UNITED STATES
NUCLEAR REGULATORY COMMISSION
WASHINGTON, D.C. 20555-0001

May 16, 2022

Mr. Ken J. Peters
Senior Vice President and
Chief Nuclear Officer
Attention: Regulatory Affairs
Vistra Operations Company LLC
Comanche Peak Nuclear Power Plant
6322 N FM 56
P.O. Box 1002
Glen Rose, TX 76043

SUBJECT: COMANCHE PEAK NUCLEAR POWER PLANT, UNIT NOS. 1 AND 2 – REVIEW OF QUALITY ASSURANCE PROGRAM CHANGES (EPID L-2021-LLQ-0003)

Dear Mr. Peters:

By letter dated August 24, 2021 (Agencywide Documents Access and Management System (ADAMS) Accession No. ML21236A291), Vistra Operations Company, LLC (Vistra OpCo, the licensee) requested U.S. Nuclear Regulatory Commission (NRC) approval of changes to the Quality Assurance Program (QAP) for Comanche Peak Nuclear Power Plant, Unit Nos. 1 and 2 (Comanche Peak), as described in chapter 17 of the Comanche Peak Final Safety Analysis Report and in accordance with Title 10 of the *Code of Federal Regulations* (10 CFR) Section 50.54(a)(4). Vistra OpCo determined that the changes in the audit intervals are reductions in commitment and require prior NRC approval to implement pursuant to 10 CFR 50.54(a).

Specifically, Vistra OpCo requested NRC approval to increase the internal audit interval from 24 months to 36 months for certain audit topics. The increased period between audits will be supplemented by an interim analysis or evaluation of functional area performance. The requested changes are for Comanche Peak and the colocated independent spent fuel storage installation (ISFSI).

The NRC staff reviewed Vistra OpCo's requested changes to its QAP, as documented in the enclosed safety evaluation, and finds that Vistra OpCo will continue to comply with the requirements of Criterion XVIII, "Audits" of appendix B, "Quality Assurance Criteria for Nuclear Power Plants and Fuel Reprocessing Plants," to 10 CFR Part 50, "Domestic Licensing of Production and Utilization Facilities; and Subpart G, "Quality Assurance," to 10 CFR Part 72, "Licensing Requirements for the Independent Storage of Spent Nuclear Fuel, High-Level Radioactive Waste, and Reactor-Related Greater than Class C Waste." Therefore, the NRC staff concluded that the requested changes to the Vistra OpCo QAP are acceptable. The requested changes in Vistra OpCo's application are hereby approved for Comanche Peak and the colocated ISFSI.

If you have any questions, please contact the project manager, Dennis Galvin, at 301-415-6256 or by email at Dennis.Galvin@nrc.gov.

Sincerely,

Jennifer L. Dixon-Herrity

Digitally signed by Jennifer L. Dixon-Herrity
Date: 2022.05.16 13:31:19 -04'00'

Jennifer L. Dixon-Herrity, Chief
Plant Licensing Branch IV
Division of Operating Reactor Licensing
Office of Nuclear Reactor Regulation

Docket Nos. 50-445, 50-446, and 72-74

Enclosure:
Safety Evaluation

cc: Listserv

UNITED STATES
NUCLEAR REGULATORY COMMISSION
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SAFETY EVALUATION BY THE OFFICE OF NUCLEAR REACTOR REGULATION

REQUEST TO REVISE THE QUALITY ASSURANCE PROGRAM

VISTRA OPERATIONS COMPANY LLC

COMANCHE PEAK NUCLEAR POWER PLANT, UNITS NO. 1 AND 2

DOCKET NOS. 50-445, 50-446, and 72-74

1.0 INTRODUCTION

By letter dated August 24, 2021 (Agencywide Documents Access and Management System (ADAMS) Accession No. ML21236A291), Vistra Operations Company, LLC (Vistra OpCo, the licensee) requested U.S. Nuclear Regulatory Commission (NRC) approval of changes to the Quality Assurance Program (QAP) for Comanche Peak Nuclear Power Plant, Unit Nos. 1 and 2 (Comanche Peak), as described in chapter 17 of the Comanche Peak Final Safety Analysis Report (FSAR) and in accordance with Title 10 of the *Code of Federal Regulations* (10 CFR) Section 50.54(a)(4). Vistra OpCo determined that the changes in these audit intervals are reductions in commitment and require prior NRC approval to implement pursuant to 10 CFR 50.54(a).

Specifically, Vistra OpCo requested NRC approval to increase the internal audit interval from 24 months to 36 months for certain audit topics. The increased period between audits will be supplemented by an interim analysis or evaluation of functional area performance. The requested changes are for Comanche Peak and the colocated independent spent fuel storage installation (ISFSI).

2.0 REGULATORY EVALUATION

2.1 Description of Proposed Changes

Currently, Comanche Peak FSAR, chapter 17.2.18, “Audits” (ML20315A033), requires internal audits that are conducted or coordinated by nuclear oversight personnel to include evaluation and examination of the listed quality-related activities at least once per 24-months. This proposed change replaces the 24-month frequency requirement with a 36-month frequency requirement. The 25 percent grace period is maintained ensuring that the period between audit performance will not exceed 45 months. Comanche Peak FSAR chapter 17.2.18.2, “Nuclear Oversight,” is also revised to require an evaluation once per calendar year to determine the need for additional audit activities. Results of the evaluation will be assessed and, when necessary, a review of the identified areas of performance weaknesses will be planned at the earliest possible opportunity.

The change does not impact audits performed to meet specific regulations (e.g., physical security or emergency preparedness) or audits of suppliers. These audits will continue to be performed in accordance with the applicable requirements.

Regarding the internal audits of radiation protection activities, the specific areas that are impacted by the proposed change are the (1) training and qualification of entire staff, (2) radiological environmental monitoring program, (3) offsite dose calculation manual, and (4) the process control program for processing and packaging of radioactive wastes.

2.2 Regulatory Requirements and Guidance

Regulatory Requirements

The regulatory requirements for nuclear power plant QAPs are set forth in Appendix B, "Quality Assurance Criteria for Nuclear Power Plants and Fuel Reprocessing Plants," to 10 CFR Part 50, "Domestic Licensing of Production and Utilization Facilities"; 10 CFR 50.34(b)(6)(ii); and 10 CFR 50.54(a). The regulatory requirements for ISFSI QAPs are described in Subpart G, "Quality Assurance," to 10 CFR Part 72, "Licensing Requirements for the Independent Storage of Spent Nuclear Fuel, High-Level Radioactive Waste, and Reactor-Related Greater than Class C Waste." An NRC-approved QAP that complies with 10 CFR Part 50, appendix B, is acceptable for meeting the requirements in 10 CFR Part 72, Subpart G, except that the licensee shall also meet the recordkeeping requirements of 10 CFR 72.174, "Quality assurance records." Comanche Peak's request does not affect recordkeeping. The regulatory requirements for the periodic review of radiation protection programs are set forth in 10 CFR 20.1101(c)

Appendix B to 10 CFR Part 50 establishes the quality assurance requirements for the design, fabrication, construction, and testing of structures, systems, and components for nuclear power plants. Criterion XVIII, "Audits," of 10 CFR Part 50, appendix B, states, in part:

> A comprehensive system of planned and periodic audits to be carried out to verify compliance with all aspects of the quality assurance program and to determine the effectiveness of the program. The audits shall be performed in accordance with written procedures or check lists by appropriately trained personnel not having direct responsibilities in the areas being audited. Audit results shall be documented and reviewed by management having responsibility in the area audited. Followup action, including reaudit of deficient areas, shall be taken where indicated.

The audit requirements for ISFSIs in 10 CFR 72.176, "Audits," are equivalent to Criterion XVIII of 10 CFR Part 50, appendix B.

The regulations in 10 CFR 50.34(b)(6)(ii) require the FSAR for a nuclear power facility to include information on the managerial and administrative controls to be used to ensure safe operation. The information on the controls shall also include a discussion on how the applicable requirements of appendix B to 10 CFR Part 50 will be satisfied.

The regulations in 10 CFR 50.54(a)(1) require each nuclear power plant licensee subject to the requirements of 10 CFR Part 50, appendix B, to implement the QAP described or referenced in the safety analysis report, including changes to that report. Additionally, 10 CFR 50.54(a)(3) and (4) specifies the requirements for making changes to the QAP description. In accordance with 10 CFR 50.54(a)(4), changes to the QAP description that reduce commitments must be

submitted to the NRC and receive NRC approval prior to implementation. The submittal must include all pages affected by the change and must be accompanied by a forwarding letter identifying the change, the reason for the change, and the basis for concluding that the revised QAP incorporating the change continues to satisfy the criteria of 10 CFR Part 50, appendix B, and the QAP description commitments previously accepted by the NRC.

The regulations in 10 CFR 20.1101(c) require licensees to "periodically (at least annually) review the radiation protection program content and implementation." The answer to Question 118 in the Health Physics Questions and Answers[1] (Question 118) provides guidance to nuclear power plants on using a combination of reviews and audits to comply with 10 CFR 20.1101(c). Specifically, licensees can review multiple aspects of their radiation protection program such that all phases of the program are reviewed in a 2–3-year cycle.

Guidance

Regulatory Guide (RG) 1.28, Revision 5, "Quality Assurance Program Criteria (Design and Construction)," dated October 2017 (ML17207A293), describes, in part, methods acceptable to the NRC staff for complying with the provisions of 10 CFR Part 50, appendix B, for establishing and implementing a QAP for the design and construction of nuclear power plants. RG 1.28, Revision 5, endorses Part I and Part II of multiple revisions of the American Society of Mechanical Engineers (ASME) standard NQA-1, "Quality Assurance Requirements for Nuclear Facility Applications," including Part I of ASME NQA-1-2015, with clarifications and exceptions. Although RG 1.28, Revision 5, and ASME NQA-1-2015 are not currently applicable to Vistra OpCo facilities, as Vistra OpCo has not adopted, and is not proposing to adopt, ASME NQA-1-2015, these guidance documents were cited in the application to support the requested changes.

NUREG-0800, "Standard Review Plan for the Review of Safety Analysis Reports for Nuclear Power Plants: LWR [Light-Water Reactor] Edition" (the SRP), section 17.5, "Quality Assurance Program Description - Design Certification, Early Site Permit and New License Applicants," Revision 1, dated August 2015 (ML15037A441), provides guidelines for the review of QAP descriptions.

3.0 TECHNICAL EVALUATION

Internal Audits in General

In evaluating the adequacy of the proposed change, the NRC staff considered the guidance of SRP section 17.5 and ASME NQA-1–2015, as endorsed by RG 1.28, Revision 5. The guidance in ASME NQA-1–2015, requirement 18, section 200, requires that audits be scheduled in a manner to provide coverage and coordination with ongoing activities, based on the status and importance of the activity. The scheduled audits are to be supplemented by additional audits of specific subjects, when necessary, to provide adequate coverage. A grace period of 90 days may be applied to scheduled audits. Except where specific regulatory guidance exists or Code restrictions apply, organizations are to audit internal activities of all applicable QAP elements for each functional area within a period of 2 years. For well-established activities, the period may be

[1] The answer to Question 118 is available on the NRC's public Website at https://www.nrc.gov/about-nrc/radiation/protects-you/hppos/qa118.html. Additional information is available in NUREG-1736, "Consolidated Guidance: 10 CFR Part 20 - Standards for Protection Against Radiation," October 2001 (ML013330179).

extended 1 year at a time beyond the 2-year interval based on the results of an annual evaluation of the applicable functional area and objective evidence that the functional area activities are being satisfactorily accomplished. However, the internal audit interval is not to exceed a maximum of 4 years.

Vistra OpCo's proposed changes are consistent with the audit frequency changes evaluated in the NRC's safety evaluation for Exelon Generation Company, LLC (Exelon) (now Constellation Energy Corporation) regarding, "Review of Quality Assurance Program Changes (EPID L-2019-LLQ-0003)," dated November 5, 2020 (ML20287A130). The NRC staff has determined that the evaluation of the Exelon audit frequency change is specifically applicable to the proposed QAP change for Vistra OpCo facilities. The variations between the proposed changes and the NRC endorsed ASME NQA-1-2015 standard include setting the audit frequency to 36 months with a 25 percent grace period versus the 2-year frequency with a 1-year extension not to exceed 4 years. Vistra OpCo stated each functional audit area will receive an additional performance analysis or evaluation within 2 years of the last audit performed, based on internal and external data; functional area changes in responsibility, resources, or management; and consideration of the impacts, as applicable, to determine if additional audit activities are necessary prior to the 36-month scheduled performance.

Vistra OpCo has a well-established audit program, and except where other specific regulatory guidance exists, or Code restrictions apply to functional areas to be audited, may apply changes to its internal audit frequency as noted above. In addition, the NRC staff determined that Vistra OpCo's proposed changes in internal audit frequency is in alignment with current NRC staff guidance, and therefore, are acceptable. Internal audits, with changes in audit frequency, are to provide the same oversight, level of consistency, and reasonable assurance as before the changes to the audit frequency was implemented. Vistra OpCo will ensure follow-up actions, including reaudit of deficient areas, will be performed where indicated by the additional performance of an analysis or evaluation. Therefore, the NRC staff concludes that there is reasonable assurance that Vistra OpCo's proposed changes will continue to meet the requirements of 10 CFR 50.34(b)(6)(ii), 10 CFR 50.54(a), and Criterion XVIII of appendix B to 10 CFR 50 for Comanche Peak and the quality assurance requirements for ISFSIs in 10 CFR Part 72, Subpart G. Therefore, the NRC staff finds the proposed change to Vistra OpCo's internal audit frequency to be acceptable.

Internal Audits of Radiation Protection Activities

Vistra OpCo's proposed changes to the QAP includes a change to the internal audit of radiation protection activities. The specific areas that are impacted by this frequency change are the (1) training and qualification of entire staff, (2) radiological environmental monitoring program, (3) offsite dose calculation manual, and (4) the process control program for processing and packaging of radioactive wastes.

The regulations in 10 CFR 20.1101(c) require licensees to "periodically (at least annually) review the radiation protection program content and implementation." The annual program review of 10 CFR 20.1101(c), as clarified by Question 118, does not require that the program review be completed through the licensee's QAP. The answer to Question 118 clarified that these periodic reviews required by 10 CFR 20.1101(c) could be completed by radiation protection supervisory reviews and corporate or third-party audits, as well as periodic QAP audits. The answer to Question 118 also allows for up to a 3-year review cycle for review of various aspects of the radiation protection program. Vistra OpCo's proposed changes only impacts one method a licensee can use to comply with the regulatory requirement to conduct an

annual radiation protection program review. Therefore, the proposed change is acceptable because Vistra OpCo may use other methods for completing reviews required by 10 CFR 20.1101(c), as described in the regulation and its associated clarification; and Vistra OpCo intends to continue complying with the regulatory requirement as stated in its application.

4.0 CONCLUSION

As discussed above, the NRC staff reviewed Vistra OpCo's requested changes to the internal audit requirements in the Vistra OpCo QAP, as described in its application. The NRC staff finds that Vistra OpCo will continue to comply with 10 CFR 50.34(b)(6)(ii), 10 CFR 50.54(a), Criterion XVIII of appendix B to 10 CFR Part 50, 10 CFR 20.1101(c), and 10 CFR Part 72, Subpart G. Therefore, the NRC staff concludes that the requested changes to the internal audit requirements in the Vistra OpCo QAP are acceptable.

Principal Contributors: Aaron Armstrong, NRR
Sean Meighan, NRR

Date: May 16, 2022

SUBJECT: COMANCHE PEAK NUCLEAR POWER PLANT, UNIT NOS. 1 AND 2 – REVIEW OF QUALITY ASSURANCE PROGRAM CHANGES (EPID L-2021-LLQ-0003) DATED MAY 16, 2022

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