

# Part 21: Questions and Answers

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**Kerri Kavanagh**

**Office of New Reactors**

# Agenda



- 10 CFR Part 21 History
- First Workshop on Vendor Oversight for New Reactor Construction
- Discussion of Some Questions and Answers from 2008 Vendor Workshop
- Audience Questions

# 10 CFR Part 21 History



- Section 206 of the Energy Reorganization Act of 1974 requires the licensees and suppliers to report all defects and noncompliances directly to NRC.
- NRC in response to the ERA 1974 drafted 10 CFR Part 21 in 1977.
- NRC published NUREG-0302 Rev 1 to document the questions/answers discussed in the public meetings during the rulemaking process. <http://www.nrc.gov/reactors/new-reactors/oversight/quality-assurance/vendor-insp/nureg-0302.html>

# First Workshop on Vendor Oversight for New Reactor Construction



- NRC conducted the First Workshop on Vendor Oversight for New Reactor Construction in December 2008.
- NRC published all the questions and NRC’s answers about 10 CFR Part 21 from the workshop in October 2009.
- The Memorandum titled “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” can be found in the NRC’s public website or <http://www.nrc.gov/reactors/new-reactors/oversight/quality-assurance/vendor-oversight/past/2008/index.html>

# Part 21: Questions and Answers



- Purpose and Scope
- Definitions
- Procedures
- Evaluations
- Part 21 Responsibilities under Different Situations
- Procurement Documents
- International

## Purpose and Scope (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.

## Purpose and Scope (Answer 7)



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

## Definitions (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.



## Definitions (Answer 17)

- (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 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.

## Definitions (Question 19)

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

## Definitions (Answer 19)

- If the structure is a basic component, then all parts that support the building's safety-related function are considered basic components regardless of whether they are attached to (“on”), embedded within, or located in or under the building.
- 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.
- It is the responsibility of the licensee to identify safety-related components that are part of, or support, a safety related structure.

## Procedure (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?

## Procedure (Answer 28)

- 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 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.

## Procedure (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?

## Procedure (Answer 29)

- 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.

## Evaluations (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.



## Evaluations (Answer 35)

- Yes... 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.

## Part 21 Responsibilities under Different Situations (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?

## **Part 21 Responsibilities under Different Situations (Answer 41)**

- 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.

# Procurement Documents (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?

# Procurement Documents (Answer 56)

- Assuming that the supplier does not have an Appendix B program, then the supplier may not be considered a supplier of a basic component.
- Accordingly, it would be irrelevant to invoke the Part 21 requirements to suppliers of commercial grade goods or services.

## International (Question 78)

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

## International (Answer 78)

- Part 21 requires that the procuring entity invoke the requirements of Part 21 in the procurement documents of basic components... §21.31
- If any entity fails to agree to comply with Part 21:
  - The item being supplied does not meet the requirements for a basic component.
  - The licensee or applicant must dedicate the item in accordance with NRC requirements.

## International (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?



## International (Answer 79)

- It is the procuring entity's responsibility to ensure that procurement documents specify that the provisions of Parts 21 apply when purchasing basic components.
- It is the NRC's responsibility to evaluate the adequacy of the program.
- 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.

## International (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?

## International (Answer 82)

- If the foreign supplier does not recognize or meet Appendix B:
  - The NRC will not consider the item being supplied as a basic component.
  - Part 21 requirements would not apply.
- If the item is to be used in goods or services constituting a basic component:
  - The item must be dedicated in accordance with NRC requirements.
  - Part 21 would apply during dedication.

## International (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?

## International (Answer 83)

- No
- If you are buying basic components:
  - Part 21 requirements apply
  - Part 21 requirements must be cited and invoked in procurement documents as required by § 21.31.

# Questions?



## Backup Slide

- Purpose of the regulation is to notify the Commission of a defect in a basic component or a failure to comply.
- The regulation applies to:
  - NRC licensed facilities
  - Suppliers of basic components for NRC licensed facilities
- Discovery----Evaluation----Notification