



NRC Workshop on Vendor Oversight for New Reactor Construction

10 CFR Part 21 Evaluations

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TOPIC AREAS

1. How to speak “Part 21”
2. Identifying DEVIATIONS
3. Evaluating for DEFECTS

How to speak “Part 21”

- For vendors 10 CFR Part 21 is the governing regulation. It is the law.
 - Appendix B is contractually imposed on vendors. It is a regulatory (legally binding) requirement imposed on licensees.
- Vendors must ensure that a Part 21 program is properly implemented.
 - The NRC inspects to Inspection Procedure 36100.
- NRC inspections have resulted in numerous violations of 10 CFR Part 21.
 - Information Notice 2007-40 summarized the NRC’s recent findings.

How to speak “Part 21” (cont’d)

Examples of key terms in plain English

NOTE: The definitions of terms used in Part 21 are set forth in 10 CFR 21.3.

- **Deviation:** Any departure from a Purchase Order’s technical requirements. Deviations require further evaluation.



EXAMPLE

ACME Co. shipped stainless steel bolts to Springfield Nuclear, but the Purchase Order specified carbon steel bolts.

How to speak “Part 21” (cont’d)

- **Discovery**: Completion of documentation first describing a deviation.



EXAMPLE

During an inventory check, ACME Co. identifies that it shipped stainless steel bolts, instead of carbon steel bolts and completes a Corrective Action Report (CAR).

- **Evaluation**: The process within the Part 21 program used to determine whether a deviation is a defect.



EXAMPLE

ACME Co. starts its Part 21 Evaluation. It contacts Springfield Nuclear, who tells ACME that the safety-related bolts are welded to carbon steel flanges on the Reactor Coolant System.

How to speak “Part 21” (cont’d)

- **Defect**: A Deviation in a delivered basic component that could create a substantial safety hazard. The NRC must be notified of Defects.
- **Substantial Safety Hazard**: A loss of safety function. This is a determination that a nuclear plant will typically make, or at least be involved in making.



EXAMPLE ACME Co. continues its Evaluation. The stainless bolts have different welding properties, and could cause the flanges to fail at the plant. ACME Co. has enough information to determine that the bolts could cause a substantial safety hazard. ACME Co. has identified a Defect.

How to speak “Part 21” (cont’d)

- **Notification**: Official communication from a director or responsible officer, to the NRC, of a defect. Notification has minimum requirements in 21.21(d).



EXAMPLE

The President of ACME Co. notifies the NRC of the bolt defect by a complete Part 21 Notification.



EXAMPLE

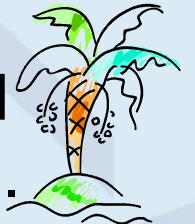
If ACME Co. determined that it could not perform a Part 21 Evaluation, it would have to inform Springfield Nuclear of the Deviation within five days. This is different than Notification.

Identifying DEVIATIONS

- Strong Corrective Action Programs are VITAL for identifying potential deviations.



A vendor's corrective action program did not interface with the Part 21 program. The vendor did not have a programmatic way to identify deviations.



A vendor had numerous types of corrective action programs, some of which did not interface with the Part 21 program.

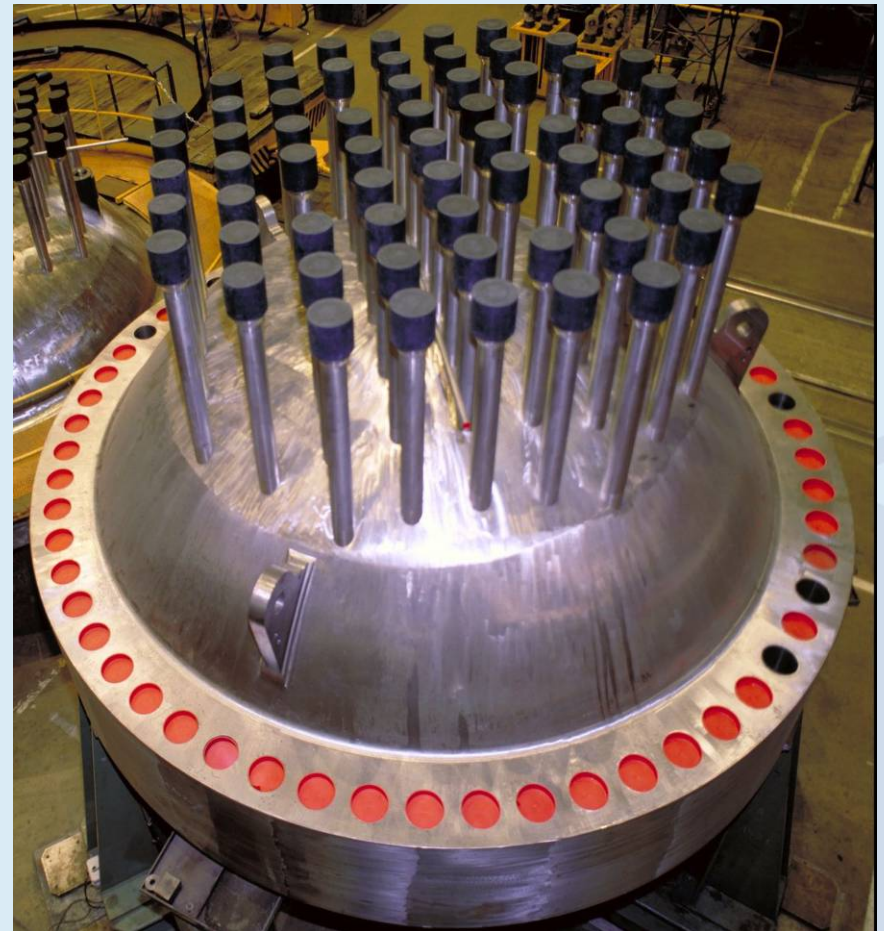
Identifying DEVIATIONS (cont'd)

- A common misconception is that isolated deviations do not need to be evaluated. After all, if there's just one item...



Identifying DEVIATIONS (cont'd)

- A common misconception is that isolated deviations do not need to be evaluated. After all, if there's just one item...
- All Deviations must be evaluated.



Evaluating for DEFECTS

Vendors must have procedures to either:

- Evaluate deviations to identify defects;



NRC

FINDINGS

Vendor did not have procedures in place to evaluate deviations.

- Or inform their customers, within five days, if they determine that they do not have the capability to evaluate.



NRC

FINDINGS

Vendor did not meet 5-day timeliness requirement to inform customers of deviations when the vendor was not capable of performing the evaluation.

Evaluating for DEFECTS (cont'd)

- Evaluations must include a determination of whether a deviation could create a substantial safety hazard.



Vendor evaluations focused on technical engineering aspects but did not address substantial safety hazard.



Vendor evaluations of deviations were inadequate because the vendor did not know the specific application of the item at the affected licensee facility.

Thank you for your attention!

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