



# REPORT OF QA AUDIT

Audited Organization Name and Location: <b>Framatome SAS</b> 1. 1 Place[ ]Paris, France 2. 2 Rue du Professeur[ ]Lyon, France  <b>Framatome GmbH</b> 1. [ ]Strasse 100, Erlangen, Germany	File No. T5.1
	Audit No. 730-1
	Audit Date(s): 9/18 - 27/2023, Erlangen 10/9 – 19/2023, Paris & Lyon

## I. PURPOSE/SCOPE

The audit purpose is to evaluate program compliance and effectiveness of the TXS Compact V1 project implementation in accordance with the[ ]10CFR50 Appendix B, and applicable references in Erlangen, Paris, and Lyon in support of the submittal of the TXS Compact V1 Topical Report.

## II. QUALITY REQUIREMENTS

ANSI/ASME NQA-1, 10CFR50 Appendix B, 10CFR21,[

]

## III. AUDITOR(S)

## IV. PERSONNEL CONTACTED



## REPORT OF QA AUDIT (continued)

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- \* Attended Pre-Audit Conference only.  
 \*\* Attended Post-Audit Conference only.  
 \*\*\* Attended Pre- and Post-Audit Conference.

### V EXECUTIVE SUMMARY

This audit evaluated program compliance and effectiveness of project implementation in accordance with the[ ]10CFR50 Appendix B, and applicable references necessary for US Nuclear Regulatory Commission (USNRC) certification of TXS Compact V1. As a result, the audit evaluated activities in the following locations:

- Erlangen, GmbH
- Paris, France
- Lyon, France

The Audit Team assessment in Erlangen, concluded that the content of the GmbH Quality Assurance Program and applicable implementing procedures were compliant with the[ ]10CFR50 App. B and applicable references. [ ]



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The Audit Team assessment of capabilities concluded that resolution of the issues in this report are achievable with appropriate management support. The technical capabilities of staff in each location was found to be very strong.

Regarding the TXS Compact V1 Topical Report, the Team concludes:

*“Framatome Inc. has completed a 10CFR50, App. B assessment and documented issues as appropriate in the Corrective Action Program. These issues will be managed in accordance with the Framatome Inc. Quality Assurance Program through resolution.”*

[

] as detailed below in

Section VI.D.

## VI. REPORT

### A Introduction

The Audit entrance meeting was conducted on Monday September 18, 2023, at GmbH in Erlangen, and an Audit exit meeting was conducted on Thursday October 19, 2023, remotely from Lyon, where the results of the Audit were presented to Management.

### B Items/Activities Audited

Items/Activities were reviewed utilizing [

]

### C Audit Results

Based on interviews of personnel, record reviews, program evaluation, and a performance-based assessment of activities, the audit team identified gaps between the TXS Compact V1 quality assurance program and implementing procedures, and 10CFR50, Appendix B. [

]



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Based on the methodology employed to qualify “safety related” suppliers, the Audit Team found that

However, the Audit Team recognizes that, when developed, the TXS Compact V1 was not intended to meet US requirements as the product was developed to meet European safety related requirements.

### D Findings



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### E Observations

No Observations have been identified.

### F Comments

N/A

### G Positive Comments

A notable area of strength was the technical capabilities of staff at each location.

### H Previous Audit Finding Evaluation

This is the initial audit of the TXS Compact V1 development, therefore, this is not applicable.

### I Requested Date for Evaluation of the Audit Finding(s)/Audit Observation(s)

Response to be provided no later than[ ]



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### VII CONCLUSION

The TXS Compact "Project" is executed in various locations. The overall applicable Quality Program is the [ ]

[ ] The audit evaluated program compliance and effectiveness of project implementation in accordance with the [ ] 10CFR50, Appendix B, and applicable references in Erlangen, Paris, and Lyon.

The Audit Team found the content of the GmbH Quality Assurance Program and applicable implementing procedures fully compliant with 10CFR50, Appendix B and applicable references.

Regarding the TXS Compact V1 Topical Report, the Team concludes:

*"Framatome Inc. has completed a 10CFR50, App. B assessment and documented issues as appropriate in the Corrective Action Program. These issues will be managed in accordance with the Framatome Inc. Quality Assurance Program through resolution."*

**Prepared**
**Date:**
11/16/2023
**Approved**
**JAMEY LAUGHLIN FOR**
**DUANE NEWMAN**
**Manager, Quality Programs & Supplier Oversight**
**Date:**
11/16/2023