

**REQUEST FOR ADDITIONAL INFORMATION
BY THE OFFICE OF NUCLEAR REACTOR REGULATION
FRAMATOME ANP-10357P, REVISION 0, TXS COMPACT PLATFORM TOPICAL REPORT
FRAMATOME INC.
DOCKET NO. 99902041
ISSUE DATE: 07/02/2025**

Background

By letter dated August 2, 2024, Framatome Inc. (Framatome) submitted ANP-10357P, Revision 0, "TXS COMPACT Platform Topical Report" (hereafter referred to as the TR) (Agencywide Documents Access and Management System (ADAMS) Package Accession No. ML24218A279), for the U.S. Nuclear Regulatory Commission (NRC)'s staff review and approval. Based on the NRC staff's review of the information presented in the TR, the NRC staff identified that additional information is needed for the review of the TR. The NRC staff also conducted an audit (ADAMS Accession No. ML24352A156) of the TR.

The NRC staff's request for additional information (RAI)-10688 is provided below.

Regulatory Basis

The regulatory basis for this RAI can be found in Title 10 of the *Code of Federal Regulations* (10 CFR) Part 50, "Domestic Licensing of Production and Utilization Facilities," Appendix B, "Quality Assurance Criteria for Nuclear Power Plants and Fuel Processing Plants," and 10 CFR 52.47, "Contents of Applications; Technical Information," (a)(19).

Question 1

The regulation at 10 CFR 52.47(a)(19) requires the applicant of a design certification to include in the application a description of the quality assurance (QA) program applied to the design of structures, systems, and components of the facility. Appendix B to 10 CFR Part 50 sets forth the requirements for QA programs for nuclear power plants. The description of the QA program for a nuclear power plant shall include a discussion of how the applicable requirements of Appendix B to 10 CFR Part 50 were satisfied.

Section 8.1, "Regulatory Basis," of the TR, states that for the TR, the submittal is considered a design certification (DC) activity. The NRC staff requests Framatome to clarify whether this TR is only intended to apply to DC applications. If applicable to DC applicants, the NRC staff requests that Framatome address how the requirements of 10 CFR 52.47(a)(19) are satisfied.

Question 2

Section 8.1 of the TR states that design engineering for the TXS COMPACT platform was completed by the Framatome SAS organization in accordance with applicable European Standards. The decision to certify the TXS COMPACT Platform for NRC safety-related applications was made after the design was fully complete. The TXS COMPACT Platform TR is being submitted by Framatome in accordance with its Quality Assurance Program (QAP). Section 8.2, "Framatome QA Program," of the TR states that the Framatome QAP applicability is based the elements of the Framatome Inc. QAP applicable to product development in

Framatome SAS. TXS COMPACT Platform components will be provided to Framatome as basic components design and manufactured under the applicable elements of the Framatome Integrated Management System Manual (IMS).

Therefore, regarding the TXS COMPACT Platform and implementing procedures, as defined in the TXS COMPACT Quality Management Plan (QMP), Framatome SAS is considered a “supplier” subject to the controls imposed under the Framatome QAP. Applicable elements of Framatome QAP are as follows:

- “Quality Assurance Program” – 10 CFR Part 50, Appendix B, Criterion II.
- “Control of Purchased Materials, Items, and Services” – 10 CFR Part 50, Appendix B, Criterion VII.
- “Control of Nonconforming Items” – 10 CFR Part 50, Appendix B, Criterion XV.
- “Corrective Action” – 10 CFR Part 50, Appendix B, Criterion XVI.
- “Audits” – 10 CFR Part 50, Appendix B, Criterion XVIII.”

Section 6.0, “TXS Compact Life Cycle Management,” of the TR describes the development processes for the TXS COMPACT platform, and credits the processes and procedures used by Framatome SAS and Framatome Inc. to develop and qualify the TXS COMPACT platform. The NRC staff reviewed the information contained in Sections 6 and 8 of the TR and the following supporting documents:

- 56-9141754-012, “Framatome Inc. Quality Assurance Program,” dated January 19, 2023
- D02-ARV-01-101-817, “Framatome Integrated Management System Manual,” Revision F
- D02-AR-01-230-852, “TXS COMPACT Quality Management Plan (QMP),” Revision A

Based on the NRC staff’s review of the information, the NRC staff finds that additional information is required to demonstrate how the applicable criteria in Appendix B to 10 CFR Part 50 are satisfied as specified below:

- a. The TXS COMPACT QMP, does not address the role of “supplier” in terms of Framatome SAS. Framatome SAS and Framatome GmbH roles are identified to be the owner of the QAP. The NRC staff requests that Framatome address this discrepancy.
- b. Given that Framatome Inc. considers Framatome SAS as a supplier of the TXS COMPACT Platform, it is not clear why Criterion III, “Design Control,” Criterion IV, “Procurement Document Control,” and Criterion XVII, “Quality Assurance Records” of Appendix B to 10 CFR Part 50 are not identified as applicable elements of the Framatome QAP that apply to the procurement. The NRC staff requests that Framatome address this issue and modify the TR, as necessary.
- c. Section 6.0 of the TR credits Framatome SAS processes and procedures used to develop the TXS Compact Platform, which are governed by Framatome IMS Manual. It is not clear whether Framatome is crediting Framatome SAS’s IMS processes and procedures to address Criterion III and Criterion VII of Appendix B to 10 CFR Part 50. The NRC staff requests that Framatome clarify this information and revise the TR, as necessary.

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Question 3

Criterion II of Appendix B to 10 CFR Part 50, requires, in part, that “the applicant shall identify the structures, systems and components, to be covered by the quality assurance program and the major organizations participating the program, together with the designated functions of these organizations. Activities affecting quality shall be accomplished under suitably controlled conditions. The program shall take into account the need for processes, and skills to attain the required quality, and the need for verification of quality by inspection and tests...The program shall provide for indoctrination and training of personnel performing activities affecting quality as necessary to assure that suitable proficiency is achieved and maintained.”

Section 8.2.1, "Quality Assurance Program," of the TR states that the Framatome QAP complies with Criterion II of 10 CFR Part 50, Appendix B, and Requirement 2 of ASME NQA-1-2015. This section states that Framatome QAP provides for development, control, and use of computer programs. The NRC staff reviewed Section 8.2.1 of the TR and the Framatome QAP and finds it is not clear how the TR's description of Framatome QAP conforms to Criterion II of Appendix B to 10 CFR Part 50 as applied to the procurement of TXS COMPACT Platform from Framatome SAS.

Specifically, the NRC staff find that for the procurement of the TXS COMPACT platform:

- a. Framatome did not identify that the TXS Platform is classified as safety-related, subject to the Framatome QAP in the TR.
- b. It is not clear to the NRC staff whether Framatome is imposing its QAP Section 2.6 on Framatome SAS personnel.
- c. It is not clear to the NRC staff whether Framatome is imposing Sections 3.6.10, 3.11, and 3.12 of the Framatome QAP onto Framatome SAS as part of a purchase order.

Therefore, the NRC staff requests that Framatome provides the necessary clarification and address the issues identified above.

Question 4

Criterion VII, "Control of Purchased Material, Equipment, and Services," of Appendix B to 10 CFR Part 50, states, in part, that measures are established to assure that purchased material, equipment, and services, whether purchased directly or through contractors and subcontractors, conform to the procurement documents. These measures shall include provisions, as appropriate, for source evaluation and selection, objective evidence of quality

furnished by the contractor or subcontractor, inspection at the contractor or subcontractor source, and examination of products upon delivery. Documentary evidence that material and equipment conform to the procurement requirements shall be available procurement requirements prior to installation or use of such material and equipment. This documentary evidence shall be retained and shall be sufficient to identify the specific requirements, such as codes, standards, or specifications, met by the purchased material and equipment. The effectiveness of control of quality by contractors and subcontractors shall be assessed by the applicant or designee at intervals consistent with importance, complexity, and quantity of the products or services.

Section 8.2.2, "Control of Purchased Materials, Items, and Services," of the TR states that the Framatome QAP, Section 7, "governs control of purchased safety-related materials, items, and services including source evaluation and selection, source inspection, and receiving inspection in accordance with regulatory and contract requirements...The Quality and Performance organization audits the capability of suppliers of safety-related materials, items, and services, and maintains a list of approved suppliers. Acceptability suppliers of safety-related materials, items, or service are based on the following items:

- An evaluation of their QA Program to 10 CFR Part 50, Appendix B and NQA-1 to determine the capability to supply materials, items, or services meeting procurement document requirements.
- A survey/audit of the supplier's facility."

The NRC staff reviewed Framatome's report of QA Audit, including the audit findings, and Framatome SAS and GmbH's corrective actions to address the findings. Based on the review of this information, the NRC staff requests Framatome to:

- a. Clarify why Section 8.2.2 of the TR only addresses the source evaluation and selection requirements in Criterion VII of Appendix B to 10 CFR Part 50 and no other aspects of Criterion VII such as objective evidence of quality furnished by the contractor or subcontractor, inspection at the contractor or subcontractor source, and examination of products upon delivery.
- b. Incorporate into the TR a description of the specific activities performed by Framatome to place Framatome SAS and Framatome GmbH on their approved supplier's list to issue purchase orders for safety-related procurement of the TXS Compact Platform.

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- d. Provide the results of the gap analysis performed to address audit findings on gaps between the Framatome SAS and Framatome GmbH's QA Program and procedures and Appendix B to 10 CFR Part 50 and the impact on completed activities affecting quality for the versions of TXS Compact Modules referenced in the TR.

ADAMS Accession Nos.:
ML25178A329 (Package)
ML25178A323 (Proprietary)
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