KM/KT

Oct. 27, 2022

Tim Steadham, SRI – Grand Gulf

Overview of Part 21 Reporting

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

Disclaimer

- This training session is being recorded for future use in the NRC's knowledge management program.
- The recorded contents of the session, including any questions posted by audience members, will be preserved in accordance with the NRC's record management program and are subject to FOIA disclosure.
- Please refrain from including any sensitive information (i.e., SUNSI/SGI) in any questions that you may ask.
- Please leave your chat box open to view all questions and answers posed during the session.

Topics

- Recent events
- Purpose and scope
- Definitions
- Overview of the reporting process
- Interfaces with other regulations
- Examples
- Resources

Recent Events

- In the past two years, I have been involved in four inspections with two licensees where each licensee should've entered their Part 21 process but did not
- Language in the EFEs should've triggered a Part 21 review (e.g. "Vendor defect", "Sub-par engineering", etc.
- Two of the issues are currently being considered for potential escalated enforcement

Purpose and Scope

- Part 21 establishes requirements for implementation of section 206 of the Energy Reorganization Act of 1974 related to the reporting of defects or failures to comply potentially associated with substantial safety hazards
- Applies to *essentially* every licensee and supplier of basic components
- Part 21 also discusses CGD but we will not be discussing CGD today

Definitions

Basic component

A safety related part or analysis/design/testing/etc.

Deviation

A departure from the technical requirements included in a procurement document

Failure to comply

Licensee is not in compliance with a rule, regulation, order, license, etc.

Definitions

Defect

A deviation or failure to comply in a delivered basic component which could create a substantial safety hazard or a condition in a basic component which could contribute to exceeding a safety limit

Discovery

Completion of the documentation first identifying the existence of a defect

Definitions

Substantial Safety Hazard (SSH)

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

NEI 14-09, Rev. 1 as endorsed by RG 1.234

Substantial Safety Hazard

From Section 8.5 of NEI 14-09

- Analyses and calculations may need to be performed to evaluate the safety significance
- Judgment may also be needed
- Generally speaking, a SSH is a major reduction in the degree of protection provided to public health and safety
  - "Public" means everyone

Substantial Safety Hazard

Three categories of substantial safety hazards

Moderate Exposure

Moderate exposure to, or release of, licensed material

Major Degradation

Major degradation of essential safety-related equipment

Major Deficiency

Major deficiencies involving design, construction, inspection, test or use

SSH – Moderate Exposure

Exposure in excess of 25 rem whole body and exposure to an individual in an unrestricted area of *0.5* rem

Moderate exposure to, or release of, licensed (i.e., radioactive) material, reportable under the provisions of 10 CFR 20.2202(a) or the exposure of any 'individual in an unrestricted area to a dose to the whole body in any period of one calendar year in excess of 0.5 rem (10 CFR 20.1301(c))

SSH – Major Degradation

A loss of redundancy in essential safety related equipment if, in conjunction with a single failure, a required safety function could not be performed

Exceeding a safety limit as defined in the facility technical specification is also considered a major degradation

SSH – Major Deficiency

Involves the design, construction, inspection, test or use of licensed material or safety related equipment, which under normal operating conditions or anticipated transient could contribute to exceeding a safety limit or cause an accident or in the event of an accident due to other causes could, considering an independent single failure, result in a loss of safety function necessary to mitigate the consequences of the accident

Overview of the reporting process

21.21 requires procedures to:

- Evaluate deviations and failures to comply to identify defects associated with SSHs
  - Must be a basic component
  - Must be delivered
  - Must be possible to create a SSH
- Evaluation must be completed as soon as practicable and, in all cases, within 60 days of the point of discovery
- If the report cannot be completed within 60 days then submit an interim report

Overview of the reporting process

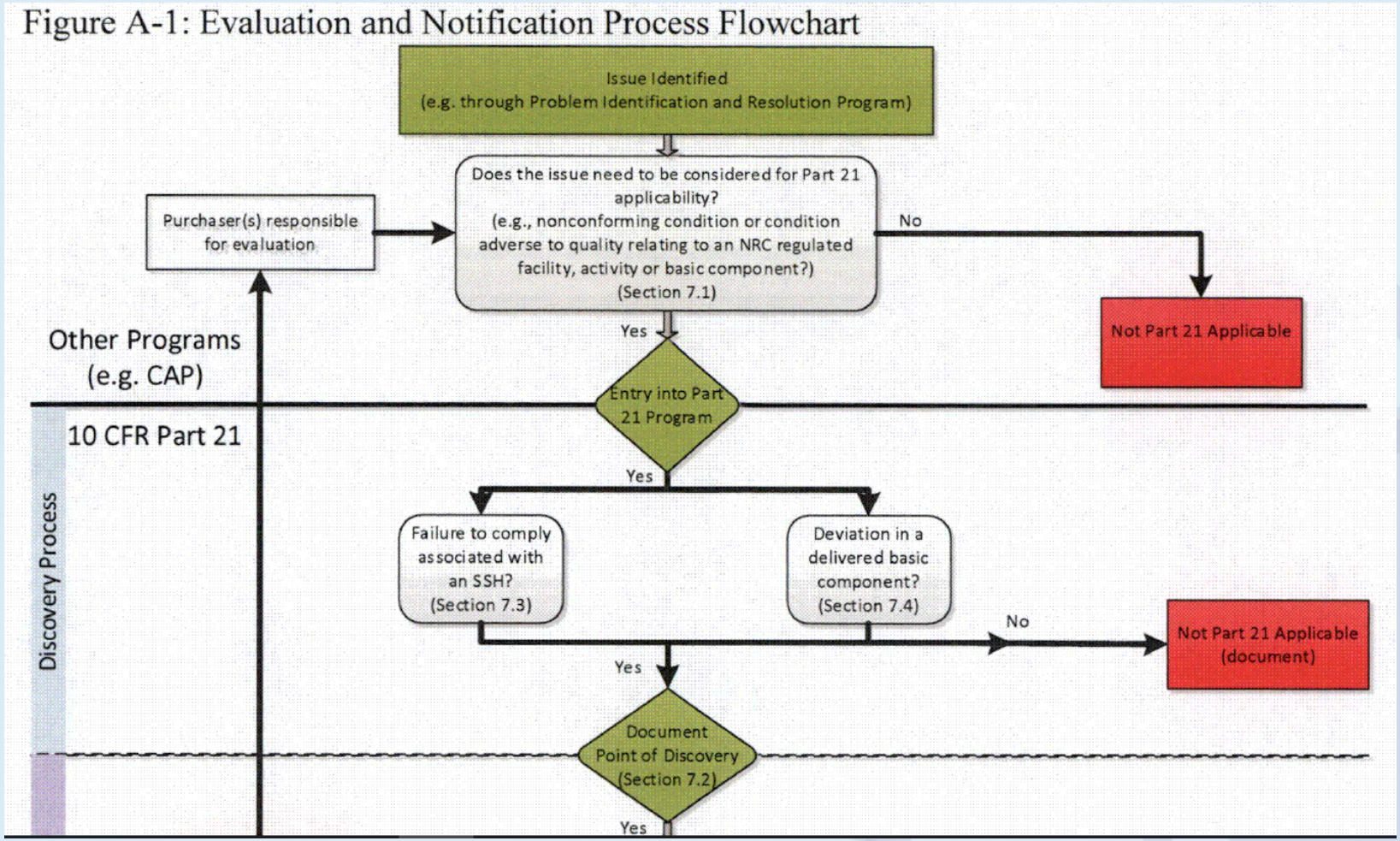
21.21 requires procedures to:

- Notify a director within five *working* days after discovery
- Director informs the NRC within two days of being notified
- Essentially, they have nine days to report
- All of this is required to be documented and maintained for a minimum of five years

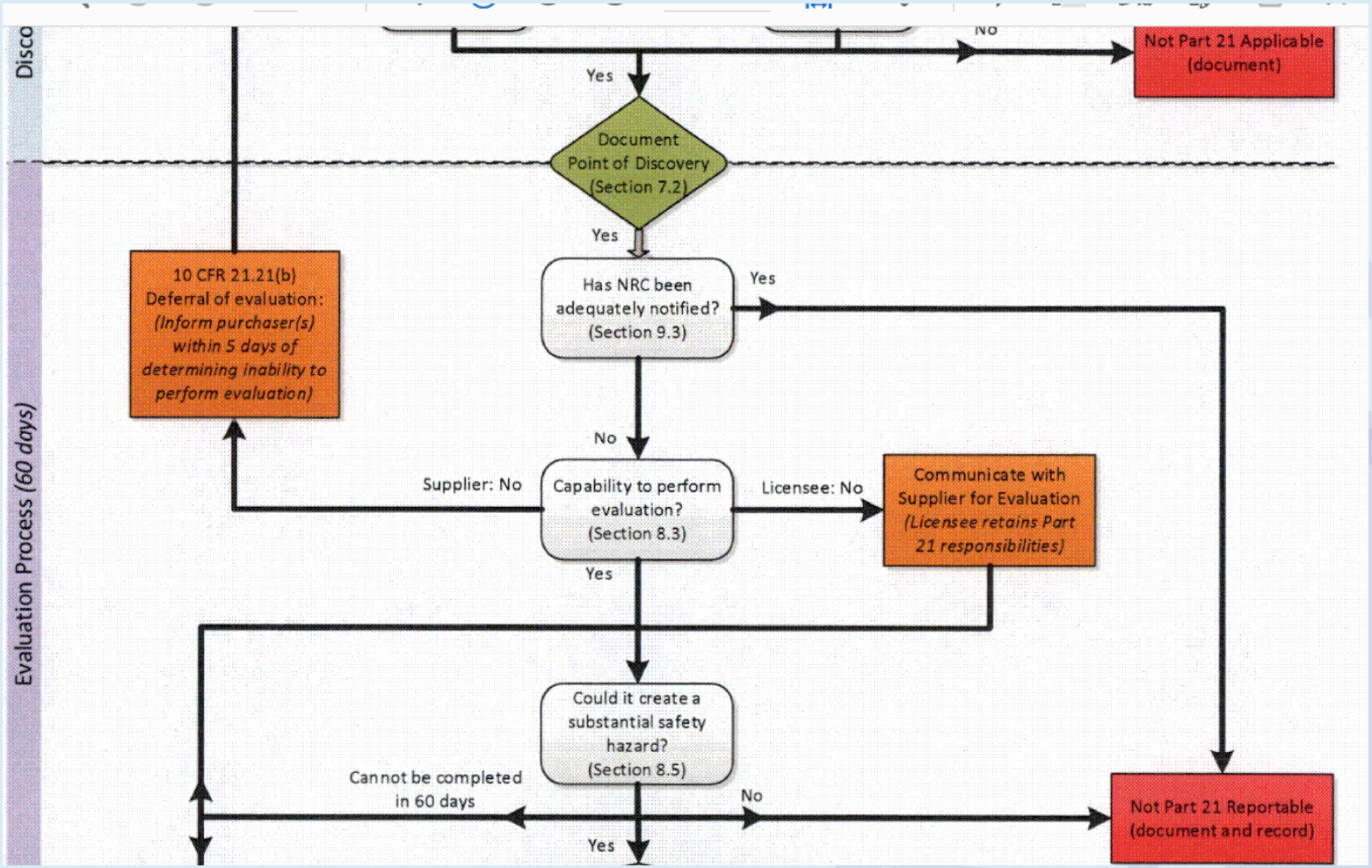
Overview of the reporting process

- Issue related to a basic component identified
- Is there a deviation or failure to comply
- Point of discovery
- Could it create a SSH?
- Document essentially everything (10CFR21.51)
- Notify the director
- Report the issue

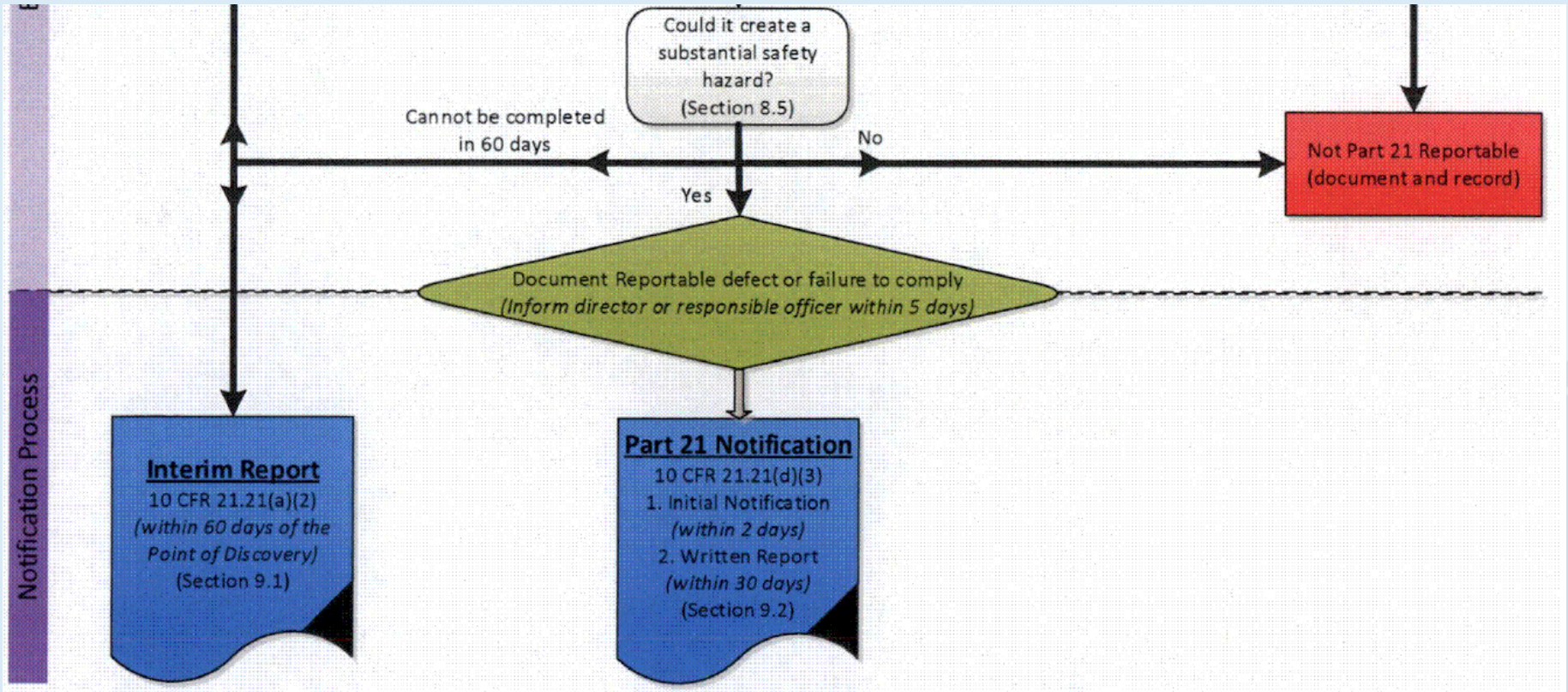
Eval & Notification Flowchart



Eval & Notification Flowchart



Eval & Notification Flowchart



Interfaces with other regulations

- Licensees do not need to make redundant notifications
  - For example: 50.72, 50.73, and 73.71
- If the licensee is crediting a previous 50.72 and 50.73 report then that report needs to include essentially all of the info that would be required in a Part 21 report (i.e. vendor, nature of the defect, corrective actions, any advice related to the defect, etc.)
- Make sure you have the most current version of NUREG-1022!!

NUREG-1022

- NUREG-1022, Rev. 2 included:

  As discussed in the Statement of Considerations for 10 CFR 21, the only case where a defect in a basic component of an operating reactor might be reportable under Part 21, but not under §§ 50.72, 50.73, or 73.71 would involve Part(s) on the shelf.

- IG Report OIG-11-A-08 dated 3/23/11 pointed out this was wrong and not consistent with Section 206 of the ERA.
- NUREG-1022, Rev. 3, deleted this statement because it was false

Example 1

A barrel test is done on a containment airlock. The leakage exceeded the TS SR limit. During the EFE, the licensee determined that the failure was caused by an unlubricated O-Ring for the outer equalizing valve. The valve was rebuilt and the test was re-performed and the leakage was still high but within TS limits. It was discovered that the inner valve was also unlubricated. It, too, was rebuilt. Barrel test was then sat.

Their long term corrective action was to disassemble the valves upon receipt and lubricate the O-rings.

The valves were purchased as safety-related and the procurement documents required the valves to be properly lubricated.

An LER was submitted which mentioned that equalizing valves failed which could have prevented a safety function but no real discussion on the failure mechanism, the type of valve, etc.

Example 1

- Does the issue need to be considered for Part 21?
- Is this either a deviation or failure to comply that is potentially associated with an SSH?
- When is the point of discovery?
- Was the NRC adequately notified?
- Does the licensee have the capability to perform the evaluation?
- Could it create a SSH?
- Should this be reported under Part 21?

Example 2

A licensee receives a safety related part.

During receipt inspection two days later, a defect is identified and the part is rejected.

The licensee notifies the supplier of the defect and returns the part to the supplier three months later.

Example 2

- Does the issue need to be considered for Part 21?
- Is this either a deviation or failure to comply that is potentially associated with an SSH?
- When is the point of discovery?
- Was the NRC adequately notified?
- Does the licensee have the capability to perform the evaluation?
- Could it create a SSH?
- Should this be reported under Part 21?

Example 3

A safety related relay was removed from the warehouse and sent to I&C for pre-installation checks. Bench testing identified the contacts were not closing properly. This issue was immediately entered into the CAP but it was not readily apparent wat the cause was because other potential mechanisms, such as setpoint drift, could be the cause of the problem. The relay was sent to a laboratory to identify the cause of the failure. The review by the laboratory was concluded and documented on June 1st, which determined that a faulty manufacturing process was the cause which was contrary to the requirements contained in the purchase order. The failure of the relay to close properly could have prevented the relay from performing its safety function. The licensee reviewed the laboratory report and documented the results in a second CR on June 2.

Example 3

- Does the issue need to be considered for Part 21?
- Is this either a deviation or failure to comply that is potentially associated with an SSH?
- When is the point of discovery?
- Was the NRC adequately notified?
- Does the licensee have the capability to perform the evaluation?
- Could it create a SSH?
- Should this be reported under Part 21?

Example 4

On October 1st, leakage from a safety-related check valve was observed during post maintenance testing and was immediately entered into the corrective action program. Upon further investigation, which concluded on October 6th, it was determined that the leakage was caused by the valve body material, which was not in conformance with the material specifications referenced in the procurement documents. On October 15th, the licensee concluded that the nonconforming material could prevent the valve from performing its safety function. This issue was entered in the corrective action process on October 15th and the licensee declared this to be the point of discovery. The licensee began a 10 CFR Part 21 evaluation on October 15th commencing the 60 day evaluation period.

Example 4

- Does the issue need to be considered for Part 21?
- Is this either a deviation or failure to comply that is potentially associated with an SSH?
- When is the point of discovery?
- Was the NRC adequately notified?
- Does the licensee have the capability to perform the evaluation?
- Could it create a SSH?
- Should this be reported under Part 21?

Example 5

A licensee received belts for a safety related room cooler. The receipt inspection identified no issues. As part of the procurement process, the belts needed to be installed and the cooler ran for one hour as a final inspection/test for the dedication plan.

The belts were installed and the cooler failed during the one-hour run because the belts failed catastrophically.

The investigation determined that the belts failed due to a manufacturing defect which would not have been readily apparent during the receipt inspection.

Example 5

- Does the issue need to be considered for Part 21?
- Is this either a deviation or failure to comply that is potentially associated with an SSH?
- When is the point of discovery?
- Was the NRC adequately notified?
- Does the licensee have the capability to perform the evaluation?
- Could it create a SSH?
- Should this be reported under Part 21?

Resources

NUREG-1022: https://www.nrc.gov/reading-rm/doc-collections/nuregs/staff/sr1022/index.html

OIG-11-A-08: https://www.oversight.gov/sites/default/files/oig-reports/NRC/ML110820426.pdf

RG 1.234, NUREG-0302, & NEI 14-09, Rev. 1: https://www.nrc.gov/reactors/new-reactors/how-we-regulate/oversight/quality-assurance/part-21-rulemaking.html

Questions or Comments?