NR-3605-0003

Quality Assurance Program Description

for the American Centrifuge Plant in Piketon, Ohio

Revision 15

Docket No. 70-7004
Docket No. 70-7003

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Information contained within does not contain Export Controlled Information

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QUALITY ASSURANCE PROGRAM DESCRIPTION FOR THE AMERICAN CENTRIFUGE PLANT

in Piketon, Ohio

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ACRONYMS

ACP	American Centrifuge Plant
ANSI	American National Standards Institute
ASL	Approved Suppliers List
ASME	American Society of Mechanical Engineers
CFR	*Code of Federal Regulations*
IROFS	Items Relied on for Safety
M&TE	Measuring and Test Equipment
NRC	U.S. Nuclear Regulatory Commission
QA	Quality Assurance
QAPD	Quality Assurance Program Description
QL	Quality Level

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FIGURES

1.0 INTRODUCTION

The Quality Assurance Program Description (QAPD) described herein applies to the design, procurement, refurbishment/construction, manufacturing, testing, start-up, operation, inspection, maintenance and modification of the American Centrifuge Lead Cascade Facility (Lead Cascade) and the American Centrifuge Plant (ACP) and meets 10 *Code of Federal Regulations* (CFR) 70.64 (a)(1).

When discussed together, the Lead Cascade and ACP are called the American Centrifuge Program (AC Program).

In addition, this QAPD applies to Regulatory Oversight Agreement (ROA) related activities involving the Gas Centrifuge Enrichment Plant (GCEP) leased or subleased facilities.

The Lead Cascade and ACP are located in Piketon, Ohio. The QAPD is applied using a graded approach as described in Section 2.0 of this QAPD.

1.1 Organization

The Licensee maintains overall responsibility for design, procurement, refurbishment/construction, manufacturing, testing, start-up, and operation, and maintenance of the Lead Cascade and the ACP.

Figure 1.1-1 of this plan shows the organization for the ACP. Figure 1.1-2 of this plan shows the organization for the Lead Cascade. The organization is managed by Licensee staff and operated by a combination of Licensee personnel, supplier-provided augmented staff, and consultants where appropriate.

1.2 Responsibilities

The Vice President, American Centrifuge has overall responsibility for the American Centrifuge program's design, quality assurance (QA), refurbishment/construction, manufacturing, testing, start-up, operation, maintenance, and decommissioning and reports to the Senior Vice President.

The Vice President, American Centrifuge is responsible for the QA Program and for determining the status, adequacy, and effectiveness of the QAPD. The QA Manager reports to the Director, Regulatory and Quality Assurance and has independent oversight responsibility for implementation of the QAPD. The QA Manager has direct access to the Vice President, American Centrifuge and interacts directly with line management for QA matters. The QA Manager is responsible for the programmatic administration of the QAPD, policies, and procedures.

The Vice President, American Centrifuge has designated the General Manager, American Centrifuge Plant Operations the responsibility for design, start-up, operation, and associated support activities for the AC Program. The General Manager, American Centrifuge Plant Operations is responsible for the AC Program and overall responsibility for implementation of the QAPD. The QAPD is binding on all Licensee and contractor personnel involved with the AC Program.

The Vice President, American Centrifuge has designated the Director, Technology and Process Engineering the responsibility for providing technical expertise and is the subject matter expert for the engineering of the core centrifuge technologies involving the centrifuge machine and Feed and Withdrawal Systems.

The Vice President, American Centrifuge has designated the Director, Engineering, Procurement, and Construction, during the refurbishment/construction of the ACP, the responsibility for providing technical administration and direction to the Engineering, procurement, and construction contractor(s); providing the primary interface with the refurbishment/construction contractor(s); and managing the execution of the Balance of Plant work which the Licensee self performs for the deployment of the ACP.

The Vice President, American Centrifuge has designated the Director, Centrifuge Manufacturing the responsibility for providing technical administration and direction to strategic suppliers for manufacturing and delivery activities of centrifuge components and systems and for the assembly of centrifuge machines.

The Vice President, American Centrifuge has designated the Technical Director, American Centrifuge Project the responsibility for overall Technical Authority for the ACP. The Technical Director is responsible for integration of engineering activities across all ACP functional organizations to ensure engineering activities are coordinated and aligned with overall project priorities. The Technical Director is also responsible for the management of the Risk and Reliability program.

The Technical Services Manager reports to the General Manager, American Centrifuge Plant Operations. This manager is responsible for engineering activities and has design authority in support of operations. This includes configuration management; nuclear safety, including nuclear criticality safety; system engineering; and environmental, safety, and health, including radiation protection; Customer Order Management; acceptance test coordination, including test control; and approving disposition of nonconforming items when dispositioned as “repair” or “use-as-is.”

The Integrated Systems Test/Start-up Manager reports to the General Manager, American Centrifuge Plant Operations. This manager is responsible for the development and execution of the Integrated Systems Test Plans which demonstrate the proper operation of completed systems to ensure that the systems meet their intended design functions. This manager is also responsible for the acceptance of turnover from the Engineering, Procurement, and Construction, initial acceptance testing, and initial start-up of equipment and support systems.

The Manager, Enrichment Operations reports to the General Manager, American Centrifuge Plant Operations and is responsible for operations, maintenance, integrated planning, scheduling, and materials management.

The Operations Manager reports to the Manager, Enrichment Operations and is responsible for enrichment operations; production management; shift operations; and select repair of centrifuge machines.

The Maintenance Manager reports to the Manager, Enrichment Operations and is responsible for overall maintenance activities associated with the AC Program to ensure safe and reliable performance of equipment and facilities using preventive, predictive, and corrective maintenance techniques, with the exception of centrifuge machines, and for integrated planning, scheduling, and materials management (including receiving and control of nonconforming items, handling, storage, and shipping).

The Plant Services Manager reports to the General Manager, American Centrifuge Plant Operations and is responsible for fire safety, emergency management, security, information technology, and facility services.

The Business Services Manager reports to the General Manager, American Centrifuge Plant Operations and is responsible for finance, public affairs, human resources, procurement, training, procedures, and records management and document control.

The Training Manager reports to the Business Services Manager and is responsible for development and implementation of programs for indoctrination and training identified in Section 2.0 of this QAPD. Also, this manager is responsible for the program for development, review, approval, and issuance of procedures and the records management and document control program.

The Procurement Manager reports to the Director, Procurement and Contracts and is responsible for providing support services to the Business Services Manager for procurement and providing procurement material control services (including supplier qualification coordination, purchasing, contracting). This manager is also responsible for supply strategy and development of qualified long-lead-time and complex-system suppliers.

The Director, Regulatory and Quality Assurance reports to the Vice President, American Centrifuge and is responsible for the management of the regulatory and QA functions. This individual is the primary day-to-day interface with the U.S. Nuclear Regulatory Commission (NRC) and has overall responsibility for management of activities related to license requirements for the AC Program.

The Regulatory Manager reports to the Director, Regulatory and Quality Assurance and is responsible for regulatory oversight functions and commitment management. This manager

has responsibility for maintaining the plant change process and ensuring the plant change reporting requirements are met. The Regulatory Manager is also responsible for implementing the Corrective Action Program; ensuring incident investigations are performed and providing management with data to assure that corrective actions and commitments are properly addressed and managed to facilitate compliance with the implementing policies and procedures. The Regulatory Manager is also responsible for the Nuclear Materials Control and Accountability (NMC&A) program.

The QA Manager reports to the Director, Regulatory and Quality Assurance and is responsible for independent oversight of AC Program activities covered by this QAPD. This includes maintenance of the QAPD and assessing its effective implementation. This includes the responsibility and authority for:

- Formulating the program described in the Quality Assurance Program Description for the American Centrifuge Plant;
- Review and approval of QAPD implementing procedures;
- Review and approval of contractor and supplier QA programs;
- Monitoring the implementation of the QAPD and assessing the effectiveness of the QAPD through audits and assessments;
- Investigating any aspect of the QAPD to identify problems with execution and to verify that corrective action is taken in a timely manner;
- Stopping unsatisfactory work or controlling further processing when warranted for safety considerations;
- Attending status meetings, and staying abreast of day-to-day activities to ensure adequate oversight; and
- Providing quality control activities for purchased and in-house manufactured items.

The organizational philosophy is based on the following principles:

- Quality is achieved by those responsible for performing work. This includes identifying, correcting, or recommending solutions for quality problems.
- Quality verifications and controls are performed by persons who are independent of the work performance activities, but who may report to the management of the same organization. Persons responsible for assurance and verification of quality have sufficient organizational freedom to identify problems, initiate solutions, verify solutions and control further processing when necessary.

- Quality related activities may be delegated to others, but management retains responsibility for the overall effectiveness of the QAPD.

- Suppliers and contractors are required to have approved QA programs consistent with this QA program, as applicable to the scope of work as specified in Section 4.0 of this QAPD.

Specific organizational responsibilities are defined in the implementing procedures developed and implemented in accordance with Section 5.0 of this QAPD.

2.0 QUALITY ASSURANCE PROGRAM

QA elements of this section are applied to the design, refurbishment/construction, manufacturing, testing, start-up, operation, procurement, inspection, maintenance, and modification of items relied on for safety (IROFS), and activities affecting those IROFS, to ensure they will be available and reliable to perform their safety function when needed. The QAPD is applied to IROFS in a graded approach to an extent commensurate with their importance to safety. Quality Levels (QL) are established in accordance with their importance to safety as follows:

Level	Criteria
QL-1	A single IROFS that prevents or mitigates a high consequence event.
QL-2	Two or more IROFS that prevent or mitigate a high consequence event; or one or more IROFS that prevents or mitigates an intermediate consequence event.
QL-3	Any item other than QL-1 and QL-2.

The requirements of the QAPD are applied in total to QL-1 IROFS. The process for selecting modifications to QAPD requirements for QL-2 IROFS is described below. QL-3 items are outside the scope of this QAPD and are controlled in accordance with standard commercial practices. The application of the QAPD is documented, planned, implemented, and maintained to provide reasonable assurance that, together with other management measures, IROFS will be available and can be relied on, when needed.

Procedures provide for a graded approach taking into consideration:

- QL (risk significance);

- Applicable regulations, industry codes, and standards;

- Complexity or uniqueness of an item or activity and the environment in which it has to function;
- Quality history of the item in service;
- Degree to which functional compliance can be demonstrated or assessed by test, inspection, or maintenance methods;
- Anticipated life span;
- Degree of standardization;
- Importance of data generated;
- Reproducibility of results; and
- Consequence of failure.

By appropriately balancing considerations of importance and process capability, an appropriate level of quality is achieved commensurate with the activity's importance to safety.

The results of the application of the graded approach to quality are incorporated into design requirement documents, specifications, procedures, instructions, drawings, inspection plans, test plans, procurement documents, and other documents that establish the requirements for items or activities.

Compliance with QAPD requirements and associated procedures is mandatory. Questions on QAPD requirements are referred for resolution to the QA Manager, who is the final authority on QAPD requirements.

The terms used in the QAPD are as defined in 10 CFR 70.4, *Definitions* and American Society of Mechanical Engineers (ASME) NQA-1—1994, Part I, Section 4. The term "design output" as used in this QAPD means "drawings, specifications, and other documents used to define technical requirements of IROFS."

Indoctrination and training of personnel performing or managing activities affecting quality will meet the requirements of Part 1 of ASME NQA-1—1994, Supplement 2S-4, *Supplementary Requirements for Personnel Indoctrination and Training*.

Quality Control personnel performing inspection and testing will meet the requirements of Part 1 of ASME NQA-1—1994, Supplement 2S-1, *Supplementary Requirements for the Qualification of Inspection and Test Personnel*.

Personnel performing nondestructive examination will meet the requirements of SNT-TC-1A, *The American Society for Nondestructive Testing Recommended Practice,* June 1980 Edition.

QA audit personnel will meet the requirements of ASME NQA-1—1994, Part 1, Supplement 2S-3, *Supplementary Requirements for the Qualification of Quality Assurance Program Audit Personnel*.

Each manager is responsible for the applicable indoctrination, training, and qualification of their personnel.

Management of those organizations implementing the QAPD, or portions thereof, regularly assesses the adequacy of that part of the program for which they are responsible and will assure its effective implementation.

Responsible senior managers regularly assess the adequacy and effective implementation of the QA elements through methods such as review meetings, audit reports, and corrective action reports.

3.0 DESIGN CONTROL

Approved procedures provide for performing the design process in a planned, controlled and documented manner. The design control process includes the Integrated Safety Analysis and Management Measures.

Design inputs, such as design bases, performance requirements, regulatory requirements, codes and standards, are identified and documented as design requirements (e.g., primary requirements, functional requirements, and system requirements). Design requirement documents are reviewed and approved on a timely basis and to the level of detail necessary to permit the design activity to be carried out correctly and to provide a consistent basis for making design decisions, accomplishing design verification measures, and evaluating design changes. Changes, including the reason for the changes and whether or not prior NRC approval is required to make the changes, are identified, approved, documented, and controlled.

Design process activities are planned on a timely basis and to the level of detail necessary to permit the design process to be carried out correctly; to permit verification that the design inputs are correctly translated into design documents; and to support interfacing design, procurement, manufacturing, and operation. Appropriate quality standards are identified and documented. Changes from specified quality standards, including the reasons for the changes and whether or not prior NRC approval is required to make the changes, are identified, approved, documented, and controlled. Design methods, materials, parts, equipment, and processes that are essential to the function of the IROFS are selected and reviewed for suitability of application. Assemblies, subassemblies and parts are clearly identified. Commercial grade items that have been modified or which need to meet special verification requirements are uniquely identified.

Final design output documents, including changes thereto, are relatable to the design input by documentation in sufficient detail to permit design verification.

Design outputs that consist of computer programs are developed, validated, and managed in accordance with ASME NQA-1—1994, Basic Requirement 11 and NQA-1—1994, Part II, Subpart 2.7, *QA Requirements for Computer Software for Nuclear Plant Applications*.

Design analyses documents (e.g., calculations) contain sufficient detail as to the purpose, method, assumptions, design input, references, and units such that a person technically qualified in the subject can understand the analyses and verify the adequacy of the results without recourse to the originator. Design analysis, performed with computer systems, will list the software and version; hardware; inputs and outputs; and evidence of computer program verification/validation or alternate verification of the results. Design analysis documents are identifiable by subject, originator, reviewer, and date or by other identification such that the documents are retrievable.

Design verification is performed and documented, in accordance with approved procedures, by competent individuals or groups other than those who performed the original design. The extent and method of the design verification is a function of the importance to safety, the complexity of the design, the degree of standardization, the state of the art, past performance, and similarity with previous proven designs. Where changes to previously verified designs are made, design verification is performed for the changes, including an evaluation of the effects of the changes on the overall design and on any design analysis on which the design is based. Methods of design verification include any one or a combination of the following (as defined in Supplement 3S-1 of ASME NQA-1—1994): design reviews, alternate calculations, or the performance of qualification tests. Verification by testing is performed when deemed necessary and demonstrates adequacy of performance under conditions that simulate the most adverse design requirements. Verification of computer programs includes appropriate testing and validation. Design verification is performed in a timely manner and is completed prior to relying upon the IROFS, or computer program to perform its function.

Verifiers are knowledgeable in the areas to be verified. The verifier may be a supervisor, provided the supervisor was not directly responsible for the design (i.e., did not specify a singular design approach or rule out certain design consideration and did not establish the design inputs used in the design) or provided the supervisor is the only individual in the organization competent to perform the verification. However, verification is more than a cursory supervisory review. A supervisor with direct responsibility for the design may verify QL-2 items and services.

Changes to final designs, field changes, modifications, and nonconforming items dispositioned “use-as-is” or “repair” are justified, documented, and subject to the design control measures commensurate with the original design. Changes are reviewed and approved by the person or group with assigned design authority. Changes to designs that have been approved or certified by the NRC (e.g., 10 CFR Part 71 package design) are subject to the necessary additional controls.

Internal and external design interfaces are identified and controlled and design efforts are coordinated among participating organizations. Design information transmitted across interfaces is reviewed, approved, documented, and controlled.

Final design documentation and records that provide evidence that the design and design verification processes were performed in accordance with this section are collected, stored, and maintained.

4.0 PROCUREMENT DOCUMENT CONTROL

Procurement documents include those requirements necessary to assure that the items and services to be provided will be of the desired quality. These include the following, as appropriate:

- Scope of Work.
- Basic Technical Requirements — These include drawings, specifications, codes and industrial standards with applicable revision data; test and inspection requirements; special processes; and special requirements such as for designing, fabricating, cleaning, identification marking, erecting, packaging, handling, shipping, and storage.
- QA Requirements — These include the requirements for suppliers of QL-1 items and services and QL-2 services to have an acceptable QA program consistent with the applicable portions of this QAPD (the requirement for the supplier to have a documented QA program may be waived for QL-1 commercial grade items); provisions for access to the supplier's facilities and records for source inspection and audit; and requirements for reporting. The extent of the program required will depend upon the type and use of the item or services being procured.
- Requirements for the control of nonconformances and changes — These include provisions to control and report nonconformance and changes to products being delivered.
- Requirements on Subtier Suppliers — These include the specification of procurement requirements on subtier suppliers.
- Documentation Requirements — These include requirements identifying documents to be submitted for information, review or approval; instructions on record retention, turnover and disposition; and the requirements for delineating the technical and quality data required for ordering recommended spare and replacement parts and assemblies.

Procurement documents and changes thereto are reviewed to ensure they include the appropriate requirements as listed above. The review and documented concurrence is performed

by independent personnel having an understanding of the requirements and intent of the procurement document.

Changes to procurement documents, including changes made during bid review, contract negotiations or post award, are subject to the same control as the original document.

5.0 INSTRUCTIONS, PROCEDURES, AND DRAWINGS

Activities affecting the availability and/or reliability of IROFS are prescribed by and accomplished in accordance with documented procedures, instructions, and drawings of a type appropriate to the circumstances. These documents include or reference appropriate acceptance criteria for determining that prescribed activities have been satisfactorily accomplished. Standard guidelines for the format, content, and review and approval processes are established.

The QAPD establishes the policy requirements approved by the Vice President, American Centrifuge. Procedures are the second tier of documents that implement the QAPD. Third tier instructions provide specific step-by-step directions when deemed necessary. Procedure and instruction preparation, review, and approval are the responsibility of the applicable manager. The QA organization reviews QA implementing procedures for compliance and consistency with this QAPD. QA review of procedures is performed to ensure that the provisions of this QAPD are effectively incorporated into QA implementing procedures.

Adherence to policy, procedures, and instructions is mandatory. In the case of conflict the higher tier document governs unless approved by appropriate management. In the case of an error involving a procedure, the activity in question shall be placed in a safe condition and the procedure shall be corrected or changed before proceeding to implement the procedure.

Activities that require skills normally possessed by qualified personnel do not require detailed step-by-step delineation in a procedure. They are performed in accordance with documents of a type appropriate to the circumstances such as planning sheets, job descriptions, external manuals, or other form.

6.0 DOCUMENT CONTROL

Documents and changes to documents that prescribe or specify quality requirements or activities affecting the availability and/or reliability of IROFS are controlled in a manner that assures the use of correct documents. Such documents, including changes thereto, are reviewed for adequacy and approved for release by authorized personnel.

Procedures and instructions assure that documents are prepared; reviewed for adequacy, correctness, and completeness by a qualified individual; approved for release by authorized personnel; distributed to the location where the activity is performed prior to commencing work;

and used in performing the activity. Obsolete or superseded documents are removed or appropriately identified. Procedures identify documents to be controlled; responsibility for preparing, reviewing, approving, and issuing documents to be used; and require the establishment of current and updated distribution lists. Procedures also require the creation and maintenance of a controlled document index to track and control approved revision levels of those documents.

Changes to documents are reviewed and approved in the same manner as the original unless other organizations are specifically designated. Reviewing personnel have access to the pertinent background information upon which to base their approval. Procedures provide for simplified approval of editorial or inconsequential changes. Procedures describe the type of minor changes that do not require review and approval in the same manner as the original and who can authorize minor changes.

7.0 CONTROL OF PURCHASED ITEMS AND SERVICES

7.1 General

The procurement of items and services is controlled to assure conformance with specified requirements. These controls provide for the following, as appropriate: source evaluation and selection; evaluation of objective evidence of quality furnished by the supplier; source inspection; audit; and examination of items or services upon delivery or completion.

The following interface and responsibilities apply for purchasing actions discussed in Sections 4.0 and 7.0 of this QAPD.

- The QA Manager is responsible for providing the necessary QA functions to support procurement. These QA functions include review of supplier quality documentation; evaluation of supplier's QA capability; supplier audits and evaluations; and for the development and maintenance of an approved suppliers list. The QA Manager provides support functions (i.e., source verification or surveillance; receipt inspections; installation inspections; and review of procurement documents during receipt inspections).

- The Technical Services Manager is responsible for assisting the QA Manager by performing evaluations of supplier's technical capabilities. This manager is responsible for determining specific methods of acceptance to be applied to purchased items and reviewing the specific method of acceptance to be applied to services. This manager is also responsible for the approval of dispositions and technical evaluation of supplier-generated nonconformances for items and services dispositioned as "repair" or "use-as-is."

- The Procurement Manager is responsible for procurement planning, bid evaluation, and procurement of items and services on the Approved Suppliers List (ASL), when required.

7.2 Procurement Planning

Procurement activities are planned and documented to assure a systematic approach to the procurement process. Procurement document control is described in Section 4.0 of this QAPD.

7.3 Supplier Selection

Supplier selection is based, in part, on a pre-award evaluation of capability to provide items or services in accordance with the requirements of procurement documents. The evaluation includes one or more of the following:

- An evaluation of the potential supplier's history of providing an identical or similar product that performs satisfactorily in actual use. The supplier's history will reflect current capability. The potential supplier's current quality records are supported by documented qualitative and quantitative information that can be objectively evaluated.

- Depending on the part or service involved, a supplier QA program meeting the applicable requirements of accepted industry regulations or standards such as, NQA-1, ISO 9000 series, American National Standards Institute (ANSI) Z540-1, 10 CFR Part 50, Appendix B, or 10 CFR 830.120, may be acceptable. When actions that demonstrate the implementation of the QA program have commenced, the potential supplier's facility (if appropriate), technical and quality capability is determined by a direct evaluation of the supplier's personnel, and implementation of the supplier's quality assurance program. Supplier audits are conducted in accordance with Section 18.2 of this QAPD.

- QA reviews and approves the results of recognized industry shared supplier audits, (i.e., third party audits such as the Nuclear Industry Assessment Committee, etc.). The review ensures that the requirements in Section 7.1, first bullet, have been met. When using this method, an initial implementation audit will be performed in accordance with Section 18.2 of this QAPD.

- The supplier has an applicable valid Certificate of Accreditation issued by the National Voluntary Laboratory Accreditation Program of the National Institute of Standards and Technology. When using this method, an initial implementation audit will be performed in accordance with Section 18.2 of this QAPD.

- The supplier maintains a valid ASME Code certification for the item or service being provided. When using this method, an initial implementation audit will be performed in accordance with Section 18.2 of this QAPD.

Suppliers with acceptable technical, quality and commercial qualifications are placed on the ASL maintained by the QA organization. Retention on the list is based on performance. Suppliers that are not pre-qualified may be used with appropriate compensatory controls as agreed upon by the QA organization.

7.4 Bid Evaluation

Bids are evaluated and unacceptable conditions are resolved prior to award of the contract. Depending on the type of procurement, bids are evaluated for technical considerations, quality assurance requirements, supplier personnel, supplier production capability, past performance, alternates, and exceptions; as well as commercial, cost, and schedule considerations, as applicable.

7.5 Supplier Performance Evaluation

Measures are established to interface with the supplier and to verify supplier's performance, as necessary. The purchaser's verification activities; however, do not relieve the supplier of their responsibilities for verification of quality achievement. The measures include:

- Establishing an adequate understanding between the Licensee and the supplier on the provisions and specifications of the procurement documents;
- Requirements for the supplier to identify the methods and processes to be used by the supplier in fulfilling the requirements of the procurement;
- Reviewing the supplier documents generated or processed during activities fulfilling procurement requirements;
- Identifying and processing necessary change information;
- Establishing methods for exchange of information with the supplier; and
- Establishing the extent of source surveillance and inspection activities for subtier suppliers.

Activities to verify conformance to requirements in procurement documents are recorded as specified in procedures. Source surveillances, inspections, audits, receiving inspections, Condition Notifications, Material Condition Reports, dispositions, waivers, conditional releases, and corrective actions are all documented. These records are evaluated during performance evaluations to ensure suppliers are effectively implementing their QA programs.

7.6 Control of Supplier Generated Documents

Supplier-generated documents required for submittal are reviewed for acceptability. Measures ensure that submittal of these documents is accomplished as required by the procurement documents. Evaluation depends on the type of documents submitted. The three categories are: engineering documents requiring technical approval (e.g., shop drawings and test procedures); verification documents (e.g., test reports and inspection reports); and information documents (e.g., external manuals and parts lists).

7.7 Acceptance of Items and Services

Acceptability verification activities are based on quality level, complexity, and quantity of items or services provided.

Acceptance of items, including spare and replacement parts, includes one or more of the following methods:

- **Certificate of Conformance** — When this method is utilized, the following minimum criteria are met:
  - The certificate identifies the purchased material or equipment or purchase order number.
  - The certificate identifies the specific procurement requirements met.
  - The certificate identifies any procurement requirements that were not met and approved waiver.
  - The certificate is authenticated by a person responsible for this QA function.
  - The procedures, used for the preparation, review, and approval of the certificate, are described in the supplier's quality assurance program or the purchase order.
  - The validity of the supplier's certificates and effectiveness of certification system is verified, and the interval of verification is based on the supplier's past quality performance.
- **Source Verification** — When this method is utilized, it is performed at intervals consistent with the quality level and complexity of the item or service. This method provides plans to perform inspections, examinations, or tests at predetermined points. Source inspection may be performed at lower tier suppliers when necessary. Results may be utilized at receiving inspection.

- **Receiving Inspection** — When this method is utilized, purchased items are inspected to verify conformance to procurement documents. This method verifies by objective evidence such features as proper configuration; identification; dimensional, physical, or other characteristics; freedom of damage from shipping; cleanliness, and review of supplier documentation when procurement documents require the documentation to be furnished.

- **Post-Installation Testing** — When this method is utilized, post-installation test requirements and acceptance criteria are established in conjunction with the supplier, if necessary.

Documented evidence of acceptability must be complete prior to placing an item in service. Controls are established for conditional release, such as for post-installation testing.

Acceptance of services is based on one or more of the following methods:

- Technical verification of data produced;

- Surveillance and/or audit of the activity; and

- Review of objective evidence for conformance to procurement document requirements.

Acceptance of services includes review of contractor deliverables (including documentation and records), determination of acceptability for use, completion of acceptance testing, completion of start-up testing, turnover, etc.

7.8 Control of Supplier Nonconformances

Supplier nonconformances are processed in accordance with Section 15.0 of this QAPD. Supplier nonconformances consist of one or more of the following:

- Violation of technical or material requirement;

- Violation of requirement of purchaser-approved supplier document;

- Nonconformance that cannot be corrected by continuation of the manufacturing process or by rework; and

- Items that do not conform to the original requirements even though the item can be restored to a condition such that the capability of the item to function is unimpaired.

Supplier nonconformance may be identified either by the Licensee or by the supplier. For supplier identified nonconformance, the Licensee expects a supplier recommended

disposition and technical justification. Nonconforming items are not released for use until the nonconforming condition is reviewed and accepted by Responsible Disposition Authority and the implementation of the disposition is verified, except under conditional release provisions. Records of supplier nonconformance are maintained.

Nonconformances associated with QL-1 items or services are evaluated for reportability pursuant to 10 CFR Part 21, *Reporting of Defects and Noncompliance*, and CMP-3603-0001, *Graded Approach to Configuration Management and Quality Assurance.*

7.9 Commercial Grade Items

Commercial grade items are identified in procurement documents by manufacturer's published product descriptions, in accordance with Section 4.0 of this QAPD. A commercial grade item satisfies the following:

- Not subject to design or specification requirements that are unique to nuclear facilities;
- Used in applications other than nuclear facilities; and
- Is to be ordered from the manufacturer/supplier on the basis of a specification set forth in the manufacturer's published product description (e.g., catalog).

The criteria and methods for identifying the critical characteristics for acceptance of commercial grade items are established. Critical characteristics for acceptance are identified in Engineering Specifications and provide reasonable assurance that the item provided meets specified requirements. When selecting these characteristics, the impact of the activities associated with the item on the safety function of plant equipment is considered. Changes to commercial grade items specified in design documents are subject to design control measures in accordance with Section 3.0 of this QAPD.

As a minimum for acceptance of commercial grade items, receipt inspection is performed to provide reasonable assurance that damage was not sustained during shipment; that the item received is the item ordered; that inspection and testing was performed by the supplier, as required by Technical Services, to ensure conformance with manufacturer's published requirements; and to ensure that required documentation is received and is acceptable. If designated by Technical Services, based on the complexity of the item or its importance to safety, one or more of the following may also be used:

- Source evaluation and selection may be specified in accordance with Section 7.3 above;
- Special test or inspection;
- Commercial grade survey of the supplier;

- Source verification;
- Acceptable supplier/item performance record.

Dedication of commercial grade items occurs after receipt when that item is accepted in accordance with engineering specification requirements and applies to QL-1 only. The term dedication defines the point in time when the commercial grade item becomes subject to 10 CFR Part 21 reporting requirements.

8.0 IDENTIFICATION AND CONTROL OF ITEMS

Controls are established to assure that only correct and accepted items are used or installed. Identification is maintained on the items or in documents traceable to the items, or in a manner that assures identification is established and maintained as described in this section.

Items are identified and controlled, as necessary, from initial receipt and fabrication of the items up to and including installation and use to assure that only correct and accepted items are used or installed. Physical identification is used to the maximum extent possible. When physical identification is either impractical or insufficient to control the item, physical separation, procedural controls, or other means are employed. When markings are used, measures are established to ensure that the markings are clear, legible, and do not have a detrimental affect on the function or service life of the item. Markings are transferred to each part of an identified item when subdividing and are not to be obliterated by surface treatments or coatings unless other means of identification are provided.

Traceability of items to specific records is provided when specified by codes, standards, or specifications.

Where specified, items having a limited operating life or shelf life are identified and controlled to preclude use of items whose operating life or shelf life has expired.

Procedures provide for item identification consistent with the planned duration and conditions of storage, such as:

- Provisions for maintenance or replacement of markings and identification records due to damage during handling or aging;
- Protection of identifications on items subject to excessive deterioration due to environmental exposure; and
- Provision for updating existing records. Documentation is provided to show that items released for use are the items specified.

9.0 CONTROL OF PROCESSES

Processes affecting quality of items and services are controlled. Procedures, instructions, drawings, checklists, travelers, work orders, or other appropriate means control processes. These means assure that process parameters are controlled and that specified environmental conditions are maintained.

Special processes that control or verify quality (i.e., those used in welding, heat treating, and nondestructive examination) are performed by qualified personnel using qualified procedures in accordance with specified requirements, codes, or standards. When the outcome of the process is highly dependent on personal skills, such individuals are certified in accordance with specified requirements. When the outcome is highly dependent on control of process parameters, the process and equipment are pre-qualified in accordance with specified requirements. Special process procedures prescribe the necessary equipment, process parameters, calibration, and acceptance criteria.

Records are maintained of currently qualified personnel, processes, and equipment for special processes.

10.0 INSPECTION

Planned inspections are performed, as required, to verify conformance of items or activities to specified requirements. Inspection requirements are specified in written procedures, or design requirement documents, with provisions for documenting and evaluating the inspection results. Quality Control inspection personnel are qualified in accordance with Section 2.0 of this QAPD. Personnel other than those who performed or directly supervised the work being inspected perform inspection for acceptance.

Inspection planning provides for hold points to ensure that work does not bypass required inspections. The hold points are established in work controlling documents. Work does not proceed beyond an inspection hold point without specific documented consent of the designated inspection representative.

The planning of inspection activities, methods, and attributes is based on the importance of the item or activity to be inspected; mandatory inspections required by codes, standards, regulatory requirements and commitments; the complexity of the item or activity; and the quality history of the process. Inspection planning includes characteristics to be inspected; responsibility; method; measuring and test equipment; acceptance criteria; and referenced instructions and design documents.

When a sample is used to verify acceptability of a group of items, the sampling procedure is documented and clearly identifies the sampling basis (typically based on recognized standard/practices).

If inspection of completed work is impossible or disadvantageous, indirect verification by process monitoring is provided. Both inspection and process monitoring are provided, when necessary, to ensure quality.

Final inspections include record review of the results and resolution of nonconformance identified by prior inspections. Acceptance by final inspection verifies conformance of the item to specified requirements.

Modifications, repairs, or replacements of items performed subsequent to final inspection require re-inspection or re-test, appropriate to the circumstances, to verify acceptability.

Inspection records contain the following, as a minimum:

- Item inspected;
- Date of inspection;
- Inspector;
- Type of observation and inspection plan;
- Results or acceptability; and
- Action taken in connection with nonconformance.

11.0 TEST CONTROL

Planned tests are performed as required to verify conformance with specified requirements, to demonstrate satisfactory performance, or to collect data. Tests include design verification tests, acceptance tests, pre-operational tests, post-maintenance tests, and operational tests. Planning for tests may include mandatory hold points, as required.

Test procedures or design requirement documents contain the following information as appropriate to the test:

- Test purpose or objectives, responsibilities, characteristics to be tested, hold points and test methods to be employed;
- References and related documents;

- Provisions for ensuring that prerequisites for a given test have been met. These include, as applicable: calibrated instrumentation, appropriate equipment, trained personnel, condition of test equipment and the item to be tested, and provisions for data acquisition;

- Adequate instrumentation is available and suitable environmental conditions are maintained;

- Provisions for documenting and evaluating the test results for conformance with acceptance criteria; and

- Qualifications for test personnel.

In lieu of written test procedures or design requirement documents, appropriate sections of related documents (e.g., American Society for Testing and Materials methods, external manuals, maintenance instructions, or approved drawings or travelers with acceptance criteria) may be used. Such documents must include adequate instructions to ensure the required quality of work.

Test records contain the following information: item tested, test date, tester or data recorder, type of observation, test procedure or design requirement documents, results and acceptability, actions taken in connection with any deviations noted, and person evaluating the results.

Computer Program Testing is carried out in accordance with ASME NQA-1—1994, Basic Requirement 11, *Test Control*, and Supplement 11S-2, *Supplementary Requirements for Computer Program Testing*.

12.0 CONTROL OF MEASURING AND TEST EQUIPMENT

Measuring and Test Equipment (M&TE) used in activities affecting the availability and/or reliability of IROFS are controlled, calibrated, and adjusted at specified intervals to maintain equipment performance within required limits. Procedures ensure that devices and standards used for measurement, tests, and calibration activities are of the proper type, range, and accuracy. Calibration control is not necessary for rulers, tape measures, levels, and other such devices.

A list of devices is established to identify those items within the calibration control system. This identification listing includes, as a minimum, the due date of the next calibration and any use limitations (when it is calibrated for limited use).

M&TE is calibrated at specified intervals or prior to use against equipment having a known valid relationship to nationally recognized standards. If no nationally recognized standard exists, the basis for calibration is documented. M&TE is properly handled and stored to maintain accuracy.

When M&TE is found to be out of calibration, as-found data are recorded and an evaluation is made and documented as to the validity of previous inspection and test results and of the acceptability of items previously inspected or tested. Out-of-calibration devices are tagged or segregated and are not used until re-calibrated. When M&TE is consistently found to be out of calibration, it is repaired or replaced. Also, calibrations are performed when personnel performing measurements and tests deem the accuracy of the equipment suspect.

Records are maintained and equipment is suitably marked or otherwise identified to indicate its calibration status.

13.0 HANDLING, STORAGE, AND SHIPPING

Material and equipment are handled, stored, and shipped in accordance with design and procurement requirements to protect against damage, deterioration, or loss.

Special coverings, equipment, and protective environments are specified and provided where necessary for the protection of particular items from damage or deterioration. When such special protective features are required, their existence is verified and monitored as necessary to ensure they continue to serve the intended function.

Special handling tools and equipment are provided where necessary to ensure items can be handled safely and without damage. Special handling tools and equipment are controlled and maintained in a manner such that they will be ready and fit to serve the intended function when needed. Such control includes periodic inspection and testing to verify that special handling tools and equipment has been properly maintained. Operators of special equipment are experienced or trained as required.

Attention is given to marking and labeling items during packaging, shipment, and storage. Additional marking or labeling is provided as necessary to ensure that items can be properly maintained and preserved. This includes indication of the presence of special environments or the need for special control.

Special handling, preservation, storage, cleaning, packaging, or shipping instructions are established and used when essential to maintain acceptable quality.

14.0 INSPECTION, TEST, AND OPERATING STATUS

Procedures are established to ensure that the status of inspection and test activities are either marked or labeled on the item or in documents traceable to the item. This activity is required when it is necessary to ensure that required inspections and tests are performed, and to ensure items that have not passed the required inspections and tests are not inadvertently installed, used, or operated.

Status indicators (i.e., physical location and tags; markings; work controlling documents; stamps; inspection records; or other suitable means) are utilized when required. This includes indicating the operating status of systems and components (i.e., by tagging valves and switches) to prevent inadvertent operation. Authority for the application and removal of tags, markings, labels, and stamps is specified.

15.0 CONTROL OF NONCONFORMING ITEMS

Items and related activities that do not conform to specified requirements are controlled to prevent inadvertent installation or use.

Nonconforming items are identified in a manner that does not adversely affect the end use of the item, by markings, tagging, and other appropriate methods.

Nonconforming items are segregated, when practical, by placing them in a clearly identified and designated area until properly dispositioned. When segregation is impractical or impossible due to physical conditions (e.g., size, weight, or access limitations), other measures are employed to preclude inadvertent use of the item.

Nonconforming items are reviewed and dispositioned. Further processing, delivery, installation, or use of the nonconforming item is controlled pending an evaluation and approved disposition by the Responsible Disposition Authority personnel, and documented notification to affected organizations is provided.

The responsibility and authority for the evaluation and disposition of nonconforming items is defined. The personnel performing evaluations to determine the dispositions have demonstrated competence in the specific area they are evaluating, have an adequate understanding of the requirements, and have access to pertinent background information. The disposition of nonconforming items is identified and documented as required to carry out the disposition. Technical justification for the acceptability of nonconforming items dispositioned "repair" or "use-as-is" is documented and subject to design control measures as described in Section 3.0 of this QAPD. The disposition process includes consideration of the need for design documents to be "as-built" to facilitate operations, maintenance, or modification. The as-built records, if the disposition determines such records to be required, reflect the accepted deviation.

Repaired items are re-examined in accordance with the original acceptance criteria unless the nonconforming item disposition has established alternate acceptance criteria. Reworked items are re-examined in accordance with the original acceptance criteria.

Nonconformance documentation identifies the nonconforming item; describes the nonconformance; contains the disposition and any re-inspection requirements; and contains the signature(s) approving the disposition.

16.0 CORRECTIVE ACTION

Conditions adverse to quality are identified and corrected promptly. In the case of a significant condition adverse to quality, the cause of the condition is determined, and corrective action is taken to preclude recurrence. Significant conditions, their causes, and corrective actions are documented, reported to appropriate levels of management, and follow-up action is taken to verify implementation of corrective actions.

17.0 QUALITY ASSURANCE RECORDS

The QA records system ensures that records are specified, prepared, and maintained in a manner to provide protection and retrievability. Design specifications, procurement documents, test procedures, operational procedures, or other documents specify the records to be generated, supplied, or maintained.

Records are considered valid when they are complete, identified, authenticated and legible. Documents are considered valid records only if stamped, initialed, or signed and dated by authorized personnel or otherwise authenticated. Lifetime records are entered into record storage after receipt or validation. Temporary storage in approved containers is provided until records are entered into lifetime storage.

Lifetime records are defined in accordance with ASME NQA-1—1994, Supplement 17S-1, Section 2.7.1, *Supplementary Requirements for Quality Assurance Records*. The applicable document that specifies the record indicates those to be forwarded for lifetime storage. In the case of specified records produced by suppliers, an agreement for records turnover is established.

Lifetime records are retained for the life of the item to which they apply or as required by a regulatory agency. An indexing system ensures the record can be retrieved. Storage is in a central location unless the applicable procedure specifies otherwise. Records may be originals, copies, or electronic format.

Nonpermanent records are those required to show evidence that an activity was performed in accordance with applicable requirements. Nonpermanent records are not retained

for the life of a particular item. Nonpermanent records are retained by the responsible organization until they are no longer useful. The retention periods for nonpermanent records will be established in writing by the responsible organization.

Corrections to records are approved by the originating organization. The corrections include the date and the identification of the individual authorized to issue the correction.

Custodianship responsibility is assigned for lifetime records storage. Custodianship includes receipt and status control; storage; preservation; and safekeeping using hard copy, microfilm, or electronic document management system.

Storage facilities protect against the risk of loss or deterioration of lifetime records. Hard copy or microfilm storage facilities meet the requirements of ASME NQA-1—1994, Supplement 17S-1, Section 4.4, *Supplementary Requirements for Quality Assurance Records*. For electronic storage, backups or duplicate files are generated. Lost or damaged records are replaced, unless deemed impractical with the concurrence of the QA organization.

Single copy records are checked out of storage only if they cannot be copied and then only for a limited period. Temporary protection in such cases is provided by prudent business practices (e.g., record of custody, office environment, and work place security).

18.0 AUDITS

Planned and scheduled audits are performed by the QA organization to verify compliance with the aspects of the QA program and to determine its effectiveness.

18.1 Internal Audits

Internal audits of organizational units performing quality program activities are performed at a frequency commensurate with the status and importance of the activity. Regularly scheduled audits are supplemented by additional audits/assessments of specific subjects. The system of audits and assessments is designed to ensure comprehensive program oversight at least once every three years. The three-year cycle provides for flexibility to maximize effectiveness of QA resources by targeting areas of weakness using supplemental assessments verses using resources auditing areas that are known to be functioning adequately. This flexibility will result in more effective quality oversight and use of resources. The proper mix of audit and assessment will provide an effective and comprehensive QA independent oversight program. Audits are conducted in accordance with a documented procedure. A plan is prepared for each audit to identify the audit scope, requirements, audit personnel, activities to be audited, applicable documents, organizations to be audited, schedule and written procedures or checklists.

The audit team contains one or more auditors, one being designated lead auditor who prepares, organizes, and directs the audit; coordinates the preparation and issuance of the audit

report; and evaluates responses. Audit team members are independent of any direct responsibility for performance of the activities of which they will audit. Auditors (including technical specialists) have experience commensurate with the scope, complexity, or special nature of the audit. The lead auditor is qualified in accordance with Section 2.0 of this QAPD.

Audits are performed in accordance with checklists or equivalent. Organizations being audited provide access and assistance to the audit team. Objective evidence is examined to determine if the QAPD elements are being implemented effectively. Conditions requiring prompt corrective action are reported immediately to management of the audited organization. The results of the audit are discussed with management of the audited organization.

The audit report includes the following information, as appropriate:

- Description of the audit scope;
- Identification of the auditors;
- Identification of persons contacted during audit activities;
- Summary of audit results, including a statement on the effectiveness of the QA program elements audited; and
- Description of each reported adverse audit finding in sufficient detail to enable corrective action to be taken by the audited organization.

Management of the audited organization or activity investigates adverse audit findings, schedules corrective action, including measures to prevent recurrence, and notifies the QA organization in writing of the action taken. Adequacy of audit responses is evaluated by the QA organization and verification of corrective action is documented.

Follow-up action is taken by the QA organization to verify the implementation and effectiveness of the corrective action and to determine if repetitive problems require further corrective action in accordance with Section 16.0 of this QAPD. Audit records include audit plans, audit reports, written replies, and the record of completion of corrective action.

18.2 External Audits

External audits are performed to verify the acceptability of QL-1 suppliers. After the placement of the supplier ASL, follow-up audits are performed at a frequency commensurate with the status and importance of the activity, based on annual evaluations of the QL-1 suppliers performance.

Third party audits may be used to satisfy the supplier audit requirement, after review and acceptance of the audit records by QA.

QL-2 suppliers need not be audited provided their performance continues to be acceptable.

The external audit team contains one or more auditors, one being designated lead auditor who prepares, organizes, and directs the audit; coordinates the preparation and issuance of the audit report; and evaluates responses. Auditors (including technical specialists) have experience commensurate with the scope, complexity, or special nature of the audit. The lead auditor is qualified in accordance with Section 2.0 of this QAPD.

External audits are performed in accordance with checklists or equivalent. Objective evidence is examined to determine if the QAPD elements are being implemented effectively. Conditions requiring prompt corrective action are reported immediately to management of the audited organization. The results of the audit are discussed with management of the audited organization.

The external audit report includes the following information, as appropriate:

- Description of the audit scope;
- Identification of the auditors;
- Identification of persons contacted during audit activities;
- Summary of audit results, including a statement on the effectiveness of the QA program elements audited; and
- Description of each reported adverse audit finding in sufficient detail to enable corrective action to be taken by the audited organization.

Follow-up action is taken by the QA organization to verify the implementation and effectiveness of the corrective action and to determine if repetitive problems require further corrective action in accordance with Section 16.0 of this QAPD. Audit records include audit plans, audit reports, written replies, and the record of completion of corrective action.

19.0 PROVISIONS FOR CHANGES

QAPD changes are controlled by 10 CFR 70.72, *Plant Changes and Change Process*. QAPD changes may be initiated by events such as reorganizations, revised activities, as a result of lessons learned, changes to applicable regulations, process changes, or other reasons. QAPD changes are governed by approved procedures.

Changes not requiring NRC approval prior to implementation will be submitted to the NRC annually, in accordance with 10 CFR 70.72.

20.0 REFERENCES

1. 10 CFR 70.4, *Definitions*

2. 10 CFR 70.72, *Facility Changes and Change Process*

3. American Society of Mechanical Engineers (ASME) NQA-1, 1994, *Quality Assurance Requirements for Nuclear Facility Applications*

4. NR-2605-0001, Quality Assurance Program Description for the American Centrifuge Lead Cascade Facility in Piketon, Ohio

5. SNT-TC-1A, *The American Society for Nondestructive Testing Recommended Practice,* June 1980 Edition

6. 10 CFR 830, Exemption Decision, August 31, 2007

7. Exhibit M, Regulatory Oversight Agreement (Between United States DOE and United States Enrichment Corporation for the Gas Centrifuge Enrichment Plant Leased Premises), Rev. 0

8. 10 CFR 21, *Reporting of Defects and Noncompliance*

9. CMP-3603-0001, *Graded Approach to Configuration Management and Quality Assurance*

10. EPRI NP-5652, Guideline for the Utilization of Commercial Grade Items in Nuclear Safety Related Applications (NCIG-07)

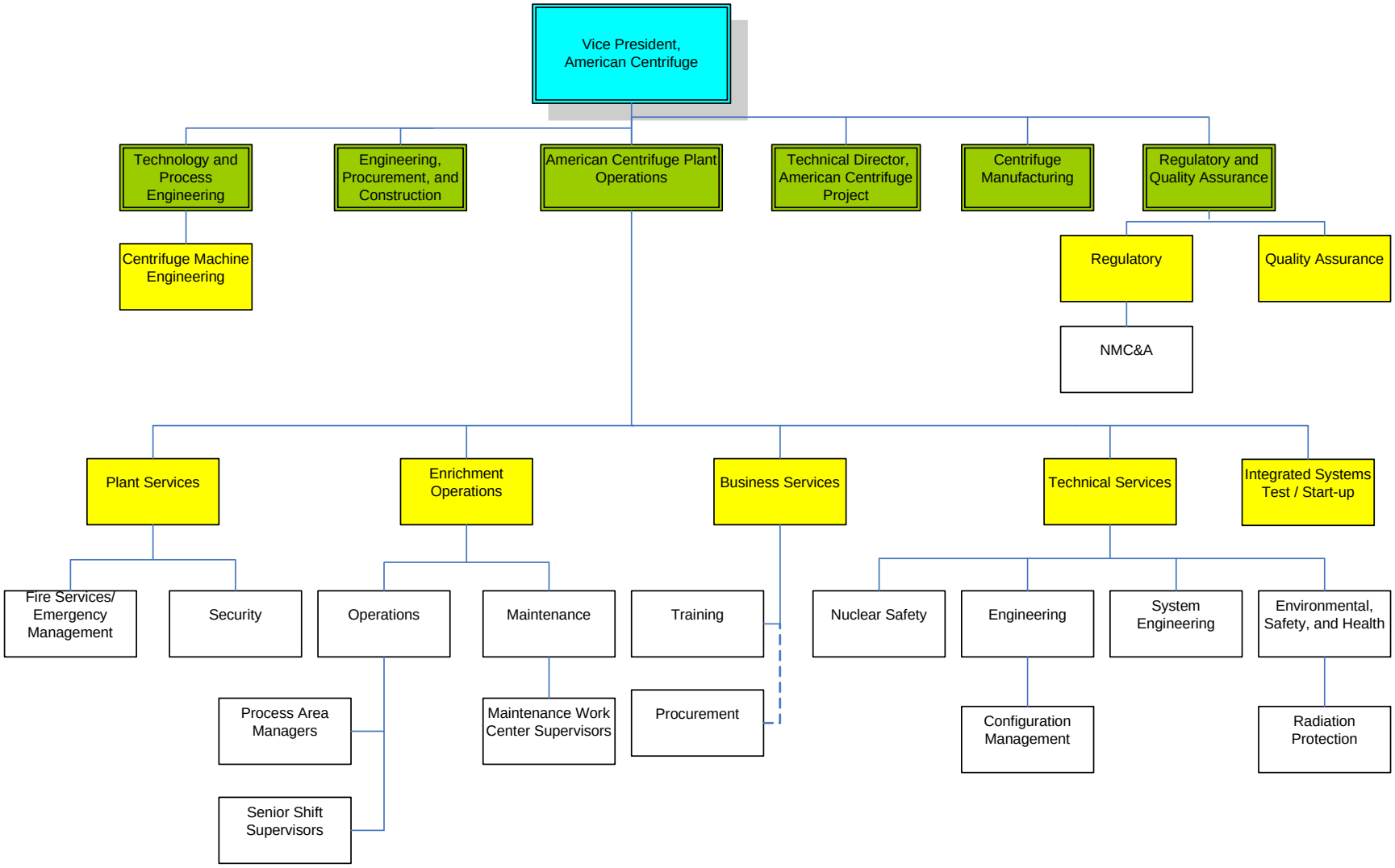

Figure 1.1-1 American Centrifuge Plant Organizational Chart

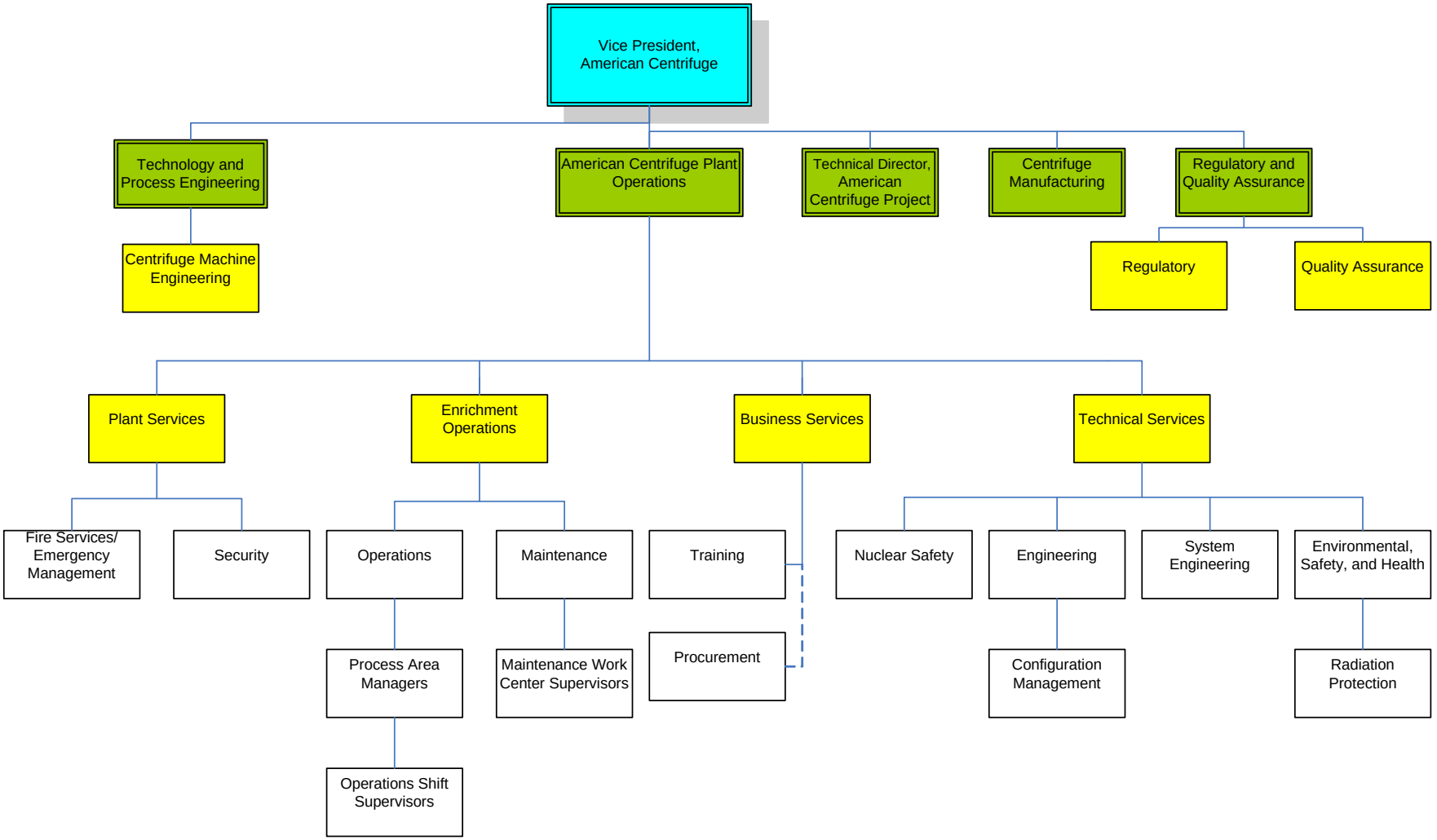

Figure 1.1-2 Lead Cascade Organizational Chart

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