



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

May 2, 2024

MEMORANDUM TO: Anthony Masters, Director
Division of Fuel Facility Inspection
Region II

FROM: Shana Helton, Director *Shana R. Helton* Signed by Helton, Shana
Division of Fuel Management on 05/02/24
Office of Nuclear Material Safety
and Safeguards

SUBJECT: TECHNICAL ASSISTANCE REQUEST FOR GUIDANCE
RELATED TO FUEL FACILITY INSPECTION UNDER TITLE 10
OF THE *CODE OF FEDERAL REGULATIONS* PART 21

I am responding to your Technical Assistance Request (TAR) dated, September 15, 2023 (Enclosure 1). The U.S. Nuclear Regulatory Commission (NRC) Region II Office requested assistance from the Office of Nuclear Material Safety and Safeguards (NMSS) to provide guidance to determine how Title 10 of *Code of Federal Regulations* (10 CFR) Part 21 should be applied to 10 CFR Part 40 and 70 licensees for fuel facilities.

Issue:

Due to the complexity of the technical issues associated with this activity, Region II requested NMSS, Division of Fuel Management's assistance to determine following items:

- 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?
- Was the control module – a necessary part of an active engineered control – a basic component as defined in 10 CFR Part 21?
- If the module is a basic component, was the failure of the Item(s) Relied-on for Safety a substantial safety hazard as defined in 10 CFR Part 21?
- 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?

CONTACT: Tomeka Terry, NMSS/DFM
301-415-1488

~~A. Masters~~

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Response:

The staff response to the TAR is in Enclosure 2 of this letter. In addition, the NMSS staff provided guidance and training to Region II staff on the requirements contained in 10 CFR 21 and how it applies to facilities licensed under Parts 40, 70 and other non-power production facilities (Agencywide Documents Access and Management System Accession No. ML24116A265, non-public).

Enclosures:

1. TAR (ML23258A040, non-public)
2. Evaluation Report (ML24115A277, non-public)

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