10 CFR 21 Evaluations: A Part 50 Licensee Perspective

NRC Workshop on Vendor Oversight for New Reactor Construction

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10CFR21 Purpose & Scope Review

- Purpose is to notify the NRC of
  - A defect in a basic component, or
  - A failure to comply.

- Applies to anyone
  - constructing,
  - owning,
  - operating, or
  - supplying materials or services

  for a licensed facility or activity.

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Scope Provision - Part 50 Licensees

Special stipulation for nuclear power plant licensees (10 CFR 21.2(c)):

The following reporting regulations satisfy the evaluation, notification, and reporting obligations of Part 21.

- § 50.72 - Immediate notification requirements
- § 50.73 - Licensee event report system
- § 73.71 - Reporting of safeguards events

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Provisions for Part 50 Licensees

- Therefore, there are only two conditions under which nuclear power plants perform reportability evaluations per 10 CFR 21:

1. Failures to Comply.

2. Items Received but Not Installed.

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Provisions for Part 50 Licensees

There is a third condition where nuclear power plant licensees may choose to perform an evaluation under Part 21:

- Supplier Is Unable to Make Reportability Determination

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Nuclear Utility as a Supplier

If a Part 50 licensee sells a Basic Component to another licensee, then the seller becomes a “Supplier” under Part 21:

- In this case, the supplier notification requirements would apply to the selling utility. (10 CFR 21.21(b), 21.51(a)(2), & 21.51(a)(3))

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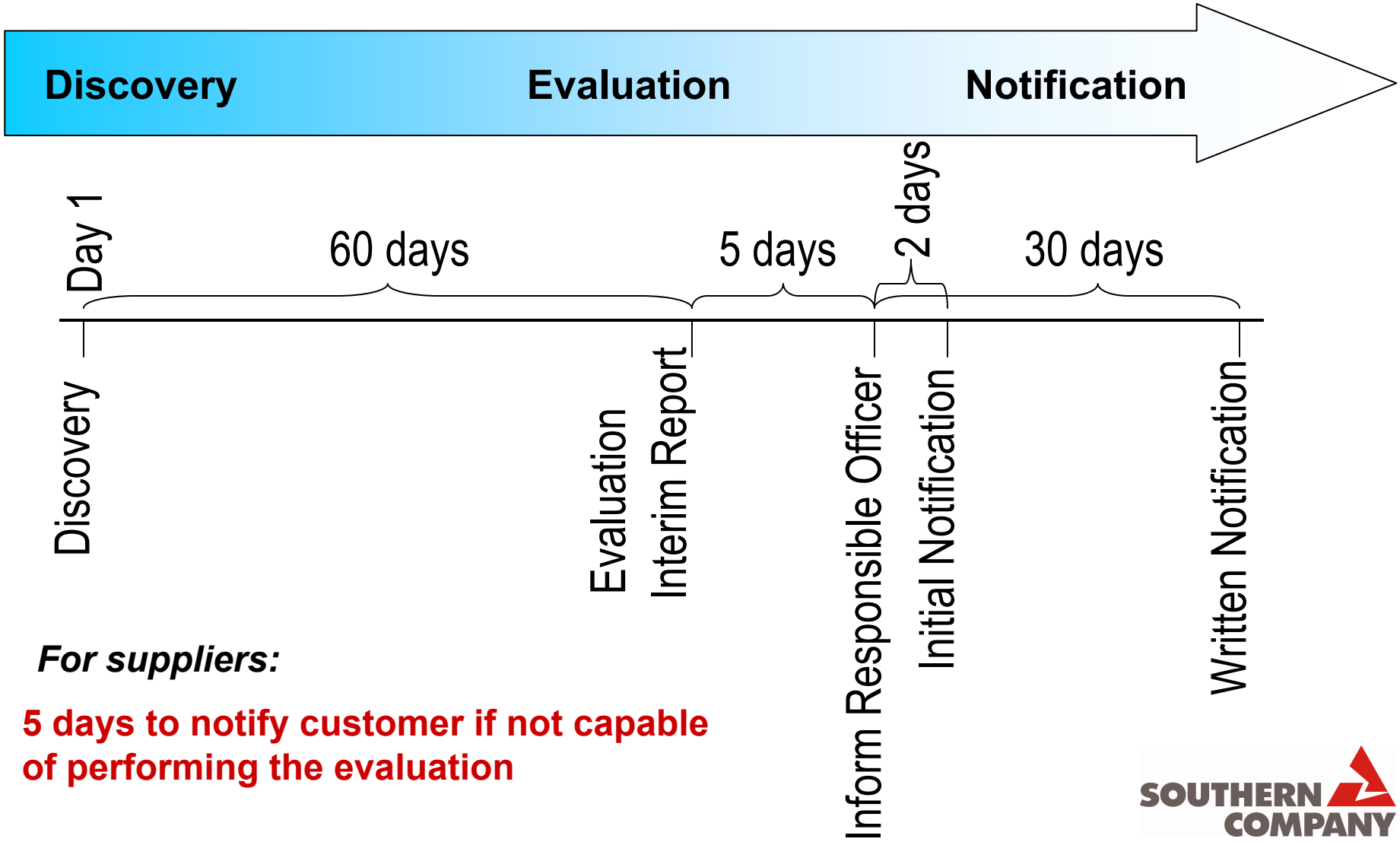
Part 21 Process Timeline Review



For suppliers:

5 days to notify customer if not capable of performing the evaluation

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Time Line Summary Chart

ACTIVITY	PERMISSIBLE TIME
-Discovery	unspecified
-Evaluation	60 days after discovery
-Interim Report	60 days after discovery
-Notify Responsible Officer	5 working days after eval
-Notification to NRC	2 days after R.O. informed
-Written NRC Report*	30 days after R.O. informed
-Supplier Notification	5 working days after determining supplier is unable to perform evaluation

* The Plant Review Board reviews the report prior to submittal to the NRC.

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Discovery, Identification, & Tracking

- Screen Condition Reports for reportability
- Screen industry information for applicability
- Capture Potential 10 CFR 21 concerns
- Log each 10 CFR 21 concern
- Assign a Part 21 issue tracking number
- Record the evaluator, due dates, and completion dates for status tracking.

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SNC Evaluation Initiation

- Key Process Element
  - ***Effective Corrective Action Process***
- Identification may come from any party
- Potentially reportable issues are screened
- Trained evaluator is assigned
- Checklist format guides the evaluation
  - Potential Defect Checklist
  - Potential Failure to Comply Checklist
    - Sample Checklists are included at the end of presentation

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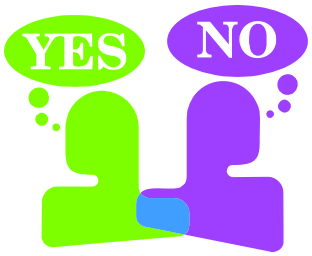
SNC Evaluation Process Goal

- Evaluation Goal:
  To determine two things about the deviation or the failure to comply.

  1. Is it is associated with a Basic Component?
  2. Could it create a substantial safety hazard?

- To be reportable, the answer to both questions must be “YES.”



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SNC Evaluation Process

- 60 Day Maximum

- Complex evaluations can exceed 60 days if an interim report is submitted to the NRC:
  - Describing the condition being evaluated
  - Establishing date for final report
  - Processed through the Responsible Officer

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SNC Evaluation Criteria

- Basic Component Criteria (from Part 21 Definitions)
- Substantial Safety Hazard Criteria (from NUREG-0302 clarifying information)
  - Moderate Exposure
  - Major Degradation
  - Major Deficiency

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SNC Evaluation Outcome

- If the evaluation results in recommendation to report a potential defect or a failure to comply:
  - Notifications are made to management and to the Responsible Officer (5 days maximum).
  - An additional checklist is initiated as an aid in assimilating the data to support the report to the NRC. (Go to Sample Checklist)

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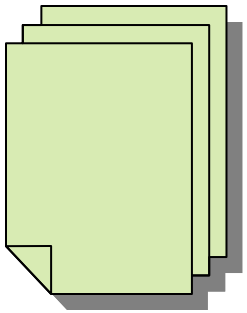
SNC Evaluation Process Outcome

- If the evaluation results in recommendation NOT being made to report a potential defect or failure to comply:
  - Written notification must be made to supervision before the 60 day evaluation period expires.



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References

- 10 CFR Part 21, “Reporting of Defects and Noncompliance”
- NUREG-0302, Rev. 1, “Remarks Presented (Questions/Answers Discussed) at Public Regional Meetings to Discuss Regulations (10 CFR Part 21) For Reporting of Defects and Noncompliance“
- Regulatory Guide 1.16, "Reporting of Operating Information”

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References

- 10 CFR Part 50.72, “Immediate Notification Requirements for Operating Nuclear Power Reactors”
- 10 CFR Part 50.73, “Licensee Event Report System”
- SECY 77-439, “Single Failure Criterion”
- NUREG-1022, Rev. 2, “Event Reporting Guidelines 10 CFR 50.72 and 50.73”

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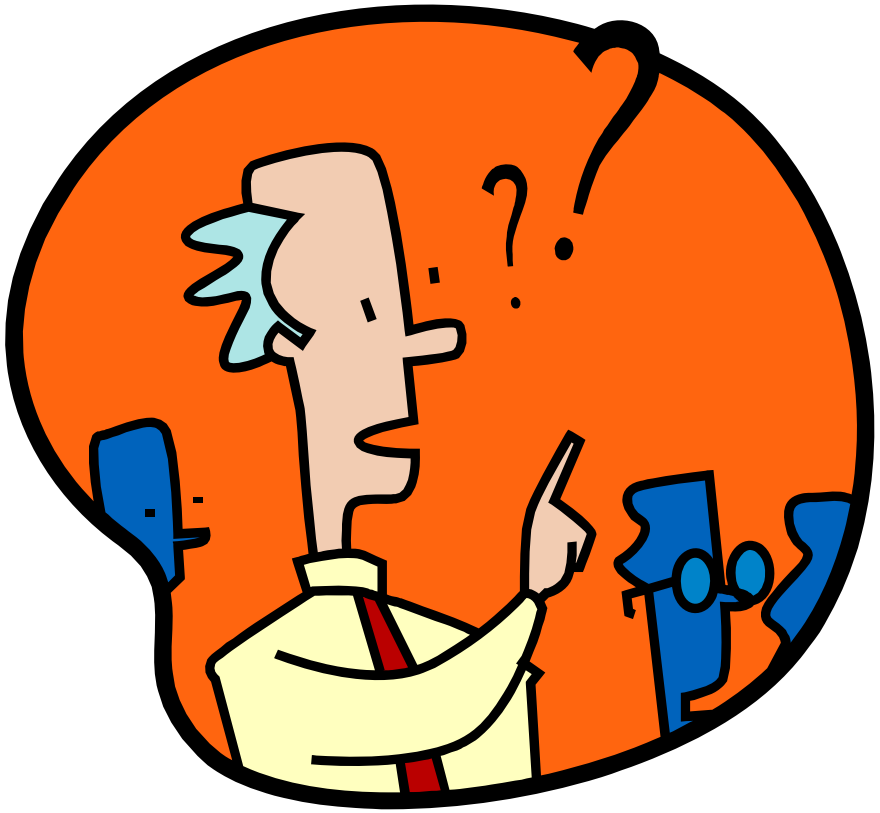
Thank you for your attention!

Questions and Comments…



Please hold questions and comments for our discussion time.

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Sample Checklist – Potential Defect

10 CFR 21 Potential Defect Checklist
(Sample)

Issue Title:_____

10 CFR 21 No:_____

Subject Plant:_____

Subject Unit:_____

Part A of this checklist identifies the document under review and determines applicability of a 10 CFR Part 21 review by the Company. The applicable portions of Part A shall be completed for all 10 CFR 21 evaluations.

Part B is used to identify defects in basic components that are potentially reportable under 10 CFR Part 21.

Part C summarizes the conclusion for potential reportability and provides for submittal and approval signatures.

Checklists used for the review of concerns shall be retained for 5 years. An approval signature is required for all checklists whether the issue is determined to be potentially reportable or not. In all cases, the form needs to be completed only to the extent necessary to reach a conclusion relative to a recommendation on reportability.

Sample Checklists (continued)

10 CFR 21 Potential Defect Checklist
(Page 2)

A. <u>IDENTIFICATION AND APPLICABILITY DETERMINATION</u>

1. Document Title and Type:_____
2. Document ID Number:_____
3. Document Date:_____
4. Discovery Date:_____
5. 10 CFR Part 21 Review Applicability:

   a. Have Basic Component(s)* affected by the concern been sold?

      ( ) Yes; Consider notifying purchaser of the concern, and continue with the reportability evaluation for Company operated plants. A representative from the supply chain organization shall be contacted to determine if the affected equipment has been sold.

      ( ) No; Continue with the reportability evaluation for Company operated plants.

   b. Is the concern shown to be applicable to the Subject Plant? If this factor is not known, obtain an engineering evaluation for plant applicability. A reasonable amount of time to perform this "discovery" process is not applicable to the 60 day time limit for the evaluation to determine reportability.

      ( ) Yes; continue review

      ( ) No; no further review needed

Sample Checklists (continued)

10 CFR 21 Potential Defect Checklist
(Page 3)

c. The concern is related to something (structure, system, or component) supplied or offered for acceptance for use at the Subject Plant in accordance with a procurement document:

( ) Yes; continue review

( ) No; no further review needed

d. The concern is related to something offered to the Subject Plant but which was rejected during receipt inspection:

( ) Yes; no further review needed

( ) No; continue review

e. The concern is related to something offered to and accepted by the Subject Plant and installed for use:

( ) Yes; no further review needed for licensee identified deviation unless A.5.f is also answered "yes." If a supplier identified the deviation and the supplier is unable to perform the evaluation, the evaluation may be performed under Part 21 or the LER Rule at the discretion of the licensee.

( ) No; continue review

f. The concern is related to something offered to and accepted by the Subject Plant, but it has not been installed for use:

( ) Yes; continue review

( ) No; no further review needed

Sample Checklists (continued)

10 CFR 21 Potential Defect Checklist
(Page 4)

6. Has the concern already been adequately reported to the NRC?
   ( ) Yes; no further review necessary; complete 6.a through 6.d
   ( ) No; continue review with Question 7.

   a. What was the reporting method?
      ( ) Licensee Event Report (LER)
      ( ) 10 CFR 21
      ( ) Other; identify_____

   b. Who reported the concern?
      ( ) Company
      ( ) Other; identify_____

   c. What is the source of information that confirms that the concern has been reported?
      ( ) Written report; Identification: _____
      ( ) NRC verbal confirmation; name/title:_____
      ( ) Other; identify

   d. Does report already made satisfy the information requirements of 10 CFR 21?
      ( ) Yes
      ( ) No; Basis for determining whether the report is adequate_____

Sample Checklists (continued)

10 CFR 21 Potential Defect Checklist
(Page 5)

7. Has it been determined by completion of Part A of this checklist that the concern is not reportable?

   ( ) Yes; Identify section that led to the conclusion that the concern is not reportable (e.g. Section A.6.a), sign off on the evaluator signature line below, obtain manager's approval, and delete Part B of the checklist.

   Applicable section(s) _____

   ( ) No; Delete the evaluator and manager signature spaces for Part A below and complete Part B of the checklist.

NOTE: Additional evaluation may be necessary to determine reportability requirements for components sold to other utilities or whether notification to those purchasers may be appropriate.

Submittal: _____ _____
Evaluator Date

Approval: _____ _____
Manager Date

Sample Checklists (continued)

10 CFR 21 Potential Defect Checklist
(Page 6)

B. Review of Document for Basic Component Defect

NOTE: This Section of this checklist applies only to potential component defects. If the concern is associated with a potential failure to comply, the Failure to Comply Checklist should be used.

1. Use the following criteria to determine if the document addresses a problem with a Basic Component* supplied* to the Subject Plant:

   a. Necessary to assure the integrity of the reactor coolant pressure boundary?

      ( ) Yes
      ( ) No

      Basis of conclusion: _____

      Additional Reference: _____
      (if applicable)

   b. Necessary to assure the capability to shutdown the reactor and indefinitely maintain it in cold shutdown?

      ( ) Yes
      ( ) No

      Basis of conclusion: _____

      Additional Reference: _____
      (if applicable)

Sample Checklists (continued)

10 CFR 21 Potential Defect Checklist
(Page 7)

c. Necessary to assure the capability to prevent or mitigate the consequences of accidents which could result in potential offsite exposures comparable to 10 CFR Part 50.34(a)(1), 10 CFR Part 50.67(b)(2), or 10 CFR Part 100.11 (25 rem whole body or 300 rem Thyroid), as applicable?

( ) Yes
( ) No

Basis of conclusion: _____

Additional Reference: _____
(if applicable)

d. Necessary to assure the capability of Security System to prevent terrorism or sabotage?

( ) Yes
( ) No

Basis of conclusion: _____

Additional Reference: _____
(if applicable)

e. **Based upon the above criteria, the document addresses a problem with a Basic Component*?**

( ) Yes
( ) No

If "Yes", briefly describe: _____

Sample Checklists (continued)

10 CFR 21 Potential Defect Checklist
(Page 8)

2. Use the following criteria to determine if a "potential defect"* exists in the Basic Component*;

   a. A deviation* in a delivered Basic Component* that has not been installed, used, or operated (i.e., spare parts)?

      ( ) Yes
      ( ) No

      Basis of conclusion: _____

      Additional Reference: _____
      (if applicable)

   b. A deviation* in a delivered Basic Component* that may have been installed, used, or operated, but for which the supplier has informed the Subject Plant that the supplier is unable to perform the 10 CFR 21 reportability determination?

      ( ) Yes
      ( ) No

      Basis of conclusion: _____

      Additional Reference: _____
      (if applicable)

Sample Checklists (continued)

10 CFR 21 Potential Defect Checklist
(Page 9)

c. Condition or circumstance* involving an accepted but unused Basic Component* that could, based on an evaluation, contribute to exceeding a safety limit as defined in the Operating Technical Specifications?

( ) Yes
( ) No

Basis of conclusion: _____

Additional Reference: _____
(if applicable)

d. **If the answer to B.2.a, B.2.b, or B.2.c is yes, a "Potential Defect"* exists. Does a "Potential Defect"* exist?**

( ) Yes
( ) No

If "Yes", briefly describe: _____

3. Use the following criteria to determine if the "potential defect"* is a defect* in that it could create a Substantial Safety Hazard* based on any of the following conditions:

a. Moderate exposure to*, or release of, radioactive material?

( ) Yes
( ) No

Basis of conclusion: _____

Additional Reference: _____
(if applicable)

Sample Checklists (continued)

10 CFR 21 Potential Defect Checklist
(Page 10)

b. Major degradation* of essential safety-related equipment?

( ) Yes
( ) No

Basis of conclusion: _____

Additional Reference: _____
(if applicable)

c. Major deficiencies* involving design, construction, inspection, test, or use?

( ) Yes
( ) No

Basis of conclusion: _____

Additional Reference: _____
(if applicable)

d. Other, as specified herein: _____

( ) Yes
( ) No

Basis of conclusion: _____

Additional Reference: _____
(if applicable)

Sample Checklists (continued)

10 CFR 21 Potential Defect Checklist
(Page 11)

e. **If the answer to B.3.a, B.3.b, B.3.c, or B.3.d is yes, the component deviation likely represents a substantial safety hazard. Does a defect exist in that a substantial safety hazard could be created?**

( ) Yes
( ) No

If "Yes", briefly describe: _____

f. **If the answer to B.3.a, B.3.b, B.3.c, or B.3.d is yes, and the answer to A.5.a is yes, the component deviation may represent a substantial safety hazard* at a purchasing utility's plant. Does a defect exist in that a substantial safety hazard could be created at a purchasing utility's plant?**

( ) Yes; Prepare description of deviation for transmittal to the purchasing utility.

( ) No; Notification not required.

( ) UTD; (Unable to determine) Prepare description of the deviation for transmittal to the purchasing utility, and inform the company organization making the transmittal that the notification to the purchaser(s) shall be made within 5 working days.

Sample Checklists (continued)

10 CFR 21 Potential Defect Checklist
(Page 12)

C. Summary and Approvals

If B.1.e, B.2.d, and B.3.e responses are "Yes", then the defect* in the Basic Component* should be recommended as reportable under 10 CFR Part 21. Is the Basic Component* concern being recommended as reportable under 10 CFR Part 21?

( ) Yes

( ) No

Submittal: _____ _____
Evaluator Date

Approval: _____ _____
Manager Date

Footnotes

- term formally defined in Definitions Section

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Sample Checklist - Noncompliance

10 CFR 21 Potential Failure to Comply Checklist
(Sample)

Issue Title:_____

10 CFR 21 No:_____

Subject Plant:_____

Subject Unit:_____

Part A of this checklist identifies the document under review and determines applicability of a 10 CFR Part 21 review by the Company. The applicable portions of Part A shall be completed for all 10 CFR 21 evaluations.

Part B is used to identify failures to comply that are potentially reportable under 10 CFR Part 21.

Part C summarizes the conclusion for potential reportability and provides for submittal and approval signatures.

Checklists used for the review of concerns shall be retained for 5 years. An approval signature is required for all checklists whether the issue is determined to be potentially reportable or not. In all cases, the form needs to be completed only to the extent necessary to reach a conclusion relative to a recommendation on reportability.

Sample Checklists (continued)

10 CFR 21 Potential Failure to Comply Checklist
(Page 2)

A. IDENTIFICATION AND APPLICABILITY DETERMINATION

1. Document Title and Type:_____
2. Document ID Number:_____
3. Document Date:_____
4. Discovery Date:_____
5. 10 CFR Part 21 Review Applicability:

   a. Have Basic Component(s)* affected by the concern been sold?

      ( ) Yes; Consider notifying purchaser of the concern, and continue with the reportability evaluation for Company operated plants. A representative from the supply chain organization shall be contacted to determine if the affected equipment has been sold.

      ( ) No; Continue with the reportability evaluation for Company operated plants.

   b. Is the concern shown to be applicable to the Subject Plant? If this factor is not known, obtain an engineering evaluation for plant applicability. A reasonable amount of time to perform this "discovery" process is not applicable to the 60 day time limit for the evaluation to determine reportability.

      ( ) Yes; continue review

      ( ) No; no further review needed

Sample Checklists (continued)

10 CFR 21 Potential Failure to Comply Checklist
(Page 3)

c. The concern is related to something (structure, system, or component) supplied or offered for acceptance for use at the Subject Plant in accordance with a procurement document:

( ) Yes; continue review

( ) No; no further review needed

d. The concern is related to something offered to the Subject Plant but which was rejected during receipt inspection:

( ) Yes; no further review needed

( ) No; continue review

e. The concern is related to something offered to and accepted by the Subject Plant and installed for use:

( ) Yes; no further review needed for licensee identified deviation unless A.5.f is also answered "yes." If a supplier identified the deviation and the supplier is unable to perform the evaluation, the evaluation may be performed under Part 21 or the LER Rule at the discretion of the licensee.

( ) No; continue review

f. The concern is related to something offered to and accepted by the Subject Plant, but it has not been installed for use:

( ) Yes; continue review

( ) No; no further review needed

Sample Checklists (continued)

10 CFR 21 Potential Failure to Comply Checklist
(Page 4)

6. Has the concern already been adequately reported to the NRC?

   ( ) Yes; no further review necessary; complete 6.a through 6.d
   ( ) No; continue review with Question 7.

   a. What was the reporting method?

      ( ) Licensee Event Report (LER)
      ( ) 10 CFR 21
      ( ) Other; identify_____

   b. Who reported the concern?

      ( ) Company
      ( ) Other; identify_____

   c. What is the source of information that confirms that the concern has been reported?

      ( ) Written report; Identification: _____
      ( ) NRC verbal confirmation; name/title:_____
      ( ) Other; identify

   d. Does report already made satisfy the information requirements of 10 CFR 21?

      ( ) Yes
      ( ) No; Basis for determining whether the report is adequate_____

Sample Checklists (continued)

10 CFR 21 Potential Failure to Comply Checklist
(Page 5)

7. Has it been determined by completion of Part A of this checklist that the concern is not reportable?

   ( ) Yes; Identify section that led to the conclusion that the concern is not reportable (e.g. Section A.6.a), sign off on the evaluator signature line below, obtain manager's approval, and delete Part B of the checklist.

   Applicable section(s) _____

   ( ) No; Delete the evaluator and manager signature spaces for Part A below and complete Part B of the checklist.

NOTE: Additional evaluation may be necessary to determine reportability requirements for components sold to other utilities or whether notification to those purchasers may be appropriate.

Submittal: _____ _____
Evaluator Date

Approval: _____ _____
Manager Date

Sample Checklists (continued)

10 CFR 21 Potential Failure to Comply Checklist
(Page 6)

B. Review of Document for Failure to Comply with Regulatory Requirement

NOTE: This Section of this checklist applies only to potential failures to comply. If the concern is associated with a potential component defect, the Potential Defect Checklist should be used.

1. Use the following criteria to determine if the document addresses a problem with a Basic Component* supplied* to the Subject Plant:

   a. Necessary to assure the integrity of the reactor coolant pressure boundary?

      ( ) Yes

      ( ) No

      Basis of conclusion: _____

      Additional Reference: _____
      (if applicable)

   b. Necessary to assure the capability to shutdown the reactor and indefinitely maintain it in cold shutdown?

      ( ) Yes

      ( ) No

      Basis of conclusion: _____

      Additional Reference: _____
      (if applicable)

Sample Checklists (continued)

10 CFR 21 Potential Failure to Comply Checklist
(Page 7)

c. Necessary to assure the capability to prevent or mitigate the consequences of accidents which could result in potential offsite exposures comparable to 10 CFR Part 50.34(a)(1), 10 CFR Part 50.67(b)(2), or 10 CFR Part 100.11, as applicable?

( ) Yes
( ) No

Basis of conclusion: _____

Additional Reference: _____
(if applicable)

d. Necessary to assure the capability of Security System to prevent terrorism or sabotage?

( ) Yes
( ) No

Basis of conclusion: _____

Additional Reference: _____
(if applicable)

e. Based upon the above criteria, the document addresses a problem with a Basic Component* supplied to the Subject Plant?

( ) Yes
( ) No

If "Yes", briefly describe: _____

Sample Checklists (continued)

10 CFR 21 Potential Failure to Comply Checklist
(Page 8)

2. Use the following criteria to determine if the failure to comply could create a Substantial Safety Hazard:*

   a. Moderate exposure to*, or release of, radioactive material?

      ( ) Yes
      ( ) No

      Basis of conclusion: _____

      Additional Reference: _____
      (if applicable)

   b. Major degradation* of essential safety-related equipment?

      ( ) Yes
      ( ) No

      Basis of conclusion: _____

      Additional Reference: _____
      (if applicable)

   c. Major deficiencies* involving design, construction, inspection, test, or use?

      ( ) Yes
      ( ) No

      Basis of conclusion: _____

      Additional Reference: _____
      (if applicable)

Sample Checklists (continued)

10 CFR 21 Potential Failure to Comply Checklist
(Page 9)

d. Other, as specified herein: _____

( ) Yes
( ) No

Basis of conclusion: _____

Additional Reference: _____
(if applicable)

e. **Based on the above criteria, failure to comply could create a substantial safety hazard?***

( ) Yes
( ) No

If "Yes", briefly describe: _____

3. If the responses to A.5.a and B.2.e are both “yes”, the concern could potentially represent a substantial safety hazard* at a purchasing utility’s plant. Could the concern represent a substantial safety hazard at a purchasing utility’s plant?

( ) Yes; Prepare description of deviation for transmittal to the purchasing utility.

( ) No; Notification not required.

( ) UTD; (Unable to determine) Prepare description of the concern for transmittal to the purchasing utility, and inform the company organization responsible for notifying the purchaser(s) that the notification shall be made within 5 working days.

Sample Checklists (continued)

10 CFR 21 Potential Failure to Comply Checklist
(Page 10)

C. Summary and Approvals

If B.1 and B.2.e responses are "Yes", then the failure to comply should be recommended as reportable under 10 CFR Part 21. Is the failure to comply concern being recommended as reportable under 10 CFR Part 21?

( ) Yes; Recommend reporting

( ) No; No further review necessary – not reportable

Submittal: _____ _____
Evaluator Date

Approval: _____ _____
Manager Date

Footnotes

- term formally defined in Definitions Section

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Sample Checklist – Support Data

10 CFR 21 Support Data Checklist
(Page 1)

Issue Title:_____ 10 CFR 21 No._____

Subject Plant:_____ Subject Unit _____

This form should be completed to the extent of the knowledge of the responsible evaluator and using the information provided by the Project / Plant points of contact. This information will form the preliminary basis for documentation of reportability under 10 CFR 21 for those concerns identified by either a Potential Defect Checklist, a Failure to Comply Checklist, or by other means as being potentially reportable.

A. Concern is ( ) failure to comply, ( ) defective Basic Component

Briefly describe:_____

B. Identify the firm supplying the Basic Component that fails to comply or has a defect:

C. If appropriate, identify departure from the technical requirements of the procurement document:

Sample Checklists (Continued)

10 CFR 21 Support Data Checklist
(Page 2)

D. Identify the substantial safety hazard that could be created by the noncompliance or defect:

_____

_____

_____

_____

_____

E. Date on which the defect or noncompliance was discovered:_____

_____

F. Method of discovery of defect or noncompliance:_____

_____

_____

G. For Basic Components, provide identification and location of all such supplied components:

_____

_____

_____

Sample Checklists (Continued)

10 CFR 21 Support Data Checklist
(Page 3)

H. Corrective actions to be cited in the report to the NRC:

1. Corrective actions taken and date completed:
   a. Corrective action taken:_____
   _____
   _____
   _____
   b. Completion date:_____
   c. Name of individuals and/or organizations responsible for the corrective actions:_____
   _____
2. Corrective action being taken and estimated date of completion:
   a. Corrective action being taken:_____
   _____
   _____
   _____
   b. Estimate date of completion:_____
   c. Name of individuals and/or organization responsible for the corrective actions:_____
   _____

Sample Checklists (Continued)

10 CFR 21 Support Data Checklist
(Page 4)

3. Corrective action to be taken and estimated date of completion:
   a. Corrective action to be taken:_____

   _____

   b. Estimated date of completion:_____
   c. Name of individuals and/or organizations responsible for the corrective actions:_____

   _____

I. Identification and date of any previous reports to the NRC regarding this concern:_____

_____

_____

_____

J. Recommended method of reporting:
   ( ) 10 CFR Part 21 Report
   ( ) Licensee Event Report (LER) or LER Revision
   ( ) 10 CFR Part 50.55(e) Report or revision
   ( ) Other (specify)_____

K. Is a separate safety evaluation report attached? ( ) Yes ( ) No

Sample Checklists (Continued)

10 CFR 21 Support Data Checklist
(Page 5)

L. Project/Plant points of contact

_____

_____

_____

Prepared by: _____ _____
Evaluator Date

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Conclusion

End of Checklists

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