10 CFR Part 21 Break-Out Discussion

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Outline

- Introduction
- Overview of Part 21 Process
- Corrective Action Program
- Screening
- Questions

Introduction

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Introduction

"It is no secret that *10 CFR 21* has been one of the most controversial rules ever promulgated by the Commission.."

NUREG-0302

10 CFR 21 Application

- *10 CFR 21 applies to anyone:*
  - applying for or holding a license or permit to possess, use, or transfer source material, byproduct material, special nuclear material….
  - that constructs a production or utilization facility licensed for manufacture, construction, or operation under parts 50 and 52….
  - applying for a design certification rule under Part 52 or supplying basic components
  - applying for or holding a standard design approval under Part 52 or supplying basic components

10 CFR 21 Definitions

- **Deviation**
  - **A departure from the technical requirements included in a procurement document, or specified in early site permit information, a standard design certification or standard design approval.**

10 CFR 21 Definitions

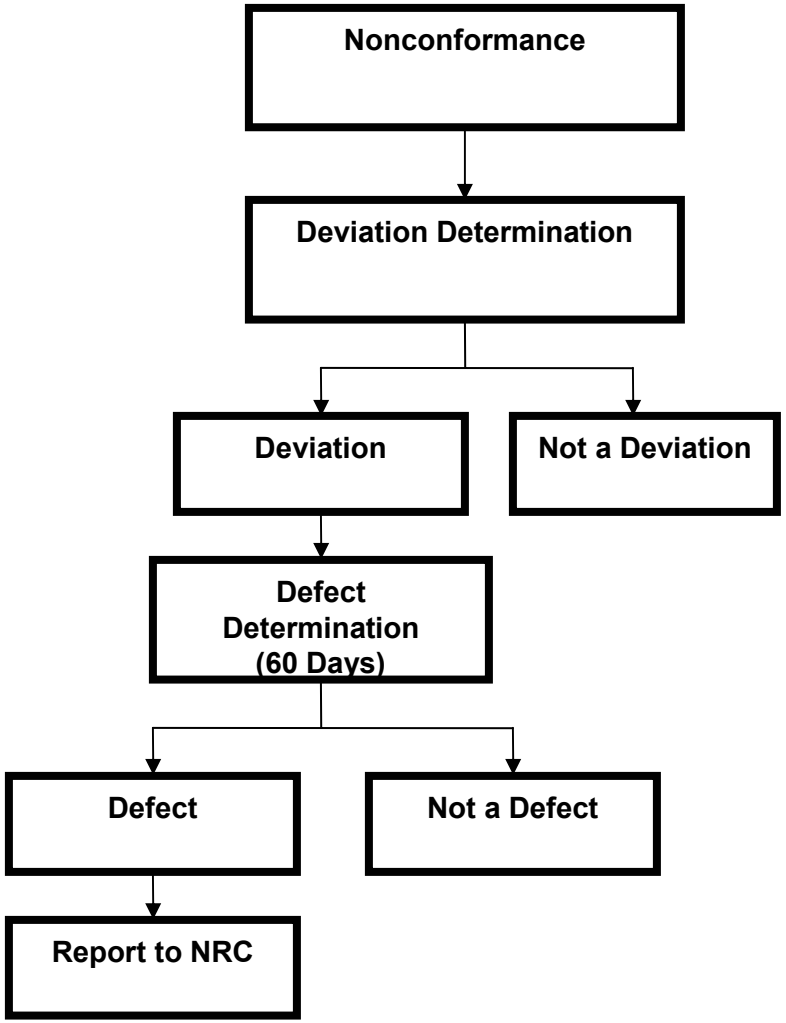
- **Defect**
  - *A deviation in a basic component delivered to a purchaser for use in a facility or an activity subject to the regulations if, on the basis of an evaluation, the deviation could create a substantial safety hazard;*
  - *The installation, use, or operation of a basic component containing a defect;*
  - *A deviation in a portion of a facility subject to the early site permit, standard design certification, standard design approval, construction permit, combined license or manufacturing licensing requirements of Part 50 or Part 52, provided the deviation could, on the basis of an evaluation, create a substantial safety hazard and the portion of the facility containing the evaluation has been offered to the purchaser for acceptance;*
  - *A condition or circumstance involving a basic component that could contribute to the exceeding of a safety limit, as defined in the technical specifications of a license for operation issued under Part 50 or Part 52;*
  - *An error, omission or other circumstance in a design certification, or standard design approval that, on the basis of an evaluation, could create a substantial safety hazard.*

Procedures

- ***Administrative Procedure 1707-01: Evaluation and Reporting of Safety Significant Issues***
- ***Administrative Procedure 1717-06: Corrective Action Program – WebCAP***

Overview of Part 21 Process

Process Flow Chart



Corrective Action Program

Jim Bartleman
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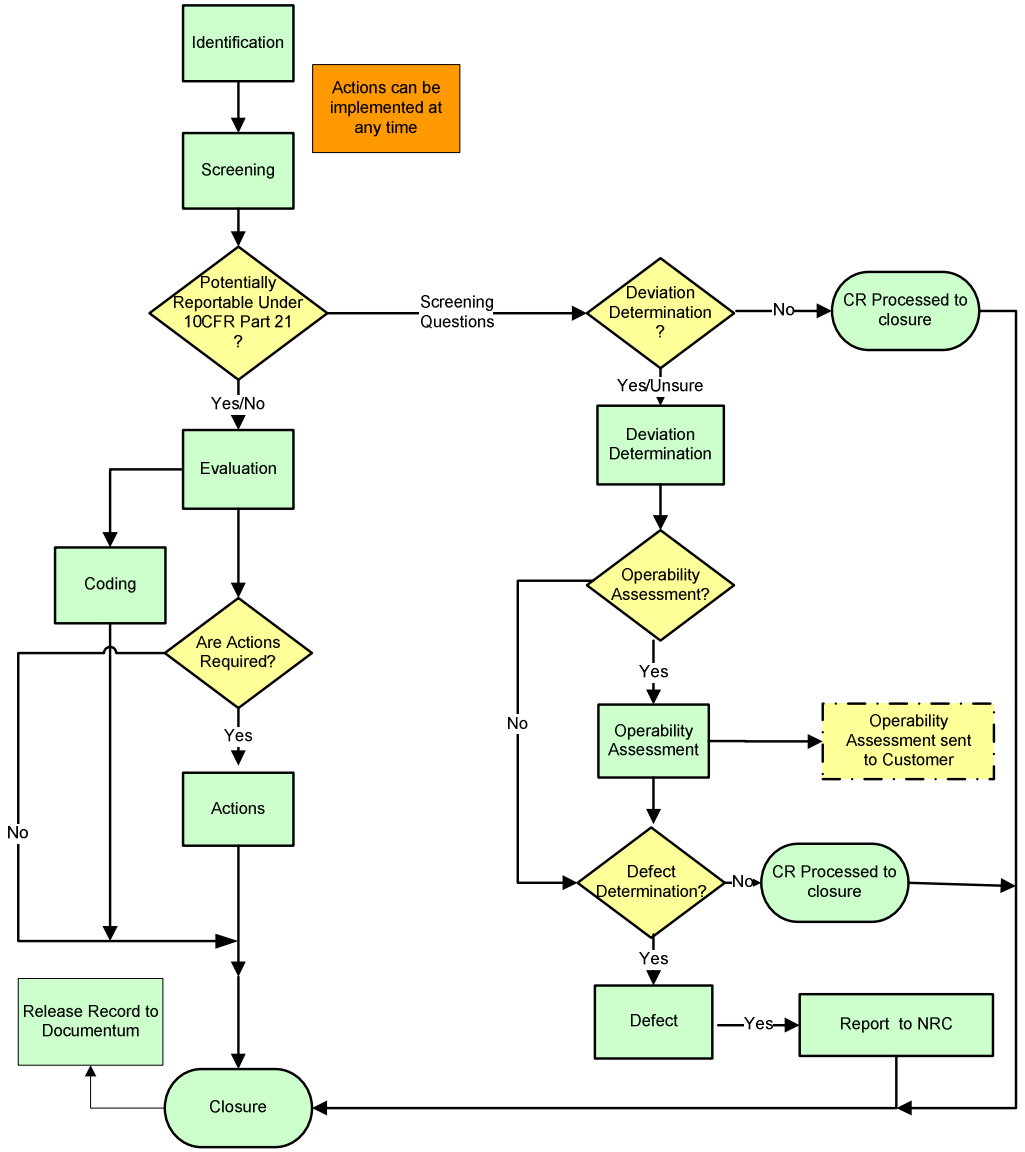
10 CFR Part 21 Requirements Processed in the Corrective Action Program

- Actions to determine if a condition is reportable in accordance with 10 CFR Part 21 are processed in the Corrective Action Program.
- The WebCAP software includes “Wizard” technology that allow questions to be asked that, based on the answer, open additional screens to process events identified as potentially reportable.

10 CFR Part 21 Process Flow



Processing Times

- Identification – A CR is written as soon as practical following discovery of the Adverse Condition.
- Screening - WebCAP default due date of 7 days from Identification being submitted.
- Deviation Determination – WebCAP default due date of 7 days from completion of screening.
- Defect Determination - WebCAP default due date of 45 days from completion of Deviation Determination.

Screening Questions - New Plants

Does the condition affect the design or procurement information approved or to be approved within the scope of the design certification or approval for a structure, system, or component, or part thereof under 10 CFR 52/New Plants?

(IF YES, CONTACT REGULATORY AFFAIRS FOR PART 21 APPLICABILITY AND REFER TO PROCEDURE 1707-01)

- **The Regulatory Affairs Representative becomes a member of the Screening Team to assist in identifying if the condition is potentially reportable under 10 CFR Part 21.**

(Yes) - No

Screening Questions - New Plants

1. Is the condition a deviation to a technical requirement specified in early site permit information, a standard design certification, or standard design approval?

   Yes - No - Unsure

2. Does the condition affect the design or procurement information approved or to be approved within the scope of the design certification or approval for a structure, system, or component, or part thereof under 10 CFR 52?

   Yes - No - Unsure

3. Could the deviation create a substantial safety hazard that could cause a major reduction in the degree of protection provided to public health and safety for any facility or activity licensed or otherwise approved or regulated by the NRC?

   Yes - No - Unsure

Screening Questions - New Plants

If the Answer Questions 1- 3 is Yes or Unsure a Deviation Determination is required and WebCAP opens the Deviation Determination Screen. If the answer to the Questions is No then Question 4 is asked.

4. Is the Condition Potentially Reportable Under 10 CFR Part 21?

Yes - No – Unsure

If the Answer Questions 4 is Yes or Unsure a Deviation Determination is required and WebCAP opens the Deviation Determination Screen.

Screening Questions - Operating Plants

Does the condition affect the design or procurement information approved or to be approved within the scope of the design certification or approval for a structure, system, or component, or part thereof under 10 CFR 52/New Plants?

(IF YES, CONTACT REGULATORY AFFAIRS FOR PART 21 APPLICABILITY AND REFER TO PROCEDURE 1707-01)

Yes - (No)

NO means that the condition is not associated with New Plants and the Screening Questions are associated with 10 CFR Part 21 requirements for an Operating Plant.

Screening Questions - Operating Plants

1. **Is the condition a deviation to a technical requirement included in a procurement document?**

   Yes - No - Unsure

2. **Does the condition affect a basic component designed/fabricated under a 10 CFR Part 50 Appendix B QA Program or one that has successfully completed dedication?**

   Yes - No - Unsure

3. **Could the deviation create a substantial safety hazard that could cause a major reduction in the degree of protection provided to public health and safety for any facility or activity licensed or otherwise approved or regulated by the NRC?**

   Yes - No - Unsure

Screening Questions - Operating Plants

If the Answer Questions 1- 3 is Yes or Unsure a Deviation Determination is required and WebCAP opens the Deviation Determination Screen. If the answer to the Questions is No then Question 4 is asked.

4. Is the Condition Potentially Reportable Under 10 CFR Part 21?

Yes - No – Unsure

If the Answer Questions 4 is Yes or Unsure a Deviation Determination is required and WebCAP opens the Deviation Determination Screen.

Screening
Deviation Determination Assignments

If the 10 CFR Part 21 Screening Questions are Answered Yes or Unsure the Following Assignments are made to perform Deviation Determination

- **Investigator - Accept Deviation Determination Task**
- **Investigator - Deviation Determination Completion**
- **Independent Technical Reviewer - Accept Deviation Determination**
- **Issue Owner - Accept Deviation Determination**
- **QA Manager - Accept Deviation Determination**
- **Regulatory Affairs - Accept Deviation Determination**

Deviation Determination

Question: Does the Customer Request Input to an Operability Assessment?

Yes – No

- **Issue Description - Describes the condition that requires review to determine if the condition is a deviation that requires further evaluation to determine is the condition is a Defect.**
- **Discussion - Provide information as to whether the issue has or does not have the potential to affect a safety function. Include licensing and regulatory requirements that are affected.**
- **Conclusion - Describe whether the issue has the potential to pose a significant safety hazard or a risk of violating a safety limit as defined in 10 CFR Part 21.**
- **Deviation Determination**
  - **Is the issue a 10 CFR Part 21 Deviation? Yes - No**
  - **Is a Defect Determination Needed? Yes - No**

Assignments to Perform Defect Determination

If the Deviation Determination Team identifies that a Defect Determination is required (Yes) the following assignments are made to perform the Defect Determination and WebCAP opens the Defect Determination Screen.

- **Investigator - Accept Defect Determination Task**
- **Investigator - Defect Determination Completion**
- **Independent Technical Reviewer - Accept Defect Determination**
- **Issue Owner - Accept Defect Determination**
- **QA Manager - Accept Defect Determination**
- **Regulatory Affairs - Accept Defect Determination**

Defect Determination

- Issue Description - Describes the Deviation that requires evaluation.
- Discussion - Documents the evaluation results and supporting information required to support the conclusion regarding 10 CFR Part 21 reportability.
- Conclusion - Identifies conclusion and why or why not the Condition is reportable.
- Is the issue a 10 CFR Part 21 Defect?

Yes - No

Defect Determination

If the Condition is Considered a Defect Reportable to the NRC (Yes), WebCAP opens the screen to provide the following information to support the NRC report:

- **Facility/Activity/Basic Component**
- **Firm/Supplier of Basic Component**
- **Nature of Defect**
- **Number/Location of Basic Component Affected**
- **Corrective Action**
- **Advise Given to Purchasers**

Questions?