U. S. NUCLEAR REGULATORY COMMISSION

OFFICE OF NUCLEAR REACTOR REGULATION

AUDIT PLAN FOR THE REGULATORY AUDIT OF THE TOPICAL REPORT

WCAP-19042-P/NP, REVISION 0, "PROTK™ NUCLEAR INSTRUMENTATION SYSTEM

TOPICAL REPORT" (PROPRIETARY/NON-PROPRIETARY)

WESTINGHOUSE ELECTRIC COMPANY

DOCKET 99902038; EPID: L-2025-TOP-0034

1.0 BACKGROUND

By letter dated October 3, 2025 (Agencywide Documents Access and Management System (ADAMS) Accession No. ML25276A293), Westinghouse Electric Company (Westinghouse) submitted a Topical Report (TR) WCAP-19042-P/NP, Revision 0, "proTK™ Nuclear Instrumentation System Topical Report" (Proprietary/Non-Proprietary), for U.S. Nuclear Regulatory Commission (NRC) review and approval. Prior to the TR submittal, Westinghouse requested two closed pre-submittal meetings for Westinghouse representatives to present and discuss with the NRC staff proprietary information related to the official submittal of the TR. On May 20, 2025 (ML25127A387), a closed hybrid pre-submittal meeting was held between the NRC staff of the Office of Nuclear Reactor Regulation (NRR) Division of Operating Reactor Licensing (DORL), Division of Engineering and External Hazards (DEX), and Division of Reactor Oversight (DRO) staff, and Westinghouse and Mirion Technologies, Inc. (Mirion) representatives. On September 3, 2025 (ML25189A152), a closed second follow up pre-submittal meeting was held between the NRC staff of NRR DORL, DEX, DRO, and Westinghouse and Mirion representatives.

The NRC staff performed a completeness review per NRR Office Instructions LIC-500, Revision 9, "Topical Review Process" (ML20247G279) and LIC-109, "Acceptance Review Procedures" (ML20036C829) of Westinghouse TR WCAP-19042-P/NP, Revision 0. The completeness/acceptance review was performed to determine if there is sufficient technical information in scope and depth to allow the NRC staff to begin conducting its detailed technical review.

On February 24, 2026 (ML26041A154), the NRC staff held a virtual closed meeting to discuss with Westinghouse the NRC completeness/acceptance review results for TR WCAP-19042-P/NP, Revision 0, and next steps for the review.

On March 16, 2026 (ML26062A161), per Westinghouse's request for a follow-up closed meeting, a virtual closed meeting was held to discuss a clarification letter that Westinghouse planned to submit with the supplemental information and next steps for the review.

By letter dated March 20, 2026 (ADAMS added date March 23, 2026, and ML26082A092), Westinghouse submitted additional information supporting the acceptance review of TR WCAP-19042-P/NP, Revision 0.

The NRC staff evaluated the TR and additional information for the acceptance review. By letter dated April 13, 2026 (ML26084A132), the NRC staff determined that the TR WCAP-19042-P/NP, Revision 0, contained sufficient information as supplemented to begin a detailed technical safety review under standard complex TR review pathway.

During the on-going review, the NRC staff determined that a regulatory audit is needed to assist in the effective and efficient review of the new TR WCAP-19042-P/NP, Revision 0. This regulatory audit will enable the NRC staff to gain more understanding, verify information, and identify information that may be required to support the safety determination in its safety evaluation. This regulatory audit will also be used to clarify the questions included in this audit plan in order to minimize the number of requests for additional information (RAIs).

2.0 REGULATORY AUDIT BASES

An audit is a planned regulatory activity that includes the examination and evaluation of primarily non-docketed information and other associated aspects. Performing a regulatory audit is expected to assist the NRC staff in efficiently conducting its review and gaining insights into the applicant's processes, specification, plans, procedures, analyses, testing results, and other associated activities. Information that the NRC staff relies upon to make the safety determination must be submitted on the docket. This regulatory audit is to be conducted to support the NRC staff's review of the TR WCAP-19042-P/NP, Revision 0.

Regulations relevant to the NRC staff's audit on the equipment qualification (EQ), quality assurance (QA) and software life cycle development process management, secure development environment, and reliability portions of the TR include:

- Title 10 of the *Code of Federal Regulations* (10 CFR) 50.54(jj) and 10 CFR 50.55(i) require that structures, systems, and components subject to the codes and standards in 10 CFR 50.55a, "Codes and Standards," must be designed, fabricated, erected, constructed, tested, and inspected to quality standards commensurate with the importance of the safety function to be performed.

- Appendix A, General Design Criterion (GDC) 2, "Design bases for protection against natural phenomena," of 10 CFR Part 50, "Domestic Licensing of Production and Utilization Facilities," states, in part, that structures, systems, and components important to safety shall be designed to withstand the effects of natural phenomena such as earthquakes, tornadoes, hurricanes, floods, tsunami, and seiches without loss of capability to perform their safety functions.

- Appendix A, GDC 4, "Environmental and Dynamic Effects Design Bases," of 10 CFR Part 50, states, in part, that structures, systems, and components important to safety shall be designed to accommodate the effects of and to be compatible with the environmental conditions associated with normal operation, maintenance, testing, and postulated accidents, including loss-of-coolant accidents.

- Appendix A, GDC 21, “Protection System Reliability and Testability,” of 10 CFR Part 50 requires, in part, that protection systems be designed for high functional reliability commensurate with the safety function to be performed.

- Appendix A, GDC 24, “Separation of protection and control systems,” of 10 CFR Part 50 requires, in part, that the protection system shall be separated from control systems to the extent that failure of any single control system component or channel, or failure or removal from service of any single protection system component or channel which is common to the control and protection systems leaves intact a system satisfying all reliability, redundancy, and independence requirements of the protection system.

- 10 CFR 50.55a(h), “Protection and safety systems,” states that protection systems of nuclear power reactors of all types must meet the requirements specified in 10 CFR 50.55a(h), and each combined license for a utilization facility is subject to the conditions in 10 CFR 50.55a(h). 10 CFR 50.55a(h)(2) mandates compliance with the requirements stated in Institute of Electrical and Electronics Engineers (IEEE) Standard (Std.) 279-1968, “Proposed IEEE Criteria for Nuclear Power Plant Protection Systems,” IEEE Std 279-1971, “Criteria for Protection Systems for Nuclear Power Generating Stations,” or IEEE Std 603-1991, “IEEE Criteria for Safety Systems for Nuclear Power Generating Stations,” and the correction sheet dated January 30, 1995, for nuclear power plants with construction permits (CPs) issued between January 1, 1971, and May 13, 1999. For nuclear power plants with CPs issued before January 1, 1971, 10 CFR 50.55a(h)(2) requires compliance with their plant-specific licensing basis or IEEE Std 603-1991 and the correction sheet dated January 30, 1995. For applicants for CPs, operating licenses, combined licenses, standard design approvals, design certifications, or manufacturing licenses filed after May 13, 1999, 10 CFR 50.55a(h)(3) requires compliance with IEEE Std 603-1991 and the correction sheet dated January 30, 1995.

- Appendix B “Quality Assurance Criteria for Nuclear Power Plants and Fuel Reprocessing Plants,” of 10 CFR Part 50, with the following applicable criteria:

    - Criterion II, “Quality Assurance Program,” in part, requires an established QA program that shall be documented by written policies, procedures, or instructions and shall be carried out throughout plant life. The QA program shall provide control over activities affecting quality of identified structures, systems, and components to an extent consistent with their importance to safety.

    - Criterion III, “Design Control,” requires, in part, that quality standards be specified and that design control measures shall provide for verifying or checking the adequacy of design. The design control measures shall be established for the identification and control of design interfaces and for coordination among participating design organizations. Measures shall also be established for the selection and review for suitability of application of materials, parts, equipment, and processes that are essential to the safety-related functions of the structures, systems and components.

    - Criterion IV, “Procurement Document Control,” requires that measures shall be established to assure that applicable regulatory requirements, design bases, and

other requirements which are necessary to assure adequate quality are suitably included or referenced in the documents for procurement of material, equipment, and services, whether purchased by the applicant or by its contractors or subcontractors.

- Criterion VII, “Control of Purchased Material, Equipment, and Services,” requires, in part, measures to be established to assure that purchased material, equipment, and services, conform to procurement documents. The effectiveness of control of quality by contractors and subcontractors shall be assessed by the applicant or designee at intervals consistent with the importance, complexity, and quantity of the product or services.

- Criterion XV, “Nonconforming Materials, Parts, or Components,” requires, in part, that measures be established to control materials, parts, or components that do not conform to requirements in order to prevent their advertent use or installation.

- Criterion XVI, “Corrective Action,” requires that measures be established to promptly identify and correct conditions adverse to quality, and to assure that the cause of the condition is determined and corrective action is taken to preclude repetition.

- Criterion XVII, “Quality Assurance Records,” requires that sufficient records shall be maintained to furnish evidence of activities affecting quality. Records such as qualifications of personnel, procedures, and equipment shall be included in Westinghouse’s program and consistent with applicable regulatory requirements.

- Criterion XVIII, “Audits,” requires that a comprehensive system of planned and periodic audits shall be carried out to verify compliance with all aspects of the quality assurance program and to determine the effectiveness of the program.

3.0 PURPOSE AND SCOPE

The scope of this regulatory audit mainly includes the EQ, software life cycle development, analysis of compliance with IEEE Std. 7-4.3.2-2016 and IEEE Std. 1012-2016, reliability, and QA for the review of the new Westinghouse TR WCAP-19042-P/NP, Revision 0. Potential RAIs may also be issued to ensure an effective review of this TR. The NRC audit team members will evaluate non-docketed testing plans, technical requirements, specifications, procedures, life-cycle development plans, analyses, and relevant records for this new Westinghouse TR WCAP-19042-P/NP, Revision 0.

During the course of the audit, the NRC staff will review and discuss the overall EQ program, testing plans, and procedures utilized by Westinghouse and/or its contractors for qualifying all equipment covered by the Westinghouse TR WCAP-19042-P/NP, Revision 0. The NRC staff will discuss with and interview both Westinghouse’s and Mirion’s subject matter experts and testing engineers/technicians associated with the EQ testing results of the Westinghouse TR WCAP-19042-P/NP, Revision 0. The NRC staff may also tour the EQ testing facilities and audit relevant accreditation information for the EQ testing facilities and qualification of testing personnel.

The NRC staff will assess associated documents and records to support the software life cycle process management for developing the proTK platform including the secure

development environment. Specifically, the NRC staff will review plans, procedures, activities, and records related to the TR WCAP-19042-P/NP, Revision 0, platform development processes. The NRC staff will evaluate the effectiveness of software development activities for the proTK platform to determine the degree to which processes described in the TR WCAP-19042-P/NP, Revision 0, were implemented to achieve a high-quality system for use in a nuclear facility in the U.S.

Additionally, the NRC staff will audit the analysis reports for compliance with IEEE Std. 7-4.3.2-2016 and Std. 1012-2016 performed by a third-part entity. The failure mode and effects analysis (FMEA) record for the typical proTK safety system will also be assessed.

The regulatory guidance for the EQ, QA, software life cycle development process management, secure development environment, and reliability that the NRC staff plan to use for the audit activities includes:

- Regulatory Guide (RG) 1.28, “Quality Assurance Program Criteria (Design and Construction),” Revision 4, which endorses American Society of Mechanical Engineers (ASME) Nuclear Quality Assurance (NQA)-1, “Quality Assurance Requirements for Nuclear Facility Applications,” and the ASME NQA-1a, “Addenda to ASME NQA-1-2008, Quality Assurance Requirements for Nuclear Facility Applications,” and is subject to the provisions and modifications identified in the RG, provides an adequate basis for complying with the pertinent QA requirements of Appendix B to 10 CFR Part 50.

- RG 1.75, “Criteria for Independence of Electrical Safety Systems,” describes a method acceptable to the NRC staff for complying with the NRC’s regulations with respect to the physical independence requirements of the circuits and electric equipment that comprise or are associated with safety systems.

- RG 1.100, “Seismic Qualification of Electric and Mechanical Equipment for Nuclear Power Plants,” which describes methods that the NRC staff considers acceptable for use in the seismic qualification of electrical and active mechanical equipment and the functional qualification of active mechanical equipment for nuclear power plants.

- RG 1.180, “Guidelines for Evaluating Electromagnetic and Radio-Frequency Interference in Safety-Related Instrumentation and Control Systems,” endorses and includes guidance for conformance with Military Standard MIL-STD-461G, “Requirements for the Control of Electromagnetic Interference Characteristics of Subsystems and Equipment,” and International Electrotechnical Commission (IEC) 61000 series standards for evaluation of the impact of electromagnetic interference, radio frequency interference, an electrical fast transient, and electrical power surges on safety-related instrumentation and control (I&C) systems.

- RG 1.209, “Guidelines for Environmental Qualification of Safety-Related Computer-Based Instrumentation and Control Systems in Nuclear Power Plants,” which endorses IEEE Std. 323, “IEEE Standard for Qualifying Class 1E Equipment for Nuclear Power Generating Stations,” with enhancements and exceptions.

- Electric Power Research Institute TR-107330, “Generic Requirements Specification for Qualifying a Commercially Available PLC for Safety-Related Applications in

Nuclear Power Plants," as endorsed by NRC presents a specification in the form of a set of requirements to be applied to the generic qualification of programmable logic controllers (PLCs) for application and modification to safety-related I&C systems in nuclear power plants. It is intended to provide a qualification envelope corresponding to a mild environment that should meet regulatory acceptance criteria for a wide range of plant-specific safety-related applications.

- RG 1.152, "Criteria for use of Computers in Safety Systems of Nuclear Power Plants," which endorses IEEE Std. 7-4.3.2, "IEEE Standard Criteria for Digital Computers in Safety Systems of Nuclear Power Generating Stations," with a few noted exceptions, provides guidance for complying with requirements for safety systems that use digital computer systems. Additional guidance on the application of IEEE Std. 7-4.3.2 is provided in NUREG-0800, "Standard Review Plan for the Review of Safety Analysis Reports for Nuclear Power Plants: LWR Edition" (SRP) Appendix 7.1-D, "Guidance for Evaluation of the Application of IEEE Std 7-4.3.2."

- RG 1.168, "Verification, Validation, Reviews, and Audits for Digital Computer Software Used in Safety Systems of Nuclear Power Plants," endorses IEEE Std. 1012, "IEEE Standard for Software Verification and Validation," as providing methods acceptable to the NRC for meeting the regulatory requirements as they apply to verification and validation (V&V) of safety system software, subject to the exceptions listed. Further, it also endorses IEEE Std. 1028, "IEEE Standard for Software Reviews and Audits," as providing an approach acceptable to the NRC staff for carrying out software reviews, inspections, walkthroughs, and audits, subject to the exceptions listed.

- RG 1.169, "Configuration Management Plans for Digital Computer Software Used in Safety Systems of Nuclear Power Plants," endorses IEEE Std. 828, "IEEE Standard for Configuration Management Plans," as providing an acceptable approach for planning configuration management, subject to specific provisions identified in the RG.

- RG 1.170, "Software Test Documentation for Digital Computer Software Used in Safety Systems of Nuclear Power Plants," which endorses IEEE Std. 829, "IEEE Standard for Software Test Documentation," subject to the provisions and exceptions identified in the RG, identifies an acceptable method for satisfying test documentation requirements.

- RG 1.171, "Software Unit Testing for Digital Computer Software used in Safety Systems of Nuclear Power Plants," which endorses the American National Standards Institute (ANSI)/IEEE Std. 1008, "IEEE Standard for Software Unit Testing," subject to the provisions and exceptions identified in the RG, identifies an acceptable method for satisfying software unit testing requirements.

- RG 1.172, "Software Requirements Specifications for Digital Computer Software Used in Safety Systems of Nuclear Power Plants," which endorses IEEE Std. 830, "IEEE Recommended Practice for Software Requirements Specifications," subject to the provisions and exceptions identified in the RG, describes an acceptable approach for preparing software requirements specifications for safety system software.

- RG 1.173, "Developing Software Life Cycle Processes for Digital Computer Software used in Safety Systems of Nuclear Power Plants," which endorses IEEE Std. 1074,

"IEEE Standard for Developing Software Life Cycle Processes," subject to the provisions and exceptions identified in the RG, as providing an approach acceptable to the NRC staff for meeting the regulatory requirements and guidance as they apply to development processes for safety system software. NUREG/CR-6101, "Software Reliability and Safety in Nuclear Reactor Protection Systems."

- SRP Chapter 7, "Instrumentation and Controls," which provides guidance for review of the I&C portions of: (1) applications for nuclear reactor licenses or permits and (2) amendments to existing licenses. The SRP guidance may also be applied in the review of TRs submitted to the NRC for SE, especially reports requesting generic acceptance of systems or components that may be used in nuclear power plant I&C systems.

4.0 LIST OF AUDIT QUESTIONS

Quality Assurance

1. Section 4.3 of the Quality Management Manual (QMM) identifies "Compliance to QA standards (ISO 19443:2018, ISO 9001:205, 10 CFR 50 App. B, ASME NQA-1, KTA 1404, KTA 3507, 10 CFR 21, NSQ-100)" as a skill or strength. Section 7.5.1 of the QMM states that "In internal directives and instructions, it is documented, how to realize specifications derived from relevant specific standards (ISO 19443, KTA, 10 CFR 50, ASME-NQA-1, etc.) as well as the specifications and procedures regarding product development, production and testing." The NRC staff requests information to demonstrate how applicable criteria from Appendix B to 10 CFR Part 50 are met, as discussed in the QMM.

2. Project QA Plan for DWK 260, Edition 1, Section 2, states that "Mirion MUC's management has implemented a QMS [Quality Management System] in accordance with the standard ISO 9001:2015. Also taken into consideration are the quality requirements of the KTA regulation 1401 for supplier to German NPPs and foreign orders which have thus far been the relevant or stipulated regulations required, e.g. in accordance with NRC 10 CFR 50 app. B and part 21 for class 1E equipment according IEEE 323…A list of all relevant applicable standard and regulations for this project are given in [5]." Reference 5 is identified as "Applicable Standards and Regulations for DWK 260," Doc. No. Z-2250015 Y0-L0001E, Mirion Technologies (MGPI H&B) GmbH.

   Further, Section 5 of the project QA plan only states that "Mirion MUC operates to a quality management system that complies with ISO 9001:2015 quality standard." To support this review area, the NRC staff requests the following information:

   - A mapping of where in the Mirion MUC QMM and Project QA Plan to demonstrate how Appendix B to 10 CFR Part 50 is met by Mirion's QA program.
   - If references to lower level Mirion MUC procedures and work instructions are required to demonstrate compliance with Appendix B, please make the sections within those documents available for review.

3. In Section 3 of the TR, the NRC staff found that commercial microprocessors MSP432, TMS570, and 80C31 are used in the proTK 260 platform as its main processor, I/O processor, and communication processor, respectively. However, the NRC staff could not identify sufficient information in the TR to demonstrate that the three types of microprocessors are qualified for nuclear safety applications. The NRC staff requests a summary of dedication or qualification information to demonstrate that the above commercial microprocessors are qualified to comply with Criterion VII. *Control of Purchased Material, Equipment, and Services* in Appendix B to 10 CFR Part 50.

Equipment Qualification

4. In Section 8, "Equipment Qualification," of TR WCAP-19042-P/NP, Revision 0, the NRC staff noted there is limited information to demonstrate compliance with IEEE Std. 603-1991, Clause 5.4 on equipment qualification as incorporated by reference in 10 CFR 50.55a(h). Additional information is needed to demonstrate qualification of the equipment for the proTK 260 platform. The NRC staff requests additional information including but not limited to the following areas to show that the qualification of the proTK 260 platform components meets the regulatory requirement in 10 CFR 50.55a(h):

    - List of equipment with identification and description tested and qualified
    - EQ test plans and methodologies
    - Summary EQ testing acceptance criteria and results
    - Testing equipment and facilities
    - Any failures or deficiencies occurred during the complete EQ testing process and associated corrections or mitigation methods

5. In Sections 3 and 10 of the TR, the NRC staff noted there is limited information to demonstrate the equipment qualification for the pulse preamplifier NV 320, current/frequency converter NV 102, and wide range preamplifier NV 230, which are not installed in the neutron instrumentation system (NIS) cabinets. In Section 3.3, "proTK Hardware Modules," of the TR, the NRC staff also noted that there are multiple variants of each module which are parts of the proTK 260 platform. The NRC staff requests equipment list/bill of materials used in the Westinghouse proTK reference configurations which will be evaluated and approved by the NRC. Additionally, the NRC staff requests information to demonstrate the EQ for the pulse preamplifier NV 320, current/frequency converter NV 102, wide range preamplifier NV 230, and all variants of the modules included for the proTK 260 platform reference configurations comply with the regulatory requirement in Clause 5.4 on EQ of IEEE Std. 603-1991 as incorporated by reference in 10 CFR 50.55a(h).

6. In Sections 8 and 11 of the TR, it states the compliance with IEEE Std. 603-1991. As incorporated by reference in 10 CFR 50.55a(h), Clause 5.4 of IEEE Std. 603-1991 requires, in part, that safety system equipment 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 the performance requirements as specified in the design basis. The Class 1E to non-Class 1E interface isolation qualification is part of the EQ, the guidance on how the Class 1E to non-Class 1E

isolation qualification meets the above regulatory requirement is included in RG 1.75 and Section 6.3.6 of EPRI TR-107330 which is endorsed in RG 1.209. Both RG 1.75 and RG 1.209 are used in the TR. The proTK 260 platform includes two interface connections: (1) from its signal post-processing hardware to non-safety I&C systems and (2) from its communication processors to external systems. However, the NRC staff could not identify sufficient information in the TR to support the Class 1E to non-Class 1E isolation qualification for the above two interface connections. The NRC staff requests information to demonstrate compliance with the regulatory requirements in 10 CFR 50.55a(h) on the qualification of the Class 1E to non-Class 1E isolation for the proTK 260 platform.

7. In Section 8.1 of the TR, it states, in part, that “This report summarizes the completed qualification … and outlines the qualification activities for wide range systems.” In Section 8.3 of the TR, it states, in part, that “Future seismic qualifications and as documented in GQS, will be performed based on IEEE/IEC 60980-344:2020.” In Section 8.5 of the TR, it states, in part, that “Future qualifications follow EMC requirements specified in the GQS, which qualifies representative configurations of the proTK™ platform (260 Series) for electromagnetic compatibility according to later version RG 1.180 Revision 2 and EPRI TR-102323 Revision 5.” In Tables 8.2-2 and 8.2-3 of the TR, future qualification is mentioned for environmental qualification.

   The NRC staff requests details on the status of these future EQ activities, as mentioned in the TR. If activities have been completed, the NRC staff requests information related to the completed activities, and if needed, revision to the TR accordingly. For activities that have not been completed, the NRC staff requests the schedule for completing all future EQ activity and additional EQ information to support the review of this proTK 260 platform. The above requested information will be used to evaluate the compliance with the regulatory requirement in Clause 5.4 on EQ of IEEE Std. 603-1991, which is incorporated by reference in 10 CFR 50.55a(h).

8. In Section 8, “Equipment Qualification," of the TR, the NRC staff could not identify sufficient information to support the review and requests clarification, justification, or additional information to support these areas and demonstrate the compliance with the regulatory requirement in Clause 5.4 on EQ of IEEE Std. 603-1991, which is incorporated by reference in 10 CFR 50.55a(h):

   - Whether the radiation aging test was conducted for the proTK™ 260 platform.
   - Standards and testing profiles used for the environmental qualification in Section 8.2 of the TR. The NRC staff notes differences from standards and testing profiles in EPRI TR-107330 which is endorsed by the NRC in RG 1.209.
   - Please clarify what “*Qualified in project*” in Table 8.1-1 of the TR means.

Regulatory Compliance

9. In Section 11, “Regulatory Compliance,” of the TR, the NRC staff reviewed the summary compliance analysis for IEEE Std, 603-1991, which includes adequate information for the NRC staff to conduct the review. However, in Section 11.2 of the TR, it states, in part, that “These reports conclude that proTK™ complies with IEEE 7-4.3.2” without additional information to support this conclusion. The NRC staff requests a similar summary compliance analysis to demonstrate the conformance with regulatory guidance in RG 1.152, Rev. 4, and its endorsed IEEE Std. 7-4.3.2-2016 for the proTK 260 platform.

Deterministic Performance

10. In Section 3 of the TR, the NRC staff could not identify sufficient information to support review of how the watchdog timers**,** interrupt, and exception handling mechanism if applicable are used in the proTK 260 platform. The NRC staff requests additional information to show how watchdog timers**,** interrupt, and exception handling mechanism are used to ensure deterministic behavior of the proTK 260 platform for safety-related applications and further demonstrate its compliance with the regulatory requirement in Clause 5.2 on completion of protective action of IEEE Std. 603-1991, which is incorporated by reference in 10 CFR 50.55a(h).

Interfaces

11. The NRC staff noted that the proTK 260 platform in the TR includes external serial communication to external systems. In Section 3.5, “Communications,” of the TR, it states, in part, that “The system architecture incorporates a dedicated communications board to ensure a strict segregation between communication functions and safety-related operations.” However, the NRC staff could not identify sufficient information to demonstrate how the strict segregation is designed and implemented. The NRC staff requests additional information on how the strict segregation is designed and implemented to ensure that any failure and fault within the external communication interface does not affect the safety functions to be performed by the proTK 260 platform. The above additional information is requested to evaluate the compliance with the regulatory requirements in Clause 5.6 on independence of IEEE Std. 603-1991 and GDC 24 on separation of protection and control systems.

5.0 INFORMATION AND OTHER MATERIAL NECESSARY FOR THE REGULATORY AUDIT

1. The NRC staff requests the following documents, relevant to the Westinghouse reference configurations of the Mirion proTK 260 platform, be available for audit, to support answers to the above audit questions and understanding of the proTK 260 platform. The NRC staff will identify if any additional information in these documents should be docketed to support its safety conclusions on the proTK 260 platform. Associated question numbers listed in Section 4.0 above are included in parentheses.

Quality Assurance

- Westinghouse Audit Report on Mirion QA Program for compliance with 10 CFR Part 50 Appendix B QA Requirements (Questions 1 and 2).

- Westinghouse corrective actions implemented to address Mirion MUC QA program audit findings (Questions 1 and 2).

- Mirion MUC corrective actions implemented to address Westinghouse audit findings (Questions 1 and 2).

Equipment Qualification

- EQ testing plans, procedures, and sequences used for the EQ and associated testing records and detailed reports for EQ tests conducted, including any failures which might have occurred during the complete environmental qualification testing process and the documentation that demonstrates the failures or deficiencies were corrected or resolved (Questions 4, 5, 6, 7, and 8).

- Documentation to demonstrate the implementation of a suitable QA program implemented at the EQ testing facilities. Documents showing the Certifications of Accreditation and Calibration for the EQ test equipment and facilities (Questions 3 and 4).

- Documentation to show equipment safety function(s) demonstrated during the EQ tests (Question 4).

Regulatory Compliance

- Reports by the external Independent V&V Team for the proTK Platform (Question 9).

Deterministic Performance

- Documentation explaining how the watchdog timer performs its function and the repeatable and predictable performance of the microprocessor is assured. Documentation explaining how the interrupts and exception handling mechanisms used in the proTK platform are used to ensure its deterministic behavior (Question 10).

Platform Development

- Evaluation Report by Mirion MUC and TÜV SÜD on suitability of SAFERTOS for safety applications (Questions 10 and 11).

- Dedicated assessment reports for software tools used for the development of proTK 260 series (Questions 10 and 11).

- Typical Requirements Traceability Matrix (RTM) to trace high-level requirements to detailed ones throughout the proTK 260 platform development lifecycle (Questions 10 and 11).

2. The NRC staff requests the following documents, referenced in the TR, be available for audit. The NRC staff will identify if any additional information in these documents should be docketed to support its safety conclusions on the proTK 260 platform.

Qualification and Quality Assurance

- **SA-2430017 A30E, Edition 1, "proTK - General Qualification Strategy for Neutron Measurement Systems," Mirion Technologies (MGPI H&B) GmbH, 2024-03-08.**

- **DWK260-TN2025-02-548A-IEEE-AR, Revision 2, "Inspection Report for the IEEE Compliance Analysis of the DWK 260 Digital Wide Range Channel Software, TÜV NORD Systems GmbH & Co. KG.**

- **DxK260-TN2025/03-542A-IEEE-AR, Revision 1, "Inspection Report for the IEEE Compliance Analysis of the DxK 260 Digital Measuring Channel Software," TÜV NORD Systems GmbH & Co. KG**.

- Mirion MUC procedures and work instructions that support demonstrating compliance with Appendix B to 10 CFR Part 50.

Reliability

- **Z-1950004 Y3-B0001E, Revision 2, "FMEA and CCF Analysis for DxK 260," Mirion Technologies (MGPI H&B) GmbH.**

- **Z-2250015 Y3-B0001E, Revision 2, "FMEA and CCF Analysis for DWK 260," Mirion Technologies (MGPI H&B) GmbH.**

- **Z-1950004 Y3-Q0001E, Revision 1, "Reliability Analysis for DxK 260," Mirion Technologies (MGPI H&B) GmbH.**

- **Z-2250015 Y0-Q0001E, Revision 1, "Reliability Analysis for DWK 260," Mirion Technologies (MGPI H&B) GmbH.**

- **Z-1350020 V10E Revision 3, "Wide Range Preamplifier NV 230.1 - Technical Information," Mirion Technologies (MGPI H&B) GmbH.**

- **5-0218 V10E, Edition 4, "Technical Information, Pulse Preamplifier NV 320," Mirion Technologies (MGPI H&B) GmbH.**

- Z-1950004 D2000E, Revision 2, "DAK 260 – Technical Information," Mirion Technologies (MGPI H&B) GmbH.

- Z-2250015 D2000E, Revision 1, "Technical Information, DWK 260," Mirion Technologies (MGPI H&B) GmbH.

Secure Development and Operational Environment

- **SA-2030087 D0001E, Edition 2, "General System Requirements, Security Requirements Specification for proTK™ / 260 series," Mirion Technologies (MPGI H&B) GmbH.**

- **SA-1930071 A6000E, Edition 1, "Company Cybersecurity Plan," Mirion Technologies (MGPI H&B) GmbH.**

- Z-1950004 Y1-D0004E, Edition 2, "Security Specification for DxK 260 (SecSpecs)," Mirion Technologies (MPGI H&B) GmbH.

- Z-2250015 Y1-D0004E, Edition 1, "Security Specification for DWK 260," Mirion Technologies (MPGI H&B) GmbH.

Platform Development

- **Z-1950004 Y0-A0001E, Revision 3, "Project Development Plan for DxK 260," Mirion Technologies (MGPI H&B) GmbH**.

- **Z-1950004 Y0-A0004E, Revision 1, "System Verification Plan for DxK 260," Mirion Technologies (MGPI H&B) GmbH.**

- **348664 A61E, Edition 4, "Software Quality Assurance Plan for the proTK™/260 Series," Mirion Technologies (MPGI H&B) GmbH.**

- **348666 A61E, Edition 4, "Software Verification and Validation Plan for the proTK™ / 260 Series," Mirion Technologies (MPGI H&B) GmbH.**

- **SA-1930044 A6E, Edition 1, "Generic Requirements Engineering and Management Plan," Mirion Technologies (MPGI H&B) GmbH.**

- 348665 A61E, Edition 5, "Software Configuration Management Plan for the proTK™/260 Series," Mirion Technologies (MPGI H&B) GmbH.

- SA-2030052 A3000E, Edition 2, "Software Tool Qualification Strategy for proTK/260 Series," Mirion Technologies (MPGI H&B) GmbH.

- SA-1930062 A60E, Edition 2, "Generic System Configuration Management Plan for proTK /260 Series," Mirion Technologies (MGPI H&B) GmbH.

- SA-1930057 A6E, "Generic Change Management Plan," Mirion Technologies (MGPI H&B) GmbH.

- Z-2250015 S0-A0002E, Edition 2, "Development Tool Management Plan for DWK260," Mirion Technologies (MPGI H&B) GmbH.

- Z-1950004 S0-A0002E, Edition, 2, "Development Tool Management Plan for DxK 260," Mirion Technologies (MPGI H&B) GmbH.

- 348662 A61E, Edition 4, “Software coding rules for proTK™/260 Series,” Mirion Technologies (MPGI H&B) GmbH.

6.0 AUDIT TEAM

The members of the audit team are:

Team Member	Division	Area of Responsibility
Ekaterina Lenning	NRR/DORL/LLPB	Project Management
Jack Zhao	NRR/DEX/EICB	Technical Reviewer (Digital I&C)
Youssef Rokes	NRR/DSS/EICB	Technical Reviewer (Digital I&C)
Deanna Zhang	NRR/DRO/IQVB	Technical Reviewer (QA Inspection)
Tiffany Lee	NRR/DRO/IQVB	Technical Reviewer (QA Inspection)

7.0 SCHEDULE AND LOGISTICS

This regulatory audit is planned as a hybrid activity and will consist of the following two phases:

Phase I: Virtual Audit:

- Start two weeks after audit plan issuance and continue through September 2026.
- The initial information needs are included in the audit plan. Any additional information needs will be sent to Westinghouse weekly (as needed) via the NRC’s secure external sharing SharePoint site.
- The NRC staff will review Westinghouse’s documents and audit responses via online portal established by Westinghouse.
- The following conditions associated with Westinghouse’s online portal must be maintained throughout the duration that the NRC staff have access to the online portal:
    - The online portal will be password-protected, and separate passwords will be assigned to the NRC staff who are participating in the audit.
    - The online portal will be sufficiently secure to prevent the NRC staff from printing, saving, downloading, or collecting any information on the online portal.
    - Conditions of use of the online portal will be displayed on the login screen and will require acknowledgement by each user.

Phase II: In-person Audit:

The hybrid audit (in-person at a mutually agreed upon location and via MS Teams) will start on July 13, 2026, and end on July 17, 2026, in order to facilitate the review and ensure the most efficient and effective face-to-face discussions with Westinghouse and Mirion technical experts.

During the audit entrance briefing, the NRC staff will provide an overview of the audit plan, agenda, and objectives. During the exit briefing, the NRC staff will provide a summary of the audit, and its observations to be made during the audit.

Meetings and tours conducted during the audit will be scheduled on an as-needed basis and as requested by the NRC staff or Westinghouse.

The audit team will not remove any non-docketed documents or other materials from the location of the audit. If the audit team identifies information that requires docketing to support the basis for a regulatory decision concerning the review of the WCAP-19042-P/NP, Revision 0, the NRC staff will use the RAI process.

Any changes in the audit logistics will be properly coordinated and communicated with Westinghouse. The NRC point of contact for this audit is Ekaterina Lenning, Project Manager with email at Ekaterina.Lenning@nrc.gov.

8.0 SPECIAL REQUEST

Please provide the NRC audit team with an enclosed conference room or similar space for the NRC audit team's use during the in-person portions of the audit.

9.0 DELIVERABLES

An audit summary report will be prepared within 90 days after the completion of the audit.