April 16, 2004

- LICENSEE: Duke Energy Corporation
- FACILITY: Catawba Nuclear Station, Units 1 and 2, McGuire Nuclear Station, Units 1 and 2, and Oconee Nuclear Station, Units 1, 2, and 3
- SUBJECT: SUMMARY MEETING WITH DUKE ENERGY CORPORATION ON REQUEST TO MODIFY THE QUALITY ASSURANCE PROGRAM FOR THE CATAWBA, MCGUIRE, AND OCONEE NUCLEAR STATIONS (TAC NOS. MB7166, MB7167, MB7168, MB7169, MB7170, MB7171, AND MB7172)

Representatives of Duke Energy Corporation (DEC, the licensee), met with members of the Nuclear Regulatory Commission (NRC) staff at NRC Headquarters on April 8, 2004, in Rockville, Maryland. The meeting addressed issues related to the licensee's application dated December 18, 2002 (Reference 1), as supplemented by letters dated April 24 and October 16, 2003 (References 2 and 3), for Catawba Nuclear Station, Units 1 and 2, McGuire Nuclear Station, Units 1 and 2, and Oconee Nuclear Station Units 1, 2, and 3. In its application, the licensee requested approval of Amendment 32 to the DEC Topical Report Duke-1-A, "Quality Assurance Program." A list of attendees is provided in Attachment 1 and the handouts provided in the meeting are included in Attachment 2.

BACKGROUND

By letter dated December 18, 2002, the licensee forwarded Amendment 32 to DEC Topical Report Duke-1-A. This amendment included organizational, administrative, and editorial changes to the topical report. Furthermore, the amendment eliminates holdpoint inspections for routine maintenance activities by substituting an indirect monitoring process. In DEC's evaluation of the proposed changes, the licensee determined that the elimination of the holdpoint inspections for routine maintenance would constitute a reduction in commitment. Discussions with DEC have indicated that the implementation of the proposed change would result in a reduction of holdpoint inspections for routine maintenance programs are controlled by the change process defined under Title 10 of *The Code of Federal Regulations* (10 CFR) Part 50.54(a). As stated in 10 CFR 50.54(a)(4), changes that constitute reductions in commitments must be submitted to the NRC staff for approval prior to implementation.

However, 10 CFR 50.54(a)(3)(ii) permits licensees to implement alternatives or exceptions approved by an NRC Safety Evaluation without prior NRC staff approval. As a consequence of this provision, implemented in 1999, the NRC staff notes an increasing number of submittals with generic industry implications. Because of the possible generic implications, the NRC staff must ensure that the bases for these changes are adequately documented and properly justified.

Upon review of the licensee's submittal, by letter dated April 4, 2003 (Reference 4), the NRC staff requested additional information. The questions raised by the NRC staff mostly covered the classification of routine maintenance and holdpoints and the implementation of the

proposed program. DEC responded to the questions by letter dated April 24, 2003. However, by letter dated July 10, 2003 (Reference 5), the NRC staff informed the licensee that the submittal to date had not adequately or clearly described the scope of activities to which the proposed alternative would apply. Furthermore, the NRC staff determined that the description of the monitoring process was neither specific nor robust enough to demonstrate that process monitoring would maintain a level of control comparable to holdpoint inspections. Therefore, the NRC staff requested further clarification regarding the scope of activities to which process monitoring would be applied, a description of the elements of the selection process, and a description of the proposed monitoring process. The licensee responded to the NRC staff's questions by letter dated October 16, 2003. However, the NRC staff determined that this response was also inadequate to support approval of Amendment 32.

In order to facilitate continued review of this application, the licensee requested a meeting with the NRC to present their proposal. This meeting was held on April 8, 2004, at NRC Headquarters in Rockville, Maryland.

SUMMARY OF MEETING

DEC's presentation utilized the enclosed handouts entitled, "Discussion of Duke Energy QA Topical Report Amendment 32" (Enclosure 2). This presentation provided a brief overview of the DEC quality assurance program, including the documents used to manage the program. From this foundation, DEC established how the proposed changes to the topical report would affect the overall quality assurance processes, the maintenance quality process monitoring steps, and the required training and duties of the quality assurance staff. Following the conclusion of the licensee's presentation, the NRC staff identified the areas that were of concern with regards to DEC's submittals. These concerns included the following:

1. Background/Regulatory Basis

The licensee's application should provide additional background supporting the requested changes, including the original basis for establishing holdpoints. Applicable consensus standards and regulatory guides should be cited. The current methodology for establishing holdpoints should be discussed. A description of how the proposed process differs from the current process should be provided. Furthermore, DEC should classify whether this difference constitutes a clarification, alternative, or exception to the current regulatory commitments.

Additionally, the need for mandatory inspection holdpoints is established by 10 CFR Part 50, Appendix B, Criterion X, "Inspection." DEC should specifically address how the proposed process meets the requirements of Criterion X.

2. Holdpoints

The licensee must clearly define holdpoints. DEC must also define when holdpoints are needed, what the current required qualifications are for individuals establishing holdpoints, and what the current required qualifications are for individuals performing holdpoint inspections.

Assuming that a holdpoint is required when an independent, in-process inspection is needed to verify that critical activities are completed satisfactorily, it is not clear that the definition would apply to modifications, replacement, or repair activities. The submittal should discuss why the

holdpoint definition is not applicable to routine maintenance activities to the extent that it is applicable to non-routine maintenance or modification activities. Also, DEC should discuss why the margin of safety is not reduced when the number of holdpoints is reduced by approximately 75 percent.

Furthermore, the submittal places the responsibility for establishing holdpoints on work planners. Currently, this responsibility resides within the Quality Assurance organization. The knowledge level of work planners with regard to holdpoints may not be equivalent to experienced quality control personnel and may not be adequate. The submittal should provide justification for placing this responsibility in the planning organization.

3. Determination of What Activities Constitute Routine Maintenance

10 CFR 50.54(a)(3) allows licensees to adopt alternatives or exceptions approved by an NRC safety evaluation, provided that the bases of the NRC approval are applicable to the licensee's facility. The process for determining whether a maintenance work activity is "routine" should be described at a level of detail that the Safety Evaluation can document the bases of approval.

The information provided in the licensee's letter dated October 16, 2003, provided examples of maintenance activities that the process would categorize as routine. Using the process description that the licensee has provided to date, the NRC staff could not arrive at the same conclusion that all of these items are routine. The process for categorizing maintenance activities as routine should include such factors as:

- critical attributes of the activity,
- complexity,
- frequency,
- inspection requirements of applicable technical standards and vendors,
- verifiability of adequacy through post-maintenance testing or inspection, and
- qualification/experience of individual(s) performing the activity.

4. Process Monitoring

The submittal refers to process monitoring to determine process effectiveness, without describing the monitoring process. A description of process monitoring should be included in the submittal, which addresses the following factors as a minimum:

- The monitoring process,
- Performance Indicators,
- Acceptance criteria for determining effectiveness,
- Frequency of monitoring,

- Methods for determining which activities to monitor (For example, is the method based on random sampling, risk significance, personnel expertise?),

- The audit/assessment process for determining the adequacy of determinations made by work planning (Determinations of what maintenance activities are routine appears to be subjective.), and

- The corrective action process for resolving process deficiencies, evaluation of extent of condition, verification that corrective actions have been effective.

5. Quality Assurance Topical Description

The quality assurance topical should describe the essential elements of holdpoint process, subject to the change control provisions of 10 CFR 50.54(a). Significant process attributes, such as holdpoint determinations, performance monitoring, and oversight by the quality assurance/control organization should be described. Process terminology, such as "holdpoint", "non-routine, complex, and critical" maintenance activities, should be defined; personnel qualifications and/or training necessary for personnel implementing the process should be addressed.

Details of the process description and implementation not subject to the change control requirements of 10 CFR 50.54 may be incorporated into lower tier procedures. However, the NRC staff may request copies of these lower tier procedures as part of its review of the proposed holdpoint process.

6. Independence of Inspection Personnel

The licensee's topical report states that the quality assurance program places responsibility on line management for achieving and assuring quality. Placing responsibility for holdpoint inspections on work planners/maintenance personnel may not satisfy the Appendix B requirement for independence. For the activities assigned to these personnel, the submittal should address qualification requirements, such as knowledge and experience levels, and how assigned personnel meet these requirements. The submittal should also describe how the quality assurance personnel, independent of cost and schedule, provide independent oversight of the process. Furthermore, the submittal should address how defense-in depth is maintained by the proposed changes, i.e., how the separation of the functions of the workers, supervisors, and quality control personnel are not reduced by the proposed changes.

7. Other Considerations

The submittal should address the process for acceptance of procured items for post-installation testing, and it should address how quality control personnel would identify problems and the criteria for dispositioning items as QC (Hold) or QC (Release).

CONCLUSION

At the conclusion of the meeting, the licensee indicated that it would consider the information gained and would submit a revised application for approval of Amendment 32 to Duke Topical Report Duke-1-A, that would supersede all of the previous submittals.

No members of the public attended this meeting. There were no public comments.

REFERENCES

1. Letter from Michael S. Tuckman, Executive Vice President, Nuclear Generation, Duke Power to NRC, "Nuclear Quality Assurance Program Amendment 32," December 18, 2002.

- 2. Letter from W. R. McCollum, Senior Vice President, Nuclear Support, Duke Energy Corporation to NRC, "Duke Energy Topical Report, Duke-1-A, Amendment 32 Response to Request for Additional Information Letter Dated April 4, 2003," April 24, 2003.
- Letter from W. R. McCollum, Senior Vice President, Nuclear Support, Duke Energy Corporation to NRC, "Duke Energy Topical Report, Duke-1-A, Amendment 32 Response to Request for Additional Information Letter Dated July 10, 2003," October 16, 2003.
- 4. Letter from Robert E. Martin, Senior Project Manager, NRC to Michael S. Tuckman, Executive Vice President, Duke Energy Corporation, "Duke Energy Corporation Nuclear Quality Assurance Program Request for Additional Information," April 4, 2003.
- Letter from Robert E. Martin, Senior Project Manager, NRC to M. S. Tuckman, Executive Vice President, Duke Energy Corporation, "Catawba Nuclear Station, Units 1 and 2, McGuire Nuclear Station, Units 1 and 2 and Oconee Nuclear Station, Units 1, 2 and 3 Re: Nuclear Quality Assurance Program, Amendment 32 (TAC Nos. MB7166, MB7167, MB7168, MB7169, MB7170, MB7171 and MB7172)," July 10, 2003.

Sincerely,

/RA/

Sean E. Peters, Project Manager, Section 1 Project Directorate II Division of Licensing Project Management Office of Nuclear Reactor Regulation

Docket Nos. 50-413, 50-414, 50-369, 50-370, 50-269, 50-270, and 50-287

Attachments: 1. Attendance List 2. Meeting presentation materials

cc w/atts: See next page

- 2. Letter from W. R. McCollum, Senior Vice President, Nuclear Support, Duke Energy Corporation to NRC, "Duke Energy Topical Report, Duke-1-A, Amendment 32 Response to Request for Additional Information Letter Dated April 4, 2003," April 24, 2003.
- Letter from W. R. McCollum, Senior Vice President, Nuclear Support, Duke Energy Corporation to NRC, "Duke Energy Topical Report, Duke-1-A, Amendment 32 Response to Request for Additional Information Letter Dated July 10, 2003," October 16, 2003.
- 4. Letter from Robert E. Martin, Senior Project Manager, NRC to Michael S. Tuckman, Executive Vice President, Duke Energy Corporation, "Duke Energy Corporation Nuclear Quality Assurance Program Request for Additional Information," April 4, 2003.
- Letter from Robert E. Martin, Senior Project Manager, NRC to M. S. Tuckman, Executive Vice President, Duke Energy Corporation, "Catawba Nuclear Station, Units 1 and 2, McGuire Nuclear Station, Units 1 and 2 and Oconee Nuclear Station, Units 1, 2 and 3 Re: Nuclear Quality Assurance Program, Amendment 32 (TAC Nos. MB7166, MB7167, MB7168, MB7169, MB7170, MB7171 and MB7172)," July 10, 2003.

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Sean E. Peters, Project Manager, Section 1 Project Directorate II Division of Licensing Project Management Office of Nuclear Reactor Regulation

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Mr. Peter R. Harden, IV VP-Customer Relations and Sales Westinghouse Electric Company 6000 Fairview Road 12th Floor Charlotte, North Carolina 28210 DISTRIBUTION FOR - SUMMARY - MEETING WITH DUKE ENERGY CORPORATION ON REQUEST TO MODIFY THE QUALITY ASSURANCE PROGRAM FOR THE CATAWBA, MCGUIRE, AND OCONEE NUCLEAR STATIONS (TAC NOS. MB7166, MB7167, MB7168, MB7169, MB7170, MB7171, MB7172)

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