Operations Management

10CFR21 – Reporting of Defects and Noncompliance

NUPIC Vendor Meeting - Workshop

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Operations Management

Avantis Eurotherm Foxboro IMServ InFusion SimSci-Esscor Skelta Triconex Wonderware

Introduction

10CFR21 defines a process for evaluating deviations, defects or failures to comply, and reporting to customers and the Nuclear Regulatory Commission (NRC) as required.

The regulation applies to activities, products and/or systems supplied as basic components to nuclear customers.

This includes items designed and manufactured under a quality assurance program complying with 10CFR50 Appendix B or commercial grade items which have successfully completed the dedication process.

The Invensys Nuclear Safety Committee (NSC) Evaluation form, used to guide and document Part 21 evaluations will be used as the framework for the discussion.

Key Definitions

Basic Component:

A structure, system, component, or part thereof that affects its safety function necessary to assure:

- Integrity of the reactor coolant pressure boundary
- Capability to shut down the reactor and maintain it in a safe shutdown condition
- Capability the prevent or mitigate the consequences of accidents that could result in offsite exposure

Basic components are items designed and manufactured under a QA program complying with 10CFR50, App. B or Commercial Grade Items which have completed the dedication process.

Key Definitions (cont.)

Commercial Grade Item:

A structure, system, component, or part thereof that affects its safety function, that was not designed as manufactured as a basic component.

An item that is:

• Not subject to design or specification requirements specific to nuclear facilities; and

• Used in applications other than those facilities; and

• Ordered from the manufacturer/supplier on the basis of specifications set forth in published product descriptions (e.g. catalog)

Key Definitions (cont.)

Dedication:

An acceptance process undertaken to provide reasonable assurance that a Commercial Grade Item to be used as a Basic Component will perform its intended safety function.

This assurance is achieved by identifying Critical Characteristics of the item and verifying their acceptability by inspections, tests or analyses, supplemented as necessary by one or more of the following:

- Commercial grade surveys;
- Inspections or witness/hold points at the manufacturing facility; and
- Analysis of historical records of acceptable performance.

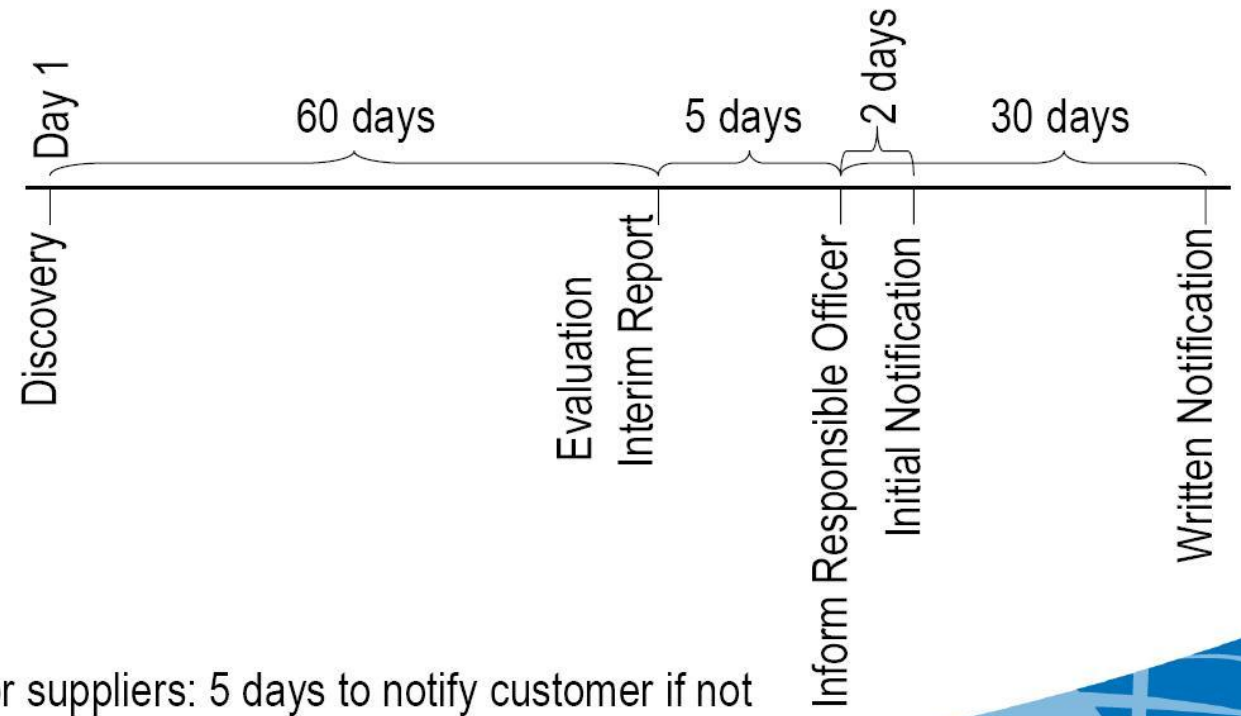
Key Definitions (cont.)

Discovery:

The completion of the documentation first identifying the existence of a deviation or failure to comply potentially associated with a substantial safety hazard within the evaluation procedures discussed in § 21.21. (a) of 10CFR21.

10 CFR Part 21 Timeline

U.S.NRC
United States Nuclear Regulatory Commission
Protecting People and the Environment



For suppliers: 5 days to notify customer if not capable to perform evaluation

Key Definitions (cont.)

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.

Evaluation:

The process of determining whether a particular deviation could create a substantial hazard or determining whether a failure to comply is associated with a substantial safety hazard.

Key Definitions (cont.)

Defect:

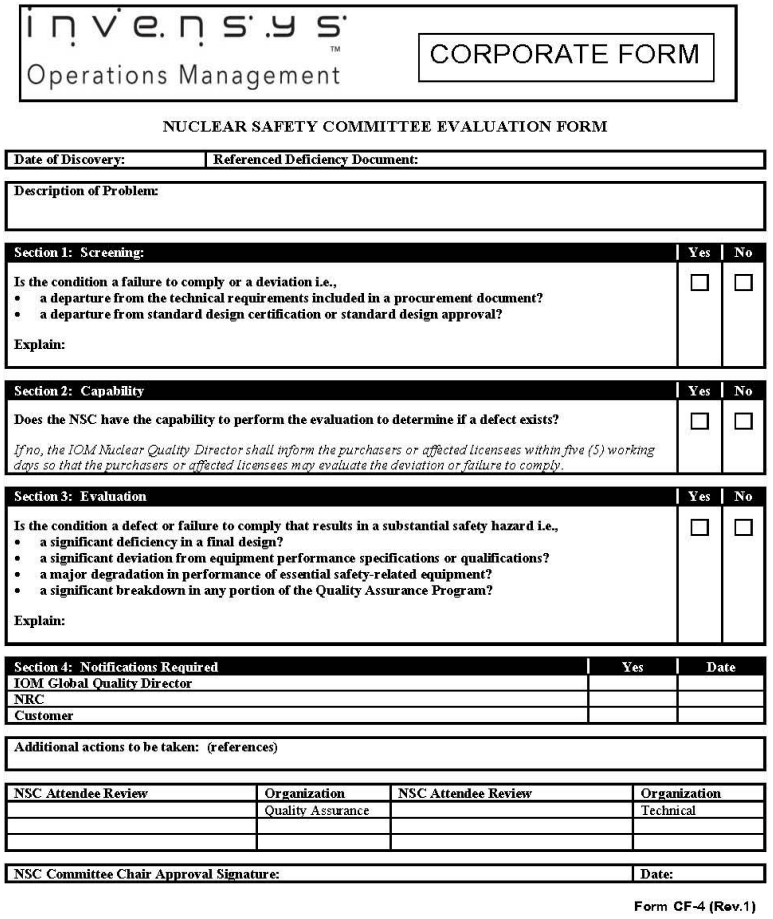
- A deviation in a delivered Basic Component that, on the basis of an evaluation, could create a *substantial safety hazard*; or
- Installation, use or operation of a Basic Component containing a defect as define herein; or
- A deviation in a portion of a facility subject to the construction permit or manufacturing licensing requirements of Part 50; or
- A condition or circumstance involving a Basic Component that could contribute to exceeding a safety limit as defined in technical specifications of a license for operation.

Key Definitions (cont.)

Substantial Safety Hazard:

A loss of safety function to the extent that there is a major reduction in the degree of protection provided to public health and safety for any licensed facility or activity.

Evaluation Process



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CORPORATE FORM

NUCLEAR SAFETY COMMITTEE EVALUATION FORM

Date of Discovery:	Referenced Deficiency Document:

Description of Problem:

Section 1: Screening:	Yes	No
Is the condition a failure to comply or a deviation i.e., • a departure from the technical requirements included in a procurement document? • a departure from standard design certification or standard design approval? Explain:	☐	☐

Section 2: Capability	Yes	No
Does the NSC have the capability to perform the evaluation to determine if a defect exists? *If no, the IOM Nuclear Quality Director shall inform the purchasers or affected licensees within five (5) working days so that the purchasers or affected licensees may evaluate the deviation or failure to comply.*	☐	☐

Section 3: Evaluation	Yes	No
Is the condition a defect or failure to comply that results in a substantial safety hazard i.e., • a significant deficiency in a final design? • a significant deviation from equipment performance specifications or qualifications? • a major degradation in performance of essential safety-related equipment? • a significant breakdown in any portion of the Quality Assurance Program? Explain:	☐	☐

Section 4: Notifications Required	Yes	Date
IOM Global Quality Director		
NRC		
Customer		

Additional actions to be taken: (references)

NSC Attendee Review	Organization	NSC Attendee Review	Organization
	Quality Assurance		Technical

NSC Committee Chair Approval Signature:	Date:

Form CF-4 (Rev.1)

In accordance with 10CFR21 and Invensys Corporate Quality Procedures, a Nuclear Safety Committee (NSC) evaluation is conducted and documented on a NSC Evaluation form when NCR or CAPA screening processes identify potential Part 21 issues.

Evaluation Process (cont.)

NUCLEAR SAFETY COMMITTEE EVALUATION FORM

Date of Discovery:	Referenced Deficiency Document:

Description of Problem:

Section 1: Screening:	Yes	No
Is the condition a failure to comply or a deviation i.e., • a departure from the technical requirements included in a procurement document? • a departure from standard design certification or standard design approval? Explain:	☐	☐

Date of Discovery, Reference Deficiency Document, Description of Problem, and

Section 1: Screening – (see "Deviation")

Evaluation Process (cont.)

Section 2: Capability	Yes	No
Does the NSC have the capability to perform the evaluation to determine if a defect exists? *If no, the IOM Nuclear Quality Director shall inform the purchasers or affected licensees within five (5) working days so that the purchasers or affected licensees may evaluate the deviation or failure to comply.*	☐	☐

Section 2: Capability – (see "Defect" and "Substantial Safety Hazard")

Evaluation Process (cont.)

Section 3: Evaluation	Yes	No
Is the condition a defect or failure to comply that results in a substantial safety hazard i.e., • a significant deficiency in a final design? • a significant deviation from equipment performance specifications or qualifications? • a major degradation in performance of essential safety-related equipment? • a significant breakdown in any portion of the Quality Assurance Program? Explain:	☐	☐

Section 3: Evaluation – (see "Defect" and "Substantial Safety Hazard")

Evaluation Process (cont.)

Section 4: Notifications Required	Yes	Date
IOM Global Quality Director		
NRC		
Customer		

Additional actions to be taken: (references)

NSC Attendee Review	Organization	NSC Attendee Review	Organization
	Quality Assurance		Technical

NSC Committee Chair Approval Signature:	Date:

Section 4: Determine if notifications are required; list additional actions to be taken; list NSC members in attendance; and NSC Chair approval signature.

Examples and Discussion

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