UNITED STATES
NUCLEAR REGULATORY COMMISSION
REGION III
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July 24, 2024

EA-23-126

Carolyne Joseph
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SUBJECT: REVISED NON-CITED VIOLATIONS – DRESDEN NUCLEAR POWER STATION INTEGRATED INSPECTION REPORT 05000237, 05000249/2020001 (NCV 05000237, 05000249/2020001-02; FAILURE TO ACCOUNT INSTRUMENT UNCERTAINTIES) AND COMPREHENSIVE ENGINEERING TEAM INSPECTION REPORT 05000237, 05000249/2023011 (NCV 05000237, 05000249/2023011-01; FAILURE TO CORRECT CONDITION ADVERSE TO QUALITY AFTER HPCI TEST CONTROL VIOLATION)

Dear Carolyne Joseph,

On October 6, 2023, Dresden Nuclear Power Station (DNPS) provided a written response (Agencywide Document and Access Management System (ADAMS) (ML23279A071)) to the U.S. Nuclear Regulatory Commission (NRC) Inspection Report 05000237,05000249/2023011 (ML23242A188) dated September 6, 2023. The letter contested Non-Cited Violation (NCV) 0500037, 05000249/2023011-01, related to the failure to correct a condition adverse to quality (CAQ) identified by the NRC in 2020. This CAQ was previously dispositioned as NCV 05000237,05000249/2020001-02 in Inspection Report 05000237,05000249/2020001 (ML20133J811) dated May 11, 2020. In the letter, DNPS asserted that no CAQ existed at the time of the 2020 NCV, challenging the basis of the 2023 NCV.

The NRC carefully reviewed DNPS's response and determined that there are two valid NCVs. However, the staff determined that the 2020 NCV for failure to meet the requirements of 10 CFR 50 Appendix B, Criterion XI is better characterized as a failure to meet Appendix B, Criterion III, "Design Control." Additionally, in both cases, the supporting statements of the original enforcement decisions did not clearly establish a connection between the licensee's actions and the requirement language. As a result, this review recommended modifying both NCVs to enhance clarity, as discussed in the enclosures. This review also included a backfit assessment, which determined that the NCVs, both original and modified, do not constitute a backfit because they enforce existing requirements and are not a new staff interpretation of those requirements. The bases for the staff's conclusion are detailed in the Enclosures.

This letter, its enclosures, Dresden Nuclear Power Station's October 6, 2023, response, and your response (if any) will be made available for public inspection and copying at http://www.nrc.gov/reading- rm/adams.html and at the NRC Public Document Room in accordance with 10 CFR 2.390, "Public Inspections, Exemptions, Requests for Withholding."

Sincerely,

Shuaibi, Mohammed signing on behalf of Giessner, Jack on 07/24/24

John B. Giessner
Regional Administrator

Docket No. 50-237 and 50-249
License No. DPR-19 and DPR-25

Enclosures:
1. NRC Staff Assessment of Disputed NCV 05000237, 05000249/2023011-01
2. Detailed Review of Disputed NCV 05000237, 05000249/2023011-01

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Letter to C. Joseph from J. Giessner dated July 24, 2024.

SUBJECT: REVISED NON-CITED VIOLATIONS – DRESDEN NUCLEAR POWER STATION INTEGRATED INSPECTION REPORT 05000237, 05000249/2020001 (NCV 05000237, 05000249/2020001-02; FAILURE TO ACCOUNT INSTRUMENT UNCERTAINTIES) AND COMPREHENSIVE ENGINEERING TEAM INSPECTION REPORT 05000237, 05000249/2023011 (NCV 05000237, 05000249/2023011-01; FAILURE TO CORRECT CONDITION ADVERSE TO QUALITY AFTER HPCI TEST CONTROL VIOLATION)

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NRC STAFF ASSESSMENT OF DISPUTED NCV 05000237, 05000249/2023011-01

The NRC's staff reviewed information provided in the Dresden Nuclear Power Station letter dated October 6, 2023 (ML23242A188). This review was performed by staff members having relevant technical and regulatory knowledge.

Documents referenced are listed in the Reference Section of this Enclosure. Additionally, the detailed description of the NRC staff review is documented in Enclosure 2.

1. BACKGROUND

In the first quarter of 2020, inspectors identified an NCV of 10 CFR 50, Appendix B, Criterion XI, "Test Control," for, in part, the failure to account for instrument uncertainties in surveillance procedure acceptance criteria for high pressure coolant injection (HPCI) required flow. Specifically, the inspectors noted the HPCI minimum required flow value used in design documents was the same as the acceptance criteria for the associated surveillance test, raising questions about the consideration of instrument uncertainty in the design calculation. The licensee did not demonstrate the incorporation of surveillance instrument uncertainty, leading to the identification of the NCV, documented in Inspection Report 05000237, 05000249/2020001(ML20133J811).

In 2023, during a comprehensive engineering team inspection (CETI), the inspectors reviewed corrective actions taken by the licensee in response to the 2020 violation. The licensee conducted a sensitivity study intended to demonstrate that the available margin bounded HPCI flow instrument uncertainty. However, inspectors determined these actions did not rectify the 2020 NCV because the method chosen to resolve the issue did not demonstrate the instrument uncertainty was accounted for in the analysis. This resulted in the issuance of a new NCV, specifically of 10 CFR 50, Appendix B, Criterion XVI, "Corrective Actions." This determination was documented in Inspection Report 05000237, 05000249/2023011(ML23242A188).

On October 6, 2023, the licensee disputed both violations in a letter to the NRC (ML23279A071). The following report details the NRC review of the licensee's position.

2. ORIGINAL ENFORCEMENT DECISIONS

The initial (2020) original enforcement decision as stated in Inspection Report 05000237,05000249/2020001 was:

Title 10 CFR Part 50, Appendix B, Criterion XI, "Test Control," requires, in part, that a test program be established to assure that all testing required to demonstrate that structures, systems, and components will perform satisfactorily in service is identified and performed in accordance with written test procedures which incorporate the requirements and acceptance limits contained in applicable design documents.

For high pressure coolant injection, a safety-related SSC:
Procedure DOS 2300-03, "High Pressure Coolant Injection System Operability and Quarterly IST Verification Test," Revision 11, is the implementing procedure to comply with applicable design documents. Section H of this procedure, "Acceptance Criteria", include step H.5.a which states "The HPCI pump develops a flow of greater than or equal to 5000 gpm against a system head corresponding to reactor pressure head with reactor pressure greater than or equal to 920 psig and less than or equal to 1005 psig. (Tech Spec SR 3.5.1.6)."

For the Ultimate Heat Sink, a safety-related SSC:
Procedure Unit 2(3) Appendix B, "Assist NSO and Common Unit Daily Surveillance Log," Revision 90, is the implemented procedure to comply with applicable design documents. Attachment A to this procedure was a table which included the established acceptance criteria for the UHS average water temperature of less than or equal to 95 degrees F as required by TS SR 3.7.3.2.

Contrary to the above, as of March 11, 2020, the licensee failed to assure that the testing required to demonstrate that the HPCI and UHS systems would perform satisfactorily in service was identified and performed in accordance with written test procedures which incorporated the requirements and acceptance limits contained in applicable design documents, as evidenced by the following examples:

1) *Specifically, for the HPCI systems' procedure DOS 2300-03, Revision 117, the licensee failed to account for instrument uncertainties when establishing the acceptance criteria to ensure successful completion of these tests would ensure the associated SSCs would remain operable and within the acceptable limits as determined by applicable design documents.*

2) *Specifically, for the UHS system's procedure Appendix B, Revision 90, the licensee failed to account for instrument uncertainties when establishing the acceptance criteria to ensure successful completion of these tests would ensure the associated SSCs would remain operable and within the acceptable limits as determined by applicable design documents.*

Note: The UHS example of the violation was not included in this review because it was not the subject of the licensee's denial letter.

The subsequent (2023) original enforcement decision as stated in Inspection Report 05000237,05000249/2023011 was:

Title 10 CFR Part 50, Appendix B, Criterion XVI, "Corrective Action," requires, in part, that measures shall be established to assure that conditions adverse to quality, such as deficiencies, deviations and nonconformances are corrected.

Contrary to the above, as of December 16, 2022, the licensee failed to establish measures to assure conditions adverse to quality were corrected. Specifically, a non-cited violation of Appendix B, Criterion XI, "Test Control," was identified in a 2020 NRC Integrated Inspection Report, in part, for the failure to account for instrument uncertainty in the acceptance criteria of HPCI surveillance procedure DOS 2300-03, "High Pressure Coolant Injection System Operability and Quarterly IST Verification Test," Revision 117. The licensee documented this violation in their CAP as AR 04331189. This was closed on December 16, 2022, and failed to establish measures that assured the HPCI system would remain within the bounds of the analyzed design such that the HPCI flowrate of 5,000 gpm would be achieved if instrument uncertainty was accounted for in the accident analysis or TS SR implementing procedure.

3. REVISED VIOLATIONS

After review of the licensee's letter dated October 6, 2023, and for reasons further explained in Section 5 below, the NRC staff has determined that several changes to the original violations are warranted. Specifically, the 2020 violation for failure to meet the requirements of 10 CFR Appendix B, Criterion XI is being modified. The staff has determined that because the licensee assumed the Emergency Core Cooling System (ECCS) design incorporated sufficient margin to account for instrument uncertainty, but failed to verify or demonstrate that design assumption, the violation is better characterized as a violation of 10 CFR Appendix B, Criterion III, "Design Control." The revised violation is as follows:

2020 Modified NCV

> Title 10 CFR Part 50, Appendix B, Criterion III, "Design Control," states, in part, that the design control measures shall provide for verifying or checking the adequacy of design. It also states that design control measures shall be applied to items such as the delineation of acceptance criteria for inspections and tests.
>
> Contrary to the above, as of March 2020, the licensee's design control measures failed to provide for verifying the adequacy of the design and were not applied to the delineation of test acceptance criteria for HPCI. Specifically, the licensee assumed the uncertainty of the HPCI flow instrument used in SR 3.1.5.6 was incorporated in the design margin of their ECCS evaluation model. However, the licensee did not verify the adequacy of this design assumption, even after implementing facility changes such as changes among different fuel vendors, and other modifications like extended power uprates that reduced this margin. As a result, the SR implementing procedure (i.e., DOS 2300-03, "High Pressure Coolant Injection System Operability and Quarterly IST Verification Test," Revision 117) was not assured to detect unsatisfactory HPCI performance because its acceptance criteria were based on this unverified design assumption.

Additionally, the staff identified clarity issues with the 2023 violation of 10 CFR Appendix B, Criterion XVI. The violation has been modified as follows to include the approximate timeframe that the violation persisted as well as the staff's view on why the licensee's corrective actions did not correct the condition adverse to quality.

2023 Modified NCV

> Title 10 CFR 50, Appendix B, Criterion XVI, "Corrective Action," states, in part, that measures shall be established to assure that CAQs, such as failures, malfunctions, deficiencies, deviations, defective material and equipment, and nonconformances, are promptly corrected.
>
> Contrary to the above, from approximately March 2020, to at least September 2023, the licensee failed to promptly correct a CAQ. Specifically, on March 31, 2020, the licensee initiated AR4331189, highlighting concerns about how HPCI SR 3.1.5.6 instrument uncertainty is accounted for in the overall design safety analysis or other activity. To address this CAQ, the licensee performed a sensitivity analysis to "provide a basis to not include instrument uncertainty in ECCS surveillance acceptance criteria," as stated in Corrective Action Program Evaluation (CAPE) 4331189-07. However, in September 2023, the inspectors identified that the licensee had not corrected the CAQ because the study relied on the removal of conservatisms and margins required by 10 CFR 50, Appendix K, and did not have any other plans to promptly correct the CAQ.

4. LICENSEE POSITION

The licensee disagreed with the NRC's assessment and conclusions regarding the issues leading to both the 2020 and 2023 NCVs. The licensee stated that Dresden is a “nominal value plant,” by which it asserts that its licensing basis implicitly incorporates instrument uncertainty for Technical Specification (TS) trip setpoints, and this licensing basis is “transferable” to ECCS surveillance requirement (SR) limits. According to the licensee, its conservative analytical methods inherently incorporate instrument uncertainty within the overall safety evaluation margin. During interviews, the licensee clarified that this position was also based on 10 CFR 50.46, “Acceptance criteria for emergency core cooling systems for light-water nuclear power reactors.” They interpreted this regulation as allowing an exception to their ECCS evaluation model from identifying and assessing SR instrument uncertainty.

Furthermore, they contended that neither regulatory requirements nor their licensing basis explicitly requires the inclusion of instrument uncertainty for ECCS flow and asserted that the NCVs imply a specific inspector view on how to address the underlying issue. Additionally, they emphasized that the NRC had not previously challenged the ECCS SR limit as non-conservative due to measurement uncertainty.

The licensee supported its position by referencing a sensitivity study intended to demonstrate that uncertainty was implicitly considered in the ECCS evaluation model margins. They asserted that no violation occurred in 2023 for failing to correct a CAQ because no CAQ existed at the time of the 2020 NCV.

5. NRC STAFF REVIEW

The NRC staff’s review acknowledges that the regulatory framework grants licensees flexibility in addressing the impacts of SR instrument uncertainty on activities affecting safety. In this case, the licensee states that they made a decision to implicitly include instrument uncertainty with respect to ECCS values into DNPS design margin. However, for the reasons discussed below, the NRC staff concludes that the licensee relied on a design assumption that had not been verified in accordance with applicable quality assurance requirements.

The licensee elected to implicitly incorporate the ECCS SR instrument uncertainty within their ECCS evaluation model design margin, claiming to be licensed as a “nominal value plant.” However, the term "nominal value plant" was not defined or referenced in DNPS’s licensing basis or NRC guidance documents. Though NRC NUREG-0138, “Staff Discussion of Fifteen Technical Issues Listed in Attachment to November 3, 1976, Memorandum from Director NRR to NRR Staff” (ML13267A423), described the concept of incorporating instrument uncertainty in the overall safety margin, the NUREG refers specifically to DNPS TS trip setpoints, which are process variable values chosen to ensure automatic actuation of safety systems before reaching safety limits. The NUREG is not applicable to SR instruments, which are measurement and test equipment (M&TE) intended to measure safety function characteristics to confirm operability limits used in the plant design are met.

The licensee also stated their TS trip setpoint licensing basis was “transferable” to SR instruments. It is not clear to the staff what it means to transfer the licensing basis to SR instruments, nor is there any licensing basis documentation supporting such transferability. When considering the potential for this transferability to exist, the NRC staff noted the licensee voluntarily made changes to their licensing basis to explicitly consider instrument uncertainty associated with TS trip setpoints. The licensee did not review the impact of these changes to their assumption that the design margins accounted for SR instrument uncertainty, even when those changes reduced design margins.

The licensee invoked 10 CFR 50.46, “Acceptance criteria for ECCS for light-water nuclear power reactors,” as justification for not validating their assumption. They asserted that 10 CFR 50.46(a)(1)(i) allows an exception from addressing SR instrument uncertainty in their ECCS evaluation model. However, the exception involves the alternate method allowed by 10 CFR 50.46(a)(1)(ii), which bases ECCS evaluation models on Appendix K of 10 CFR 50. The NRC staff disagrees with the licensee’s interpretation of 10 CFR 50.46(a)(1)(i) because the reference to the exception regarding uncertainty in the regulation pertained to calculational uncertainties rather than SR instrumentation, as clarified in NRC Regulatory Guide (RG) 1.157, “Best Estimate Calculations of ECCS Performance” (ML003739584). Regardless of this interpretation, the cited exception exclusively applied to the evaluation model, and the licensee remained obligated to adhere to the requirements outlined in Appendix B to 10 CFR 50, titled “Quality Assurance Criteria for Nuclear Power Plants and Fuel Reprocessing Plants,” along with their Quality Assurance Program. This position was reinforced by 10 CFR 50.46 itself, which explicitly stated that its requirements were in addition to any other 10 CFR 50 requirement applicable to ECCS.

The licensee attempted to verify their design assumption regarding ECCS SR instrument uncertainty in response to the 2020 NCV by performing a sensitivity analysis. The analysis was intended to demonstrate that instrument uncertainty did not need to be independently accounted for in ECCS SR acceptance criteria. However, the sensitivity analysis relied on the removal of conservatisms and margins required by 10 CFR 50, Appendix K, “ECCS Evaluation Models,” to address other relevant factors. Consequently, it did not correct the CAQ addressed by the 2020 NCV.

In evaluating the original enforcement decisions, despite the valid premises of the 2020 and 2023 NCVs, the staff determined that several modifications of the violations were warranted. Specifically, the 2020 violation was modified to reflect the licensee’s failure to meet 10 CFR Appendix B, Criterion III and the staff identified and corrected issues associated with the lack of a clear link between the licensee's actions and the requirement language in the supporting statements of the original enforcement decisions. As a result, the original enforcement decisions should be modified as previously discussed. This review also included a backfit assessment, which determined that the NCVs, both original and modified, do not constitute a backfit because they enforce existing requirements and are not new staff interpretation of those requirements.

6. REFERENCES

1. Letter from Patrick Boyle to U.S. Nuclear Regulatory Commission; “Response to NRC Dresden Nuclear Power Stations, Units 2 and 3 Comprehensive Engineering Team Inspection Report 05000237/2023011 and 05000249/2023011;” October 6, 2023 (ADAMS Accession No. ML23279A071)

2. Letter from J. Stephen Perry to U.S. Nuclear Regulatory Commission; “Dresden Nuclear Power Station Units 2 and 3, Core Spray System Flow Requirements, NRC Docket Nos. 50-27 and 50-249;” November 6, 1996 (ADAMS Accession No. ML17197A642)

3. Letter from J. Stephen Perry to U.S. Nuclear Regulatory Commission; “Dresden Nuclear Power Station Units 2 and 3, Evaluation of Methods to Address ECCS Flow and Pressure Measurement Uncertainties, NRC Docket Nos. 50-237 and 50-249;” March 21, 1997 (ADAMS Accession No. ML17187A875)

4. Letter from R.M. Krich to U.S. Nuclear Regulatory Commission; “RS-01-033, Supplement to GE-14 Fuel License Amendment Request;” March 1, 2001 (ADAMS Accession No ML010670137)

5. Letter from Jamie Benjamin to David Rhoades; “Dresden Nuclear Power Station, Units 2 and 3 Comprehensive Engineering Team Inspection Report 05000237/2023011 and 5000249/2023011;” September 6, 2023 (ADAMS Accession No. ML23242A188)

6. Letter from Kenneth R. Riemer to Mr. Bryan C. Hanson; “Dresden Nuclear Power Station, Units 2 and 3 – Integrated Inspection Report 05000237/2020001 and 05000249/2020001;” May 11, 2020 (ADAMS Accession No. ML20133J811)

7. Letter from Geoffrey E. Grant to Mr. Oliver D. Kingsley; “Braidwood Station, Units 1 and 2, NRC Inspection Report 50-456/01-11(DRP); 50-457/01-11(DRP) and Notice of Violation;” December 12, 2001 (ADAMS Accession No. ML013510487)

8. Letter from J. F. Stolz to O.D. Kinglsey; “Quad Cities Nuclear Power Station – Design Inspection (NRC Inspection Report Nos. 50-254/98-201);” May 6, 1998 (ADAMS Accession No. ML20247E545)

9. Letter from John M. Jacobson to O.D. Kingsley; “NRC Inspection Report 50-254/99014(DRS), 50-265/99014(DRS);” July 30, 1999 (ADAMS Accession No. ML20210M469 and ML20210M482)

10. Memorandum from Ledyard B. Marsh to Robert A. Capra; “TIA Response: Accounting for Instrument Uncertainties in Surveillance Testing Acceptance Criteria (TAC Nos. MA3776 and MA3777);” November 13, 1998

11. Memorandum from Phillip F. McKee to Richard W. Cooper; “Task Interface Agreement Evaluation Regarding Instrument Accuracy Affecting Millstone Unit 2 (TAC No. M95177);” July 22, 1996 (ADAMS Accession No. ML020360198)

12. NUREG-0138; “Staff Discussion of 15 Technical Issues Listed in Attachment to November 3, 1976, Memorandum from Director, NRR to NRR Staff;” November 1976 (ADAMS Accession No. ML13267A423)

13. NUREG-0800 Branch Technical Position 7-12; “Guidance on Establishing and Maintaining Instrument Setpoints Review Responsibilities;” Revision 6 (ADAMS Accession No. ML16019A200)

14. NUREG-1409; Backfitting Guidelines;” July 1990 (ADAMS Accession No. ML032230247)

15. NUREG-1433; “Standard Technical Specifications Geneal Electric Plants, BWR/4;” Revision 2 (ADAMS Accession No. ML031290224)

16. NRC Inspection Manual Part 9900: Technical Guidance; “Standard Technical Specifications Section 3.0 Acceptable Measurement Tolerances for Technical Specification Limits;” October 1, 1978

17. Regulatory Guide 1.105; “Instrument Setpoints;” Revision 1 and Revision 4 (ADAMS Accession Nos. ML13064A112 and ML20330A329)

18. Regulatory Guide 1.157; “Best-Estimate Calculations of Emergency Core Colling System Performance;” May 1989 (ADAMS Accession No. ML003739584)

19. NRC Regulatory Issue Summary 2006-17; “NRC Staff Position on the Requirements of 10 CFR 5036, Technical Specifications, Regarding Limiting Safety System Settings During Periodic Testing and Calibration of Instrument Channels;” August 24, 2006 (ADAMS Accession No. ML051810077)

20. 10 CFR 50.36; “Technical Specification”

21. 10 CFR 50.46; “Acceptance Criteria for Emergency Core Cooling Systems for Kight Water Nuclear Power Reactors”

22. 10 CFR 50, Appendix K; “ECCS Evaluation Models”

23. 10 CFR 50, Appendix B, Criterion III; “Design Control”

24. 10 CFR 50, Appendix B, Criterion XI; “Test Control”

25. 10 CFR 50, Appendix B, Criterion XVI; “Corrective Action”

26. DOS 2300-03; ‘High Pressure Coolant Injection System Operability and Quarterly IST Verification;” Revision 117

27. DIS-2300-02; “High Pressure Coolant Injection Flow Calibration;” Revision 38 and Revision 39

28. CC-AA-103-2001; “Setpoint Change Control;” Revisions 2, 3 and 4

29. 006N3917; “Generic ECCS Flow Reduction SAFER Sensitivity Study;” February 2021

30. 006N117; “Dresden Nuclear Power Station (DNPS) Units 2 and 3 GNF3 ECCS-LOCA Evaluation;” Revision 0

31. DG98-00985; “Instrument Uncertainties Matrix;” September 1, 1998

32. Engineering Change 633963; “Evaluation of ECCS Instrument Uncertainties Impact on ECCS-LOCA Analysis;” Revision 000

33. NED-I-EIC-0109; “High Pressure Coolant Injection (HPCI) Pump Discharge Flow Loop Accuracy and Minimum Flow Setpoints;” Revision 006

34. NO-AA-10; “Quality Assurance Topical Report (QATR);” Revision 98

35. AR 0431189; “NRC: Procedures and Instrument Uncertainty;” March 31, 2020

36. AR 04315614; “NRC Question on DOS 2300-03 Acceptance Criteria;” February 5, 2020

37. AR 0695296; “2023 CETI-NRC ID: Issue with uncertainty not in ECCS testing;” August 4, 2023

38. Constellation Energy Generation, LLC; Docket No. 50-237; Dresden Nuclear Power Station, Unit 2; Renewed Facility Operating License No. DPR-19; Appendix A; “Technical Specifications”

39. Constellation Energy Generation, LLC; Docket No. 50-249; Dresden Nuclear Power Station, Unit 3; Renewed Facility Operating License No. DPR-25; Appendix A; “Technical Specifications”

40. Dresden Nuclear Power Station Technical Specification Bases

41. Dresden Power Station Updated Final Safety Analysis Report (UFSAR), Revision 15

42. Statement of Consideration 35995-36005; ‘Nuclear Regulatory Commission, 10 CFR Part 50, Emergency Core Cooling Systems Revisions to Acceptance Criteria;” September 16, 1988

DETAILED REVIEW OF DISPUTED NCV 05000237, 05000249/2023011-01

This Enclosure contains a detailed review conducted by the NRC staff to address the major points documented by the licensee in Letter from Patrick Boyle to U.S. Nuclear Regulatory Commission; "Response to NRC Dresden Nuclear Power Stations, Units 2 and 3 Comprehensive Engineering Team Inspection Report 05000237/2023011 and 05000249/2023011;" October 6, 2023 (ADAMS Accession No. ML23279A071).

1. Implicit Instrument Uncertainty in TS Trip Setpoints and Transferability to ECCS SR Limits

In NUREG-0138, the NRC explained that TS trip setpoint instrument uncertainties were not explicitly evaluated for operating licenses issued before October 1974. Instead, these uncertainties were integrated into an overall safety margin. The magnitude of this safety margin and the resulting trip setpoints were established to minimize the likelihood of the margin being compromised by a combination of instrument calibration error, instrument error, and instrument drift. This NRC document explicitly endorsed this method as acceptable.

DNPS Units 2 and 3, operational since June 1970 and November 1971, were licensed under the draft General Design Criteria published in 1967. Their original safety analysis likely accepted implicit allowances for instrument uncertainties in TS trip setpoint values consistent with NUREG-0138, forming their original licensing basis.

Reviewing DNPS's claim of transferring this licensing basis to ECCS SR limits, the NRC staff found no documented support. Notably, the term "nominal value plant" was also not found in either DNPS licensing basis or NRC guidance documents.

The licensee asserted that their position on the transferability of the TS trip setpoint licensing basis position was supported by the NRC position on acceptable measurement tolerances for TS limits documented in Inspection Manual Part 9900 Technical Guidance, which states:

> *The TS limits are established with allowance for measurement* ***tolerances already incorporated [emphasis added].*** *The limits take into consideration measurement uncertainties as necessary to assure safe plant operation.* ***The stated limit presupposes that the licensees have tolerances consistent with normal industry standards (e.g., ASTM, IEEE, ACI, etc.) [emphasis added]****.*

The licensee asserted that:

> *For plants licensed prior to 1974 and reviewed under the general evaluation method described in NUREG-0138, the method of the measurement tolerances being "already incorporated" was by selection of the numerical value of the associated TS limit (as described in the excerpts from NUREG-0138 quoted in the section above). The uncertainty is implicitly incorporated in the design through significant safety margins built into the analyses.*

However, as shown in the last sentence of the 9900 Technical Guidance quote above, the NRC clarified that the premise for "tolerances already incorporated" is based on licensees adhering to normal industry standards. In addition, the 9900 Technical Guidance followed that quote with the following example illustrating that a known and controlled uncertainty value was incorporated in the TS limit further clarifying their position:

> *For example, assume the TS limit for the boron concentration in an accumulator is ≥ 1900 ppm. Assume an accumulator solution sample measurement was performed in accordance with Monitor Potentiometric Procedure D3032, resulting in a measured value of 1910 ppm.*

The 1910 ppm measurement would be considered acceptable because the TS limit of 1900 ppm was determined allowing for measurement tolerances. (The tolerance of this measurement is ± 2.4% according to ASTM, Part 31, D302-74).

During this review, the licensee did not find documentation demonstrating they used a specific industry standard when incorporating their HPCI SR instrument tolerance similar to the Part 9900 Technical Guidance model.

Additionally, when considering the potential for the licensing basis of TS set points to be transferable to SR instruments, the NRC staff considered changes in DNPS' licensing basis. Specifically, since original licensing, the licensee voluntarily underwent multiple fuel transitions, changes among different fuel vendors, and other modifications like extended power uprates. To justify these changes, the licensee reviewed and updated their earlier ECCS analysis aligning it with evolving methods and standards of fuel vendor evaluation models. The updated analyses, explicitly considering TS trip setpoint instrument uncertainty, were submitted to the NRC for review via license amendment requests. The NRC staff approved these analyses in line with prevailing standards and practices at the time of their review, explicitly considering instrument uncertainty associated with TS trip setpoint values. The licensee did not review the impact of these changes to their assumption that the design margin accounted for SR instrument uncertainty, even when those changes reduced design margin.

NUREG-0138 acknowledged a shift from implicit to explicit evaluation of TS trip setpoint instrument uncertainties for operating licenses issued since October 1974. This explicit consideration allowed the NRC staff, in part, to conclude that requested license amendments, incorporating advancements in fuel technology and analytical methodologies, ensured safe plant operation with reduced design margin. Each updated analysis became DNPS's new licensing basis. A review of their current licensing basis confirmed its explicit accounting for instrument uncertainty associated with TS trip setpoints.

Also, when considering if the transferability of the licensing basis from TS trip setpoint to ECCS SR instruments existed, the NRC staff observed relevant distinctions. For example, TS trip setpoints protect process variable values chosen to ensure automatic actuation of safety systems before process variables reach safety limits. Safety limits, per 10 CFR 50.36, are process variable limits necessary to reasonably protect the integrity of certain physical barriers that guard against the uncontrolled release of radioactivity. The M&TE used in determining the trip setpoint is accounted for during the setpoint calculation in accordance with RG 1.105, "Setpoints for Safety-Related Instrumentation" (ML13064A112 and ML20330A329), in accordance with licensee procedure CC-AA-103-2001, "Setpoint Change Control." In contrast, the accuracy of the M&TE used in performing ECCS SRs is controlled by the licensee's QA program with the goal of confirming operability.

While terminologies and physical characteristics of TS trip setpoints and M&TE can overlap, the NUREG specifically addresses TS trip setpoint functions. According to Branch Technical Position 7-12 of NUREG-0800, "Guidance on Establishing and Maintaining Instrument Setpoints" (ML16019A200), the NRC staff meticulously reviews TS trip setpoints and associated values, including consideration for instrument loop uncertainties. In contrast, similar detailed reviews of ECCS SR limits are generally not conducted since they do not directly protect safety limits. These distinctions underscore the varied treatment and scrutiny applied to different safety-related instruments within the regulatory framework and do not support transferability.

2. Licensee's View Regarding Lack of Specific Regulatory Requirements

The licensee correctly pointed out that there is no specific regulatory requirement explicitly mandating the consideration of ECCS flow uncertainty in SR procedures. This is because the regulatory framework maintains a high-level approach, avoiding detailed methodologies and granting licensees the flexibility to adopt diverse methods to ensure safety. For example, Appendix B to 10 CFR 50 imposes quality assurance requirements on all activities affecting safety-related functions without prescribing specific steps, emphasizing outcomes over rigid methods. Licensees are obliged to ensure the quality of safety-related activities, including verifying design assumptions that could reasonably impact safety-related components or systems.

In this case, the licensee stated that it chose to implicitly incorporate the ECCS SR instrument uncertainty in the ECCS evaluation design margin, consistent with their procedure CC-AA-103-2001, "Setpoint Change Control." Appendix B to 10 CFR 50, Criterion III, "Design Control," requires, in part:

> *The design control measures shall provide for verifying or checking the adequacy of design, such as by the performance of design reviews, by the use of alternate or simplified calculational methods, or by the performance of a suitable testing program. […] Design control measures shall be applied to items such as the […] delineation of acceptance criteria for inspections and tests.*
>
> *Design changes, including field changes, shall be subject to design control measures commensurate with those applied to the original design and be approved by the organization that performed the original design unless the applicant designates another responsible organization.*

DNPS established Quality Assurance Topical Report (QATR) in accordance with 10 CFR 50, Appendix B, Criterion II, "Quality Assurance Program," to implement their Quality Assurance Program. The QATR is their highest tiered document, describes their method for complying with the requirements of Appendix B to 10 CFR 50, and is required by Criterion II to be carried out throughout the life of the plant. Chapter 3, "Design Control," of the QATR stated, in part:

> *Any unverified portion of the design shall be identified and controlled. In all cases the design verification shall be completed prior to relying upon the SSC […]*
>
> *Changes to final designs, field changes, modifications to operating facilities, and nonconforming items dispositioned use-as-is or repair shall be justified and subject to design control measures commensurate with those applied to the original design. These measures shall include assurance that the design analyses for the SSCs are still valid.*

In accordance with the excerpts quoted above from Criterion III and the corresponding QATR chapter, the licensee was required to employ design control measures to verify the adequacy of the safety-related ECCS design. This included the verification of any design assumption related to ECCS SR instrument uncertainty, given their choice to incorporate these uncertainties into their design.

It is important to note that uncertainties from multiple sources have a cumulative effect on margin reduction. While NUREG-0138 explained that the original design safety analysis methodology contained sufficient margin to account for TS trip setpoint uncertainty, it did not discuss factors like additional uncertainty associated with SR instruments. Assuming the safety margin allocated for TS trip setpoint instruments was large enough to also account for

the effect of SR instruments was an unverified assumption. This unverified assumption about their design was not identified and controlled, which was contrary to their QATR.

In addition, Criterion III and the associated QATR chapter required design control measures be applied to design changes to assure that the design analyses for the SSCs remain valid. This included verifying any design assumption relative to ECCS SR instrument uncertainty if incorporated into their modified ECCS evaluation. Licensee procedure CC-AA-103-2001 reflected this requirement when it stated, “If the design of the system is changed where these [SR limit] values could be affected, then evaluation is required to ensure that the inherent conservatism and margin are maintained.” The implementation of this procedure is required by 10 CFR 50, Appendix B, Criterion V, “Instructions, Procedures, and Drawings.” However, the licensee did not review the impact of facility modifications, such as fuel design changes, to the assumption that design margin accounted for SR instrument uncertainty, even when those changes resulted in reduced margin.

Additionally, 10 CFR Part 50, Appendix B, Criterion XI, “Test Control,” requires, in part, that a test program be established to assure that all testing required to demonstrate that SSCs will perform satisfactorily in service is identified. SR 3.1.5.6 was required by TS to demonstrate that the HPCI pump can develop a flow rate greater than or equal to the value used as a design input to their ECCS evaluation against a system head corresponding to reactor pressure. To implement this SR, the licensee established procedure DOS 2300-03. The test contained therein assumed that sufficient margin had already been incorporated in the selection of the test acceptance criteria, as stated by procedure C-AA-103-2001. However, since this was an unverified design assumption, the test was not assured to detect unsatisfactory pump performance.

3. <u>Instrument Uncertainty in Appendix K Evaluation Models</u>

During interviews conducted by the NRC staff reviewing this disputed violation, the licensee clarified that their position that SR instrument uncertainty was inherently accounted for in the conservatisms of their ECCS evaluation was also based on 10 CFR 50.46. The licensee described their position on the conservatisms of the Appendix K model in their denial letter. According to 10 CFR 50.46(a)(1)(i):

> ***Except as provided in paragraph (a)(1)(ii) of this section****, the evaluation model must include sufficient supporting justification to show that the analytical technique realistically describes the behavior of the reactor system during a loss-of-coolant accident.* ***Comparisons to applicable experimental data must be made and uncertainties in the analysis method and inputs must be identified and assessed so that the uncertainty in the calculated results can be estimated [emphasis added]****. This uncertainty must be accounted for, so that, when the calculated ECCS cooling performance is compared to the criteria set forth in paragraph (b) of this section, there is a high level of probability that the criteria would not be exceeded.*

Paragraph (a)(1)(ii) stated that:

> *Alternatively, an ECCS evaluation model may be developed in conformance with the required and acceptable features of Appendix K ECCS Evaluation Models.*

Opting to develop an ECCS model in accordance with Paragraph (a)(1)(ii) of 10 CFR 50.46 (aka, Appendix K method), the licensee concluded that 10 CFR 50.46 made an exception for them from accounting for SR instrument uncertainty. However, the uncertainties stipulated by 10 CFR 50.46 were not directed towards SR instrumentation. Regulatory Guide 1.157, titled

"Best-Estimate Calculations of ECCS Performance," clarified that, in this context, "uncertainty" referred to calculational uncertainty, addressing factors such as the lack of precision in predicting full-scale plant responses, encompassing individual model inaccuracies, experimental data uncertainties, and the impact of simplifying assumptions. The RG, in its discussion of acceptable methods for estimating uncertainty, limited its reference to calibration errors exclusively in the context of validating the analytical model by comparing its results against experimental data.

Nevertheless, regardless of this interpretation, the cited exception applied solely to the evaluation model and did not absolve the licensee from complying with QATR and 10 CFR 50 Appendix B requirements, which are applicable to all activities affecting quality. This was supported by 10 CFR 50.46 itself; specifically, Paragraph (d) stated:

> *The requirements of this section are in addition to any other requirements applicable to ECCS set forth in this part [i.e., 10 CFR 50].*

The licensee captured the CAQ associated with the 2020 NCV in their Corrective Action Program as AR4331189. This AR highlighted concerns about how HPCI SR 3.1.5.6 instrument uncertainty is accounted for in the overall design safety analysis or other activity. To address this CAQ, the licensee performed CAPE 4331189-07, which included a sensitivity analysis. The CAPE stated that the sensitivity analysis aimed to illustrate the magnitude of margin when removing the conservatisms of the Appendix K method. The licensee applied this analysis in an attempt to demonstrate that sufficient margin would still be available if ECCS flow was reduced to compensate for instrument uncertainty. Per CAPE 4331189-07, the objective was to “provide a basis to not include instrument uncertainty in ECCS surveillance acceptance criteria.”

However, the sensitivity study removed conservatisms and margin required by Appendix K to 10 CFR 50 to address other uncertainties, such as power level instrumentation uncertainty. Once again, the licensee accounted for SR instrument uncertainty by crediting existing margin, already in use to address other relevant factors. As a result, the sensitivity study did not correct the CAQ associated with the 2020 NCV. For example, their practice used a power level margin value lower than required by Appendix K and allocated the difference to ECCS flow SR instrument uncertainty. Appendix K explicitly regulates this practice by stating:

> *An assumed power level lower than the level specified in this paragraph (but not less than the licensed power level) may be used provided the proposed alternative value has been demonstrated to account for uncertainties due to power level instrumentation error.*

However, when the sensitivity analysis reduced the power level specified by Appendix K to a value equal to the licensed power level (i.e., zero margin for power level instrument uncertainty), it did not demonstrate this alternative value accounted for uncertainties due to power level instrument error.

Additionally, the licensee did not review the sensitivity study performed by their vendor. Specifically, the licensee only obtained a summary report that did not include the inputs, assumptions, and methodology used by their vendor. Thus, the summary report did not include the information necessary to perform the design verification required by their QATR. In addition to the QATR requirements stated above, the QATR stated:

> *The design input shall be specified […] and be to the level of detail necessary to provide a consistent basis for making design decisions, accomplishing design verification, and evaluating design changes.*

[Design analyses] shall be sufficiently detailed as to purpose, method, assumptions, design input, references, and units such that a person technically qualified in the subject can review, understand the analysis, and verify the adequacy of the results without recourse to the originator.

Thus, the sensitivity study, developed with the purpose of verifying the "nominal value plant" assumption, was also not verified in accordance with the licensee's QATR.

4. Previous NRC Involvement

In its response letter, the licensee asserted that the NRC had not previously challenged the ECCS SR limit as non-conservative due to measurement uncertainty. They referenced an unresolved item from a 1998 inspection report for Quad Cities Nuclear Power Station, Units 1 and 2 (ML20247E545), addressing a similar concern related to ECCS instrument uncertainty. The licensee suggested that the closure of this item in 1999 (ML20210M469 and ML20210M482) to a subsequent NRC staff follow-up that apparently did not occur, indicated a lack of NRC concerns regarding the treatment of ECCS uncertainties at Quad Cities.

However, this interpretation conflicts with NUREG-1409, "Backfitting Guidelines" (ML032230247), which states that NRC staff positions include "documented explicit interpretations of more general regulations," in addition to legal requirements and written licensee commitments. Therefore, the absence of a written staff position does not imply a conclusive decision.

Additionally, discussions and correspondence between DNPS and the NRC addressed ECCS flow SR instrument uncertainty since the late-1990s. This dialogue occurred in the context of license amendment requests for fuel design changes and extended power uprates. For example, in a letter dated March 21, 1997, titled "JSPLTR #97-0059, DNPS Units 2 and 3 Evaluation of Methods to Address ECCS Flow and Pressure Measurement Uncertainties NRC Docket Nos. 50-237 and 50-249" (ML17187A875), the licensee presented outcomes of their evaluation on addressing SR measurement uncertainties related to ECCS pump flow and pressure. The licensee committed to reduce the ECCS flow input to their ECCS evaluation model to account for the SR instrument uncertainty. The licensee later withdrew this commitment in a letter dated March 1, 2001, titled "RS-01-033, Supplement to GE-14 Fuel License Amendment Request" (ML010670137). They stated that the vendor's methodology for the new fuel design explicitly called for using TS pump flow values from the ECCS evaluation model without uncertainty adjustments.

During this review, the NRC staff did not find a documented NRC record addressing the assessment of this commitment change since the effort focused on the fuel design change. However, the NRC staff noted that the commitment change did not explicitly state the licensee's intent to assume instrument uncertainties were inherently considered in the vendor's methodology without verifying it.

It is important to note that the withdrawal of the commitment was related to a specific method of addressing uncertainties rather than a denial of any regulatory obligation to address uncertainties in any manner. A fuel vendor's request for a value excluding uncertainty does not override the requirement for utilities holding an operating license to ensure the quality of their safety-related activities.

Another example highlighting challenges from the NRC regarding the integration of ECCS SR instrument uncertainty was illustrated through an internal licensee letter, titled "Instrument Uncertainties Matrix," dated September 1, 1998. In this letter, the licensee's corporate office

attached a matrix for each fleet station, detailing "how instrument uncertainties will be incorporated into the plant design and documents." The document explicitly mentioned that these matrices “were developed to document positions taken during the recent NRC audits/reviews.” Concerning DNPS ECCS uncertainties, the matrix indicated that the action was completed after a vendor performed an Appendix K study. Although the licensee could not retrieve this study during the review of the disputed violations, it was noted that the matrix was created after DNPS committed to reducing the ECCS flow input to their ECCS evaluation model to address the SR instrument uncertainty and before withdrawing that commitment.

Lastly, a historical review since the 2000s revealed multiple violations issued to different nuclear power plants for not incorporating SR instrument uncertainty, including a Notice of Violation (NOV) issued to Braidwood in 2001 (ML013510487). An NRC staff position consistent with the position documented in this enclosure was documented in NRC letters titled “Task Interface Agreement (TIA) Evaluation Regarding Instrument Accuracy Affecting Millstone Unit 2,” dated July 22, 1996, (ML020360198) and “TIA Response: Accounting for Instrument Uncertainties in Surveillance Testing Accepting Criteria,” dated November 13, 1998. These TIAs were determined to be applicable to and served as a basis for the NOV.

5. Evaluation of Original Enforcement Decisions

The original 2020 NCV premise was valid, but the supporting statements, particularly those starting with “Specifically,” did not clearly link the licensee’s actions to the requirement language. This lack of clarity may have contributed to the licensee believing the inspectors were imposing a view that the cited requirement prescribed a specific method for achieving compliance. Consequently, this review recommends modifying the 2020 NCV to improve its clarity.

Similarly, the original 2023 NCV premise was valid because a correct CAQ was identified and captured in the licensee’s corrective action program in 2020. However, the supporting NCV statements did not clearly connect the licensee’s actions to the requirement language. This was exacerbated by referring to the 2020 NCV as the CAQ instead of the problem statement documented in the licensee’s corrective action program in 2020. Additionally, unclear supporting statements derived from the 2020 NCV were included. The cumulative effect was an increased lack of clarity that may reinforce the perception of a prescribed method for restoring compliance. Consequently, this review also recommends modifying the 2023 NCV to enhance its clarity.