framatome

July 30, 2025
NRC:25:018

U.S. Nuclear Regulatory Commission
Document Control Desk
11555 Rockville Pike
Rockville, MD 20852

Response to First Set of Requests for Additional Information Regarding Framatome ANP-10357P, Revision 0, "TXS COMPACT Platform Topical Report", RAIs 10636, 10637, 10638 and 10688

Framatome Inc. (Framatome) requested the NRC's review and approval of the topical report ANP-10357P, Revision 0, "TXS COMPACT Platform Topical Report (TR)" in Reference 1. The NRC reviewed the proposed TR, conducted an audit (ADAMS Accession No. ML24352A156) and determined that additional information is needed to complete the review. The NRC provided Requests for Additional Information (RAIs) in References 2, 3, 4 and 5. Framatome's response to these RAIs are provided in Attachment A.

Framatome considers some of the material contained in Attachment A to be proprietary. As required by 10 CFR 2.390(b), an affidavit is provided in Enclosure 1 to support withholding of the information from public disclosure. A non-proprietary version of Attachment A is provided as Attachment B.

There are no commitments within this letter or its enclosures.

If you have any questions related to this information, please contact Mr. Philip A. Opsal, Licensing Manager, by telephone at (434) 534-1223, or by e-mail at Philip.Opsal@Framatome.com.

Sincerely,

ELLIOTT
Gayle

Digitally signed by ELLIOTT Gayle
Date: 2025.07.30 20:37:19 -04'00'

Gayle Elliott, Director
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Framatome Inc.

cc: Ngola Otto

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References:

Ref. 1: Letter: Gayle Elliott (Framatome Inc.) to Document Control Desk (NRC), “Request for Review and Approval of ANP-10357P, Revision 0, “TXS COMPACT Platform Topical Report,” NRC:24:015, August 2, 2024.

Ref. 2: Request for additional information – 10636, by the Office of Nuclear Reactor Regulation, ANP-10357P, Revision 0, TXS Compact Platform Topical Report, Framatome Inc., Docket NO. 99902041, 06/16/2025, NRC ADAMS ML25161A164 (RAI – Non-Proprietary).

Ref 3: Request for additional information – 10637, by the Office of Nuclear Reactor Regulation, Framatome Topical Report, ANP-10357P, Revision 0, “TXS Compact Platform Topical Report” Framatome Inc., Docket NO. 99902041, 06/13/2025, NRC ADAMS ML25160A110 (RAI – Non-Proprietary).

Ref 4: Request for additional information – 10638, by the Office of Nuclear Reactor Regulation Framatome Topical Report, ANP-10357P, Revision 0, “TXS Compact Platform Topical Report” Framatome Inc., Docket NO. 99902041, 06/16/2025, NRC ADAMS ML25160A168 (RAI – Non-Proprietary).

Ref 5: 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, 07/02/2025, NRC ADAMS ML25178A329 (Package), ML25178A323 (Proprietary) and ML25178A444 (Non-Proprietary).

Attachments:

A. Framatome response to NRC RAI 10636, RAI 10637, RAI 10638 and RAI 10688. (Proprietary)
B. Framatome response to NRC RAI 10636, RAI 10637, RAI 10638 and RAI 10688. (Non-Proprietary)

Enclosure:

1. Affidavit

ATTACHMENT B:

Framatome Response to NRC RAI 10636, RAI 10637, RAI 10638 and RAI 10688
(Non-Proprietary)

Request of Additional Information-10636

RAI Question 1:

“Regulation 10 CFR 50.55a(h) incorporates by reference the requirements of IEEE Std. 603-1991, “Criteria for Safety Systems for Nuclear Power Generating Stations,” and the correction sheet dated January 30,1995. Clause 5.4, “Equipment Qualification” of IEEE Std. 603-1991 requires, in part, that safety system equipment shall be qualified by type test, previous operating experience, or analysis, or any combination of these three methods, to substantiate that it will be capable of meeting, on a continuing basis, the performance requirements as specified in the design basis.

Appendix B to “Quality Assurance Criteria for Nuclear Power Plants and Fuel Reprocessing Plants,” to 10 CFR Part 50, “Domestic Licensing of Production and Utilization Facilities,” prescribes requirements for quality assurance (QA) to ensure that structures, systems, and components (SSCs) will perform satisfactorily in service. Criterion VII of Appendix B, “Control of Purchased Material, Equipment, and Services," requires, in part, that measures shall be 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.

During the regulatory audit from March 31 to April 4, 2025, the NRC staff noted that equipment qualification (EQ) testing service for the TXS COMPACT platform was conducted by third parties contracted by Framatome GmbH. However, Framatome did not perform commercial grade dedication (CGD) for the EQ testing service until the EQ testing service was already completed. The NRC staff requests that the applicant clarifies or justifies the use of the EQ testing service provided by third parties before performing the CGD for the EQ testing service.”

Response to Question 1:

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Request of Additional Information-10637

RAI Question 1:

“The regulation at 10 CFR 50.55a(h) incorporates by reference the requirements of IEEE Std. 603-1991, “Criteria for Safety Systems for Nuclear Power Generating Stations,” and the correction sheet dated January 30,1995. Clause 5.4, “Equipment Qualification,” of IEEE Std. 603-1991 requires, in part, that safety system equipment shall be qualified by type test, previous operating experience, or analysis, or any combination of these three methods, to substantiate that it will be capable of meeting, on a continuing basis, the performance requirements as specified in the design basis.

As part of the equipment qualification, the Class 1E to non-Class 1E isolation qualification testing shall be performed. The regulatory guidance on the Class 1E to non-Class 1E isolation testing is included in RG 1.75, and Section 6.3.6 of EPRI TR-107330, “Requirements Compliance Traceability Matrix,” as endorsed in RG 1.209, "Guidelines for Environmental Qualification of Safety-Related Computer-Based Instrumentation and Control Systems in Nuclear Power Plants."

However, the NRC staff found that Class 1E to non-Class 1E isolation qualification testing has not been addressed in the submitted TXS COMPACT TR. The NRC staff requests that the application provides additional information to substantiate compliance with the regulatory requirement on the qualification of the Class 1E to non-Class 1E isolation for the TXS COMPACT Platform.”

Response to Question 1:

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Request of Additional Information-10638

RAI Question 1:

"The regulation at 10 CFR 50.55a(h) incorporates by reference the requirements of IEEE Std. 603-1991 and the correction sheet dated January 30,1995. Clause 5.6.3, "Between Safety Systems and Other Systems," requires, in part, that, "The safety system design shall be such that credible failures in and consequential actions by other systems, as documented in Section 4.8 of the design basis, shall not prevent the safety systems from meeting the requirements of this standard". RG 1.152, Revision 4, and its endorsed IEEE Std. 7-4.3.2-2016, "IEEE Standard Criteria for Programmable Digital Devices in Safety Systems of Nuclear Power Generating Stations," provide regulatory guidance on how to meet the requirement on independence between safety systems and other non-safety systems.

In Section 5.2.2.2, "Communication from the Service Unit to an Automation Unit," of the TXS COMPACT TR, it states, in part, that "When the SYSTEM or OPE_PARAM release is activated on an Automation Unit, an optocoupler on the PM1 temporarily activates a communication line to enable maintenance of this Automation Unit." It also states in Section 5.2.2.2 that "this communication channel can be used to parameterize the unit by changing configuration data, such as the application, parameters, etc."

The NRC staff noted that the OPE_PARAM mode allows update of parameters while still in OPERATION mode. Although this feature can be permanently or temporarily inhibited when configuring the instrumentation & control system, the NRC staff requests that the applicant provides additional information to clarify or justify the use of non-safety-related Service Unit to parameterize the safety-related automation unit during operation if the above feature is not inhibited."

Response to Question 1:

The NRC staff requests Framatome to clarify or justify the use of non-safety-related Service Unit to parameterize the safety-related Automation Unit during operation, with respect to the criteria of Clause 5.6.3 of IEEE Std. 603-1991 amended by the correction sheet dated January 30th, 1995.

The abovementioned standard states that "the safety system design shall be such that credible failures in and consequential actions by other systems, as documented in Clause 4, item h) of the design basis, shall not prevent the safety systems from meeting the requirements of this standard.". Clause 4, item h) explicitly identifies failure of a non-safety-related system as a condition having the potential for functional degradation of safety system performance.

As quoted by the present RAI, Section 5.2.2.2 of the TXS Compact Platform Topical Report, ANP-10357P Revision 0, (ML24218A279) highlights that when release OPE_PARAM is activated, then the Service Unit can upload parameters to the Automation Unit. When authorized by the regulator, this feature can be used by the I&C maintenance staff at the plant in order to, for example, optimize parameters of close loop control or adapting parameters in case of a stretch-out operation. Allowing to modify such parameters without the need to bypass the unit allows to maximize the availability of the system and its capability to actuate on demand.

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Request of Additional Information-10688

RAI Question 1:

Title 10 of the Code of Federal Regulation (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 Inc. to clarify whether this TR is only intended to apply to DC applications. If applicable to DC applicants, the NRC staff requests that Framatome Inc. address how the requirements of 10 CFR 52.47(a)(19) are satisfied.

Response to Question 1:

Framatome Inc. acknowledges a revision to Section 8.1 of the Topical Report is in progress to remove the reference to “Design Certification” as agreed to in the Framatome – NRC Meeting in May 2025.

The Framatome Inc. position is that even without referring to a formal Design Certification for the TXS Compact, the Framatome Inc. Quality Assurance Program (QAP), aligned with 10 CFR 50, Appendix B, ensures that all applicable regulatory requirements are met.

10 CFR 50, Appendix B mandates that any “structures, systems, and components important to safety” be designed, procured, fabricated, tested, and controlled under a documented quality assurance program.

The Framatome Inc. Quality Assurance Program explicitly covers every phase addressed in 10 CFR 50, Appendix B, from design, purchasing, fabrication, handling, installation, testing, to maintenance, requiring controlled conditions and verification processes.

<u>Framatome Inc. QAP</u>

By stating that “Framatome Inc. Quality Assurance Program was applied as appropriate to ensure applicable requirements of 10 CFR 50, Appendix B were satisfied”, the company is confirming:

- All safety related design, procurement, manufacturing, and testing of the TXS Compact were controlled and documented under policies and procedures aligned with Appendix B.
- Technical adequacy, traceability, inspection, verification, and revision controls were enforced.

As a result, the TXS Compact can legitimately be designated as a “safety-related platform for safety-related applications”, without invoking a specific Design Certification.

RAI 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 Inc. in accordance with the Framatome Inc. Quality Assurance Program (QAP).

Section 8.2, "Framatome QA Program," of the TR states that the Framatome Inc. 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 Inc. 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 Inc. QAP. Applicable elements of Framatome Inc. 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 Inc. address this discrepancy.

   Framatome Response

   The TXS Compact QMP (Quality Management Program) is authored and maintained by Framatome SAS and does not reflect or reference Framatome Inc.’s supplier relationship framework.

Similarly, the TXS Compact QAP (Quality Assurance Program) is a separate document, also generated and controlled by Framatome SAS under its own management structure.

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 Part 50 are not identified as applicable elements of the Framatome Inc. QAP that apply to the procurement. The NRC staff requests that Framatome Inc. address this issue and modify the TR, as necessary.

Framatome Response

The TXS Compact QMP (Quality Management Program) and the TXS Compact QAP (Quality Assurance Program) are separately authored and owned by Framatome SAS.

Framatome Inc. is not the author of these documents; its reference in correspondence (e.g., the Topical Report) pertains solely to overseeing QAP-related *supplier management activities* linked to platform qualification and acceptance.

Framatome SAS and Framatome GmbH underwent comprehensive Quality Assurance audits that addressed the applicable quality requirements, including, but not limited to:

- Design Control
- Procurement Document Control
- Quality Assurance Records

These audits, conducted at each location supporting the TXS Compact, confirmed compliance with the applicable criteria under 10 CFR 50, Appendix B, ensuring that the safety-related processes are consistently implemented.

In the Topical Report, Framatome Inc.’s Quality Assurance Program is referenced exclusively for supplier and platform acceptance management.

No assertion is made that Framatome Inc. authored or owns the core QMP/QAP documentation used by Framatome SAS or Framatome GmbH.

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 Inc. 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 Inc. clarify this information and revise the TR, as necessary.

Framatome Response

During qualification audits of Framatome SAS, Framatome Inc. identified that certain processes and procedures for the TXS Compact platform development, specifically those required to demonstrate compliance with 10 CFR 50, Appendix B, were not formally defined. The issue was formally documented as Audit Finding AF-730-01, “QA Program Definition”, which noted the following:

> "… the Framatome SAS documents which are applicable to the development, design and manufacturing of TXS Compact, V1 have not been appropriately defined. While Engineering personnel were able to identify several technical procedures that were used in this effort, many of the procedures have multiple sections … applicable to either safety related or non-safety related activities.
>
> Review of this documentation indicated that there is no objective evidence to demonstrate that the safety related (10CFR50, Appendix B) elements of these procedures were executed. Additionally, several quality affecting activities supporting TXS Compact development and design are not implemented by 10CFR50, Appendix B compliant procedures.
>
> While a TXS Compact Quality Assurance Program has been developed, this document is primarily a technical document and does not address the manner in which compliance with 10CFR50, Appendix B, or any other applicable Quality Requirement or Standard is to be accomplished.
>
> Review of Framatome SAS procedures indicate the appropriate documents for defining the manner in which Quality Assurance Program requirements are met are the Quality Management Plan and associated documentation, including implementing procedures.

In response to Finding AF-730-01, Framatome SAS implemented corrective measures under its Corrective Action Program (CAP), resulting in the development of the TXS Compact Quality Management Plan (QMP). This QMP established the necessary procedures and process definitions to ensure full compliance with 10 CFR 50, Appendix B requirements, including Audit, Design Control, Procurement Document Control, Corrective Action, Records Management, and other applicable criteria .

Framatome Inc. performed follow-up qualification audits which confirmed that the previously identified procedural gaps had been addressed and remediated in accordance with CAP requirements. The effectiveness of corrective actions was verified, and closure action items were completed.

This audit-compliant corrective action is documented in the TXS Compact Topical Report (TR), recognizing that Framatome Inc. QAP is referenced only regarding supplier oversight associated with platform qualification and acceptance.

Because the issue was properly captured via Finding AF-730-01, remediated per the Framatome SAS CAP, and verified as closed during follow-up audits, no further revisions to the QMP/QAP or TR are planned on this topic.

Should the NRC require additional evidence, such as CAP records, audit reports, or updated QMP/QAP documents, Framatome Inc. is prepared to provide them upon request.

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Framatome Response

Framatome Inc. acknowledges that [ ] currently do not maintain 10 CFR 50, Appendix B Quality Assurance Programs. As such, Framatome SAS is managing qualification of these suppliers through a Commercial Grade Dedication (CGD) process consistent with industry standard methodology (10 CFR 21; Regulatory Guide 1.164 Rev 1; NUREG-GG-0261, EPRI NP-5652).

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Framatome Inc. asserts that the CGD qualification method for [ ] executed by Framatome SAS, is fully compliant with NRC expectations for safety-related suppliers. This conclusion is based on Framatome Inc. audits of Framatome SAS and observation of select ongoing CGD activities. Completion of CGD activities [ ] remains on schedule. Framatome Inc. will reference this framework in ongoing regulatory documents and does not anticipate further revisions on this topic unless requested.

Detailed CGD documentation, such as survey checklists, inspection reports, or dedication records, are available for review if required.

RAI 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 Inc. 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 Inc. QAP provides for development, control, and use of computer programs. The NRC staff reviewed Section 8.2.1 of the TR and the Framatome Inc.

QAP and finds it is not clear how the TR’s description of Framatome Inc.’s 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 Inc. did not identify that the TXS Platform is classified as safety-related, subject to the Framatome Inc. QAP in the TR.

Framatome Response

The TXS Compact is a safety-related platform, procured as a basic component. Its procurement, receipt, and management are governed by the Framatome Inc. Quality Assurance Program, ensuring control per 10 CFR 50, Appendix B requirements during those phases.

However, the Topical Report (TR) focuses solely on the TXS Compact platform and does not encompass the overall Framatome Inc. QA Program or procurement controls.

Design Control Responsibilities

Criterion II of 10 CFR 50, Appendix B mandates that the designing entity must establish and execute a documented Quality Assurance Program, identifying SSCs and controlling all activities affecting safety-related quality. .

In this case, Framatome SAS fulfills that role as the designing entity, responsible for implementing design control procedures to meet Criterion II.

Framatome Inc. Oversight

Framatome Inc. conducted Quality Assurance audits of Framatome SAS to assess the acceptability of design controls, procurement document controls, and record-keeping per 10 CFR 50, Appendix B.

These audits confirmed that Framatome SAS’s processes and procedures are defined, managed, and compliant as required under Criterion II.

Summary

Role	Entity	Responsibility
Design Control (Criterion II)	Framatome SAS	Establish and implement Appendix B QA program for TXS Compact design
Procurement, Receipt, Management	Framatome Inc.	Apply its overall QA program to ensure procurement controls for safety-related basic components
Audit Oversight	Framatome Inc.	Verify SAS's compliance through audits ensuring ASA app B adherence

Framatome Inc. clarifies that:

1. Design control responsibility under Criterion II resides with Framatome SAS.
2. These SAS-controlled processes have been evaluated and found acceptable through Framatome Inc. audits.
3. Procurement management for the TXS Compact falls under Framatome Inc.'s QA Program, though this is outside the scope of the published TR.

b. It is not clear to the NRC staff whether Framatome Inc. is imposing its QAP Section 2.6 on Framatome SAS personnel.

Framatome Response

Framatome QAP, Section 2.6 is titled "QAP Indoctrination and Training". Section 2.6.1 applies to "Company Personnel" as follows:

> 2.6.1 Company Personnel
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> Personnel performing or managing activities affecting quality shall receive indoctrination in their job responsibilities and authority that includes general criteria, technical objectives, requirements of applicable codes and standards, regulatory commitments, company procedures, and quality assurance program requirements. On-the-job training shall be used if direct hands-on applications or experience is needed to achieve and maintain proficiency. Indoctrination and training requirements of this QAP are **provided to all personnel engaged in activities covered by this QAP**.

Section 2.6.1 of Framatome Inc.'s QAP applies only to personnel working under that specific program, i.e. personnel performing or managing activities affecting quality under the Framatome Inc. QAP.

Since Framatome SAS personnel operate under the TXS Compact Quality Management Plan, and the Framatome IMS and associated procedures, they are not subject to section 2.6.1. Therefore, Framatome Inc. is not imposing its QA requirements on SAS staff as they are governed exclusively by the Framatome SAS quality system.

c. It is not clear to the NRC staff whether Framatome Inc. is imposing Sections 3.6.10, 3.11, and 3.12 of the Framatome Inc. QAP onto Framatome SAS as part of a purchase order.

Framatome Response

Framatome QAP, Section 3 addresses Design Control. The applicability of this entire section is based on individuals conducting Design Control activities under the Framatome Inc. QAP.

Since Framatome SAS personnel are performing work under the TXS Compact Quality Management Plan and the Framatome IMS and applicable procedures, they are not conducting work under the Framatome Inc. Quality Assurance Program. This requirement is only applicable to individuals conducting work under the Framatome Inc. Quality Assurance Program.

Framatome Inc. is not “imposing” elements of their QA Program on Framatome SAS.

RAI 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 Inc. 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 Inc.’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 Inc. 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.

Framatome Response

10 CFR 50, Appendix B, Criterion VII mandates that purchasers establish controls ensuring that purchased materials, equipment, and services conform to procurement documents. These controls include:

- Source evaluation and selection
- Objective evidence of quality furnished by contractors/subcontractors
- Inspection at supplier locations
- Examination of products upon delivery
- Maintenance of documentary evidence at the receiving site

The TXS Compact is categorized as a safety-related platform; procurement under the Framatome Inc. QA program triggers the full scope of 10 CFR 50, Appendix B controls.

Framatome Inc. has conducted Quality Assurance audits at Framatome SAS to evaluate implementation of processes and procedures demonstrating compliance with 10 CFR 50, Appendix B, Criterion VII, ensuring processes for source evaluation, objective evidence collection, supplier-based inspection, and receipt examination are fully executed. During these audits, Framatome Inc. verified:

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The TXS Compact procurement is strictly controlled under Criterion VII of 10 CFR 50, Appendix B controls. Framatome Inc. internal audits confirm full compliance with source controls, quality documentation, inspections, and delivery examinations.

Though these procurement controls are not detailed in the Topical Report (which focuses on the platform) they are executed, and verified under Framatome Inc.'s QA program.

No additional revisions to the TR are planned; however, Framatome Inc. stands ready to furnish audit reports, inspection records, or objective evidence upon NRC request.

b. Incorporate into the TR a description of the specific activities performed by Framatome Inc. 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.

Framatome Response

Framatome Inc. will revise the Topical Report (TR) to explicitly document the Qualification Audits performed on Framatome SAS and Framatome GmbH, which were required to include these entities on the Framatome Inc. Approved Supplier List.

The revised TR will:

- Describe the scope and objectives of the Qualification Audits (covering design control, procurement, inspection, records, and criterion compliance).
- Identify audit dates, and locations.
- Summarize accreditations and certifications held by Framatome SAS and GmbH
- Provide evidence of audit outcomes and confirmation of compliance with 10 CFR 50, Appendix B.
- Conclude that, based on these audits, both entities meet the requirements to be included on the Approved Supplier List.

By including these Qualification Audits in the TR, Framatome Inc. will:

1. Provide transparent evidence of oversight and compliance.
2. Demonstrate that Framatome SAS and GmbH satisfy Framatome Inc.'s supplier qualification under Appendix B.
3. Clarify the link between these audits and the entities' inclusion in the Approved Supplier List.

c. **[**

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Framatome Response

Framatome Inc. confirms that the Commercial Grade Dedication (CGD) process for design and manufacturing activities remains ongoing and on track for completion **[**

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As stipulated, any open issues or conditions identified are actively being managed through the Framatome Inc. and Framatome SAS Corrective Action Programs (CAP) as applicable. All resulting Condition Reports/Quality Events will be formally closed once corrective actions are fully implemented and verified.

Upon completion of corrective activity, Framatome Inc. will make the following available to the NRC:

- Copies of all Closed Condition Reports/Quality Events relating to CGD and qualification audit findings.
- Associated supporting documentation, including root cause analyses, correction verification records, and CAP closure confirmations.

Actions will be concluded per the project schedule [ ] Corrective Action Program documentation and supporting evidence will be available immediately thereafter for NRC review. Framatome Inc. is prepared to provide:

- Interim status updates,
- Draft CAP records,
- Formal summary left in the revised TR or as stand-alone attachments.

Summary

Item	Status
CGD Validation Completion	[ ]
Issue Management	Handled via CAP
NRC Clarification Requested	Specify preference: interim updates vs. final Closed Condition Reports
Documentation Provided	Condition Reports and supporting artifacts post-CAP closure

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.

Framatome Response

Framatome Inc. Quality Assurance performed qualification audits of Framatome SAS (France) and Framatome GmbH (Germany) covering both ongoing work and TXS Compact product development. These audits assessed existing program requirements and execution as well as those in place during development cycles.

All audit findings (except those relating to Commercial Grade Dedication) have been formally resolved. As a result, both Framatome SAS and GmbH have been added to Framatome Inc.'s Approved Supplier List affirming their qualification status.

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Any remaining issues are tracked via Conditional Approvals within Framatome Inc.'s Corrective Action Program (CAP). All CGD and supplier-audit nonconformances are managed through the Framatome Inc. CAP and approved QA processes.

Once CGD activities are concluded, Framatome Inc. will issue closed Condition Reports and supporting CAP documentation which will be made available to the NRC for review, demonstrating full compliance with regulatory oversight.

A F F I D A V I T

1. My name is Philip A. Opsal. I am Manager, Product Licensing for Framatome Inc. (formally known as AREVA Inc.), and as such I am authorized to execute this Affidavit.

2. I am familiar with the criteria applied by Framatome to determine whether certain Framatome information is proprietary. I am familiar with the policies established by Framatome to ensure the proper application of these criteria.

3. I am familiar with the Framatome information contained in Attachment A to Framatome Letter NRC:25:018, "Response to First Set of Requests for Additional Information Regarding Framatome ANP-10357P, Revision 0, "TXS COMPACT PLATFORM TOPICAL REPORT", RAIs 10636, 10637, 10638 and 10688," referred to herein as "this Document." Information contained in this Document has been classified by Framatome as proprietary in accordance with the policies established by Framatome for the control and protection of proprietary and confidential information.

4. This Document contains information of a proprietary and confidential nature and is of the type customarily held in confidence by Framatome and not made available to the public. Based on my experience, I am aware that other companies regard information of the kind contained in this Document as proprietary and confidential.

5. This Document has been made available to the U.S. Nuclear Regulatory Commission in confidence with the request that the information contained in this Document be withheld from public disclosure. The request for withholding of proprietary information is made in accordance with 10 CFR 2.390. The information for which withholding from disclosure is requested qualifies under 10 CFR 2.390(a)(4) "Trade secrets and commercial or financial information."

6. The following criteria are customarily applied by Framatome to determine whether information should be classified as proprietary:

(a) The information reveals details of Framatome's research and development plans and programs or their results.

(b) Use of the information by a competitor would permit the competitor to significantly reduce its expenditures, in time or resources, to design, produce, or market a similar product or service.

(c) The information includes test data or analytical techniques concerning a process, methodology, or component, the application of which results in a competitive advantage for Framatome.

(d) The information reveals certain distinguishing aspects of a process, methodology, or component, the exclusive use of which provides a competitive advantage for Framatome in product optimization or marketability.

(e) The information is vital to a competitive advantage held by Framatome, would be helpful to competitors to Framatome, and would likely cause substantial harm to the competitive position of Framatome.

The information in this Document is considered proprietary for the reasons set forth in paragraphs 6(b), 6(c), 6(d) and 6(e) above.

7. Public disclosure of the response to RAI 10636 would reveal aspects of Framatome's strategy for qualifying components. Public disclosure of the response to RAI 10637 would reveal aspects of Framatome's design approach. Due to the extent of Framatome proprietary information in these responses, a non-proprietary version would be of no value to the public. Therefore, a non-proprietary version is not being submitted to the NRC for these responses.

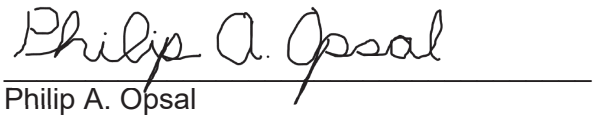
8. In accordance with Framatome's policies governing the protection and control of information, proprietary information contained in this Document has been made available, on a limited basis, to others outside Framatome only as required and under suitable agreement providing for nondisclosure and limited use of the information.

9. Framatome policy requires that proprietary information be kept in a secured file or area and distributed on a need-to-know basis.

10. The foregoing statements are true and correct to the best of my knowledge, information, and belief.

I declare under penalty of perjury that the foregoing is true and correct.

Executed on July 30, 2025.



Philip A. Opsal
Manager, Product Licensing, Framatome Inc.