



January 12, 2024
NRC-24-0007

10 CFR 71.106

Director, Division of Spent Fuel Management
Office of Nuclear Material Safety and Safeguards
U.S. Nuclear Regulatory Commission
Attention: Document Control Desk
Washington, DC 20555-0001

Fermi 1 Power Plant
NRC Docket No. 50-16 and 71-0526
NRC License No. DPR-9

Fermi 2 Power Plant
NRC Docket No. 50-341 and 71-0526
NRC License No. NPF-43

Subject: Report of Changes to Quality Assurance Program for Radioactive Material
Packages

- References:
- 1) Letter from NRC to DTE, "Revised Quality Assurance Program Approval Form for Radioactive Material Packages No. 0526, Revision 6," dated August 28, 2015 (ML15244A004)
 - 2) DTE Letter NRC-21-0046, "Report of Changes to Quality Assurance Program for Radioactive Material Packages," dated August 27, 2021 (ML21239A069)
 - 3) DTE Letter NRC-22-0042, "Submittal of Revision 24 to the Fermi 2 Updated Final Safety Analysis Report (UFSAR), 10 CFR 50.59 and 10 CFR 72.48 Evaluation Summary Reports, Commitment Management Report, Revisions to the Technical Requirements Manual and the Technical Specifications Bases, and a Summary of the Excessive Detail Removed from the UFSAR," dated November 9, 2022 (ML22313A187)
 - 4) DTE Letter NRC-22-0052, "Replacement Files for Submittal of Revision 24 to the Fermi 2 Updated Final Safety Analysis Report (UFSAR) through EIE on November 9, 2022," dated November 17, 2022 (ML22325A158)
 - 5) DTE Letter NRC-09-0072, "Renewal of Quality Assurance Program Approval for Radioactive Material Packages," dated October 29, 2009 (ML093100305)
 - 6) DTE Letter NRC-22-0046, "Submittal of Biennial Review of the Fermi 1 Safety Analysis Report," dated November 14, 2022 (ML22319A151)

In accordance with the requirements of Title 10 of the Code of Federal Regulations (10 CFR) 71.106(b), DTE Electric Company (DTE), is submitting a 24-month update of changes made to approved Radioactive Material Packages Quality Assurance Program No. 0526. This report was due on August 28, 2023; however, DTE failed to submit a letter to the NRC documenting that review. This condition was entered into the Fermi Corrective Action Program on December 5, 2023. In Reference 1, the NRC transmitted a revised 10 CFR Part 71 Quality Assurance Program Approval for Radioactive Material Packages (i.e., NRC Form 311, Approval No. 0526, Revision 6) for activities conducted at DTE's Fermi 1 and Fermi 2. The regulations in 10 CFR 71.106 require that changes to the approved Quality Assurance Program that do not reduce commitments must be submitted to the NRC every 24-months, with the reporting period starting on the date the revised NRC Form 311 was approved (i.e., August 28, 2015).

Changes made to the Radioactive Material Packages Quality Assurance Program in the previous reporting period were submitted under Reference 2.

This letter provides a report of changes made to the Radioactive Material Packages Quality Assurance Program that do not reduce commitments for the 24-month period of August 28, 2021 through August 27, 2023.

In References 3 and 4, DTE submitted Revision 24 of the Fermi 2 Updated Final Safety Analysis Report (UFSAR). As identified in Reference 5, the 10 CFR 50, Appendix B, Quality Assurance Program documented in Section 17.2 of the Fermi 2 UFSAR is utilized to satisfy the Quality Assurance requirements of 10 CFR 71. A summary of the changes included in Revision 24 of Chapter 17 of the UFSAR, but that were not already summarized in the Reference 2 report, is provided below:

- Minor administrative improvements, renumbering, clarifications, spelling corrections, and editorial items were made. These types of changes are not a reduction in commitment of the Quality Assurance Program consistent with the examples in 10 CFR 71.106(b).
- The responsibility of the Employee Concerns Program is relocated from the Director – Nuclear Oversight to the Senior Vice President and Chief Nuclear Officer. This change was not a reduction in commitment of the Quality Assurance Program consistent with the example in 10 CFR 71.106(b)(5).
- The reporting structure of the Radiological Emergency Response Preparedness (RERP) group is changed to report up through the Licensing Manager then to the Vice President Engineering & Technical Support rather than reporting directly to the Vice President Engineering & Technical Support. This change was not a reduction in commitment of the Quality Assurance Program consistent with the example in 10 CFR 71.106(b)(5).

- The position of Manager - Chemistry is merged with the position of Manager - Radiation Protection (RP), such that a single individual manages both groups. There are no changes to the roles and responsibilities of the Chemistry or RP groups. As a result, this change can be considered an organizational revision. This change was not a reduction in commitment of the Quality Assurance Program consistent with the example in 10 CFR 71.106(b)(5).
- The reporting structure of the site's Environmental group is changed from the Manager – Nuclear Licensing to the Manager – Chemistry. This change transfers the non-radiological environmental monitoring responsibilities to the Manager – Chemistry. There are no changes to the roles and responsibilities of the Environmental group; therefore, this change is considered an organizational revision. This change was not a reduction in commitment of the Quality Assurance Program consistent with the example in 10 CFR 71.106(b)(5).
- A new position for the Assistant Plant Manager was created. This new position is responsible for managing a portion of the Nuclear Production organization. Specifically, the areas of Radiation Protection (RP), Chemistry, Industrial Health and Safety (IHS), and Human Performance (HP) are now split from the responsibility of the Executive Director – Nuclear Production and are now reporting to the Assistant Plant Manager. Note, this change is implemented in a manner such that the option still exists for the Executive Director – Nuclear Production and the Assistant Plant Manager positions to be combined if needed or desired in the future. There are no changes in the roles and responsibilities of the RP, Chemistry, IHS or HP and the additional position causes no hinderance to ability of performing the functions. This change was not a reduction in commitment of the Quality Assurance Program consistent with the example in 10 CFR 71.106(b)(5).
- Revisions were made permitting of the procurement of calibration and/or testing services from domestic and international laboratories accredited to ISO/IEC 17025:2017. This is due to NRC Safety Evaluation Report endorsement (ML20322A019) of NEI 14-05A Revision 1 which recognized ISO/IEC 10725:2017 as the basis for the International Laboratory Accreditation Cooperation (ILAC) accreditation process. This change was not a reduction in commitment of the Quality Assurance Program consistent with the example in 10 CFR 71.106(b)(1).
- Revisions were made adding nondestructive testing as an area to be reviewed by the Nuclear Safety Review Group to align with ANSI N18.7-1976. This change was not a reduction in commitment of the Quality Assurance Program consistent with the example in 10 CFR 71.106(b)(1).

DTE has made the following additional changes to the Fermi 2 Quality Assurance Program (Chapter 17 of the UFSAR) since the submittal of UFSAR Revision 24 in References 3 and 4.

- Added Medical Review Officer and substance abuse expert (which are contractors/vendors) to the list of internal nuclear generation areas to be audited. Adding the new audited area clarifies 10 CFR 26 and 10 CFR 73 tied to the 12-month auditing frequency of these contractors/vendors. This change is considered a clarification and is not a reduction in commitment of the Quality Assurance Program consistent with the example in 10 CFR 71.106(b).
- Revision was made changing the reporting structure for the Manager - Chemistry moved under the Director – Operations. This change also unmerged the position of Manager - Chemistry with the position of Manager - Radiation Protection (RP) that was added in Revision 24 of References 3 and 4. As a result, this change can be considered an organizational revision. This change was not a reduction in commitment of the Quality Assurance Program consistent with the example in 10 CFR 71.106(b)(5).
- Restructuring of the Engineering organization to enhance effectiveness has resulted in the elimination of a manager position and transfer of group responsibility to other Manager positions. The following changes are (1) removed position of "Manager - Nuclear Tactical Engineering", (2) transferred responsibility of Procurement Engineering to Manager - Nuclear Design Engineering, and (3) transferred responsibility of Engineering Response Team to Manager - Nuclear Strategic Engineering. Under the current UFSAR, Manager - Nuclear Tactical Engineering, Manager - Nuclear Strategic Engineering, and the Manager - Nuclear Design Engineering report directly to the Director - Nuclear Engineering. Thus, the removal of the Manager - Nuclear Tactical Engineering and transfer of responsibility for the Engineering Response Team to the Manager - Nuclear Strategic Engineering and Procurement Engineering to the Manager - Nuclear Design Engineering does not affect the requisite authority and organizational freedom for those functions. This change was not a reduction in commitment of the Quality Assurance Program consistent with the example in 10 CFR 71.106(b)(5).
- Added 2011 NIRMA technical guidelines to provide supplemental guidance to ANSI N45.2.9-1974, Regulatory Guide 1.88 Revision 2. 2011 NIRMA standards for electronic records were previously approved by an NRC safety evaluation for Duke Energy Carolinas, LLC (ML15099A561). This change has minor safety significance and is not a reduction in commitment of the Quality Assurance Program consistent with the example in 10 CFR 71.106(b)(1).

For Fermi 1, the Radioactive Material Packages Quality Assurance Program is implemented through Fermi 2 UFSAR Chapter 17 and Fermi 1 Safety Analysis Report (F1SAR) Sections 6.2 and 6.5. Reference 6 identifies no changes in the previous 24 months to either Sections 6.2 or 6.5 of the F1SAR. In addition, no changes to the F1SAR have been made since the Reference 6 submittal.

As indicated above, these changes did not reduce the commitment in the Radioactive Material Packages Quality Assurance Program.

No new commitments are being made in this submittal.

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Should you have any questions or require additional information, please contact me at (734) 586-4772.

Sincerely,

A handwritten signature in blue ink, appearing to read 'Eric Frank', with a stylized flourish at the end.

Eric Frank
Manager - Nuclear Licensing

cc: NRC Project Manager
NRC Resident Office
Regional Administrator, Region III