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Detroit Edison Nuclear Development

Quality Assurance Program Description (QAPD)

Quality Assurance Program Description

Title: Detroit Edison Nuclear Development Quality Assurance Program Description

Process/Program Owner: Director & Project Manager Nuclear Development

DECO ND QAPD

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Detroit Edison Company

POLICY STATEMENT

The Detroit Edison Company (DECo) shall perform Combined Construction and Operating License Application (COLA) activities in a manner that will ensure that quality processes are used in the development of the COL application and that technical, quality, and administrative requirements important to public health and safety are effectively implemented for pre-COL activities.

The DECo Nuclear Development Quality Assurance Program (QAP) is the Quality Assurance Program Description (QAPD) provided in this document and the associated implementing documents. Together they provide for assurance of the integrity and reliability of the COL data or analysis that would affect the performance of safety related systems, structures, and components (SSCs). The requirements of this QAP are consistent with the applicable requirements of Appendix B to 10CFR Part 50.

The QAPD is the top-level policy document that establishes the manner in which quality is to be achieved for COLA activities and presents DECo's overall philosophy regarding achievement and assurance of quality. Implementing documents assign more detailed responsibilities and requirements and define the organizational interfaces involved in conducting activities within the scope of the QAP. Compliance with the QAPD and implementing documents is mandatory for personnel directly or indirectly associated with implementation of the DECo QAP.

Signed

Ron May

Senior Vice President DTE Energy

Date ___ 2 -/-08

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PART I INTRODUCTION

SECTION 1 GENERAL

The Detroit Edison Company (DECo) Nuclear Development Quality Assurance Program Description (QAPD) is the top-level policy document that establishes the quality assurance policy and assigns major functional responsibilities for COL activities conducted by or for DECo. The QAPD describes the methods and establishes QAPD and administrative control requirements that and is consistent with the applicable requirements of Appendix B to 10CFR Part 50. The QAPD is also consistent with the applicable (to the work scopes being performed) requirements of ASME NQA-1-1994, "Quality Assurance Requirements for Nuclear Facility Applications".

The QAPD is defined by the Quality Assurance Program (QAP) elements, along with the associated implementing documents. Procedures and instructions that control DECo Nuclear Development COLA activities will be developed prior to commencement of those activities. Procedures establish practices for certain activities which are common to all DECo organizations performing those activities such that the activity is controlled and carried out in a manner that meets these requirements. Project or organization specific procedures establish detailed implementation requirements and methods, and may be used to implement Policies or be unique to particular functions or work activities.

1.1 Scope / Applicability

This QAPD applies to COL activities affecting the integrity and reliability of the COL data or analysis that would affect the performance of safety related systems, structures, and components (SSCs).

Safety-related systems, structures, and components are identified by design control documents. The technical aspects of these items are considered when determining program applicability, including, as appropriate, the item's design safety function. Implementing documents assign more specific requirements regarding QAPD applicability.

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PART II QAPD DETAILS

SECTION 1 ORGANIZATION

This Section describes the DECo Nuclear Development organizational structure, functional responsibilities, levels of authority and interfaces for establishing, executing, and verifying QAPD implementation. The organizational structure includes corporate and onsite functions for DECo Nuclear Development including interface responsibilities for multiple organizations performing COLA functions. Implementing documents assign more specific responsibilities and duties, and define the organizational interfaces involved in conducting activities and duties within the scope of this QAPD. Management gives careful consideration to the timing, extent and effects of organizational structure changes.

COLA services are provided to the DECo Nuclear Development organization, under contract, by Black & Veatch (Kansas City). Owner's Engineering services are provided to the DECo Nuclear Development project, under separate contract, by Black & Veatch (Ann Arbor). DECo internal organizations Environmental, Nuclear Generation, Legal, Supply Chain, and Real Estate. are also supporting the DECo Nuclear Development project. The Reactor Technology Vendor is responsible for interfacing with the NRC and other organizations for Design Control Document and technology certification activities within their scope of responsibility.

The following sections describe the reporting relationships, functional responsibilities and authorities for organizations implementing and supporting the DECo Nuclear Development QA Program. The DECo organization and the DECo Nuclear Development organization are shown in Figures II.1-1 and II.1-2 respectively.

1.1 Chairman and Chief Executive Officer

The Chairman/CEO is responsible for all aspects of design, construction and operation of DECo's nuclear plants. The Chairman/CEO reports to the Board of Directors with respect to all matters.

1.1.1 Senior Vice President DTE Energy

The **DTE Energy** Senior Vice President DTE Energy (SVP) reports to the **Chairman**/CEO and is responsible for the administration of the DECo Nuclear Development QAPD. The SVP also directs the planning and development of the DECo Nuclear Development staff, and organization resources.

1.2 DECo Nuclear Development

DECo Nuclear Development (ND) organization is responsible for new nuclear plant licensing and other COLA related activities.

1.2.1 Director & Project Manager Nuclear Development

The Director & Project Manager Nuclear Development reports to the Senior Vice President DTE Energy and is responsible for the implementation of quality assurance requirements in the areas specified by this QAPD.

For the purposes of this program, the description of the duties of the Director & Project Manager Nuclear Development and staff will be limited to those activities that support the DECo Nuclear Development COLA preparation and submittal.

1.2.1.1 Owner's Engineer Organization

The Owner's Engineer Organization (Black & Veatch Ann Arbor) reports to the Director Nuclear Development Licensing/Engineering and is responsible for supporting COLA on-site work, quality assurance, scheduling of DECo activities, risk management, RTV evaluation and selection, and cost estimating.

1.2.1.2 Quality Assurance

The DECo Quality Assurance Organization is responsible for independently planning and performing activities to verify the development and effective implementation of the QAPDs activities that support COLA activities.

1.2.1.2.1 ND Quality Assurance Manager

The ND Quality Assurance Manager (QAM) reports to the Director and Project Manager Nuclear Development for the COLA activities and is responsible for developing and maintaining the DECo Nuclear Development QAPDs, evaluating compliance to the programs and managing the QA resources.

The Nuclear QA Oversight Quality Assurance function reports administratively to the Director & Project Manager Nuclear Development. This ensures that the personnel performing QA oversight functions are not subject to line influence. This also ensures that quality assurance personnel are provided direct access to senior management that is independent of the line functions for reporting QA concerns.

Day to day work direction is provided from the Manager Nuclear Development Program Office.

The QAM is responsible for assuring compliance with regulatory requirements and procedures through audits and technical reviews; for monitoring organization processes to ensure conformance to licensing document requirements; for ensuring that vendors providing quality services to DECo are meeting the requirements of 10 CFR 50, Appendix B through vendor audits. The QAM has sufficient independence from other DECo Nuclear Development priorities to bring forward issues affecting safety and quality and makes judgments regarding quality in all areas necessary regarding DECo COLA activities. The QAM may make recommendations to the DECo Nuclear Development management regarding improving the quality of work processes. If the QAM disagrees with any actions taken by the Nuclear Development organization and is unable to obtain resolution, the QAM shall bring the matter to the attention of the Senior Vice President DTE Energy who will determine the final disposition.

1.2.1.3 Reactor Technology Vendor (RTV)

The RTV provides engineering services for plant design and licensing. These engineering services for new nuclear generation include Design Certification Document (DCD) engineering

and design for their scope (as defined in the DCD) and as necessary to support development of the COL application.

1.2.1.4 Black and Veatch Kansas City

Black and Veatch Kansas City provides quality and safety related services for the development of the COL application that are not the responsibility of the RTV (as defined in the DCD). These services include site characterization and other activities necessary to support development of the COL application.

1.3 Authority to Stop Work

Quality assurance personnel have the authority, and the responsibility, to stop work in progress which is not being done in accordance with approved procedures. This extends to off-site work performed by suppliers furnishing COLA related services to DECo.

1.4 Quality Assurance Organizational Independence

For the COL, independence shall be maintained between the organization performing the checking (quality assurance) functions and the organizations performing the functions.

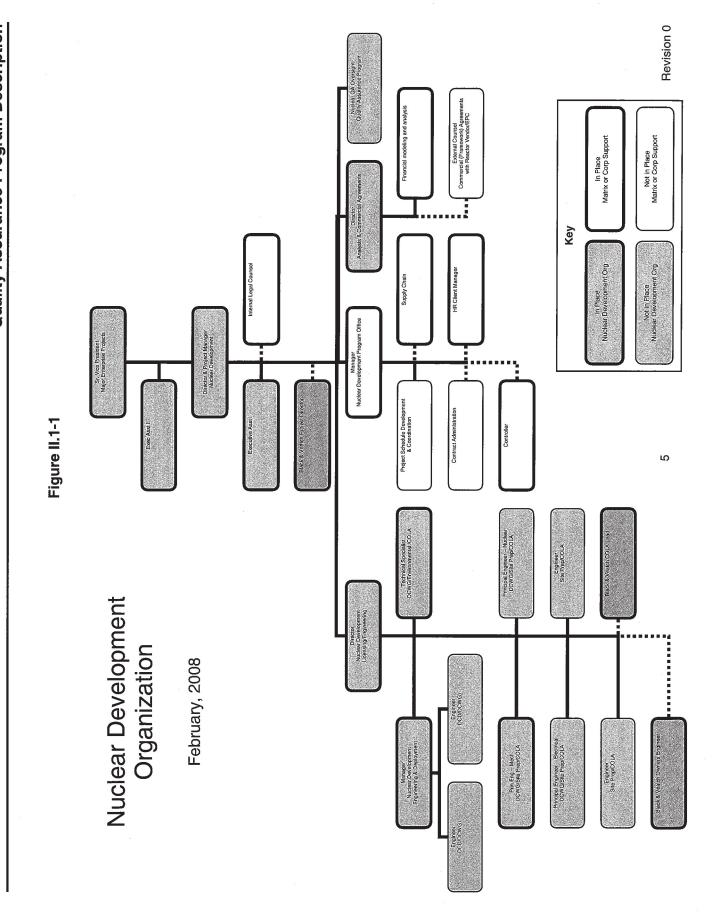
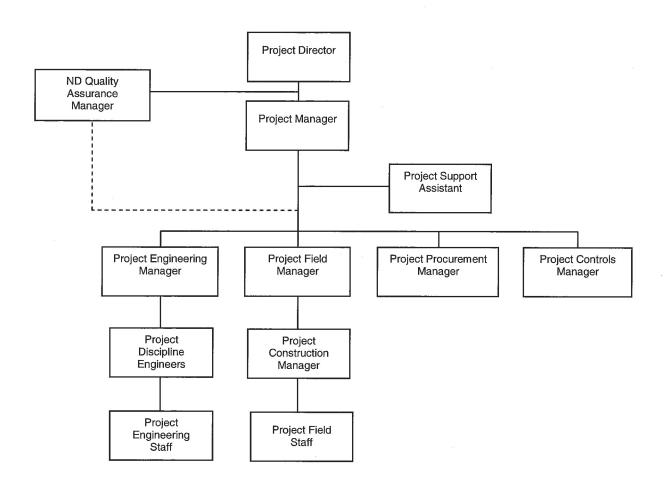


Figure II.1-2

Owner's Engineer Nuclear Development Project Organization



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----- Denotes coordination

SECTION 2 QUALITY ASSURANCE PROGRAM

DECo has established procedures to implement this QAPD. DECo is committed to implementing the Quality Assurance Program to the extent applicable for COLA activities. Further, DECo ensures that suppliers of COLA related services meet the applicable requirements of this QAPD. Senior management is regularly apprised of the adequacy of implementation of the QAPD through the audit functions described in Section 18.

The objective of the QAPD is to provide assurance of the integrity and reliability of the COL data or analysis that would affect the performance of safety related systems, structures, and components (SSCs). The requirements of this QAP are consistent with the applicable requirements of Appendix B to 10CFR Part 50 and ASME NQA-1-1994, "Quality Assurance Requirements for Nuclear Facility Applications."

The QAPD applies to processes used in the development of the COL application and to technical, quality, and administrative requirements important to public health and safety including:

- COL Final Safety Analysis Report, Emergency Plan, Security Plan, and the Environmental Report.
- Site geotechnical investigations, seismic analysis, and meteorological analysis and engineering activities that are used to characterize the site or analyze that characterization.

The RTV Design Control Document is used as the detailed basis for classification of SSCs that are within the scope of this QAPD.

Delegated responsibilities may be performed under a supplier's QAPD, provided that the supplier activities are within the scope of this QAPD, and the supplier has been approved in accordance with this QAPD. Periodic audits and assessments of suppliers are performed to assure compliance with the supplier's quality program. In addition, routine interfaces with project personnel assure that quality expectations are met.

The program requirements specified herein are detailed in implementing procedures that are either DECo implementing procedures, or an approved supplier quality program.

2.1 Responsibilities

Personnel who work directly or indirectly for DECo are responsible for performing quality work covered by this QAPD. This includes those activities delineated in Part I, Section 1.1 of this QAPD. Activities governed by the QAPD are performed as directed by documented instructions, procedures and drawings that are of a detail appropriate for the activity's complexity and effect on safety. Instructions, procedures and drawings specify quantitative or qualitative acceptance criteria as applicable or appropriate for the activity, and DECo personnel performing review and acceptance activities ensure verification against these criteria. Provisions are established to designate or identify the proper documents to be used in an activity, and to ascertain that such documents are being used. The ND Quality Assurance Manager is responsible to verify that processes and procedures comply and are implemented in accordance with the QAPD and other applicable requirements.

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2.2 Delegation of Work

DECo has the responsibility for the scope and implementation of an effective QAPD. Positions identified in the Organization Section of this QAPD may delegate responsibility for all or part of the activities of planning, establishing, and implementing the program but retain the responsibility for the program's effectiveness. Decisions affecting safety are made at the level appropriate for its nature and effect, and with any necessary technical advice or review.

2.3 COL Identification of Site Specific Safety-Related Design Basis Activities

COL site specific safety-related activities are defined as those activities, including sampling, testing, data collection and supporting engineering calculations and reports that will be used to establish design inputs for safety-related SSCs. The development of the DECo COL application will involve site testing, data collection and calculations that may create or bound safety-related design basis data. Site testing and data collection of information pertaining to the physical characteristics of the site that have the potential to affect safety-related design will be treated as safety-related.

2.4 Periodic Review of the Quality Assurance Program

Management of those organizations implementing the QA program or portions thereof, assess the adequacy of that part of the program for which they are responsible and assure its effective implementation at least once each year or at least once during the life of the activity, should the activity duration be less than one year.

2.5 Issuance and Revision to Quality Assurance Program

Changes to the QAPD are evaluated by the ND Quality Assurance Manager to ensure that such changes do not degrade previously approved quality assurance controls specified in the QAPD. This document shall be revised as appropriate to incorporate additional QA commitments that may be established during the COL application development process. New revisions to the document will be reviewed, at a minimum, by the Director & Project Manager Nuclear Development and approved by the Senior Vice President DTE Energy.

2.6 Personnel Qualifications

Management shall ensure that personnel assigned to implement elements of the QAPD be capable of performing their assigned tasks, i.e., qualified by experience.

2.7 Independent Review Body

A group may function as an independent review body (IRB). In discharging its review responsibilities, the IRB keeps safety considerations paramount when opposed to cost or schedule considerations. One or more organizational units may collectively perform this function.

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SECTION 3 DESIGN CONTROL

DECo has established a Project Steering Committee (PSC) to review the RTV recommendations, design changes and impacts to the nuclear development project.

3.1 Project Steering Committee (PSC)

The Project Steering Committee (PSC) will review recommendations for 1) design departures from the selected reactor technology Design Certification Document; 2) significant design features to adapt the selected reactor technology to DECo FERMI site specific design conditions, and 3) shared common equipment for a dual unit site, for potential incorporation into the DECo FERMI design. Departures from RTV design will not be made without discussions that include other US utilities which have filed Letters of Intent to the U.S. NRC for submittal of COLAs for like technology, and Black & Veatch Kansas City.

3.2 Project Design Control

Design activities being performed during the COLA development are performed under contract by the RTV and Black & Veatch Kansas City. Contracts for design activities will incorporate the requirements of ASME NQA-1 Requirement 3 and 10CFR52.79 (a) (17).

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SECTION 4 PROCUREMENT DOCUMENT CONTROL

DECo procedures assure that purchased items and services are subject to appropriate quality and technical requirements. Procurement document changes shall be subject to the same degree of control as utilized in the preparation of the original documents. These controls include provisions such that:

- Applicable technical, regulatory, administrative, quality and reporting requirements are invoked for procurement of items and services. 10 CFR 21 requirements for posting, evaluating and reporting will be followed and imposed on suppliers when applicable. Applicable design bases and other requirements necessary to assure adequate quality shall be included or referenced in documents for procurement of items and services. To the extent necessary, procurement documents shall require suppliers to have a documented QA program that is determined to meet the applicable requirements of this QAPD as appropriate to the circumstances of procurements (or the supplier may work under this QAPD.
- Where original technical or quality assurance requirements cannot be determined, an
 engineering evaluation is conducted and documented by qualified staff to establish
 appropriate requirements and controls to assure that interfaces, interchangeability, safety,
 fit and function, as applicable, are not adversely affected or contrary to applicable
 regulatory requirements.

Reviews of procurement documents shall be performed by personnel who have access to pertinent information and who have an adequate understanding of the requirements and intent of the procurement documents.

SECTION 5 INSTRUCTIONS, PROCEDURES, AND DRAWINGS

DECo has procedures to ensure that activities affecting quality are performed in accordance with instructions, procedures or drawings of a type appropriate to the circumstances and which, where applicable, include quantitative or qualitative acceptance criteria to implement this QAPD. Such documents are prepared and controlled according to Part II, Section 6 of this QAPD. Provisions are included for reviewing, updating, and canceling such procedures.

5.1 Procedure Adherence

The DECo policy is that procedures are followed, and the requirements for use of procedures have been established in administrative procedures. Where procedures cannot be followed as written, provisions are established for making changes in accordance with Part II, Section 6 of this QAPD.

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SECTION 6 DOCUMENT CONTROL

DECo has procedures to control the preparation of, issuance of, and changes to documents that specify quality requirements or prescribe how activities affecting quality are controlled to assure that correct documents are being employed. The control system shall be documented and shall provide for the following:

- a method to identify the correct document and revision to be used and control of superseded documents;
- 2) review of documents for adequacy, completeness, and correctness prior to approval and issuance.
- 3) coordinating and controlling interface documents and procedures.

The types of documents to be controlled include:

- 1) purchase orders and related documents
- 2) vendor-supplied documents
- 3) audit, surveillance, and quality verification/inspection procedures
- 4) test reports
- 5) instructions and procedures for activities covered by this QAPD.

6.1 Review and Approval of Documents

Documents shall be reviewed for adequacy by qualified persons other than the preparer. The documented review signifies concurrence.

Prior to issuance or use, documents, shall be approved by the designated authority. A listing of all controlled documents identifying the current approved revision, or date, is maintained so personnel can readily determine the appropriate document for use.

6.2 Changes to Documents

Changes to documents shall be reviewed and approved by the same organizations that performed the original review and approval unless other organizations are specifically designated. The reviewing organization shall have access to pertinent background data or information upon which to base their approval.

SECTION 7 CONTROL OF PURCHASED MATERIAL, EQUIPMENT, AND SERVICES

DECo has procedures to control the procurement of items and services to assure conformance with specified requirements. Such control shall 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.

7.1 Acceptance of Item or Service

DECo establishes and implements measures to assess the quality of purchased items and services, whether purchased directly or through suppliers, at intervals and to a depth consistent with the item's or service's importance to safety, complexity, quantity and the frequency of procurement. Verification actions include testing, as appropriate, during design, fabrication and construction activities. Verifications occur at the appropriate phases of the procurement process.

Measures to assure the quality of purchased items and services include the following, as applicable:

- Items are inspected, identified, and stored to protect against damage, deterioration, or misuse.
- Prospective suppliers of safety-related items and services are evaluated to assure that only qualified suppliers are used. Qualified suppliers are audited on a triennial basis. In addition, if a subsequent contract or a contract modification significantly enlarges the scope of or changes the methods or controls for activities performed by the same supplier, an audit of the modified requirements is conducted, thus starting a new triennial period. DECo may utilize audits conducted by outside organizations for supplier qualification provided that the scope and adequacy of the audits meet DECo requirements. Documented annual evaluations are performed for qualified suppliers to assure they continue to provide acceptable items and services. Industry programs, such as those applied by ASME, Nuclear Procurement Issues Committee (NUPIC), or other established utility groups, are used as input or the basis for supplier qualification whenever appropriate. The results of the reviews are promptly considered for effect on a supplier's continued qualification and adjustments made as necessary. In addition, results are reviewed periodically to determine if they constitute a significant condition adverse to quality requiring additional action.
- Provisions are made for accepting purchased items and services, such as source verification, receipt inspection, pre- and post-installation tests, certificates of conformance, and document reviews. Acceptance actions/documents should be established by the Purchaser with appropriate input from the Supplier and be completed to ensure that procurement, inspection, and test requirements, have been satisfied before relying on the item to perform its intended safety function.
- Controls are imposed for the selection, determination of suitability for intended use (critical characteristics), evaluation, receipt and acceptance of commercial-grade services or items to assure they will perform satisfactorily in service in safety-related applications.

DTE Nuclear Development Quality Assurance Program Description

• If there is insufficient evidence of implementation of a QA program, the initial evaluation is of the existence of a QA program addressing the scope of services to be provided. The initial audit is performed after the supplier has completed sufficient work to demonstrate that its organization is implementing a QA program.

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SECTION 8 IDENTIFICATION AND CONTROL OF MATERIALS, PARTS, AND COMPONENTS

This section does not apply to the DECo Nuclear Development project scope of work at this time.

SECTION 9 CONTROL OF PROCESSES

This section does not apply to the DECo Nuclear Development project scope of work at this time.

SECTION 10 INSPECTION

This section does not apply to the DECo Nuclear Development project scope of work at this time.

SECTION 11 TEST CONTROL

This section does not apply to the DECo Nuclear Development project scope of work at this time.

SECTION 12 CONTROL OF MEASURING AND TEST EQUIPMENT

This section does not apply to the DECo Nuclear Development project scope of work at this time.

SECTION 13 HANDLING, STORAGE, AND SHIPPING

This section does not apply to the DECo Nuclear Development project scope of work at this time.

SECTION 14 INSPECTION, TEST, AND OPERATING STATUS

This section does not apply to the DECo Nuclear Development project scope of work at this time.

SECTION 15 NONCONFORMING MATERIALS, PARTS, OR COMPONENTS

This section does not apply to the DECo Nuclear Development project scope of work at this time.

SECTION 16 CORRECTIVE ACTION

DECo has procedures to promptly identify, control, document, classify and correct conditions adverse to quality. DECo procedures assure that corrective actions are documented and initiated following the determination of conditions adverse to quality in accordance with this QAPD, regulatory requirements and applicable quality standards. DECo procedures require personnel to identify known conditions adverse to quality. When complex issues arise where it cannot be readily determined if a condition adverse to quality exists, DECo documents establish the requirements for documentation and timely evaluation of the issue. In the case of a significant condition adverse to quality, the cause is determined and actions to preclude recurrence are taken.

In the case of suppliers working on safety-related activities, or other similar situations, DECo may delegate specific responsibilities of the Corrective Action program but retains responsibility for the program's effectiveness.

16.1 Reporting Program

DECo has procedures that implement a program to identify, evaluate and report defects and non-compliances in accordance with 10 CFR Part 21. Such a reporting program applies to safety-related activities and services performed by DECo and/or DECo suppliers / sub-suppliers providing input to the COL application development.

SECTION 17 QUALITY ASSURANCE RECORDS

DECo has procedures to ensure that sufficient records of items and activities affecting quality are developed, reviewed, approved, issued, used, and revised to reflect completed work. The procedures include requirements for records administration, receipt, preservation, retention, storage, safekeeping, retrieval, access controls, user privileges, and final disposition.

17.1 Record Retention

Measures are established that ensure that sufficient records of completed items and activities affecting quality are appropriately stored. Such records and their retention times are defined in procedures. In all cases where state, local, or other agencies have more restrictive requirements for record retention, those requirements will be met. Records may be stored using electronic records storage and retrieval systems.

SECTION 18 AUDITS

DECo has procedures to implement audits to verify that activities covered by this QAPD are performed in conformance with the requirements established. The audit programs are themselves reviewed for effectiveness as a part of the overall audit process.

18.1 Performance of Audits

Internal audits of selected aspects of the COLA process are performed with a frequency commensurate with safety significance and in a manner which assures that audits of safety-related activities are completed. Audits will focus on site investigation, procurement, corrective action and other areas as directed by the ND Quality Assurance Manager. Effectiveness of implementation of an organization's QA program will be verified.

The audits are scheduled on a formal preplanned audit schedule. The audit system is reviewed periodically and revised as necessary to assure coverage commensurate with current and planned activities. Additional audits may be performed as deemed necessary by management. The scope of the audit is determined by the quality status and safety importance of the activities being performed. These audits are conducted by trained personnel not having direct responsibilities in the area being audited and in accordance with preplanned and approved audit plans or checklists, under the direction of a qualified lead auditor and the cognizance of the ND Quality Assurance Manager.

DECo is responsible for conducting periodic internal and external audits. Internal audits are conducted to determine the adequacy of programs and procedures (by representative sampling), and to determine if they are meaningful and comply with the overall QAPD. External audits determine the adequacy of supplier and contractor quality assurance program.

The results of each audit are reported in writing to the responsible director within the Nuclear Development Organization, or designee, as appropriate. Additional internal distribution is made to other concerned management levels in accordance with approved procedures.

Management responds to all audit findings and initiates corrective action where indicated. Where corrective action measures are indicated, documented follow-up of applicable areas through inspections, review, re-audits, or other appropriate means is conducted to verify implementation of assigned corrective action.

Audits of suppliers of services are conducted as described in Section 7.1.

18.2 Surveillances

As part of the oversight activities conducted by the DECo Nuclear Development QA Organization, surveillances will be conducted on the DECo COL work. Surveillance personnel shall be qualified to the Surveillance procedure by the ND Quality Assurance Manager. Surveillance activities include initial planning, conducting, reporting, and tracking of surveillance findings.