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GENERAL ATOMICS ELECTROMAGNETIC SYSTEMS - DRAFT SAFETY EVALUATION OF TOPICAL REPORT 30599T00006, "FAST MODULAR REACTOR QUALITY ASSURANCE PROGRAM DESCRIPTION," REVISION 5 (EPID NO. L-2023-TOP-0025)

SPONSOR AND SUBMITTAL INFORMATION

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Brief Description of the Topical Report and Background: By letter dated July 31, 2023 (Reference 1), GA-EMS, submitted for U.S. Nuclear Regulatory Commission (NRC) staff review topical report (TR), Revision 3, "Fast Modular Reactor Quality Assurance Program Description." For the review, the NRC staff issued RAIs by letters dated February 16, 2024 (Reference 2) and August 9, 2024 (Reference 3). A clarification call was held on May 2, 2024 (Reference 4). On June 27, 2024, and October 1, 2024, GA-EMS submitted Revision 4 (Reference 5) and Revision 5 (Reference 6), respectively, of the TR to incorporate changes made consistent with the RAI responses listed above (References 7 through 9). This safety evaluation (SE) is based on the NRC staff's review of Revision 5 of the TR.

The TR addresses power reactor quality assurance (QA) requirements to support license applications for GA-EMS's gas-cooled fast modular reactor (FMR). The TR addresses design phase activities, including those in support of standard design approval (SDA) and design certification (DC) activities affecting the quality and performance of safety-related structures, systems, and components (SSCs) of the FMR. The quality assurance program description (QAPD) is based on the applicable portions of appendix B, "Quality Assurance Criteria for Nuclear Power Plants and Fuel Reprocessing Plants," to Title 10 of the *Code of Federal Regulations* (10 CFR) Part 50, "Domestic Licensing of Production and Utilization Facilities." GA-EMS's QAPD commits to applicable requirements of the American Society of Mechanical Engineers (ASME) NQA-1-2015, "Quality Assurance Program Requirements for Nuclear Facility

Applications," (Reference 10), as endorsed by NRC Regulatory Guide (RG) 1.28, Revision 5, "Quality Assurance Program Criteria (Design and Construction)" (Reference 11).

REGULATORY EVALUATION

Regulatory Basis: 10 CFR 52.47, 10 CFR 52.137, and Appendix B to 10 CFR Part 50

The regulatory requirements related to quality assurance programs (QAPs) are set forth in 10 CFR 52.47, "Contents of applications; technical information," 10 CFR 52.137, "Contents of applications; technical information," and appendix B to 10 CFR Part 50, "Quality Assurance Criteria for Nuclear Power Plants and Fuel Reprocessing Plants."

The regulations in 10 CFR 52.47 establish the technical information requirements for DC applications. The regulations in 10 CFR 52.47(a) require that a DC application contain a final safety analysis report (FSAR) that describes the facility, presents the design bases and the limits on its operation, and presents a safety analysis of the SSCs and of the facility as a whole. The regulations in 10 CFR 52.47(a)(19) require that DC applications provide a description of the QAP applied to the design of the SSCs of the facility. Further, 10 CFR 52.47(a)(19) requires that the description of the QAP include a discussion of how the applicable requirements of appendix B to 10 CFR Part 50 have been satisfied.

The regulations in 10 CFR 52.137 establish the technical information requirements for SDA applications. Specifically, 10 CFR 52.137(a) requires that an SDA application contain an FSAR that describes the facility, presents the design bases and the limits on its operation, and presents a safety analysis of the SSCs and of the facility. Additionally, 10 CFR 52.137(a)(19) states that the FSAR must include a description of the QAP, applied to the design of the SSCs of the facility.

Appendix B to 10 CFR 50 sets forth the regulatory requirements for QAP for nuclear power plants (NPPs), and establishes QA requirements for design, fabrication, construction, and testing for SSCs for the facility. The description of the QAP for a NPP must include a discussion of how the applicable requirements of appendix B have been and will be satisfied, including a discussion of how the QAP will be implemented. The pertinent requirements of appendix B apply to all activities affecting the safety-related functions of those SSCs and include designing, purchasing, fabricating, handling, shipping, storing, cleaning, erecting, installing, inspecting, testing, operating, maintaining, repairing, refueling, and modifying SSCs.

Additionally, the NRC staff evaluated the adequacy of the GA-EMS QAPD TR in accordance with the guidance of NUREG-0800, "Standard Review Plan [(SRP)] for the Review of Safety Analysis Reports for Nuclear Power Plants," section 17.5, "Quality Assurance Program Description - Design Certification, Early Site Permit and New License Applicants," Revision 1 (Reference 12). Section 17.5 of the SRP describes regulatory and industry guidance determined to be acceptable methods for meeting the requirements of appendix B to 10 CFR Part 50, "Domestic Licensing of Production and Utilization Facilities." Although the SRP is written for NRC reviews of light water reactors (LWRs), QA criteria associated with technology development and high-level design activities of GA-EMS and LWRs are similar; therefore, the guidance in section 17.5 of the SRP is applicable to the staff's review of the GA-EMS QAPD.

TECHNICAL EVALUATION

Quality Assurance Program Description Details:

The GA-EMS QAPD TR, Revision 5, provides for the control of activities affecting quality and performance of safety-related SSCs and select nonsafety-related SSCs to the design phase activities, including those in support of an SDA and DC for the GA-EMS FMR.

Organization

The GA-EMS QAPD is consistent with SRP section 17.5, subsection II.A, for providing an organizational description that includes the organizational structure, functional responsibilities, levels of authority, and interfaces for establishing, executing, and verifying GA-EMS's QAP implementation. For organizations performing QA functions, the GA-EMS QAPD establishes organizations with sufficient authority and organizational freedom to identify quality problems; to initiate, recommend, or provide solutions; and to verify implementation of solutions. The GA-EMS QAPD provides an organizational structure where persons and organizations performing QA functions report to a higher management level to maintain required authority and organizational freedom, including sufficient independence from cost and schedule. Additionally, the responsibility and authority for planning, establishing, and implementing an effective overall QAP are clearly described and defined, including identifying the position responsible for directing and managing the GA-EMS QAPD during the design phase. The GA-EMS QAPD provides for applicable management to be responsible to size the QA organization commensurate with the duties and responsibilities assigned. The GA-EMS QAPD provides the authority and responsibility to stop work in progress not being done in accordance with approved procedures or where the safety of personnel of SSC integrity may be jeopardized.

The GA-EMS QAPD commits to implement the quality standards described in NQA-1-2015, Requirement 1, "Organization," without further clarifications or exceptions. As stated in RG 1.28, Revision 5, NQA-1-2015 is considered acceptable to the NRC staff and provides an adequate basis for complying with the requirements of appendix B to 10 CFR Part 50. Based upon its review, the NRC staff determined that the description of GA-EMS's organization, as detailed above, complies with the requirements of Criterion I, "Organization," of appendix B to 10 CFR Part 50, and, therefore, is acceptable.

Quality Assurance Program

The GA-EMS QAPD is consistent with SRP section 17.5, subsection II.B, for establishing the necessary measures to implement a QAP to ensure that the design activities are in accordance with governing regulations. The QAP applies to those quality-related activities that involve the functions of safety-related SSCs associated with the design of the SSCs of the facility. A list identifying the SSCs and activities to which the GA-EMS QAPD applies is maintained at GA-EMS. GA-EMS may delegate all or part of the activities for which they are responsible to others; however, GA-EMS retains overall responsibility for the QAP effectiveness. The GA-EMS QAPD provides for measures to assess the adequacy of the QAP and to ensure its effective implementation, at least once each year or at least once during the life of the activity, whichever is shorter.

In addition, consistent with SRP section 17.5, subsection II.B.10, the GA-EMS QAPD allows for the application of a grace period of 90 days to activities that must be performed on a periodic

basis. Annual evaluations and audits that must be performed on a triennial basis are examples where the 90-day general period could be applied. The grace period does not allow the “clock” for a particular activity to be reset forward. In addition, the “clock” for an activity is not reset backwards by performing the activity early.

The GA-EMS QAPD is consistent with SRP section 17.5, subsections II.S and II.T, by providing the necessary measures to establish and maintain formal indoctrination and training programs for personnel performing, verifying, or maintaining activities within the scope of the QAPD to ensure that suitable proficiency is achieved and maintained. The GA-EMS QAPD provides the minimum training qualification for all personnel responsible for implementation of GA-EMS’s QAP.

The GA-EMS QAPD commits to implement the quality standards described in NQA-1-2015, Requirement 2, “Quality Assurance Program,” with two clarifications and exceptions. GA-EMS QAPD section 3.2.6, “NQA-1 Commitment/Exception,” states, in part, the following:

1. GA-EMS follows section 301 for qualification of nondestructive examination personnel, except that GA-EMS will follow the applicable standard cited in the version(s) of section III and section XI of the ASME Boiler and Pressure Vessel (B&PV) Code approved by the NRC for use at GA-EMS sites for the scope of activities governed by these cited standards.

The regulations in 10 CFR 50.55a, “Codes and Standards,” endorses versions of ASME B&PV Code sections III and XI for activities within the scope of these sections. Therefore, the NRC staff has determined the alternative proposed for the use of sections III and XI of the ASME B&PV Code for qualification of nondestructive examination personnel to be acceptable.

GA-EMS QAPD section 3.2.6 also states:

2. Section 401 (g) requires the date of certification expiration be included on the qualification record. GA-EMS considers the certification expiration date to be the date from the certification or recertification date plus the certification interval time and its inclusion on the qualification record is optional.

The NRC staff evaluated this exception and determined that the date of certification establishes the expiration date when combined with the certification interval. The certification interval is normally a function of a code or standard and is identified in the organization’s procedure; therefore, because having both dates on the form is redundant, the NRC staff determined the exception to be acceptable.

As stated in RG 1.28, Revision 5, NQA-1-2015 is considered acceptable to the NRC staff and provides an adequate basis for complying with the requirements of appendix B to 10 CFR Part 50. Based upon its review, the NRC staff has determined that the description of GA-EMS’s QAP, as detailed above, complies with the requirements of Criterion II, “Quality Assurance Program,” of appendix B to 10 CFR Part 50, and, therefore, is acceptable.

Design Control

The GA-EMS QAPD is consistent with SRP section 17.5, subsection II.C, for establishing the necessary measures to control the design, design verification, and analysis activities of items that are subject to the provisions of the QAPD. The GA-EMS QAPD design process includes

provisions to control design inputs, outputs, changes, interfaces, records, and organizational interfaces within GA-EMS and with suppliers. These provisions ensure that the design inputs (such as design bases and the performance and regulatory quality and quality verification requirements) are correctly translated into design outputs (such as analyses, specifications, drawings, procedures, and instructions) so that the final design output can be related to the design input in sufficient detail to permit verification. In addition, the GA-EMS QAPD provides for design documents to be reviewed by individuals knowledgeable in QA to ensure that the documents contain the necessary quality assurance requirements.

Consistent with SRP section 17.5, subsection II.C, the GA-EMS QAPD design processes provide for design verification to ensure that items and activities subject to the provisions of the QAP are suitable for their intended application and are consistent with their effect on safety. Design changes are subject to these controls, which include verification measures commensurate with those applied to original plant design. The extent of the design verification required is a function of the importance to safety of the item under consideration, the complexity of the design, the degree of standardization, the state of the art, and the similarity with previously proven designs. Verification methods may include, but are not limited to, design reviews, alternative calculations, and qualification testing.

The GA-EMS QAPD governs the development, procurement, testing, maintenance, and use of computer application and digital equipment software when used in safety-related applications and designated non-safety-related applications. GA-EMS and its suppliers are responsible for developing, approving, and issuing procedures, as necessary, to control the use of such computer application and digital equipment software. The GA-EMS QAPD states that procedures shall require that the application software be assigned a proper quality classification and that the associated quality requirements be consistent with this classification.

The GA-EMS QAPD commits to implement the quality standards described in NQA-1-2015, Requirement 3, “Design Control,” as well as the standards contained in NQA-1-2015, Part II, subpart 2.7, “Quality Assurance Requirements for Computer Software for Nuclear Facility Applications,” without further clarifications or exceptions.

As stated in RG 1.28, Revision 5, NQA-1-2015 is considered acceptable to the NRC staff and provides an adequate basis for complying with the requirements of appendix B to 10 CFR Part 50. Based upon its review, the NRC staff determined that the description of GA-EMS’s design control, as detailed above, complies with the requirements of Criterion III, “Design Control,” of appendix B to 10 CFR Part 50, and, therefore, is acceptable.

Procurement Document Control

The GA-EMS QAPD is consistent with SRP section 17.5, subsection II.D, for establishing the necessary measures and governing procedures for preparing and reviewing procurement documents to ensure that applicable regulatory, technical, and QAP requirements are included or referenced in procurement documents. The GA-EMS QAPD ensures the procurement documents are developed and reviewed by relevant personnel and that changes are subject to the same degree of control as utilized in the preparation of the original documents.

The GA-EMS QAPD states that applicable technical, regulatory, administrative, quality, and reporting requirements (such as specifications, codes, standards, tests, inspections, special processes, 10 CFR Part 21, “Reporting of Defects and Noncompliance”) are invoked for the procurement of items and services.

To the extent necessary, procurement documents shall require suppliers to have a documented QAP that is determined to meet the applicable requirements of appendix B to 10 CFR 50. Alternatively, the QAPD allows the supplier to work under GA-EMS's approved QAP.

In QAPD section 3.4.1, "NQA-1 Commitment/Exceptions," GA-EMS commits to implement the quality standards described in NQA-1-2015, Requirement 4, "Procurement Document Control," with the following three clarifications and exceptions:

1. With regard to service performed by a supplier, GA-EMS procurement documents may allow the supplier to work under the GA-EMS QAP, including implementing procedures, in lieu of the supplier having its own QAP.

The NRC staff evaluated this proposed exception and determined that it provides adequate control for establishing and executing the responsibilities for the QAP because it is consistent with SRP section 17.5, paragraph II.D.1. In addition, Criterion IV, "Procurement Document Control," of appendix B to 10 CFR Part 50, requires suppliers to have a QAP consistent with the regulations. Therefore, the NRC staff determined that the exception is acceptable.

2. Sections 300 and 400 of Requirement 4 require the review of technical and [QAP] requirements of procurement documents prior to award of a contract and for procurement document changes. GA-EMS may satisfy this requirement through the review of procurement specifications when the specification contains the technical and [QA] requirements of the procurement.

The NRC staff evaluated this proposed clarification and determined that it provides adequate QA review of procurement documents before awarding the contract and after any change to the contract. Therefore, the NRC staff determined that the clarification is acceptable.

3. Procurement documents for commercial-grade items that will be procured by GA-EMS for use as safety-related items shall contain technical and quality requirements such that the procured item can be appropriately dedicated in accordance with the GA-EMS QAPD 3.7, "Control of Purchased Material, Equipment and Services."

The NRC staff evaluated this proposed clarification and determined that it is consistent with NRC staff guidance provided in RG 1.164, Revision 1, "Dedication of Commercial-Grade Items for Use in Nuclear Power Plants," issued April 2024 (Reference 13). The proposed clarification is also consistent with Generic Letter (GL) 89-02, "Actions to Improve the Detection of Counterfeit and Fraudulently Marked Products," dated March 21, 1989 (Reference 14), and GL 91-05, "Licensee Commercial-Grade Procurement and Dedication Programs," dated April 9, 1991 (Reference 15), as delineated in SRP section 17.5, paragraphs II.V.1.d and II.V.1.e.

As stated in RG 1.28, Revision 5, NQA-1-2015 is considered acceptable to the NRC staff and provides an adequate basis for complying with the requirements of appendix B to 10 CFR Part 50. Based upon its review, the NRC staff determined that the description of GA-EMS's procurement document control, as detailed above, complies with the requirements of Criterion IV, "Procurement Document Control," of appendix B to 10 CFR Part 50, and, therefore, is acceptable.

Instructions, Procedures, and Drawings

The GA-EMS QAPD is consistent with SRP section 17.5, subsection II.E, for establishing the necessary measures and governing procedures to ensure that activities affecting quality are prescribed by, and performed in accordance with, documented instructions, procedures, or drawings of a type appropriate to the circumstances and which, where applicable, include quantitative or qualitative acceptance criteria to implement the QAP.

The GA-EMS QAPD commits to the quality standards described in NQA-1-2015, Requirement 5, “Instructions, Procedures, and Drawings,” without further clarifications or exceptions. As stated in RG 1.28, Revision 5, NQA-1-2015 is considered acceptable to the NRC staff and provides an adequate basis for complying with the requirements of appendix B to 10 CFR Part 50. Based upon its review, the NRC staff determined that the description of GA-EMS’s instructions, procedures, and drawings, as detailed above, complies with the requirements of Criterion V, “Instructions, Procedures, and Drawings,” of appendix B to 10 CFR Part 50, and, therefore, is acceptable.

Document Control

The GA-EMS QAPD is consistent with SRP section 17.5, subsection II.F, for establishing the necessary measures and governing procedures to control the preparation, review, approval, issuance of, and changes to documents that specify quality requirements or prescribe how activities affecting quality, including organizational interfaces, are controlled. Measures are provided to assure that documents, including revisions or changes (other than those defined in implementing procedures as minor changes), are reviewed and approved by the same organization that performed the original review and approval, unless other organizations are specifically designated. A list of all controlled documents, identifying the current approved revision or date, is maintained so personnel can determine the appropriate document for use.

The GA-EMS QAPD commits to implement the quality standards described in NQA-1-2015, Requirement 6, “Document Control,” without further clarifications or exceptions. As stated in RG 1.28, Revision 5, NQA-1-2015 is considered acceptable to the NRC staff and provides an adequate basis for complying with the requirements of appendix B to 10 CFR Part 50. Based upon its review, the NRC staff finds that the description of GA-EMS’s document control, as detailed above, complies with the requirements of Criterion VI, “Document Control,” of appendix B to 10 CFR Part 50, and, therefore, is acceptable.

Control of Purchased Material, Equipment, and Services

The GA-EMS QAPD is consistent with SRP section 17.5, subsection II.G, for establishing the necessary measures and governing procedures to control the procurement of items and services to ensure conformance with specified requirements. The GA-EMS QAPD provides measures for source evaluation and selection, evaluation of objective evidence of quality furnished by the supplier, source inspection, audit, and examination of items or services. The GA-EMS QAPD establishes and implements measures to assess the quality of purchased items and services, whether purchased directly or through contractors, at intervals and to a depth consistent with the item's or service's importance to safety, complexity, quantity, and frequency of procurement.

The GA-EMS QAPD provides measures for evaluating prospective suppliers and selecting only qualified suppliers, as well as auditing and evaluating suppliers to ensure that qualified suppliers

continue to provide acceptable products and services. Qualified suppliers are audited on a triennial basis. The GA-EMS QAPD provides for utilizing audits conducted by outside organizations for supplier qualification, including industry programs such as those applied by the Nuclear Industry Assessment Corporation or other established utility groups, provided that the scope and adequacy of the audits meet GA-EMS requirements. GA-EMS will also perform annual evaluations of qualified suppliers to document that these suppliers continue to provide acceptable products and services.

The GA-EMS QAPD also outlines acceptance actions, such as source verification, receipt inspection, pre- and post-installation tests, certificates of conformance, and document reviews (e.g., certified material test reports/certificates) to ensure that the procurement, inspection, and test requirements have been satisfied before relying on the item to perform its intended safety function. In addition, the QAPD establishes controls for the selection, determination of suitability for intended use (critical characteristics), evaluation, receipt, and acceptance of commercial-grade services or items to assure they will perform satisfactorily in service in safety-related applications.

In establishing procurement verification controls and commercial-grade item requirements, the GA-EMS QAPD commits to implement the quality standards described in NQA-1-2015, Requirement 7, with the following four clarifications and exceptions.

1. GA-EMS considers that other 10 CFR Parts 50 and 52 licensees, authorized nuclear inspection agencies, National Institute of Standards and Technology (NIST), or other state and federal agencies that may provide items or services to the GA-EMS plants are not required to be evaluated or audited.

The NRC staff has documented its current regulatory position regarding this exception in SE section 3.1.7.1 of the Tennessee Valley Authority (TVA) New Nuclear QAPD, dated December 12, 2023 (Reference 16). The NRC staff verified that the GA-EMS QAPD provided the same commitments associated with supplier oversight activities as those provided in the TVA New Nuclear QAPD. Therefore, the NRC staff's position associated with this exception, as documented in the TVA New Nuclear QAPD SE, would apply to the GA-EMS QAPD. The NRC staff concludes that the requested exception regarding audit and evaluation, as described above, is acceptable subject to the limitations described in the TVA New Nuclear QAPD SE, as identified below in the "Limitations and Conditions" section of this SE, for control of purchased material, equipment, and services.

2. When purchasing commercial-grade calibration and testing services from a laboratory, procurement source evaluation and selection measures need not be performed provided each of the following conditions are met:

    a. The purchase documents impose any additional technical and administrative requirements, as necessary, to comply with the GA-EMS QAP and technical provisions. At a minimum, the purchase document shall require that the calibration certificate/report include identification of the laboratory equipment/standard used.

    b. The purchase documents require reporting as-found calibration data when calibrated items are found to be out-of-tolerance.

c. Use of Third-Party ISO/IEC 17025:2017, “General requirements for the competence of testing and calibration laboratories,” accreditation (Reference 17) and Nuclear Energy Institute (NEI) 14-05A, “Guidelines for the Use of Accreditation in Lieu of Commercial-Grade Surveys for Procurement of Laboratory Calibration and Test Services,” Revision 1 (Reference 18). As documented in NEI 14-05A, the International Laboratory Accreditation Cooperation (ILAC) process cannot be used for the commercial-grade dedication of nondestructive examination services.

d. In accordance with the NRC-accepted NEI 14-05A, Revision 1, when purchasing commercial-grade calibration and testing services from domestic and international calibration and testing laboratories accredited by an ILAC Mutual Recognition Arrangement (MRA) signatory, suppliers of basic components may use the ILAC accreditation process in lieu of performing a commercial-grade survey as part of the commercial-grade dedication process provided the following standards are met. A documented review of the supplier’s accreditation is performed and includes verification of the following criteria including requirements in the GA-EMS critical characteristics acceptance plan for calibration or testing services:

    i. The calibration or test lab holds an accreditation by an accrediting body recognized by the ILAC MRA that encompasses ISO/IEC 17025: 2017.

    ii. For procurement of calibration services, the published scope of accreditation for the calibration lab covers the needed measurement parameters, ranges, and uncertainties.

    iii. For procurement of testing services, the published scope of accreditation for the test lab covers the needed testing services including test methodology and tolerances/uncertainties.

    iv. The lab has achieved accreditation based on an onsite accreditation assessment by the selected accreditation bodies within the past 48 months. The lab’s accreditation cannot be based on two consecutive remote accreditation assessments.

e. Purchase documents require the following:

    i. The supplier of the accredited calibration or testing services must certify that the GA-EMS purchase order requirements are met. A certificate of conformance or equivalent document is acceptable.

    ii. The contracted services must be provided in accordance with the lab’s accredited ISO/IEC 17025:2017 program and is within their scope of accreditation.

    iii. As-found calibration data must be reported in the certificate of calibration when calibrated items are found to be out-of-tolerance (for calibration services only).

iv. The equipment/standards used to perform the calibration must be identified in the certificate of calibration (for calibration services only).

v. Subcontracting of the contracted services is prohibited.

vi. The customer must be notified of any condition that adversely impacts the lab's ability to maintain the scope of accreditation.

vii. Performance of the contracted services is contingent on the lab's accreditation having been achieved through an onsite accreditation assessment by the selected accreditation bodies within the past 48 months.

viii. Other technical and quality requirements may be added as necessary based upon a review of the procured scope of services, including but not limited to tolerances, accuracies, ranges, and industry standards.

f. At receipt inspection, validating the lab's documentation certifies that:

i. The contracted services have been performed in accordance with the lab's accredited ISO/IEC 17025:2017 program and is within their scope of accreditation.

ii. The GA-EMS purchase order's requirements are met.

The NRC staff evaluated this proposed clarification and determined that it is consistent with the NRC staff's current regulatory position, documented in RG 1.28, "Quality Assurance Program Criteria (Design and Construction)," Revision 6, issued September 2023 (Reference 19). In this RG, the NRC staff concluded that NEI 14-05A, Revision 1, provides an acceptable approach for licensees and suppliers subject to the QA requirements of appendix B to 10 CFR Part 50. This NEI document relates to using laboratory accreditation by accreditation bodies that are signatories to the ILAC MRA in lieu of performing commercial-grade surveys as part of the commercial-grade dedication process for procuring calibration and testing services performed by domestic and international laboratories accredited by signatories to the ILAC MRA. Therefore, the NRC staff concludes that this clarification is acceptable.

3. For section 501, GA-EMS considers documents that may be stored in approved electronic media under GA-EMS or vendor control, not physically located on the plant site but accessible from the respective nuclear facility site, as meeting the NQA-1 requirement for documents to be available at the site. The GA-EMS records management system will provide for timely retrieval of necessary records.

Based on the NRC staff's evaluation of GA-EMS's use of electronic records as documented below in the "Quality Assurance Records," section of this SE, the NRC staff concludes that GA-EMS's position that documents stored in approved electronic media under GA-EMS or vendor control is an acceptable alternative to section 501 of NQA-1- 2015, Requirement 7.

4. In establishing commercial-grade item requirements, GA-EMS commits to compliance with NQA-1-2015, section 700 and subpart 2.14, with the following clarification:

a. For commercial-grade items, quality verification requirements are established and described in GA-EMS documents to provide the necessary assurance an item will perform satisfactorily in service. The GA-EMS documents address determining the critical characteristics that ensure an item is suitable for its intended use, technical evaluation of the item, receipt requirements, and quality evaluation of the item.

The NRC staff considers that the establishment of quality verification requirements and processes for identification of critical characteristics of GA-EMS documents as part of the commercial-grade dedication process is acceptable because this is consistent with NRC positions in GL 89-02, GL 91-05, and the guidance in SRP section 17.5, subsection II, Item G, and is therefore acceptable.

b. GA-EMS will assume 10 CFR 21 reporting responsibility for all items that GA-EMS dedicates as safety-related.

Under 10 CFR Part 21, any individual director or responsible officer of a firm constructing, owning, operating, or supplying the components of any licensed or regulated facility or activity, who obtains information reasonably indicating: (a) that the facility, activity or basic component supplied to such facility or activity fails to comply with the Atomic Energy Act of 1954, as amended, or any applicable rule, regulation, order, or license of the Commission relating to substantial safety hazards; or (b) that the facility, activity, or basic component supplied to such facility or activity contains defects that could create a substantial safety hazard, must immediately notify the Commission of such failure to comply or such defect, unless they have actual knowledge that the Commission has been adequately informed of such defect or failure to comply.

The NRC staff evaluated this clarification and determined that it ensures that 10 CFR Part 21 reportability requirements encompass all items that are dedicated as safety-related and does not remove the supplier's responsibilities under 10 CFR Part 21. Therefore, the NRC staff concludes that this clarification is acceptable.

As stated in RG 1.28, Revision 5, NQA-1-2015 is considered acceptable to the NRC staff and provides an adequate basis for complying with the requirements of appendix B to 10 CFR Part 50. Based upon its review, the NRC staff determined that the description of GA-EMS's controls for purchased material, equipment, and services, as detailed above, complies with the requirements of Criterion VII, "Control of Purchased Material, Equipment, and Services," of appendix B to 10 CFR Part 50, and, therefore, is acceptable.

Identification and Control of Materials, Parts, and Components

The GA-EMS QAPD is consistent with SRP section 17.5, subsection II.H, for establishing the necessary measures and governing procedures to identify and control items to prevent the use of incorrect or nonconforming items. Identification and control measures include controls for consumable materials and items with a limited shelf-life. The identification of items is maintained throughout fabrication, erection, installation, and use so that the materials, parts, or components can be traced back to their documentation, consistent with the item's effect on safety. The identification location and methods are selected so the function or quality of the item being identified is not affected.

The GA-EMS QAPD commits to implement the quality standards described in NQA-1-2015,

Requirement 8, “Identification and Control of Items,” without further clarifications or exceptions. As stated in RG 1.28, Revision 5, NQA-1-2015 is considered acceptable to the NRC staff and provides an adequate basis for complying with the requirements of appendix B to 10 CFR Part 50. Based upon its review, the NRC staff determined that GA-EMS’s description of identification and control of materials, parts, and components, as detailed above, complies with the requirements of Criterion VIII, “Identification and Control of Materials, Parts, and Components,” of appendix B to 10 CFR Part 50, and, therefore, is acceptable.

Control of Special Processes

This element is not applicable to the GA-EMS FMR design activities and has not been reviewed or approved by the NRC staff.

Inspection

The GA-EMS QAPD is consistent with SRP section 17.5, subsection II.J, for establishing the necessary measures and governing procedures to implement inspections that ensure items, services, and activities affecting safety meet established requirements and conform to applicable documented specifications, instructions, procedures, and design documents.

GA-EMS’s inspection program establishes inspections (including surveillance of processes), as necessary to verify quality: (1) at the source of supplied items or services, (2) in-process during fabrication at a supplier's facility or at a GA-EMS facility, (3) for final acceptance of fabricated items, and (4) upon receipt of items for a facility. GA-EMS’s inspection program establishes requirements for planning the inspections, such as measures for: (1) group or discipline responsible for performing the inspection; (2) where the inspection hold points are to be applied; (3) the frequency of inspection to be applied; and (4) the identification of special tools required to perform the inspection. Inspection planning is performed by personnel qualified in the discipline related to the inspection and includes qualified inspectors or engineers. Inspection plans are based on, at a minimum, the importance of the item to safety, the complexity of the item, the technical requirements to be met, and the design specifications. Inspection information and results, such as rejection, acceptance criteria, reinspection results, and the person(s) performing the inspection are documented. The documentation of this information is the responsibility of the inspector, reviewed by authorized personnel qualified to evaluate the technical adequacy of the inspection results, and controlled by instructions, procedures, and drawings. Inspections are carried out by properly qualified persons, independent of those who performed or directly supervised the work, and the inspection results will be documented.

The GA-EMS QAPD commits to implement the quality standards described in NQA-1-2015, Requirement 10, and part II, subparts 2.5 and 2.8, for establishing appropriate inspection requirements without clarifications or exceptions.

As stated in RG 1.28, Revision 5, NQA-1-2015 is considered acceptable to the NRC staff and provides an adequate basis for complying with the requirements of appendix B to 10 CFR Part 50. Based upon its review, the NRC staff determined that GA-EMS’s description of inspection controls, as detailed above, complies with the requirements of Criterion X, “Inspection,” of appendix B to 10 CFR Part 50, and, therefore, is acceptable.

Test Control

GA-EMS QAPD is consistent with SRP section 17.5, subsection II.K, for establishing the necessary measures and governing procedures to demonstrate that items subject to the provisions of the QAPD will perform satisfactorily in service. Test programs include criteria for determining when testing is required during the design phase. Tests are performed according to applicable procedures that include, consistent with the effect on safety: (1) instructions and prerequisites to perform the tests; (2) use of proper test equipment; (3) acceptance criteria; and (4) mandatory verification points as necessary to confirm satisfactory test completion. Test results are documented and evaluated by the organization performing the test and reviewed by a responsible authority to ensure that the test requirements have been satisfied. If acceptance criteria are not met, re-testing is performed as needed to confirm acceptability following correction of the system or equipment deficiencies that caused the failure. Personnel who perform or evaluate tests are qualified in accordance with the requirements established in section 3.2 of the GA-EMS QAPD.

For non-computer testing, GA-EMS's QAPD commits to implement the quality standards described in NQA-1-2015, Requirement 11, without further clarifications or exceptions. For computer program testing, GA-EMS's QAPD commits to implement the quality standards described in NQA-1-2015, Requirement 11 and subpart 2.7, to establish the appropriate provisions in addition to the commitment to NQA-1- 2015, Requirement 3, without further clarifications or exceptions.

As stated in RG 1.28, Revision 5, NQA-1-2015 is considered acceptable to the NRC staff and provides an adequate basis for complying with the requirements of appendix B to 10 CFR Part 50. Based upon its review, the NRC staff determined that GA-EMS's description of testing controls, as detailed above, complies with the requirements of Criterion XI, "Test Control," of appendix B to 10 CFR Part 50, and, therefore, is acceptable.

Control of Measuring and Test Equipment

The GA-EMS QAPD is consistent with SRP section 17.5, subsection II.L, for establishing the necessary measures and governing procedures to control the calibration, maintenance, and use of measuring and test equipment (M&TE) that provides data to verify acceptance criteria are met for information important to safe plant operation. The provisions of such procedures cover equipment such as indicating and actuating instruments and gauges, tools, reference and transfer standards, and nondestructive examination equipment.

GA-EMS's QAPD commits to implement the quality standards described in NQA-1-2015, Requirement 12, with the following two clarifications and exceptions:

1. The out of calibration conditions described in section 303.2 refers to when the M&TE is found out of the required accuracy limits (i.e., out-of-tolerance) during calibration and not overdue for calibration.

The NRC staff determined that the clarification for out of calibration conditions is consistent with the overall objective of NQA-1-2015, Requirement 12, section 303.2, and Criterion XII, "Control of Measuring and Test Equipment," of appendix B to 10 CFR Part 50, which require that M&TE used in activities affecting quality are properly controlled, calibrated, and adjusted at specified

periods to maintain accuracy within necessary limits. Therefore, the NRC staff concludes that this clarification is acceptable.

2. [M&TE] are not required to be marked with the calibration status, as described in section 3.6, “Document Control,” of GA-EMS QAPD, where it is impossible or impractical due to equipment size or configuration (such as the label will interfere with operation of the device) provided the required information is maintained in suitable documentation traceable to the device.

The NRC staff determined that the clarification is consistent with the overall objective of NQA-1-2015, Requirement 12, section 303.6, and Criterion XII of appendix B to 10 CFR Part 50, which require that M&TE used in activities affecting quality are properly controlled, calibrated, and adjusted at specified periods to maintain accuracy within necessary limits.

As stated in RG 1.28, Revision 5, NQA-1-2015 is considered acceptable to the NRC staff and provides an adequate basis for complying with the requirements of appendix B to 10 CFR Part 50. Based upon its review, the NRC staff determined that GA-EMS’s description of M&TE controls, as detailed above, complies with the requirements of Criterion XII, “Control of Measuring and Test Equipment,” of appendix B to 10 CFR Part 50, and, therefore, is acceptable.

Handling, Storage, and Shipping

This element is not applicable to the GA-EMS FMR design activities and has not been reviewed or approved by the NRC staff.

Inspection, Test, and Operating Status

This element is not applicable to the GA-EMS FMR design activities and has not been reviewed or approved by the NRC staff.

Nonconforming Materials, Parts, or Components

The GA-EMS QAPD is consistent with SRP section 17.5, subsection II.O, for establishing the necessary measures and governing procedures to control items, including services that do not conform to specified requirements to prevent inadvertent installation or use. Controls provide for the identification, documentation, evaluation, segregation (when practical), and disposition of nonconforming items, and notification to affected organizations. Controls are also provided to address conditional release of nonconforming items for use on an at-risk basis prior to resolution and disposition of the nonconformance, including maintaining identification of the item and documenting the basis for such release.

Nonconformances are corrected or resolved depending on the item to perform its intended safety function. Nonconformances to design requirements which are dispositioned “repair” or “use-as-is” are subject to design control measures commensurate with those applied to the original design. Nonconformance dispositions are reviewed for adequacy, analysis of quality trends, and reported to designated management. Significant trends are reported to management in accordance with GA-EMS’s procedures, regulatory requirements, and industry standards.

The GA-EMS QAPD provides for establishing the appropriate interfaces between the QAP for identification and control of nonconforming items, including services, and the non-QA reporting program to satisfy the requirements of 10 CFR Part 21 during design. The GA-EMS QAPD commits to implement the quality standards described in NQA-1-2015, Requirement 15, without further clarifications or exceptions.

As stated in RG 1.28, Revision 5, NQA-1-2015 is considered acceptable to the NRC staff and provides an adequate basis for complying with the requirements of appendix B to 10 CFR Part 50. Based upon its review, the NRC staff determined that GA-EMS's description of controls for nonconforming materials, parts, or components, as detailed above, complies with the requirements of Criterion XV, "Nonconforming Materials, Parts, or Components," of appendix B to 10 CFR Part 50, and, therefore, is acceptable.

Corrective Action

The GA-EMS QAPD is consistent with SRP section 17.5, subsection II.P, for establishing the necessary measures and governing procedures to promptly identify, control, document, classify, correct, and verify conditions adverse to quality. The GA-EMS QAPD provides for procedures to ensure that corrective actions are documented and initiated following the determination of conditions adverse to quality in accordance with regulatory requirements and applicable quality standards.

The GA-EMS QAPD requires personnel to identify known conditions adverse to quality. Reports of conditions adverse to quality are analyzed to identify trends. Significant conditions adverse to quality and significant adverse trends are documented and reported to responsible management. In the case of a significant condition adverse to quality, the cause is determined and actions to preclude recurrence are taken. In the case of suppliers or contractors working on safety-related activities, or other similar situations, GA-EMS may delegate specific responsibilities for corrective actions, but GA-EMS maintains overall responsibility for the effectiveness of corrective action measures and the corrective action program.

The GA-EMS QAPD provides for establishing appropriate links between the implementing procedures of the QAP for corrective actions and the reporting requirements of 10 CFR 21 during design. The GA-EMS QAPD commits to implement the quality standards described in NQA-1- 2015, Requirement 16, "Corrective Action," without further clarifications or exceptions.

As stated in RG 1.28, Revision 5, NQA-1-2015 is considered acceptable to the NRC staff and provides an adequate basis for complying with the requirements of appendix B to 10 CFR Part 50. Based upon its review, the NRC staff determined that GA-EMS's description of its corrective action program, as detailed above, complies with the requirements of Criterion XVI, "Corrective Action," of appendix B to 10 CFR Part 50, and, therefore, is acceptable.

Quality Assurance Records

The GA-EMS QAPD is consistent with SRP section 17.5, subsection II.Q, for establishing the necessary measures to ensure that sufficient records of items and activities affecting quality are developed, reviewed, approved, issued, used, and revised to reflect completed work. The provisions of such procedures establish the scope of the records retention program for GA-EMS and include requirements for records administration including receipt, preservation, retention, storage, safekeeping, retrieval, access controls, user privileges, and final disposition.

The GA-EMS QAPD establishes measures to ensure that sufficient records (e.g., design, engineering, procurement, inspection, test, and audits) of completed items and activities affecting quality are appropriately stored. The records and retention times are defined in appropriate procedures and based on regulatory position C.3 of RG 1.28, Revision 5, for design. In all cases where state, local, or other agencies have more restrictive requirements for record retention, the GA-EMS QAPD provides that those more restrictive requirements will be met.

When using optical disks for electronic records storage and retrieval systems, the GA-EMS QAPD is consistent with the NRC guidance contained in NRC Generic Letter 88-18, "Plant Record Storage on Optical Disks," (Reference 20). GA-EMS will manage the storage of QA records in electronic media consistent with the intent of Regulatory Issue Summary (RIS) 2000-018, "Guidance on Managing Quality Assurance Records in Electronic Media," (Reference 21) and associated Nuclear Information and Records Management Association, Inc. (NIRMA) Technical Guide (TG)11-2011, "Authentication of Records and Media," (Reference 22), TG15-2011, "Management of Electronic Records," (Reference 23), TG16-2011, "Software Configuration Management and Quality Assurance," (Reference 24), and TG21-2011, "Electronic Records Protection and Restoration," (Reference 25).

The GA-EMS QAPD commits to implement the quality standards described in NQA-1-2015, Requirement 17, "Quality Assurance Records," and regulatory positions stated in RG 1.28, Revision 5, with the following clarifications and exceptions.

- QAPD section 3.14.3, "NQA-1 Commitment/Exceptions," states that, "[i]n establishing the provisions for a list of records, GA-EMS commits to comply with RG 1.28, Revision 5, position C.3 with the following clarifications:

    - GA-EMS commits to develop a list of QA records and their retention periods and to maintain sufficient records to furnish evidence of activities affecting quality."

The NRC staff finds this clarification is consistent with the overall objective of NQA-1-2015, Requirement 17, paragraph 700, and SRP 17.5, paragraph II Q.6.

As stated in RG 1.28, Revision 5, NQA-1-2015 is considered acceptable to the NRC staff and provides an adequate basis for complying with the requirements of appendix B to 10 CFR Part 50. Based upon its review, the NRC staff determined that the description of GA-EMS's QA records, as detailed above, complies with the requirements of Criterion XVII, "Quality Assurance Records," of appendix B to 10 CFR Part 50, and, therefore, is acceptable.

Audits

The GA-EMS QAPD is consistent with SRP section 17.5, subsection II.R, for establishing the necessary measures and governing procedures to implement audits to verify that activities covered by the QAP are performed in conformance with the established requirements and performance criteria are met. The audit programs are also reviewed by GA-EMS for effectiveness as part of the overall audit process.

The GA-EMS QAPD provides for conducting periodic internal and external audits. Internal audits are conducted to determine the adequacy of programs and procedures, and to determine if they are meaningful and comply with the overall EMS QAP. Audits are performed in such a manner as to ensure that an audit of all applicable QAP elements is completed for each

functional area at least once each year or at least once during the life of the activity, whichever is shorter. The scope of the audit is determined by the quality personnel not having direct responsibilities in the area being audited and in accordance with preplanned and approved audit plans or check lists, under the direction of a qualified lead auditor and the cognizance of the Nuclear Quality Assurance Manager.

GA-EMS's QAPD provides for all audit results to be documented and reviewed by responsible management. Management responds to all audit findings and initiates corrective actions where indicated. In addition, where corrective actions are indicated, a documented follow-up of the applicable areas through inspections, review, re-audits, or other appropriate means is conducted to verify the implementation and effectiveness of the assigned corrective actions. External audits determine the adequacy of a supplier or contractor QA program and these are conducted as described in GA-EMS QAPD, section 3.7.1.

The GA-EMS QAPD commits to implement the quality standards described in NQA-1-2015, Requirement 18, and the regulatory positions stated in RG 1.28, Revision 5, with the following clarification.

- GA-EMS annual evaluation of the supplier in NRC position C.4.b.(4)(a), (b), and (c) shall only be required to consider activities related to GA-EMS procurement activities.

The intent of NRC position C.4.b.(4)(a), (b), and (c) is for applicants or licensees to assess supplier performance on an annual basis. Activities referenced in C.4.b.(4)(a), (b), and (c) are performed as part of procurement activities in order to ensure suppliers are qualified and have performed sufficient work to demonstrate that its organization is implementing a QAP that has the required scope for purchases. Therefore, since this clarification is consistent with the intent of the staff's position document in RG 1.28, Revision 5, the NRC staff considers this clarification acceptable.

As stated in RG 1.28, Revision 5, NQA-1-2015 is considered acceptable to the NRC staff and provides an adequate basis for complying with the requirements of appendix B to 10 CFR Part 50. Based upon its review, the NRC staff determined that the description of GA-EMS's audits, as detailed above, complies with the requirements of Criterion XVIII, "Audits," of appendix B to 10 CFR Part 50, and, therefore, is acceptable.

Non-Safety-Related SSC Quality Control:

Non-Safety-Related SSCs - Significant Contributors to Plant Safety

The GA-EMS QAPD is consistent with SRP section 17.5, paragraph II.U.1, for establishing necessary measures and governing procedures to be applied to non-safety-related SSCs that are significant contributors to plant safety, but for which the requirements of appendix B to 10 CFR Part 50 are not applicable. GA-EMS applies specific controls to such items in a selected manner, targeted toward those characteristics or critical attributes that render the SSC a significant contributor to plant safety, consistent with applicable sections of the GA-EMS QAPD.

Based upon its review, the NRC staff has determined that this approach, as described in the GA-EMS QAPD, is consistent with SRP section 17.5, paragraph II.U.1 and is, therefore, acceptable.

Non-Safety-Related SSCs Credited for Regulated Events

In establishing the quality requirements for non-safety-related SSCs credited for regulatory events, the GA-EMS QAPD is consistent with the guidance of SRP section 17.5, paragraph II.U.2, and GA-EMS commits to implement the following regulatory guidance:

- The quality requirements for the fire protection system in accordance with regulatory position 1.7, “Quality Assurance,” in RG 1.189, Revision 5, “Fire Protection for Operating Nuclear Power Plants,” (Reference 26).

- The quality requirements for anticipated transient without scram (ATWS) equipment in accordance with NRC Generic Letter 85-06, “Quality Assurance Guidance for ATWS Equipment That Is Not Safety Related,” dated April 16, 1985 (Reference 27).

- The quality requirements for station blackout (SBO) equipment in accordance with RG 1.155, “Station Blackout,” dated August 1988 (Reference 28).

Based upon its review, the NRC staff has determined that this approach, as described in the GA-EMS QAPD, is consistent with SRP section 17.5, paragraph II.U.2, and, therefore, is acceptable.

Regulatory Commitments

The GA-EMS QAPD is consistent with SRP section 17.5, paragraph II.V, for establishing QAP commitments. GA-EMS commits to implement the following NRC RGs and other QA standards (or acceptable alternatives) to supplement and support the QAP, as applicable:

- RG 1.155, "Station Blackout,” Revision 0, dated August 1988 (Reference 28). RG 1.155 describes a method acceptable to the NRC staff for complying with the Commission regulation that requires NPPs to be capable of coping with a station blackout for a specified duration.

- RG 1.164, “Dedication of Commercial-Grade Items for Use in Nuclear Power Plants,” Revision 0, dated June 2017 (Reference 29). RG 1.164 describes methods acceptable to the NRC staff for complying with the regulatory requirements for dedication of commercial-grade items and services used in NPPs.

- RG 1.189, “Fire Protection for Nuclear Power Plants,” Revision 5, dated October 2023 (Reference 26). RG 1.189 describes an approach that is acceptable to the NRC staff to meet the regulatory requirements in the NRC's regulations governing a civilian nuclear power generating plant's fire protection program.

- RG 1.231, “Acceptance of Commercial-Grade Design and Analysis Computer Programs Used in Safety-Related Applications for Nuclear Power Plants,” Revision 0, dated January 2017 (Reference 30). RG 1.231 describes methods acceptable to the NRC staff for complying with the regulatory requirements for acceptance and dedication of commercial-grade design and analysis computer programs used in safety-related applications for NPPs.

- RG 1.234, “Evaluating Deviations and Reporting Defects and Noncompliance Under

10 CFR Part 21," Revision 0, dated April 2018 (Reference 31). RG 1.234 describes methods acceptable to the NRC staff for complying with the provisions of 10 CFR Part 21.

- RG 1.26, Revision 6, "Quality Group Classification and Standards for Water, Steam-, and Radioactive-Waste-Containing Components of Nuclear Power Plants," dated December 2021 (Reference 32). RG 1.26 defines classification of systems and components.

- RG 1.28, Revision 5, "Quality Assurance Program Requirements (Design and Construction)," dated October 2017 (Reference 11). RG 1.28 describes a method acceptable to the NRC staff for complying with the provisions of appendix B to 10 CFR Part 50 regarding establishing and implementing the requisite QAP for the design of NPPs.

- RG 1.29, Revision 6, "Seismic Design Classification for Nuclear Power Plants," dated July 2021 (Reference 33). RG 1.29 defines systems required to withstand a safe shutdown earthquake.

- RG 1.37, Revision 1, "QA Requirements for Cleaning of Fluid Systems and Associated Components of Water-Cooled Nuclear Power Plants," dated March 2007 (Reference 34). RG 1.37 provides guidance on specifying water quality and precautions related to the use of alkaline cleaning solutions and chelating agents. The regulatory positions of this RG were addressed in NQA-1 Part II, subpart 2.1, and subsequently accepted by RG 1.28.

- RG 1.54, Revision 2, "Service Level I, II, and III Protective Coatings Applied to Nuclear Power Plants," dated October 2010 (Reference 35). RG 1.54 provides guidance for the application of protective coatings within NPPs to protect surfaces from corrosion, contamination from radionuclides, and for wear protection.

- ASME NQA-1-2015, "Quality Assurance Requirements for Nuclear Facility Applications," (Reference 10) Part I and Part II as described above in the "Organization" through "Audits" sections of this SE.

- Commitments consistent with GL 89-02 (Reference 14) and GL 91-05 (Reference 15), as described above in the "Procurement Document Control" section of this SE.

- Commitments consistent with GL 85-06 (Reference 27) as described above in the "Non-Safety-Related SSCs Credited for Regular Events" section of this SE.

- NIRMA TGs (References 22-25), as described above in the "Quality Assurance Records" section of this SE.

Based upon its review, the NRC staff has determined that this approach, as described in the QAPD, is consistent with SRP section 17.5, paragraph II.V, and is therefore, acceptable.

LIMITATIONS AND CONDITIONS

This GA-EMS QAPD applies to design phase activities, including those in support of SDA and DC activities affecting the quality and performance of safety-related SSCs of the FMR. Any other application referencing the approved revision of the QAPD, GA-EMS "Nuclear Technologies and Materials Advanced Reactor Concepts-20, Fast Modular Reactor Quality Assurance Program Description," Revision 5, shall provide a description in its QAPD that meets appendix B to 10 CFR Part 50 and associated regulatory requirements.

As referenced above in the "Control of Purchased Material, Equipment, and Services" section of this SE, the following limitations on the use of this QAPD apply:

1. The exception to not perform audit or evaluation for procurements from other Part 50 and Part 52 licensees only applies when GA-EMS procures from other 10 CFR Part 50 and 52 power reactor licensees.

2. When GA-EMS procures from manufacturing licensees where inspections during the fabrication or manufacturing process are required to assure quality, GA-EMS must establish measures for source verification for these procurements, as required by Criterion VII of appendix B to 10 CFR Part 50.

CONCLUSION

The NRC staff concludes that the GA-EMS QAPD delineates the policies, processes, and controls and the implementing documents associated with GA-EMS's activities that affect the quality of safety-related nuclear plant SSCs and include all planned and systematic activities necessary to provide adequate confidence that such SSCs will perform satisfactorily in service. The GA-EMS QAPD may also be applied to certain equipment and activities that are not safety-related, but support safe plant operations, or where other NRC guidance establishes programmatic controls.

The NRC staff determined that the GA-EMS QAPD is consistent with the NRC guidance contained within SRP section 17.5. The NRC staff used the acceptance criteria of SRP section 17.5 as the basis for evaluating the acceptability of the GA-EMS QAPD in conformance with the provisions of 10 CFR 52.47 (a)(19), 10 CFR 52.137(a)(19), and appendix B to 10 CFR Part 50.

Based on its review of the GA-EMS QAPD, the NRC staff concludes that:

- The GA-EMS QAPD adequately describes the authority and responsibility of management and supervisory personnel, performance and verification personnel, and self-assessment personnel, in relation to activities to which the GA-EMS QAP is applicable.

- The GA-EMS QAPD adequately provides for organizations and personnel to perform verification and self-assessment functions related to GA-EMS activities that affect the quality of safety-related nuclear plant SSCs, as well as select non-safety-related SSCs, with these organizations and personnel having the authority and independence to conduct activities without undue influence from those directly responsible for costs and schedules.

- The GA-EMS QAPD adequately applies to activities and items that are important to safety.

- The GA-EMS QAPD adequately establishes controls that, when properly implemented, comply with the requirements of 10 CFR Part 52, appendix B to 10 CFR Part 50, and 10 CFR Part 21, consistent with the criteria contained in SRP section 17.5, as well as the relevant regulatory guidance.

Based on its review, the NRC staff has determined that the GA-EMS QAPD, Revision 5, adequately describes the GA-EMS QAP. Accordingly, the staff concludes that the GA-EMS QAP complies with applicable NRC regulations and is consistent with applicable industry standards and can be used by GA-EMS for activities that support GA-EMS DC or SDA application.

REFERENCES

1. GA-EMS, “Transmittal of GA-EMS Fast Modular Reactor Quality Assurance Program Description Topical Report,” Revision 3, July 31, 2023 (ML23212B187).

2. U.S. NRC, “Transmittal of Requests for Additional Information General Atomics-Electromagnetic Systems FMR Quality Assurance Program Topical Report,” February 16, 2024 (ML24047A365).

3. U.S. NRC, “Transmittal of RAIs for General Atomics FMR Quality Assurance Program Description TR Revision 4,” August 9, 2024 (ML24222A646).

4. U.S. NRC, “Summary of May 2, 2024, Teleconference Call with General Atomics – Electromagnetic Systems Regarding Quality Assurance Topical Report RAI Responses,” May 2, 2024 (ADAMS Accession No. ML24299A067).

5. GA-EMS, “Transmittal of GA-EMS Fast Modular Reactor Quality Assurance Program Description Topical Report,” Revision 4, June 27, 2024 (ML24179A337).

6. GA-EMS, “Transmittal of GA-EMS Fast Modular Reactor Quality Assurance Program Description Topical Report,” Revision 5, October 1, 2024 (ML24275A237).

7. GA-EMS, “Transmittal of Responses to Request for Additional Information on the GA-EMS Fast Modular Reactor Quality Assurance Program Topical Report,” March 18, 2024 (ML24078A428).

8. GA-EMS, “Transmittal of Revised Responses to Request for Additional Information on the GA-EMS Fast Modular Reactor Quality Assurance Program Topical Report,” May 14, 2024 (ML24135A385).

9. GA-EMS, “Transmittal of Responses to Request for Additional Information on the GA-EMS Fast Modular Reactor Quality Assurance Program Topical Report,” September 11, 2024 (ML24255A870).

10. ASME NQA-1-2015, “Quality Assurance Program Requirements for Nuclear Facilities Applications,” February 20, 2015.

11. U.S. NRC, RG 1.28, “Quality Assurance Program Criteria (Design and Construction),” Revision 5, October 2017 (ML17207A293).

12. NUREG-0800, “Standard Review Plan for the Review of Safety Analysis Reports for Nuclear Power Plants,” section 17.5, “Quality Assurance Program Description - Design Certification, Early Site Permit and New License Applicants,” Revision 1, August 2015 (ML15037A441).

13. U.S. NRC, RG 1.164, “Dedication of Commercial-Grade Items for Use in Nuclear Power Plants,” Revision 1, April 2024 (ML24038A310).

14. U.S. NRC, GL 89-02, “Actions to Improve the Detection of Counterfeit and Fraudulently Marketed Products,” March 21, 1989 (ML031140060).

15. U.S. NRC, GL 91-05, “Licensee Commercial-Grade Procurement and Dedication Programs,” April 9, 1991 (ML031140508).

16. U.S. NRC, “Transmittal Letter and Safety Evaluation - Tennessee Valley Authority Quality Assurance Program Description, New Nuclear Program,” December 12, 2023 (ML23254A050).

17. ISO/IEC 17025:2017, “General requirements for the competence of testing and calibration laboratories,” Edition 3, November 2017.

18. Nuclear Energy Institute (NEI) 14-05A, “Guidelines for the Use of Accreditation in Lieu of Commercial-Grade Surveys for Procurement of Laboratory Calibration and Test Services,” Revision 1, September 2020 (ML20259B731)

19. U.S. NRC, RG 1.28, “Quality Assurance Program Criteria (Design and Construction),” Revision 6, September 2023 (ML23177A002).

20. U.S. NRC GL 88-18, “Plant Record Storage on Optical Disks,” October 20, 1988 (ML031130450).

21. U.S. NRC RIS 2000-18, “Guidance on Managing Quality Assurance Records in Electronic Media,” October 23, 2000 (ML003739359).

22. NIRMA, TG 11-2011, “Authentication of Records and Media.”

23. NIRMA, TG 15-2011, “Management of Electronic Records.”

24. NIRMA, TG 16-2011, “Software Configuration Management and Quality Assurance.”

25. NIRMA, TG 21-2011, “Electronic Records Protection and Restoration.”

26. U.S. NRC, RG 1.189, “Fire Protection for Nuclear Power Plants,” Revision 5, October 2023 (ML23214A287).

27. U.S. NRC, GL 85-06, “Quality Assurance Guidance for ATWS Equipment That Is Not Safety Related,” April 16, 1985 (ML031140390).

28. U.S. NRC, RG 1.155, “Station Blackout,” Revision 0, August 1988 (ML003740034).

29. U.S. NRC, RG 1.164, “Dedication of Commercial-Grade Items for Use in Nuclear Power Plants,” Revision 0, June 2017 (ML17041A206).

30. U.S. NRC, RG 1.231, “Acceptance of Commercial-Grade Design and Analysis Computer Programs used in Safety-Related Applications for Nuclear Power Plants,” Revision 0, January 2017 (ML16126A183).

31. U.S. NRC, RG 1.234, “Evaluating Deviations and Reporting Defects and Noncompliance Under 10 CFR Part 21,” Revision 0, April 2018 (ML17338A072).

32. U.S. NRC, RG 1.26, “Quality Group Classification and Standards for Water-, Steam-, and Radioactive-Waste-Containing Components of Nuclear Power Plants,” Revision 6, December 2021 (ML21232A142).

33. U.S. NRC, RG 1.29, “Seismic Design Classification for Nuclear Power Plants,” Revision 6, July 2021 (ML21155A003).

34. U.S. NRC, RG 1.37, “Quality Assurance Requirements for Cleaning of Fluid Systems and Associated Components of Water-Cooled Nuclear Power Plants,” Revision 1, March 2007 (ML070250571).

35. U.S. NRC, RG 1.54, “Service Level I, II, and III Protective Coatings Applied to Nuclear Power Plants,” Revision 2, October 2010 (ML102230344).

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