AREVA

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October 30, 2009

AES-O-NRC-09-00152-0

ATTN: Document Control Desk
U.S. Nuclear Regulatory Commission
Washington, DC 20555-0001

AREVA Enrichment Services LLC
Eagle Rock Enrichment Facility
NRC Docket No: 70-7015

Subject: Request for Expedited Approval of Quality Assurance Program Description

On December 30, 2008, as revised on April 23, 2009, AREVA Enrichment Services LLC (AES) submitted a License Application to construct and operate the Eagle Rock Enrichment Facility (EREF) to the U.S. Nuclear Regulatory Commission (NRC) (Ref. 1 and Ref.2).

AES requests that the NRC expedite approval of the language of the Quality Assurance Program Description (QAPD), including the definitions of QA levels, the methods, process, and criteria for assigning QA Levels to Items Relied on for Safety (IROFS), credited attributes of safe-by-design components; and structures, systems, and components (SSCs) that could interact with IROFS or credited attributes of safe-by-design components, due to a seismic event. AES requests this expedited approval so that AES may apply the QAPD language during the procurement of services and material. The requested action is consistent with the NRC approval of the QAPD for the Louisiana Energy Services' National Enrichment Facility in a Safety Evaluation Report dated April 9, 2004 (Ref.3). AES understands that the NRC will: 1) continue to evaluate the adequacy of the QA Level categorization of AES IROFS, credited attributes of safe-by-design components, and SSCs that could interact with IROFS or credited attributes of safe-by-design components, 2) the application of management measures during the ongoing license application review; and 3) verify implementation of the QA elements, as well as other management measures and License Application commitments, during future reviews, inspections, and assessments of the EREF design and construction activities.

In response to recent discussions with the NRC Staff, the enclosure provides Revision 2 of the QAPD that includes the proposed changes provided with the AES notification of an organization change submitted on June 15, 2009 (Ref.4) and includes the QAPD proposed changes submitted with the AES responses to the NRC Requests for Additional Information submitted on September 28, 2009 including any changes agreed to as a result of follow-up conference calls (Ref.5).

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If you have any questions, or require additional information, please contact me at 508-573-6554.

Respectfully,

Jim A. Kay
Licensing Manager

Enclosure: Quality Assurance Program Description, Revision 2

References:

1) S. Shakir (AES) Letter to the U.S. Nuclear Regulatory Commission, Application for a Uranium Enrichment Facility License under 10 CFR 70, "Domestic Licensing of Special Nuclear Material," dated December 30, 2008.

2) S. Shakir (AES) Letter to the U.S. Nuclear Regulatory Commission, Revision 1 to License Application for the Eagle Rock Enrichment Facility, dated April 23, 2009.

3) J. Glitter (NRC) Letter to R. Krich (LES), Louisiana Energy Services Quality Assurance Program Description for the National Enrichment Facility, dated April 9, 2004.

4) G. H. Harper (AES) Letter to the U.S. Nuclear Regulatory Commission, Notice of Organization Change for the Eagle Rock Enrichment Facility License Application, dated June 15, 2009.

5) J. A. Kay (AES) Letter to the U.S. Nuclear Regulatory Commission, Response to Requests for Additional Information – AREVA Enrichment Services Application for the Eagle Rock Enrichment Facility, dated September 28, 2009.

cc: Breeda Reilly, U.S. NRC Senior Project Manager
Steve Lemont, U.S. NRC Senior Project Manager

Enclosure to AES-O-NRC-09-00152-0

AREVA Enrichment Services LLC

Eagle Rock Enrichment Facility

Quality Assurance Program Description, Revision 2

AREVA ENRICHMENT SERVICES, LLC

QUALITY ASSURANCE PROGRAM DESCRIPTION
FOR
DESIGN, CONSTRUCTION, OPERATION, AND DECOMMISSIONING
OF THE
EAGLE ROCK ENRICHMENT FACILITY

ACRONYMS

AES	AREVA Enrichment Services, LLC
ALARA	As Low As Reasonably Achievable
ANSI	American National Standards Institute
ASL	Approved Suppliers List
ASME	American Society of Mechanical Engineers
CFR	Code of Federal Regulations
EREF	Eagle Rock Enrichment Facility
ETC	Enrichment Technology Company
IROFS	Items Relied on for Safety
M&TE	Measuring and Test Equipment
NIST	National Institute of Standards and Technology
NRC	U.S. Nuclear Regulatory Commission
NVLAP	National Voluntary Laboratory Accreditation Program
QA	Quality Assurance
QAPD	Quality Assurance Program Description
SRC	Safety Review Committee
SSCs	Structures, Systems, and Components

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1.0 INTRODUCTION AND ORGANIZATION

The Quality Assurance Program Description (QAPD) described herein applies to the design, fabrication, testing, operation, and decommissioning of the Eagle Rock Enrichment Facility and meets the requirements of 10 CFR 70.64 (a) (1), "Quality standards and records." The Eagle Rock Enrichment Facility is located in Bonneville County, Idaho. The QAPD is applied as described in Section 2.0 of this QAPD.

1.1 ORGANIZATION

1.1.1 AREVA Enrichment Services, LLC (AES) maintains overall responsibility for design, refurbishment, construction, start-up, operations, and decommissioning of the Eagle Rock Enrichment Facility.

1.1.2 Figure 1-1 of this QAPD shows the site management operating organization for the Eagle Rock Enrichment Facility (EREF).

1.1.3 Figure 1-2 of the QAPD shows the engineering, procurement, construction, and initial start-up organization of the EREF.

1.2 DESIGN, CONSTRUCTION, START-UP, AND OPERATIONS ORGANIZATION

1.2.1 The AES President has overall responsibility for the design, construction, start-up, and operation of the Eagle Rock Enrichment Facility.

1.2.2 The AES President has overall responsibility for the Quality Assurance (QA) Program and for determining the status, adequacy, and effectiveness of the QAPD.

1.2.3 The AES President has designated the Vice President Engineering and Engineering, Procurement and Construction (EPC) Project Manager the responsibility for design, construction, procurement, and initial start-up for the Eagle Rock Enrichment Facility. The QAPD is binding on all AES and contractor personnel involved with the Eagle Rock Enrichment Facility.

1.2.4 A Deputy EPC Project Manager may assist the EPC Project Manager in planning and implementation of EPC activities.

1.2.5 The AES President has designated the Plant Manager the responsibility for operation, maintenance, and associated support activities for the Eagle Rock Enrichment Facility.

1.2.6 The QA Manager reports to the AES President and has independent oversight responsibility for implementation of the QAPD. The QA Manager has direct access to the AES President for QA matters.

1.2.7 The Quality Assurance Auditors report to the QA Manager and have the responsibility for performing audits related to the implementation of the QA Program.

1.2.8 The Quality Assurance Inspectors report to the QA Manager and have the responsibility for performing inspections related to the implementation of the QA Program.

1.2.9 The Quality Assurance Technical Support personnel report to the QA Manager and have the responsibility for providing technical support related to the implementation of the QA Program.

1.2.10 The Operations Manager reports to the Plant Manager and is responsible for day-to-day facility operations activities at the Eagle Rock Enrichment Facility. Inherent in this responsibility is the assurance that the operations are conducted safely and in compliance with license conditions. The Operations Manager is also responsible for the plant maintenance function, which includes activities to assure that Items Relied On For Safety (IROFS) are reliable and available when needed.

1.2.11 The Production Managers report to the Operations Manager. The Production Managers are responsible for enrichment operations, feed and withdrawal operations, utilities, shift operations, packaging, and transportation.

1.2.12 The Production Supervisors report to their respective Production Manager. The Production Supervisors are directly responsible for control of materials, personnel, equipment and activities in specific areas. These responsibilities include assuring that formal approved procedures are available and adhered to by operators and other applicable personnel.

1.2.13 The Maintenance Manager reports to the Operations Manager. The Maintenance Manager is responsible for safe and reliable performance of preventive and corrective maintenance and support services on systems, structures, and components (including IROFS), and for integrated planning and scheduling.

1.2.14 The Uranium Management Manager reports to the Plant Manager. The Uranium Management Manager is responsible for UF_6 cylinder management (including compliance with transportation requirements) and directing the scheduling of enrichment operations to ensure smooth enrichment process output. This includes activities such as ensuring proper feed material and maintenance equipment are available for the facility.

1.2.15 The Training Manager reports to the Plant Manager. The Training Manager is responsible for the development, implementation, and administration of the plant training programs, including maintenance of the plant training database. The training programs provided and/or coordinated by the Training Manager address qualifications of workers to perform work as well as required safety training.

1.2.16 The Project Manager reports to the Plant Manager. The Project Manager has the overall responsibility for managing the engineering, construction, initial startup and procurement activities of facility modifications and expansion. This involves managing the work and contracts with the Technology Supplier (Enrichment Technology Company (ETC)).

1.2.17 The Engineering Manager reports to the Project Manager. The Engineering Manager is responsible for site characterization; facility design and the design control process; configuration management; engineering; and acceptance test coordination, including test control of facility modifications and expansion. The Engineering Manager is also responsible for records management and document control, and approving disposition of nonconforming items when dispositioned as "repair" or "use-as-is" during operations.

1.2.18 The Procurement Manager reports to the Project Manager. The Procurement Manager is responsible for procurement; providing procurement material control services (including supplier qualification coordination, purchasing, contracting, receiving and control of nonconforming items); and material control (including handling, storage and shipping). The Procurement Manager is also responsible for supply strategy and development of qualified long-lead-time and complex-system suppliers.

1.2.19 The Construction Manager reports to the Project Manager. The Construction Manager is responsible for managing the construction of facility modifications and expansion to the Eagle Rock Enrichment Facility. This responsibility includes managing the activities of qualified contractors who are tasked with the preparation of construction documents and the construction of facility modifications and expansion.

1.2.20 The Startup Manager reports to the Project Manager. The Startup Manager is responsible for the overall preoperational and startup test program of facility modifications and expansion. This individual is responsible for the development of preoperational and startup test procedures, providing technical advice to personnel conducting the tests, briefing personnel responsible for operation of the plant during the tests, ensuring that the tests are performed in accordance with the applicable procedures, and generating test reports.

1.2.21 The Environmental, Health, Safety, and Licensing Manager reports to the Plant Manager. The Environmental, Health, Safety, and Licensing Manager has the overall responsibility for the development and implementation of programs addressing worker health and safety; environmental protection; and licensing/permitting, including monitoring compliance with those licenses and permits. The Environmental, Health, Safety, and Licensing Manager is responsible for the following areas: nuclear criticality safety, radiation protection/chemistry, environmental protection, integrated safety analysis, industrial hygiene and safety, chemical safety, fire protection, security, emergency preparedness, licensing and compliance, and nuclear material safeguards. The responsibility of the Environmental, Health, Safety, and Licensing Manager, with respect to operations, is only to confirm the safety of these operations. However, the Environmental, Health, Safety, and Licensing

Manager has the authority to order shutdown and approve re-start of operations that are judged to be unsafe for continued operation or non-compliant with applicable regulatory requirements.

1.2.22 The Nuclear Criticality Safety Manager reports to the Environmental, Health, Safety, and Licensing Manager. The Nuclear Criticality Safety Manager is responsible for the development and implementation of the nuclear criticality safety program. Key responsibilities include the performance of nuclear criticality safety analyses and evaluations of applicable operations involving special nuclear material and changes to those operations; establishing limits and controls based on those analyses and evaluations; assuring the proper incorporation of limits and controls into applicable procedures and instructions; and monitoring plant compliance with nuclear criticality safety requirements.

1.2.23 The Radiation Protection/Chemistry Manager reports to the Environmental, Health, Safety, and Licensing Manager. The Radiation Protection/Chemistry Manager is responsible for the development and implementation of the programs to limit personnel radiological exposures and environmental impacts associated with facility operations; including the As Low As Reasonably Achievable (ALARA) program. The Radiation Protection/Chemistry Manager is also responsible for the implementation of chemistry analysis programs and procedures for the facility. In matters involving radiological protection, the Radiation Protection/Chemistry Manager has direct access to the Plant Manager.

1.2.24 The Safety, Security, and Emergency Preparedness Manager reports to the Environmental, Health, Safety, and Licensing Manager. The Safety, Security, and Emergency Preparedness Manager is responsible for implementation and maintenance of the integrated safety analysis, industrial hygiene and safety, chemical safety, fire protection, security, and emergency preparedness.

1.2.25 The Licensing and Compliance Manager reports to the Environmental, Health, Safety, and Licensing Manager. The Licensing and Compliance Manager is responsible for regulatory oversight functions, regulatory and environmental compliance, facility change process, and commitment management.

1.2.26 The Safeguards Manager reports to the Environmental, Health, Safety, and Licensing Manager. The Safeguards Manager is responsible for ensuring the proper implementation of the Fundamental Nuclear Material Control Plan. This position is separate from and independent of other departments to ensure a definite division between the safeguards group and the other departments. In matters involving safeguards, the Safeguards Manager has direct access to the Plant Manager.

1.2.27 The Information Technology (IT) Manager reports to the Project Manager and is responsible for maintaining all computer software programs related to the nuclear material accounting at EREF. This individual is also responsible for EREF computer database for generation of nuclear material control charts.

1.2.28 A Safety Review Committee (SRC) is established to assist with the safe operation of the facility. The SRC reports to the President and provides technical and administrative review and evaluation of operations that could impact plant worker safety, public safety, or the environment.

1.3 QA RESPONSIBILITIES

The QA Manager is responsible for independent oversight of Eagle Rock Enrichment Plant activities covered by this QAPD. This includes maintenance of the QAPD and assessing its effective implementation. This includes the responsibility and authority for:

1.3.1 Maintaining the QAPD for the Eagle Rock Enrichment Facility;

1.3.2 Reviewing and approving implementing procedures;

1.3.3 Reviewing and approving supplier QA programs;

1.3.4 Providing oversight of supplier QA program implementation;

1.3.5 Performing QA technical reviews of procurement documents;

1.3.6 Maintaining the Approved Suppliers List (ASL);

1.3.7 Administering the corrective action and nonconformance process;

1.3.8 Administering the Auditor and Lead Auditor certification process;

1.3.9 Monitoring the implementation of the QAPD and assessing the effectiveness of the QAPD through audit and surveillance;

1.3.10 Investigating any aspect of the QAPD to identify problems with execution and to verify that corrective action is taken in a timely manner;

1.3.11 Stopping unsatisfactory work or controlling further processing when warranted for safety considerations;

1.3.12 Attending status meetings, and staying abreast of day-to-day activities to ensure adequate oversight;

1.3.13 Providing quality control activities for purchased and in-house manufactured items.

1.4 QUALITY PHILOSOPHY

The organizational philosophy regarding Quality is based on the following principles:

1.4.1 Quality is achieved by those responsible for performing work. This includes identifying, correcting, or recommending solutions for quality problems.

1.4.2 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.

1.4.3 Delegation of work between AES and contractors is identified in applicable plans, contracts and implementing procedures. In all cases of delegation, AES retains the overall responsibility for all work performed. Responsible managers have the authority to delegate tasks to another qualified individual within their organization provided the designated individual possesses the required qualifications and these qualifications are documented. All delegations are in writing. The responsible manager retains the ultimate responsibility and accountability for implementing the applicable requirements.

1.4.4 Suppliers and contractors are qualified consistent with this QAPD, as applicable to the scope of work as specified in Section 4.0 of this QAPD.

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

1.4.6 Each employee has an obligation to identify concerns using the corrective action process with respect to work within their scope of responsibility whenever the health and safety of our workers, the public, or the environment is involved or when continued work will produce results that are not in compliance with the QAPD. This process is controlled by procedures, which apply across the entire project/facility. The authorities and responsibilities for stopping work, the criteria and documentation required to process the stop work and the actions required before work may resume are detailed in procedures. This process ensures that activities are controlled until the deficiency, or unsatisfactory condition, has been resolved. Worker responsibilities are further discussed in Section 16.0 of this QAPD.

2.0 QUALITY ASSURANCE PROGRAM

2.1 QA elements of this section are applied to IROFS; credited attributes of safe-by-design components; and SSCs that could interact with IROFS or credited attributes of safe-by-design components, due to a seismic event, to assure they will be available and reliable in performing their safety functions when needed. Subcomponents of QA items may be classified, through engineering procedures, at different QA Levels based on their critical attributes. This classification QA Levels are established as follows:

Level	Description
QA Level 1	QA Level 1 items include those items whose failure or malfunction could directly result in a condition that adversely affects public, worker and the environment as described in 10 CFR 70.61. The failure of a single QA Level 1 item could result in a high or intermediate consequence.
QA Level 2	QA Level 2 items include those items whose failure or malfunction could indirectly result in a condition that adversely affects public, worker and the environment as described in 10 CFR 70.61. The failure of a QA Level 2 item, in conjunction with the failure of an additional item, could result in a high or intermediate consequence. All building and structure IROFS associated with credible external events are QA Level 2. QA Level 2 items also include those attributes of items that could interact with IROFS or credited attributes of safe-by-design components, due to a seismic event, and result in high or intermediate consequences as described in 10 CFR 70.61.
QA Level 3	QA Level 3 items include those items that are not classified as QA Level 1 or QA Level 2. QA Level 3 items are controlled in accordance with standard commercial practices.

2.2 The following applicable requirements are associated with each of the QA Levels as described below:

2.2.1 QA Level 1:

- Design documentation to verify review and approval of new designs and modifications to existing designs.
- Results of reviews, audits, and monitoring of work performance.
- Documentation to verify review and approval of qualified vendors.
- Procurement documents and material certifications from qualified vendors to verify traceability.
- Qualifications of personnel with responsibilities such as welder,

nondestructive examination inspector, lead QA auditor, and quality control inspector.

- Approved procedures used for design and fabrication activities such as welding, inspection, auditing, and procurement.
- List of equipment used and documentation to verify calibration.
- Inspection and test results for qualification and facility operation activities, identification of inspectors, type of observation, acceptance criteria, and action taken in connection with any noted deficiencies.
- A commercial parts dedication program may be used, but all supporting documentation needs to be maintained.

All applicable portions of this QAPD apply to QA Level 1 items.

2.2.2 QA Level 2:

- Design documentation to verify review and approval of new designs and modifications to existing designs.
- Results of reviews, audits, and monitoring of work performance.
- Qualifications of personnel with responsibilities such as welder, nondestructive examination inspector, lead QA auditor, and quality control inspector.
- Approved procedures used for design and fabrication activities such as welding, inspection, auditing, and procurement.
- List of equipment used and documentation to verify calibration.
- Inspection and test results for qualification and production activities, identification of inspectors, type of observation, acceptance criteria, and action taken in connection with any noted deficiencies.
- A commercial parts dedication program may be used, but all supporting documentation needs to be maintained.

All applicable portions of this QAPD apply to QA Level 2 items.

2.2.3 QA Level 3:

- Controlled in accordance with standard commercial practices.

This QAPD does not apply to QA Level 3 items as they are controlled in accordance with standard commercial practices.

2.3 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.

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

2.5 Indoctrination and training of personnel performing or managing activities affecting quality is performed in accordance with approved procedures.

2.6 Quality Control personnel performing inspection and testing are qualified in accordance with approved procedures.

2.7 Personnel performing nondestructive examination are qualified in accordance with approved procedures.

2.8 Personnel performing audits are qualified in accordance with procedures.

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

2.10 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.

2.11 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.

2.12 QA requirements for QA Level 1 and 2 items and activities are imposed on contractors and suppliers through the respective procurement documents for the particular scope of work contracted. Determination of the specific QA requirements, supplier evaluations, and proposal/bid evaluations are in accordance with the requirements of Section 4.0 and Section 7.0 of this QAPD.

3.0 DESIGN CONTROL

3.1 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.

3.2 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 U.S. Nuclear Regulatory Commission (NRC) approval is required to make the changes, are identified, approved, documented, and controlled.

3.3 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, fabrication, 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 IROFS, credited attributes of safe-by-design components, or applicable SSCs 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.

3.4 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 to meet the requirements of ASME NQA-1, 1994 edition, Basic Requirement 11 and NQA-1, Part II, Subpart 2.7, QA Requirements for Computer Software for Nuclear Plant Applications. Computer programs are controlled to assure that changes are documented and approved by authorized personnel. Where changes to previously verified computer programs are made, verification is required for the change, including evaluation of the effects of the change.

3.5 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 analyses, 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.

3.6 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 associated IROFS, credited attributes of safe-by-design components, applicable SSCs or computer program to perform its function.

3.7 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 considerations 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.

3.8 Changes to final designs, field changes, modifications, and nonconforming items dispositioned "use-as-is" or "repair," as described in Section 15.0 of this QAPD, are justified, documented, and subject to the design control measures commensurate with the original design. Design control measures for changes shall include provisions to ensure that the design analyses for the item are still valid. Changes are reviewed and approved by the person or group with assigned design authority.

3.9 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.

3.10 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 in accordance with Section 17.0 of this QAPD.

3.11 Design deficiencies discovered during the design process on subsequent design related activities that effect the design of IROFS, credited attributes of safe-by-design components, or applicable SSCs are entered into the corrective action process in accordance with Section 16.0 of this QAPD. If these

deficiencies caused constructed or partially constructed items to be deficient, the affected items are controlled in accordance with Section 15.0 of this QAPD.

3.12 Configuration management is maintained in accordance with the applicable procedures controlling changes to the various types of design documents.

4.0 PROCUREMENT DOCUMENT CONTROL

4.1 Procurement documents will include those requirements necessary to ensure that items and services relied on for safety, credited attributes of safe-by-design components and applicable SSCs to be purchased will be of the desired quality. Applicable design bases and other requirements necessary to provide reasonable assurance of quality are included or referenced in documents for procurement of IROFS, services relied on for safety, credited attributes of safe-by-design components and applicable SSCs. Procurement documents also include the following, as appropriate:

4.1.1 Scope of Work

4.1.2 Basic Technical Requirements — These include drawings, specifications, codes and industry 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.

4.1.3 QA Requirements to be included in Procurement documents. These requirements would include, but are not limited to, invoking of the Supplier's QA program, access to the supplier and sub-suppliers facilities, the establishing of Witness and Hold points, notification of Nonconformances, Inspections and Tests and all associated Quality Documentation. Procurement procedures will be utilized to identify all procurement requirements. The extent of the QA program and associated procurement requirements will depend upon the type and use of the item or services being procured.

4.1.4 Requirements for the control of nonconformances and changes — These include provisions to control and report nonconformance and changes to products being delivered. Requirements also include provisions for the supplier to report to AES, in writing, adverse conditions resulting in work stoppages and nonconformances. AES approval of partial or full work releases and disposition of nonconformances is required.

4.1.5 Requirements on Subtier Suppliers — These include the specification of procurement requirements on subtier suppliers.

4.1.6 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.

4.2 During licensing, design, fabrication, construction, operations and testing, the requirements of 10 CFR 21, "Reporting of Defects and Noncompliance," are invoked for QA Level 1 and QA Level 2 procurement or dedication of items and services. For Commercially Procured Items, which are subsequently dedicated, the reporting requirements for 10CFR 21 are the responsibility of AES.

4.3 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.

4.4 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

5.1 Activities affecting the availability and/or reliability of IROFS, credited attributes of safe-by-design components or applicable SSCs 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.

5.2 This QAPD establishes the policy requirements approved by the President, AES. 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 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 implementing procedures.

5.3 Policies, procedures, instructions, and drawings are controlled in accordance with Section 6.0 of this QAPD. Changes to policies, procedures, instructions, and drawings are reviewed and approved in accordance with Section 6.0 of this QAPD.

5.4 Adherence to policy, procedures, and instructions is mandatory. In the case of conflict or 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.

6.0 DOCUMENT CONTROL

6.1 Documents and changes to documents that prescribe or specify quality requirements or activities affecting the availability and/or reliability of IROFS or credited attributes of safe-by-design components 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.

6.2 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.

6.3 Changes to documents other than minor changes are reviewed for adequacy, correctness and completeness, prior to approval and issuance. Major changes are reviewed and approved by the same organization that performed the original review and approval unless other organizations are specifically designated. Temporary changes to procedures are approved by two members of the facility management staff, at least one of whom is a Production Manager. The applicable procedure controls the process, documentation and approval of the temporary changes.

6.4 Minor changes to documents, such as inconsequential editorial corrections, may be made to documents without being subject to the review and approval of the requirements specified above. The applicable procedure defines the organizational positions authorized and criteria acceptable for making minor changes.

7.0 CONTROL OF PURCHASED ITEMS AND SERVICES

7.1 The procurement of QA Level 1 and QA Level 2 items and services is controlled through procedures 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.

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

7.3.1 The QA Manager is responsible for providing the necessary QA function 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).

7.3.2 The Engineering Manager is responsible for assisting the QA Manager by performing evaluations of supplier's technical capabilities. The Engineering Manager is also 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. The Engineering 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."

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

7.3.4 The procurement methods described in Section 7.4 or 7.5 may be utilized to procure QA Level 1 or QA Level 2 items, components, or services. A combination of the methods may also be utilized.

7.4 Procurement of QA Level 1 and QA Level 2 Items, Components and Services

7.4.1 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. This evaluation will examine the potential supplier's current Quality Program and Implementing Procedures along with the associated Quality Records as supported by qualitative and quantitative information that can be objectively evaluated. For QA Level 1 items, at least one other method of supplier evaluation is used in addition to performance history.

- Depending on the part or service involved, a supplier QA program meeting the applicable requirements of accepted industry regulations or standards such as, but not limited to, NQA-1, ISO 9001, 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 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.
- For Calibration Services if the supplier has a valid Certificate of Accreditation issued by the National Voluntary Laboratory Accreditation Program (NVLAP) of the National Institute of Standards and Technology (NIST).
- The potential supplier maintains and implements a NRC approved QA program. 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.

7.4.2 Suppliers with acceptable technical, quality and commercial qualifications are placed on the ASL maintained by the QA organization. Each ASL listing is required to define the product or service scope of supply that the supplier is approved to provide, and define any approval restrictions and conditions. Retention on the list is based on performance.

7.4.3 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 responsibility for verification of quality achievement. The measures include:

- Establishing an adequate understanding between AES 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.

7.4.4 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 AES 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).

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

7.4.6 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 QA 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 to support 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.
- For QA Level 1 items, a Certificate of Conformance plus one or more of the other methods, established above, is used to establish acceptance of items.
- For QA Level 2 items, any one or more of the methods, established above, is used to establish acceptance of items.

7.4.7 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.

7.4.8 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.

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

7.4.10 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 of AES-supplied documents;
- Violation of requirement of purchaser-approved supplier documents.

7.4.11 Supplier nonconformances may be identified either by AES or by the supplier. For a supplier identified nonconformance, the supplier shall include a recommended disposition and technical justification for the identified condition. Nonconforming items are not released for use until the nonconforming condition is reviewed and accepted by Engineering and the implementation of the disposition is verified, except under conditional release provisions. Records of supplier nonconformance are maintained.

7.5 Procurement of QA Level 1 and QA Level 2 items and services by Commercial Grade Dedication

7.5.1 The methods to procure commercially available items and services will be performed in accordance with approved procedures. The criteria and methods for identifying the critical characteristics utilized for acceptance are established and are subject to design control measures in accordance with Section 3 of this QAPD. The critical characteristics, which once selected to be verified, provide reasonable assurance that the item or service provided meets

specified requirements. In selecting the critical characteristics, the impact of the activities associated with the item or service on the safety function of plant equipment is considered.

7.5.2 Commercial grade items are identified in procurement documents by manufacturer's published product descriptions, in accordance with Section 4.0 of this QAPD. Commercial grade services are identified in the purchase order by the service provider's published service description (e.g., supplier's bulletin describing standard calibration services that are provided by the supplier) or other appropriate documents.

7.5.3 A commercial grade item or service 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).

7.5.4 As a minimum for acceptance of commercial grade items, receipt inspection, as described in the following paragraph below, is performed to provide reasonable assurance that the item received is the item ordered and to ensure that the item will fulfill its intended safety function. Acceptance reviews will be performed, for acceptance of commercial grade services, to provide reasonable assurance that the service performed is the service ordered. Based on the complexity of the item or services or its importance to safety, one or more of the following are used to provide reasonable assurance that the item or service meets the acceptance criteria for the characteristics identified to be verified for acceptance:

- Special test(s) or inspection(s) or both:
- Commercial grade survey of the supplier;
- Source verification; or
- Acceptable supplier history of performance, this may only be used when a supplier history has been established and at that point supplier history shall be used with at least one other method.

7.5.5 The selection of the method or combination of methods as described above is based on the following:

- Selected critical characteristics;
- Available supplier information;
- Quality history;
- Degree of standardization of the service; and

- Importance to safety and complexity of the service.

7.5.6 Receipt inspections of commercial grade items are performed to determine 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 engineering, to ensure conformance with acceptance criteria and to ensure that required documentation is received and is acceptable. Acceptance reviews are performed to determine the commercial grade service performed is the service ordered and that required documentation is received and is acceptable.

7.5.7 Dedication of a commercial grade item or service occurs when that item is accepted in accordance with the above requirements. AES assumes 10 CFR 21 reporting responsibility for all items that AES dedicates as QA Level 1 or QA Level 2 items.

7.6 Approved Suppliers List

7.6.1 The AES QA Manager is responsible for the development and maintenance of the ASL. The ASL contains those suppliers with acceptable QA Programs that have been evaluated and accepted by AES in accordance with approved procedures. The AES QA organization performs and documents an evaluation of each supplier every 12 months. Satisfactory results will allow the supplier to remain on the ASL. Additionally, suppliers will be evaluated by means of an audit at least triennially, if initial approval was by audit or survey. Suppliers that have unacceptable evaluations or that have not had a procurement placed with them in three years will be removed from the ASL.

8.0 IDENTIFICATION AND CONTROL OF ITEMS

8.1 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.

8.2 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.

8.3 For QA Level 1 items, traceability of these items to specific records-is provided when specified by codes, standards, or specifications.

8.4 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.

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

8.5.1 Provisions for maintenance or replacement of markings and identification records due to damage during handling or aging;

8.5.2 Protection of identifications on items subject to excessive deterioration due to environmental exposure; and

8.5.3 Provision for updating existing records. Documentation is provided to show that items released for use are the items specified.

9.0 CONTROL OF SPECIAL PROCESSES

9.1 Special 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 special process parameters are controlled and that specified environmental conditions are maintained.

9.2 Special processes that control or verify quality (e.g., 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.

9.3 Records are maintained, in accordance with Section 17.0 of this QAPD, of currently qualified personnel, processes, and equipment for special processes.

10.0 INSPECTION

10.1 Inspections are performed to verify conformance of items or activities to specified requirements. Inspection requirements are specified in written procedures in accordance with Section 5.0 of this QAPD, with provisions for documenting and evaluating the inspection results. 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.

10.2 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.

10.3 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.

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

10.5 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.

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

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

10.8 Inspection records contain the following, as a minimum:

- Item inspected;
- Date of inspection;
- Inspector;
- Data recorder, as applicable;
- Type of observation and inspection plan;

- Acceptance criteria;
- Results or acceptability of characteristics inspected; and
- Action taken in connection with nonconformances, as applicable.

11.0 TEST CONTROL

11.1 Tests are performed as required to verify conformance with specified requirements, to demonstrate satisfactory performance, or to collect data. Test requirements are specified in written procedures (except as allowed by Section 11.3), in accordance with Section 5.0 of this QAPD, with provisions for documenting and evaluating the test results. Test personnel are qualified in accordance with Section 2.0 of this QAPD. 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.

11.2 Test procedures contain the following information as appropriate to the test:

- Test objectives, responsibilities, characteristics to be tested, hold points, test methods to be employed, and acceptance criteria;
- 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.

11.3 In lieu of written test procedures, appropriate sections of related documents (i.e., American Society for Testing and Materials methods, external manuals, maintenance instructions, or approved drawings or travelers with acceptance criteria) may be used. If used, this information is incorporated by reference in the approved test or process procedure. Implementing documents must include adequate instructions to ensure the required quality of work.

11.4 Test records contain the following information: item tested, test date, tester, data recorder (as applicable), type of observation, test procedure, acceptance criteria, results and acceptability of characteristics tested, actions taken in connection with any nonconformances or deviations noted (as applicable), person evaluating the results, and identification of the measuring and test equipment (M&TE) used during the test.

11.5 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

12.1 Measuring and Test Equipment (M&TE) used in activities affecting the availability and/or reliability of IROFS or credited attributes of safe-by-design components 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.

12.2 A list of M&TE 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).

12.3 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. Calibrated M&TE are labeled, tagged, or otherwise suitably marked or documented to indicate due date or interval of the next calibration and uniquely identified to provide traceability of its calibration date.

12.4 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.

12.5 When M&TE is lost, the validity of results obtained using that equipment since its last valid calibration shall be evaluated to determine acceptability of previously collected data, processes monitored or items previously inspected or tested.

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

13.0 HANDLING, STORAGE, AND SHIPPING

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

13.2 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 application is verified and monitored as necessary to ensure they continue to serve the intended function.

13.3 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 available and capable to serve the intended function when needed. Such control includes periodic inspection and testing to verify that special handling tools and equipment have been properly maintained. Operators of special equipment are experienced or trained as required in the use of the equipment.

13.4 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.

13.5 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

14.1 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. Status indication is required when it is necessary to ensure that required inspections and tests are performed and to ensure that items that have not passed the required inspections and tests are not inadvertently installed, used, or operated.

14.2 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 in procedures.

15.0 CONTROL OF NONCONFORMING ITEMS

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

15.2 Nonconforming items are identified by markings, tagging, and other appropriate methods that do not adversely affect the end use of the items.

15.3 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.

15.4 Nonconforming items are reviewed and dispositioned as "reject," "rework," "repair," or use-as-is." Further processing, delivery, installation, or use of the nonconforming item is controlled pending an evaluation and approved disposition by engineering personnel, and documented notification to affected organizations is provided.

15.5 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.

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

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

16.0 CORRECTIVE ACTION

16.1 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.

16.2 Procedures establish the Corrective Action Program which includes the following process elements:

- Prompt identification and correction of conditions adverse to quality;
- Evaluating significant conditions adverse to quality for reportability to the NRC (when required) under 10 CFR 21, Reporting of Defects and Noncompliance, or other applicable reporting requirements and reporting such conditions when warranted;
- Stopping work, if applicable;
- Determining root cause and corrective actions to preclude recurrence for significant conditions adverse to quality; and
- Follow-up actions to verify implementation of corrective actions taken for significant conditions adverse to quality.

16.3 Conditions adverse to quality are classified in one of two categories in regard to their significance and corrective actions to be taken. The two categories of significance include:

- Conditions adverse to quality (CAQ)
- Significant conditions adverse to quality (SCAQ)

16.3.1 CAQs including activities and services is an all-inclusive term used in reference to any of the following: failures, malfunctions, deficiencies, deviations, defective items and nonconformances. Conditions adverse to quality shall be documented and reported to the appropriate levels of management.

16.3.2 SCAQs include the following:

- A deficiency that would seriously impact an item, activity or service from meeting or performing its intended function or output of assuring public health and safety;
- A deficiency in design that has been approved for fabrication or construction where the design deviates extensively from design criteria and bases;

- A deficiency in the fabrication or construction of, or significant damage to, structures, systems or components that require extensive evaluation, re-design or repair in order to establish the adequacy of the structure, system or component to perform its intended function of assuring public health and safety;
- A deviation from performance specifications that shall require extensive evaluation, re-design, or repair to establish the adequacy of the structure, system or component to perform its intended function;
- A significant error in a computer program used to support activities affecting quality after it has been released for use;
- A deficiency, repetitive in nature, related to an activity or item subject to the AES QA Program; and
- A condition that, if left uncorrected, has the potential to have a serious negative impact on activities or items subject to the AES QA Program controls.

16.4 If a supplier or subtier supplier discovers a defect or noncompliance which the supplier evaluates as a substantial safety hazard, then the supplier shall be required to report the item under 10 CFR 21, Reporting of Defects and Noncompliance, and notify AES in writing. If the supplier or subtier supplier is unable to determine if the defect/non compliance is a substantial safety hazard then the supplier or subtier supplier is required to report the item to AES for determination of reportability in accordance with 10 CFR 21.

16.5 Significant conditions adverse to quality shall be evaluated for a stop work condition to determine if stopping work is warranted. If a stop work condition is identified, management shall issue stop work in accordance with applicable procedure. Upon resolution of the related significant condition adverse to quality, management shall take appropriate action to lift and close (in total or part) the stop work order.

16.6 Procedures establishing the Corrective Action Program include a requirement for management to take follow-up action to verify implementation of corrective action taken to address significant conditions adverse to quality. The QA organization is responsible for conducting periodic assessments of these follow-up actions.

16.7 Procedures establishing the Corrective Action Program assign organizational responsibility for trending significant conditions adverse to quality and the criteria for determining trends. Reports of significant conditions adverse to quality are evaluated to identify adverse quality trends and help identify root causes. Trend evaluation is performed in a manner and at a frequency that provides for prompt identification of adverse quality trends. Identified adverse trends are handled in accordance with the Corrective Action Program described here and reported to the appropriate management.

17.0 QUALITY ASSURANCE RECORDS

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

17.2 Documents that are designated to become records shall be legible, accurate and completed appropriate to the work accomplished. 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. Records are indexed to ensure retrievability. Records and/or indexing systems provide sufficient information to permit identification between the record and the item or activity to which it applies. 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. Records are classified for retention purposes as lifetime records or nonpermanent records in accordance with the criteria provided below.

17.3 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.

17.4 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.

17.5 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 are established in writing by the responsible organization.

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

17.7 Replacement, restoration, or substitution of lost or damaged records is performed in accordance with implementing procedures. These procedures provide for appropriate review and approval by the originating organization and any additional information associated with the replacement.

17.8 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.

17.9 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.

17.10 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.

17.11 Access to records storage facilities is controlled. A list is maintained designating personnel who are permitted access to QA records.

17.12 Records maintained by a supplier at its facility or other locations are accessible to AES directly or through the procuring organization. The supplier's records are not disposed of until contractual requirements are satisfied.

17.13 For computer codes and computerized data used for activities relied on for safety, procedures are provided for maintaining readability and usability of older codes and data as computing technology changes. The procedures include transfer of older forms of information and codes associated with older computing equipment to contemporary computing media and equipment.

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. Audits are also performed to verify that operations are being conducted in accordance with regulatory requirements and commitments in the license application.

18.1 INTERNAL AUDITS

18.1.1 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. The proper mix of audits and assessments will provide an effective and comprehensive QA 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.

18.1.2 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. Auditors (including technical specialists) have experience commensurate with the scope, complexity, or special nature of the audit and have no direct responsibility for the function or area being audited. The lead auditor is qualified in accordance with Section 2.0 of this QAPD. Audit personnel have sufficient authority and organizational freedom to make the audit process meaningful and effective.

18.1.3 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 will be documented as audit findings and will be reported immediately to management of the audited organization. The results of the audit are discussed with management of the audited organization.

18.1.4 The internal 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.

18.1.5 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.

18.1.6 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

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

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

18.2.3 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.

18.2.4 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.

18.2.5 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.

18.2.6 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

19.1 QAPD changes may be initiated by events such as reorganizations or revised activities, lessons learned, changes to applicable regulations, process changes, or other reasons. QAPD changes are governed by approved procedures.

19.2 Prior to NRC issuance of the Materials License, changes to the QA Program are incorporated in the QAPD and submitted to the NRC with the next revision of the license application or no later than annually, whichever occurs first.

After the Materials License is issued, changes to the QAPD that do not reduce the commitments as accepted by the NRC are submitted annually. The revision must reflect all changes up to a maximum of 6 months prior to the date of filing. Any changes that reduce commitments in the QAPD will be submitted to the NRC for review and approval prior to implementation.

20.0 REFERENCES

20.1 Title 10 Code of Federal Regulations, Part 21, Reporting of Defects and Noncompliance, 2008.

20.2 Title 10 Code of Federal Regulations, Part 70.4, Definitions, 2008.

20.3 Title 10 Code of Federal Regulations, Part 70.64, Requirements for new facilities or new processes at existing facilities, 2008.

20.4 American Society of Mechanical Engineers (ASME) NQA-1, Part I, Section 4, Introduction, 1994 edition.

20.5 ASME NQA-1, Basic Requirement 11, Test Control, 1994 edition.

20.6 ASME NQA-1, Part II, Subpart 2.7, QA Requirements for Computer Software for Nuclear Plant Applications, 1994 edition.

20.7 ASME NQA-1, Supplement 3S-1, Supplementary Requirements for Design Control, Part 1, 1994 edition.

20.8 ASME NQA-1-1994, Supplement 11S-2, Supplementary Requirements for Computer Program Testing, 1994 edition.

20.9 ASME NQA-1-1994, Supplement 17S-1, Supplementary Requirements for Quality Assurance Records, 1994 edition.

FIGURES

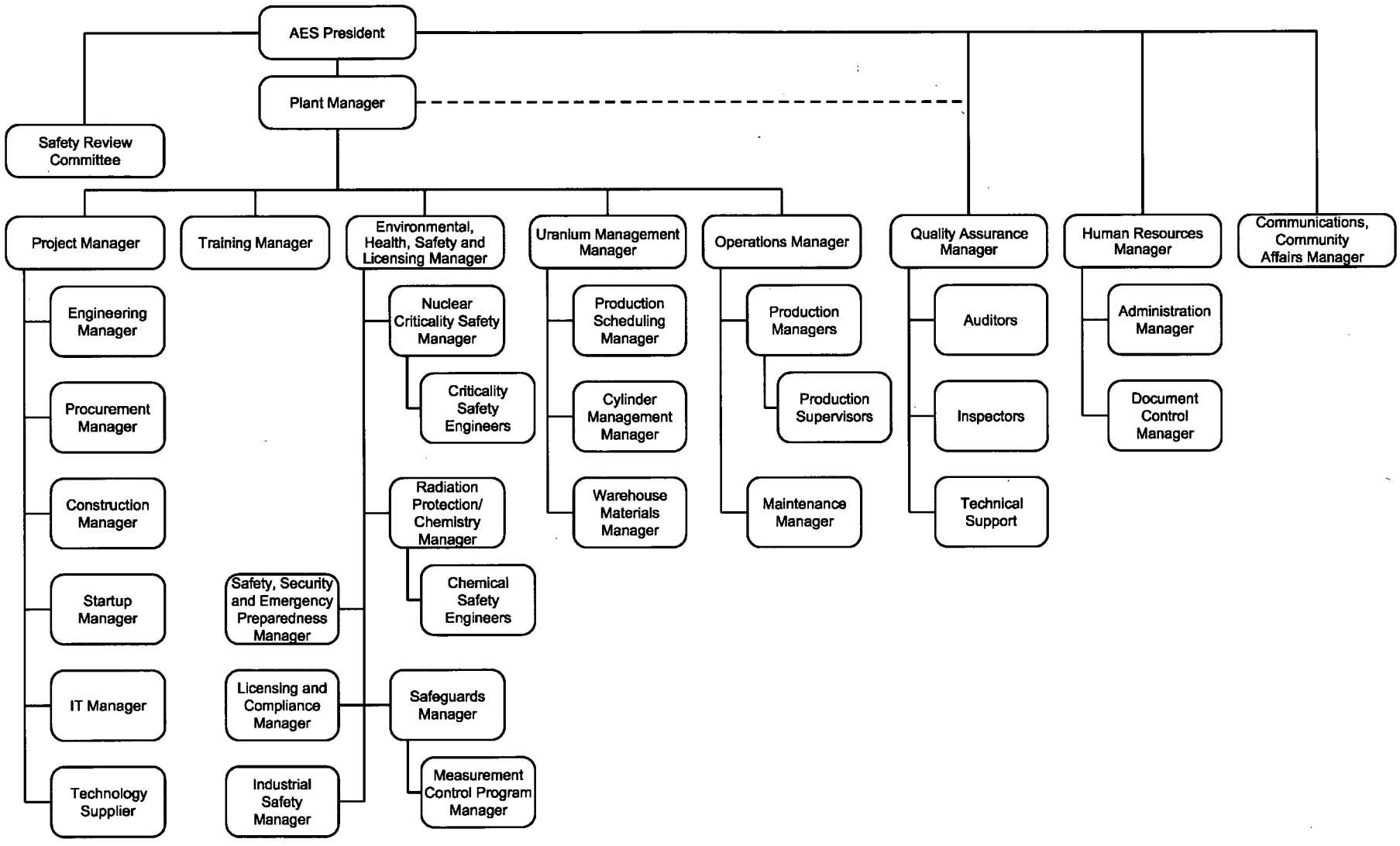

Figure 1-1 **Rev. 2**

Eagle Rock Enrichment Facility
Operations Organizational Chart

EAGLE ROCK ENRICHMENT FACILITY
QUALITY ASSURANCE PROGRAM DESCRIPTION

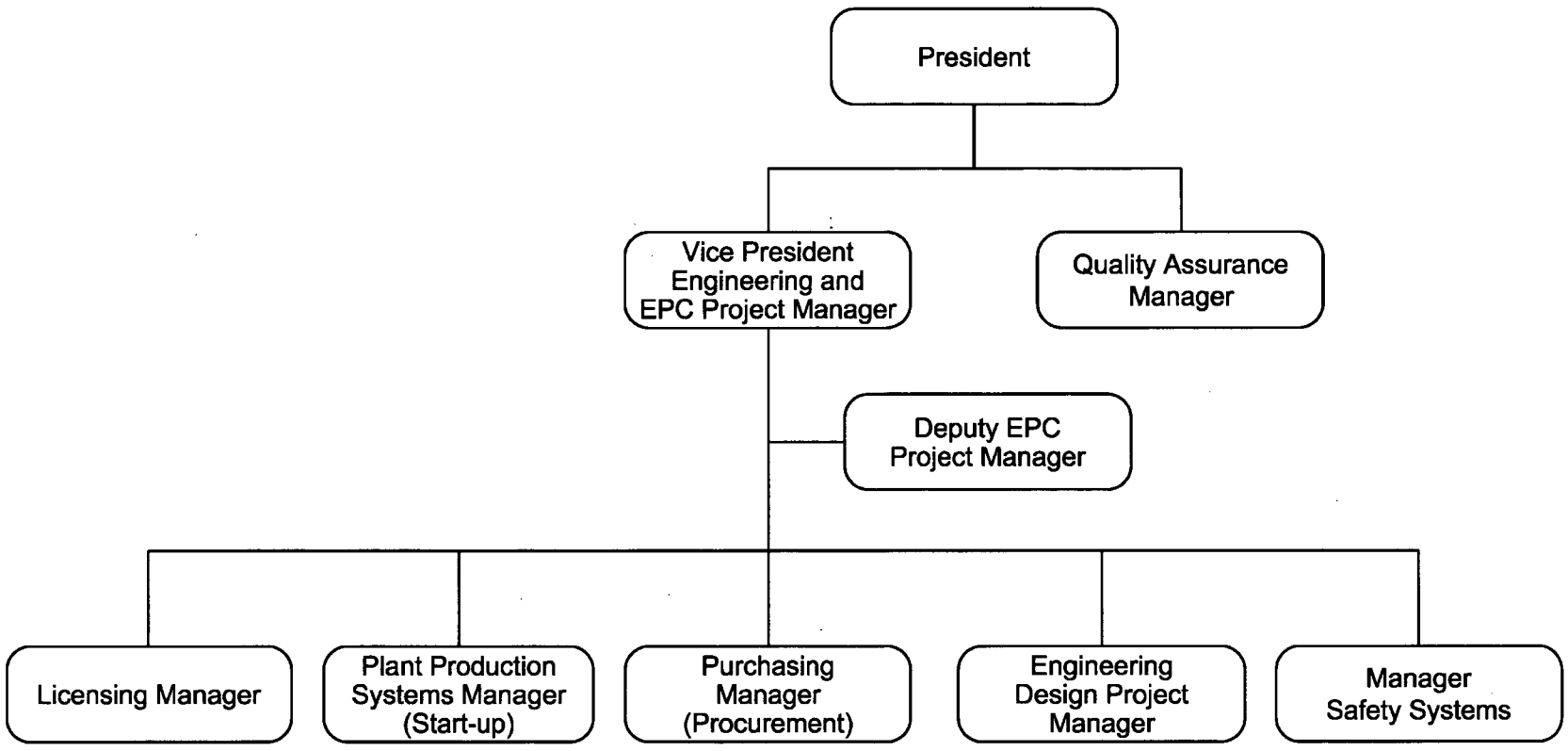

Figure 1-2 **Rev. 2**

Engineering, Procurement and Construction (EPC) Organizational Chart

EAGLE ROCK ENRICHMENT FACILITY
QUALITY ASSURANCE PROGRAM DESCRIPTION