

Technical Assistance Request Form

TECHNICAL ASSISTANCE REQUEST					
Distribute to: (Select Only One Division)		☐ MSTR	☐ DUWP	☒ DFM	☐ FCSE
Issue is:	MSTR	☐ Medical	☐ Commercial or Academic	☐ Security	
☒ Regulatory interpretation or exemption	DUWP	☐ Financial Assurance Reviews	☐ Dose Assessments for Decommissioning		
		☐ Reviews of Decommissioning Documents			
☒ Other	DFM	☐ ISFSI Operations/Pad Design Revisions		☐ 10 CFR § 72.48	
Date:	Package Accession No.				
ADAMS Send to:		Shana Helton, Director DFM, NMSS			
From:	Anthony Masters, Director DFFI, Region II		 Signed by Masters, Anthony on 09/15/23		
Licensee: Framatome (example)			CAC Number:	A38010 (EPID needed if > 40 hours expected)	
License No. SNM-1227	Docket No.	70-1257	Control No.	N/A	
Letter Dated: September 15, 2023	ADAMS Accession No. ML23258A040				
Enforcement Action being held in abeyance:			Yes	X	No
Problem or Issue: Fuel Facility Inspectors have inadequate guidance to appropriately evaluate fuel facility licensees' (licensees under 10 CFR Part 40 and 70) compliance with 10 CFR Part 21.					
Illustrative Example:					
During a fire protection and nuclear criticality inspection at Framatome (July 17-20, 2023), the team inspected two independent IROFS that had failed. [REDACTED]					
[REDACTED] The component's failure time was unknown, but it had been functional during the last annual surveillance.					
While onsite, the licensee informed the inspection team that neither they (licensee) nor the manufacturer (Flowline) had recognized this new failure mode. The team inquired about the applicability of this switch from a Part 21 perspective – which they confirmed with the manufacturer that the manufacturer does not supply this (or any) components under 10 CFR Part 21.					

APPENDIX A

The licensee currently has open corrective actions – they have already like-for-like replaced the controller; they have increased surveillance frequency from annually to semi-annually; and they have a long-term corrective action to replace all the controllers as they update/renovate the area these tanks exist in.

While the failure of this IROFS (and another) existed, the failure of these IROFS did not cause the licensee to exceed performance requirements as other functional IROFS credited maintained the consequence of the event as highly unlikely.

The inspection team reviewed the licensee's License Application and ISA Summary and could not find any commitments or other statements regarding meeting 10 CFR Part 21. During discussions with the licensee, the licensee stated that 10 CFR Part 21 only applied to their fuel manufacturing (Appendix B supplier) program, and not to the facility as licensed under 10 CFR Part 70.

The inspection staff are also aware that clarifying guidance was supposed to be provided for 10 CFR Part 21 for 10 CFR Part 40 and 70 licensees in the unpublished DG-3049 (ML18046A101).

DFFI requests assistance in the following three areas: 1) request for generic guidance and training, and 2) a backfit review.

Request for Guidance

Region II engaged with the Division of Fuel Management during the Summer 2023 Inspector Counter Part Meeting in June of 2023 in a discussion on some historical perspectives of rulemaking and Agency guidance with respect to Part 21. During this discussion, it was apparent that inspection staff lack suitable guidance to determine how 10 CFR Part 21 should be applied to 10 CFR Part 40 and 70 licensees. DFFI requests that guidance be provided and that this is included in revisions to Inspection Manual Chapters (IMC) and Inspection Procedures (IP) used for fuel facilities.

From the illustrative example, inspectors lack guidance to determine the following:

1. Does 10 CFR Part 21 only apply to the fuel manufacturing (Appendix B supplier) program at Framatome, and if not, where is this requirement and its scope of applicability?
2. Was the control module – a necessary part of an active engineered control – a basic component as defined in 10 CFR Part 21?
3. If the module is a basic component, was the failure of the IROFS a substantial safety hazard as defined in 10 CFR Part 21?
4. If the module is a basic component, was the new failure mode of the module (i.e., it could fail in a non-safe manner without alerting operators) a deviation and defect, subject to the reporting requirements of 10 CFR Part 21?

Backfit Review

The application of 10 CFR Part 21 based on final guidance (as requested) may carry backfit implications. The staff request that backfit implications be considered in the development of the guidance, and how the application of 10 CFR Part 21 should be applied to individual licensees.

Action Requested: DFFI is requesting regulatory/backfit support. DFFI requests DFM to provide 10 CFR Part 21 guidance for inspectors to address concerns like those encountered at Framatome. DFFI additionally requests that backfit considerations (generic and licensee-specific) be considered in the guidance and its intended application.

APPENDIX A

Recommended Action and Alternatives:		Accept		Reject
TARs addressing similar issues (Include subject, date and ADAMS Accession Number): This issue may have had a TAR approximately 10 years ago based on the information NMSS was able to find. That TAR (if it exists) is unknown at this time.				
Background Documents (Include date and ADAMS Accession Number):				
Remarks: Please use CAC Number _____ for activities associated with this TAR.				
Reviewer:	()	-	Reviewer Code:	
Needed By (date):				

Note: Originating Division Director signs the TAR. Submit separate TARs to each division, if needed.