting process documented. Can Part 21 be passed down to a supplier that doesn't have an Appendix B QA program?

Answer:

Assuming that the supplier does not have an Appendix B program (or ASME NQA-1 program for ASME Section III suppliers), then the supplier may not be considered a supplier of a basic component (i.e., safety-related SSC). Accordingly, it would be irrelevant to invoke ("pass down") the Part 21 requirements to suppliers of commercial grade goods or services.

Question 57:

What are my responsibilities when NQA-1 is the requirement invoked by my customer? Explain the link between Part 21 and NQA-1 and NQA-1 to Part 21. Does Part 21 apply if NQA-1 is the only call-out?

Answer:

There is no direct linkage between Part 21 and the requirements of NQA-1. The staff currently approves the use of NQA-1 in Revision 3 of Regulatory Guide 1.28, dated August 1985, as providing an acceptable method for implementing the requirements of Appendix B (licensees and vendors should check the NRC website for the latest NRC staff-approved version of regulatory guides). However, if the vendor is expected to supply a basic component (i.e., safety-related SSC) in accordance with Appendix B, this requirement should be clearly noted on the procurement document to which then Part 21 will be applicable.

Question 58:

If you cannot have Appendix B without 10 CFR Part 21, how can utilities issue purchase orders invoking Appendix B and not Part 21, or issue PO's as non-safety related when supplying a basic component?

Answer:

If the purchaser specifies that the item is a safety-related item that must be supplied as a basic component, then Part 21 must be invoked. If the purchaser fails to invoke Part 21 in the safety-related purchase order, that failure is a violation of § 21.31. Even though Part 21 is not directly invoked in the procurement documents, the supplier must still meet the requirements of Part 21 for safety-related purchase orders.

If the purchaser does not invoke Part 21 or specify that the item is safety-related or a basic component, the NRC would assume that the item is not being procured as a basic component. If the item is to be used as a basic component, the purchaser would be responsible for dedicating the component under its own Appendix B program.

Question 59:

Must a procurement document from suppliers of Appendix B materials specify Part 21 requirements on purchase orders to material manufacturers providing ASME Section III pressure boundary materials (material manufacturer is qualified to NCA3800, not Appendix B)?

Answer:

Yes. Even if the purchase order is issued to an NCA 3800 supplier, the material is safety-related and is supplied as basic component, and the purchase order must invoke Part 21.

Question 60:

The Part 21 statement of considerations state that Part 21 does not go below 1st tier suppliers. This would imply that all items and materials purchased by the 1st tier supplier are commercial grade items and must therefore be dedicated. They cannot purchase basic components. Is this a correct interpretation? If so, there are therefore many ramifications arising from this interpretation.

Answer:

The original statement of considerations for Part 21 (43 FR 28891, June 6, 1977) states, "The organizations subject to the regulations in Part 21 may be many procurement tiers away from the holder of a license to construct or operate a nuclear power reactor." Therefore, the NRC recognized, and continues to recognize, that basic components (i.e., safety-related SSCs) can be supplied at different levels of the supply chain. Any entity that has been audited and found to have an Appendix B QA program (or an ASME NQA-1 program for ASME Section III items) and that is working to a procurement document that invokes Appendix B or ASME NQA-1, as applicable, would be supplying a basic component to which all the provisions of Part 21 apply.

Question 61:

Many of our customers ask for partial dedication activity while imposing Appendix B and Part 21 on their Purchase Order. If Appendix B and Part 21 are invoked, then shouldn't we provide all necessary activities to dedicate the item?

Answer:

Part 21 requirements governing dedication of commercial grade products do not require that all dedication activities be performed by a single entity. Some dedication activities are complex and involve multiple processes which not all entities are able to perform (i.e., seismic or

environmental testing). Appendix B and Part 21 need only be invoked on those activities performed to support the dedication activity.

RECORDS

Question 62:

How long are suppliers required to maintain records of quality documents in fireproof cabinets or dual record storage? Indefinitely?

Answer:

Entities subject to Part 21 must retain records for a minimum period specified in § 21.51. For evaluations of deviations, the retention period is five years. For notifications sent to purchasers, the retention period is five years. For records of purchasers of basic components (i.e., safety-related procurement documents), the retention period is ten years. Nothing in Part 21 mandates the use of "fireproof cabinets" or "dual record storage" in maintaining necessary records.

MISCELLANEOUS

Question 63:

Does the application of Part 21 to suppliers require a full Appendix B program at the supplier?

Answer:

No. All "basic components," as defined by § 21.3, are required to be manufactured and controlled under the applicable portions of an Appendix B QA program, an ASME NQA-1 program for ASME Section III items, or dedicated under the requirements of Part 21. The dedication process must meet the requirements of 10 CFR Part 50, Appendix B, as noted in the definition of "dedication" in § 21.3.

Question 64:

How do the Appendix B requirements apply to "important to safety" classified items? Would Part 21 apply?

Answer:

Some Appendix B requirements may be imposed on "important to safety" items. Part 21 only applies to basic components (i.e., safety-related SSCs).

Question 65:

Does a third party dedicating entity operate under its own or the licensee's QA program?

Answer:

A third party dedicating entity can work under its own Appendix B QA program or the licensee's QA program. The required QA program should be specified in the purchase order or contract.

Question 66:

What version of NQA-1 is currently accepted by the NRC?

Answer:

As set forth in RG 1.28 (Revision 3, dated August 1985), the NRC endorses NQA-1-1983. In addition, the staff has reviewed and approved the use of NQA-1-1994 in safety evaluation reports issued to specific licensees. The latest revision to RG 1.28 can be found on the NRC website.

Question 67:

Due to the complexity of Part 21, it would appear that the evaluation process and persons responsible for such evaluation require specialized training. Do you foresee this becoming a skill requiring training? Are there any training resources currently available for Part 21 program development or investigation training?

Answer:

At this time, Part 21 does not specifically address or require training for individuals having functions described in an organization's Part 21 procedure. The NRC is not currently aware of any formal training offered in the area of Part 21.

Question 68:

What is the NRC position on Part 21 being imposed and material being procured from commercial vendors without a NQA-1/Appendix B program or limited certified material test report (CMTR) only review or CMTR review with only ISO/traceability audits?

Answer:

If the material is being procured and supplied as a basic component (i.e., safety-related material), all provisions of Part 21 are applicable. If the material is procured as a commercial grade item and is to be used in a safety-related application, the items must be dedicated in accordance with Part 21 and the applicable portions of Appendix B.

Question 69:

Is it conceivable that all component products and systems used in a nuclear power plant could be commercial grade products which are dedicated?

Answer:

No. Per the definition of commercial grade item in § 21.3, "commercial grade item means a structure, system, or component, or part thereof that affects its safety function, that was not designed and manufactured as a basic component." Commercial grade items do not include items where the design and manufacturing process require in-process inspections and verifications to ensure that defects or failures to comply are identified and corrected (i.e., one or more critical characteristics of the item cannot be verified). § 50.55a requires that some SSCs must be designed, fabricated, erected, constructed, tested, and inspected to quality standards (e.g., ASME) which require in-process inspections and verifications during the design and manufacturing process.

Question 70:

If the NRC expects the industry to invoke information notices (INs) as regulation, why does the NRC use terminology such as "should," "may," and "could," rather than "shall," "must," and "will"? If the CFRs are law, are the INs and NUREGs law as well?

Answer:

Neither Information Notices (INs) nor NRC documents published with NUREG identification numbers are regulatory requirements. INs are typically transmittals of recently identified information about public health and safety issues for review and possible action. NUREGs are documents containing results of research, results of incident investigations, and other technical and administrative information. Neither INs nor NUREGs are binding legal requirements, and the use of terminology such as *should*, *may*, and *could* is appropriate when referring to guidance as opposed to reiterating the requirements of a statute or regulation.

Question 71:

What is the date of the current revision of Part 21?

Answer:

The last time Part 21 was revised was on August 2007. You can also find a web version of Part 21 at the following address: http://www.nrc.gov/reading-rm/doc-collections/cfr/part021.

Question 72:

Current Part 21 on the NRC website notes Nov 2008 at the bottom of Part 21. The panel indicated that Part 21's latest revision was 2007. How do we locate what changed and can the NRC personnel indicate by "margin" notation?

Answer:

The last time Part 21 was revised was on August 2007. You can also find a web version of Part 21 at the following address: http://www.nrc.gov/reading-rm/doc-collections/cfr/part021. The NRC staff examined the NRC public website which provides the language of Part 21, and could not confirm the questioner's claim of a "Nov 2008" notation. The NRC does not currently use margin notation to denote changes between revisions to Part 21. A description of what changes have been made is included in the Federal Register notice for the revision.

Question 73:

Please discuss/review some examples of the interpretation and application of Part 21 requirements to real incidents.

Answer:

Part 21 Reports can be found on the NRC webpage: http://www.nrc.gov/reading-rm/doc-collections/event-status/part21/.

Question 74:

Is the identification of fraudulent/counterfeit materials during commercial grade dedication process a reportable deficiency?

Answer:

Although there are no current requirements specifically requiring the reporting of fraudulent/counterfeit materials, the NRC encourages these to be reported.

Question 75:

Must a supplier report deficiencies identified in a competitor's products, when the competitor's products were not procured by the supplier under Part 21 nor are they included in any of the basic components provided by the supplier?

Answer:

Under these circumstances, there is no reporting requirement under Part 21. However, § 21.2(d) states that "Nothing in these regulations should be deemed to preclude either an individual, a manufacturer, or a supplier of a commercial grade item (as defined in § 21.3) not

subject to the regulations in this part from reporting to the Commission, a known or suspected defect or failure to comply and, as authorized by law, the identity of anyone so reporting will be withheld from disclosure. NRC regional offices and headquarters will accept collect telephone calls from individuals who wish to speak to NRC representatives concerning nuclear safety-related problems. The location and telephone numbers of the four regions (answered during regular working hours), are listed in Appendix D to 10 CFR Part 20. The telephone number of the NRC Operations Center (answered 24 hours a day--including holidays) is (301) 816-5100."

Question 76:

Maybe it already exists, but if not, a process flow chart of the various documents and requirements for Part 21 would be useful to show how the various regulations fit together.

Answer:

The NRC will consider developing a flowchart that shows Part 21 requirements. At this time, there are no plans to do so.

INTERNATIONAL:

Question 77:

Part 21 is the law in the USA. When using a multinational supply chain for the new reactors, how do you ensure that this regulation is understood and implemented worldwide, even if it is not a legal document [requirement] in other countries?

Answer:

Any foreign supplier must be familiar with the applicable laws, including the requirements of Part 21 and § 50.55(e), if they are supplying basic components (i.e., safety-related SSCs). A procuring entity's procurement documents, by virtue of including the statement that the requirements of Part 21 and/or § 50.55(e) apply to the basic components (i.e., safety-related SSCs) being supplied, provides notice to the foreign entity that it must comply with Part 21 and/or § 50.55(e). However, if NRC does not have sufficient confidence in a foreign entity's compliance with all of provisions of Part 21 or § 50.55(e), then the NRC will not consider the item being supplied as complying with applicable NRC requirements for a basic component. In such cases, the licensee must implement appropriate corrective action, which may be the dedication of the supplied item in accordance with NRC requirements.

Question 78:

Briefly discuss the need to invoke the requirements of Part 21 to international suppliers of basic components in procurement documents.

Answer:

Part 21 requires that the procuring entity invoke the requirements of Part 21 in the procurement documents of basic components (i.e., safety-related procurement documents), regardless of whether the supplier is a domestic corporation, a domestic subsidiary of a foreign corporation, a foreign corporation doing business within the U.S., or a foreign corporation with no business presence within the U.S. If any of these entities fails to agree to comply with Part 21, then the item being supplied does not meet the requirements for a basic component. The NRC applicant or licensee, if it wishes to use that item in a safety-related application, must dedicate that item in accordance with NRC requirements.

Question 79:

How do we [licensees] enforce Part 21 requirements on foreign suppliers? Contract compliance only or is there any "reach" for Part 21's legal penalties?

Answer:

It is the procuring entity's responsibility to ensure that procurement documents specify that the provisions of Parts 21 apply when purchasing basic components (i.e., safety-related SSCs). It is the NRC's responsibility to evaluate the adequacy of the program. However, the NRC does not prohibit purchasers or other entities (e.g., NUPIC) from evaluating a supplier's Part 21 program and implementation. The purchaser should determine if the supplier's products meet the requirements for being supplied as a basic component.

Question 80:

Should Appendix B and Part 21 be invoked (together or separately) verbatim in purchase orders for materials (not basic components yet) produced by foreign suppliers/organizations? Are there alternatives to this process (ex. A procedure transposing the requirements for notification of 10 CFR Part 21)?

Answer:

If the material is not being supplied as a basic component (i.e., safety-related material), then Part 21 and Appendix B (or ASME NQA-1 for ASME Section III items) do not apply and do not need to be invoked in procurement documents.

Question 81:

If Appendix B and Part 21 are invoked by a foreign utility's procurement document, which requires that a US supplier send reports on defects to the foreign utility, then what, if any, notification must be provided by the U.S. supplier to the NRC?

Answer:

The U.S. supplier to a foreign utility is not required to notify under Part 21, so long as the same type of goods or services being supplied to a foreign utility have not been, or are not being offered for use to U.S.-licensed facilities in accordance with Part 21.

Question 82:

Is a foreign supplier required to comply with Part 21 if the supplier does not recognize Appendix B or meet all Appendix B requirements?

Answer:

If the foreign supplier does not recognize or meet Appendix B, the NRC will not consider the item being supplied as a basic component (i.e., safety-related SSC), and Part 21 requirements would not apply. If the item is to be used in goods or services constituting a basic component (i.e., safety-related SSC), the item must be dedicated in accordance with NRC requirements, and Part 21 would apply during dedication.

Question 83:

When procuring items from a foreign supplier, is it acceptable to contractually invoke the requirements of Part 21 without specifically invoking or citing Part 21 itself?

Answer:

No. If you are buying basic components (i.e., safety-related SSCs), Part 21 requirements apply, and Part 21 requirements must be cited and invoked in procurement documents, as required by § 21.31.

Question 84:

I have a sub supplier that is a foreign vendor. If the vendor does not accept Part 21, can my program be developed to accept the responsibility of Part 21 for this and any foreign vendor? Is this possible so I never have to pass down the Part 21 requirement but still take the responsibility?

Answer:

If the supplier will not accept Part 21, the item cannot be purchased as a basic component (i.e., safety-related SSCs). In such cases, the purchaser would be responsible for dedicating the component and would assume all Part 21 responsibilities.

Question 85:

You mentioned that postings are to be in foreign languages for domestic suppliers. Please explain the need for this, when it is applicable, or if I did not hear correctly.

Answer:

The posting requirement applies only to suppliers' physical premises located within the U.S. (which includes its territorialities and principalities). Part 21 does not contain any provision directing the posting to be in any particular language. However, for domestic suppliers with premises within the U.S., the NRC believes that the posting should be provided, at a minimum, in English.

Question 86:

What defect reporting requirements have been established by countries and regulatory agencies outside the U.S.?

Answer:

The NRC is not able to provide an answer, inasmuch as this is not a matter within the NRC's regulatory purview.

Question 87:

Is there any effort underway to create an international equivalent to Part 21 reporting, such that if a non-U.S. supplier failed to report defects to a U.S. licensee or the NRC, criminal punishments could apply in the foreign country?

Answer:

The NRC is not aware of any such effort.

Question 88:

How does NRC perform/conduct enforcement actions on foreign suppliers when violations of regulatory requirements are noted? How does NRC plan to enforce NRC Regs (which are US laws) on suppliers outside of the US? Does the NRC have reciprocity w/foreign regulatory agencies?

Answer:

The NRC does not have authority to take "enforcement action" against foreign suppliers with no business presence in the U.S., nor does the NRC have authority to demand physical access to a foreign supplier's facilities or premises located anywhere outside the U.S. Finally, the NRC does not have "reciprocity" agreements with foreign regulatory agencies which require a foreign regulatory agency to take action against an entity located in its jurisdiction based upon a communication or information provided by the NRC to that foreign regulatory agency that an NRC regulatory requirement has been violated. Furthermore, even if an NRC licensee or domestic entity in the chain of supply of a basic component (i.e., safety-related SSC) includes a condition in its procurement document requiring the foreign supplier to provide access to an NRC inspector upon demand, this does not constitute a legal requirement that the NRC can enforce as a regulatory matter. Thus, the NRC could not take enforcement action against such a foreign supplier for failing to provide access.

If a foreign supplier does not provide access to an NRC inspector with respect to a basic component (i.e., safety-related SSC) or the vendor does not comply with the requirements of Part 21 or the NRC Enforcement Policy, the item cannot be purchased as a basic component. In such cases, the licensee must either dedicate that item in accordance with NRC requirements on dedication, or use another item from a supplier who meets the NRC's requirements on compliance with Part 21 and 10 CFR Part 50, Appendix B.

Question 1:

10 CFR Part 21 addresses the requirements for evaluating and reporting defects and noncompliance's of basic components. Why is there no specific Federal Regulation for dedication of commercial grade items? Just having definitions for dedication and basic component is not enough. Since we are a Part 70 nuclear facility, we are not required to comply with 10 CFR Part 50, Appendix B. Does the definition of dedicating entity and responsibilities (as defined in 10 CFR 21.3 and described in 21.21(c)) apply, or does this mean that we can determine our own path for the rigor and degree of application for commercial grade items?

Answer:

The definition in Part 21 of dedication establishes, as a practical matter, binding legal requirements governing dedication of commercial grade items as basic components.

Inasmuch as the detailed requirements in the definition of dedication apply only to nuclear power plants, these requirements are not directly applicable to Part 70 facilities. However, the requirements for a dedicating entity, as set forth in § 21.21(c), apply to all licensees, including Part 70 licensees. In addition, all licensees should be guided by the principles underlying the dedication requirements for nuclear power plants as set forth in the definition of dedication.

Question 2:

Are the requirements for commercial grade item dedication different for fuel manufacturers and reprocessing facilities?

Answer:

No; Part 21 does not distinguish between fuel manufacturers and reprocessing facilities.

Question 3:

Should the MOX Project be complying with 50.55 instead of Part 21 because they are a construction site vs. an operating facility? (i.e., Should they invoke 50.55(e) on their purchase orders for components?)

Answer:

MOX refers to the Mixed Oxide Fuel Fabrication Facility (MOX) located at the Savannah River Site in Aiken, SC. It is a fuel fabrication facility that uses the surplus plutonium of nuclear weapons and converts it into mixed oxide fuel to commercial nuclear power plants. More info can be found on our public website: http://www.nrc.gov/materials/fuel-cycle-fac/mox/licensing.html.

10 CFR 50.55 does not apply to the Mixed Oxide Fuel Fabrication Facility because the facility is a Part 70 facility.

Question 4:

For fuel cycle facilities, what is the dedication of a first tier supplier or activity?

Answer:

The NRC staff interprets this question as asking whether the NRC's requirements governing dedication differentiate between an entity that directly supplies to the licensee, versus an entity that does not supply to the licensee but provides the commercial grade item to the entity that supplies the licensee. The NRC's requirements governing dedication do not distinguish between direct suppliers versus indirect suppliers. The requirements for dedication are the same, regardless of who the dedicating entity is. It should be noted, however, that Part 21 requirements do not govern which entity must conduct the dedication activities. Also, there is no requirement that all dedication activities be performed by the same entity. If a licensee or other entity chooses to perform dedication, some of the dedication activities can be performed by other vendors.

Question 5:

Is there going to be a NRC Workshop for 10 CFR Part 21 as it applies to other types of nuclear facilities? (i.e. those that do not have to comply with 10 CFR 50 App. B)

Answer:

The NRC is considering options for communicating Part 21 requirements to fuel fabrication facilities.

Question 6:

It has been stated several times that only Appendix B entities can perform dedication. Our plant is under Part 70, and Appendix B does not apply. Are we required to dedicate? Please explain any differences.

Answer:

Commercial grade dedication is not limited to "Appendix B entities." Any item that is designated to perform a safety function must either be (1) purchased as a basic component (i.e., safety-related SSC) or (2) purchased as a commercial grade item and dedicated. It is the ultimate responsibility of the licensee to ensure that items are procured either as basic components or dedicated. This should be done through specifications in procurement documents.

Question 7:

What is the definition of a dedicating entity for a fuel cycle facility (not under Part 50)?

Answer:

A dedicating entity for a fuel cycle facility licensed pursuant to Part 70 is not defined, *per se*, in § 21.3; however, a dedicating entity is a party who performs the activity of dedication. The NRC's requirements applicable to a dedicating entity are set forth in § 21.21(c). These requirements apply to *all* licensees, including licensees of fuel cycle facilities.

Question 8:

When is a commercial grade item designated for use as a basic component for a fuel cycle facility?

Answer:

The staff interprets this question as asking when the dedication process is completed for a commercial grade item which is dedicated for use as a basic component in a licensed fuel cycle facility. As provided in the definition of "dedication" in § 21.3 under paragraph (2), "When applied to facilities and activities licensed pursuant to 10 CFR Parts 30, 40, 50 (other than nuclear power plants), 60, 61, 63, 70, 71, or 72, dedication occurs after receipt when that item is designated for use as a basic component." Accordingly, the staff treats the dedication of a CGI as being completed after the CGI has been delivered to the purchaser (unless the purchaser is responsible for dedication).