



NUPIC Joint Utilities Audit Perspective on 10CFR Part 21

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Discussion Topics

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Introduction & Background

- 10CFR 21 evaluation and reporting is a fundamental part of supplying basic components
- 10CFR50, Appendix B and 10CFR Part 21 go hand in hand and cannot be separate with respect to basic components
- We are noticing an uptick in the number of issues being identified in the area of 10CFR Part 21



What is covered during NUPIC Joint Utilities Audits

- Verification of Postings per 10CFR21.6 (a) or 10CFR21.6 (b).
- Verification of Part 21 process including time frames for evaluations, notification and reporting timeframes per 10CFR21.21 (a), (b) and (d).
- Verification of Reporting content per 10CFR21.21 (d).

What is covered during NUPIC Joint Utilities Audits

Verification of Record Requirements

- Retain evaluations of all deviations and failures to comply for a minimum of five years after the date of the evaluation;
- Suppliers of basic components must retain any notifications sent to purchasers and affected licensees for a minimum of five years after the date of the notification.
- Suppliers of basic components must retain a record of the purchasers of basic components for 10 years after delivery of the basic component or service associated with a basic component.

What is covered during NUPIC Joint Utilities Audits

Verification of Record Requirements (continued)

- Applicants for standard design certification under subpart B of part 52 of this chapter and others providing a design which is the subject of a design certification, during and following Commission adoption of a final design certification rule for that design, shall retain any notifications sent to purchasers and affected licensees for a minimum of 5 years after the date of the notification, and retain a record of the purchasers for 15 years after delivery of design which is the subject of the design certification rule or service associated with the design.
- Applicants for or holders of a standard design approval under subpart E of part 52 of this chapter and others providing a design which is the subject of a design approval shall retain any notifications sent to purchasers and affected licensees for a minimum of 5 years after the date of the notification, and retain a record of the purchasers for 15 years after delivery of the design which is the subject of the design approval or service associated with the design.

What is covered during NUPIC Joint Utilities Audits

Verification of Record Requirements continued

- Each individual, corporation, partnership, dedicating entity, or other entity subject to the regulations in this part shall permit the Commission the opportunity to inspect records pertaining to basic components that relate to the identification and evaluation of deviations, and the reporting of defects and failures to comply, including (but not limited to) any advice given to purchasers or licensees on the placement, erection, installation, operation, maintenance, modification, or inspection of a basic component.

What is covered during NUPIC Joint Utilities Audits

- Verification that there is a connection between the 10CFR Part 21 process and nonconformance program and verification that there is a connection between the Part 21 process and corrective action process.
- Requirements for Procurement Documents

Part 21 Reporting Avenues

Interim Report - addressed to the NRC's Document Control Desk, and sent by mail to the U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001; by hand delivery to the NRC's offices at 11555 Rockville Pike, Rockville, Maryland; or, where practicable, by electronic submission, for example, Electronic Information Exchange, or CD-ROM.

Initial Notification - Facsimile which is the preferred method of notification, to the NRC Operations Center at (301) 816 - 5151 or by telephone at (301) 816 - 5100 within two days following receipt of information by the director or responsible corporate on the identification of a defect or a failure to comply. Verification that the facsimile has been received should be made by calling the NRC Operations Center. This paragraph does not apply to interim reports described in § 21.21(a)(2).

Written Communications and reports

Written communications and reports concerning the regulations in this part must be addressed to the NRC's Document Control Desk, and sent by mail to the U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001; by hand delivery to the NRC's offices at 11555 Rockville Pike, Rockville, Maryland; or, where practicable, by electronic submission, for example, Electronic Information Exchange, or CD-ROM.

Part 21 Reporting Avenues

Electronic submissions

Electronic submissions must be made in a manner that enables the NRC to receive, read, authenticate, distribute, and archive the submission, and process and retrieve it a single page at a time. Detailed guidance on making electronic submissions can be obtained by visiting the NRC's Web site at <http://www.nrc.gov/site-help/e-submittals.html>; by e-mail to MSHD.Resource@nrc.gov; or by writing the Office of Information Services, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001. The guidance discusses, among other topics, the formats the NRC can accept, the use of electronic signatures, and the treatment of nonpublic information. In the case of a licensee or permit holder, a copy of the communication must also be sent to the appropriate Regional Administrator at the address specified in appendix D to part 20 of this chapter.

Common NUPIC Joint Utilities Audit Findings

- Suppliers' procedures do not address the applicable requirements of 10CFR Part 21 including:
 - Discovery of a Deviation
 - Interim Reports
 - Customer notification when supplier is not capable of performing the evaluation of deviations
 - Performing evaluations of deviations
 - Reporting
- Failing to perform evaluation of deviations to determine if they represent defects as soon as practical.
- Failing to meet reporting time frames per 10CFR Part 21

Common NUPIC Joint Utilities Audit Findings

- Failing to meet the record retention requirements of 10CFR Part 21
- Not entering Part 21 Incidents into Corrective Action Program
- Suppliers of basic components making blanket statement that they do not have the capability to evaluate deviations
- Failing to invoke 10CFR Part 21 in procurement documents for basic components
- Incorrectly invoking 10CFR Part 21 on commercial suppliers

Tidbits

Electronic/Computer Postings are allowed for remote workers

Users can register for Part 21 Subscription for updates

Access NRC Part 21 Inspection Procedure and inspection reports can be obtained at:

<https://www.nrc.gov/reactors/new-reactors/how-we-regulate/oversight/quality-assurance.html>

Questions ???



Resources and References

- 10CFRPart 21 Regulation
- NEI 14-09, Guidelines for Implementation of 10CFR Part 21 – Reporting of Defects and Compliance, Revision 1
- NRC Inspection Procedure IP 36100, Inspection of 10 CFR Part 21 and Programs for Reporting Defects and Noncompliance
- NUPIC Joint Utilities Audit Checklist, Revision 22
- <https://www.nrc.gov/reactors/new-reactors/how-we-regulate/oversight/quality-assurance.html>