TOPICAL REPORT
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Siemens Power Corporation - Nuclear Division

QUALITY ASSURANCE PROGRAM FOR NUCLEAR FUELS & SERVICES

	Organization	Signature	Date
Prepared by:	Quality Assurance		1/10/94
Approved by:	Director, Quality Assurance		1/10/94
Approved by:	Vice President, Engineering		1/14/94
Approved by:	Vice President, Manufacturing		1/17/94
Approved by:	Vice President, Sales & Marketing		1/19/94
Approved by:	Director, Reactor Services & Systems		1/31/94

SUMMARY OF CHANGES: (Indicated by * in right margin)

The majority of changes in this revision concern incorporation of Plant Services (Chattanooga, Tennessee Operation) into appropriate sections. Specific changes are described below:

1. Changed title to "QA Program for Nuclear Fuels & Services."

2. Changed following sections to include/incorporate Reactor Services & Systems (RS&S) and/or Plant Services (PS) activities:

   - Table of Contents (inserted new sections and renumbered).
   - Sections 1.1, 1.2.1, 1.2.1.1, 1.2.1.5, 2.0, 2.3, 2.4, 5.5.1, 5.7, 6.3, 7.1, 11.0, 11.3, 13.0, 14.0, 15.0, 17.2, and Figure 1.

3. Sections 0.0, 1.2, 1.2.1.1 and 5.1.1 -- Changed "engineering services" to "reactor and fuel services."

4. Section 2.1 -- Added ASME Code, Section XI.

5. Figure 2 -- Updated to show current reporting relationship of Gage Calibration.

6. Minor changes of editorial nature and/or correction/clarity.

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0.0 INTRODUCTION

The purpose of this document is to describe the elements of the Siemens Power Corporation - Nuclear Division Quality Assurance Program which are applicable to the nuclear safety-related aspects of reactor and fuel services; the design, procurement, and fabrication of nuclear fuel components and assemblies; and to show how these meet the Quality Assurance requirements of Title 10, Code of Federal Regulations, Part 50, Appendix B, and other related standards and requirements listed in Section 2.1. *

1.0 ORGANIZATION

1.1 Corporate Organization

Siemens Power Corporation is composed of a Fossil Division and a Nuclear Division, and is wholly owned by Siemens Corporation, which is wholly owned by Siemens AG. Siemens Power Corporation is incorporated in the State of Delaware and has its principal offices at 155 - 108th Avenue NE, Bellevue, Washington, 98009, with research/technology and engineering facilities at Richland, Washington; nuclear fuel manufacturing plants at Richland, Washington and Lingen, Germany; and plant services facility at Chattanooga, Tennessee. *

1.2 Company Organization

Siemens Power Corporation - Nuclear Division, hereafter referred to as SPC, is responsible for the establishment and execution of the Quality Assurance Program for reactor and fuel services, * and the design, procurement, and fabrication of nuclear fuel assemblies and has established an organization, as shown in Figures 1 and 2, to meet this responsibility. The Quality Assurance Director is responsible for the establishment and execution of the Quality Assurance Program. This position reports to the Senior Vice President and General Manager, and has the authority to identify quality problems, to initiate remedial action, and to verify implementation of corrective action.

Responsibilities of key individuals are as follows:

1.2.1 Senior Vice President and General Manager - Nuclear Division

The Senior Vice President and General Manager - Nuclear Division reports to the President, Siemens Power Corporation, and is responsible for establishing the Corporate SPC Quality Assurance Policy, including goals and objectives, and ensuring that Corporate operations are carried out in full compliance with the policy. He is responsible for assuring that all personnel in key positions are qualified to execute their assigned functions and responsibilities. Verifications of conformance to established quality requirements for safety-related items is accomplished by individuals or groups who do not have direct responsibility for performing the work being verified.

Other significant responsibilities of the Senior Vice President and General Manager include establishing the Division's organizational structure and defining the participating management roles, and providing adequate resources.

1.2.1.1 Director, Quality Assurance

The Director, Quality Assurance reports to the Senior Vice President and General Manager, and is responsible for providing Quality Assurance Program management for all SPC activities. The Director, Quality Assurance is responsible for the overall establishment and execution of the

Quality Assurance Program for reactor and fuel services, fuel and related component design, and fabrication operations. He is charged with no direct product engineering or manufacturing responsibilities and is responsible for interpreting quality requirements, and for defining, developing, administering, executing, and auditing the Quality Assurance Program in accordance with quality requirements. He has detail responsibility for the implementation of the quality assurance-related activities, including stop work authority. In matters pertaining to Quality Assurance, he also has direct lines of communication to the Vice President, Engineering; to the Vice President, Manufacturing; to the Vice President, Sales and Marketing; and to the Director, Reactor Services & Systems. Specific responsibilities include: *

a) Preparing, interpreting, and administering Quality Assurance Procedures and program documents.

b) Assuring that Quality Assurance Procedures for fuel fabrication and services are workable and consistent with the overall Quality Assurance Program.

c) Ordering work stopped when the seriousness of a condition adverse to quality warrants such action in order to maintain the requisite quality.

d) Providing and executing an audit program, including follow-up audits, as required, of internal operations and vendor quality assurance programs to assure that quality, engineering, design, manufacturing, purchasing, and other related requirements are being met.

e) Providing indoctrination and training in Quality Assurance requirements and practices to promote the understanding of quality requirements throughout the organization.

f) Interfacing with customers and government agencies on their audits of services, and fuels and related component design and manufacturing activities.

g) Monitoring and conducting corrective action follow-ups for Quality Assurance activities.

h) Reviewing customer contracts for compliance to QA Program requirements.

i) Providing the necessary organization for carrying out the required Quality Assurance functions.

1.2.1.2 Vice President, Engineering

The Vice President, Engineering reports to the Senior Vice President and General Manager - Nuclear Division, and has authority for the day-to-day conduct of the company within the assigned areas of responsibility, including Product Mechanical Engineering, BWR Nuclear Engineering, PWR Nuclear Engineering, Product Licensing, and Corporate Information Services. He ensures that company operations in his assigned areas of responsibility are carried out in full

compliance with established policies and guidelines. He is also responsible for producing the desired results within the allocated resources and for reporting of results to the Senior Vice President and General Manager - Nuclear Division.

1.2.1.2.1 Manager, Product Mechanical Engineering

The Manager, Product Mechanical Engineering (PME) reports to the Vice President, Engineering, and is responsible for preparation and integration within SPC of the mechanical design drawings and specifications, stress analysis, and Parts Lists. The Manager, PME is also responsible for development activities, including thermal-hydraulic testing, seismic testing and analysis and supporting software products such as fuel performance models and computer codes. Materials research and cognizance of status of nuclear fuels technology developments fall under the purview of this organization. Reporting to the Manager of PME are Mechanical Design Engineering, Product Engineering, Product Development and Testing, and the Lingen Plant Engineering representative.

1.2.1.2.2 Manager, BWR Nuclear Engineering

The Manager, BWR Nuclear Engineering reports to the Vice President, Engineering, and is responsible for providing nuclear and thermal-hydraulic analyses of fuel assemblies, cores, and reactors and their protective systems. This includes technical support to customers, as needed, for licensing of SPC fuel and computer software and related services as required for on-line monitoring of BWR reactor power distribution and limits. This position is also responsible for research and development activities leading to improved methodology and computer code systems in the above mentioned areas.

1.2.1.2.3 Manager, PWR Nuclear Engineering

The Manager, PWR Nuclear Engineering, reports to the Vice President, Engineering, and is responsible for providing support for the operation of pressurized water reactors (PWRs) in the areas of neutronics, thermal-hydraulics, and safety analyses. This includes technical support to customers, as needed, for the licensing of SPC fuel. The Manager, PWR Nuclear Engineering, is also responsible for research and development activities, including computer code development, related to neutronics, thermal-hydraulic and safety analyses. Cognizance of the status of PWR nuclear fuels technology developments fall under the purview of this organization.

1.2.1.2.4 Manager, Corporate Information Services

The Manager, Corporate Information Services, reports to the Vice President, Engineering, and is responsible for providing computing tools, facilities and support for fuel design and engineering services analyses, and for manufacturing and financial systems, including Document Control.

1.2.1.2.5 Manager, Product Licensing

The Manager, Product Licensing, reports to the Vice President, Engineering, and is responsible for obtaining regulatory approval of SPC products and interpreting NRC regulations.

1.2.1.3 Vice President, Manufacturing

The Vice President, Manufacturing, reports to the Senior Vice President and General Manager - Nuclear Division, and has authority for the conduct of the company within assigned areas of responsibility, including Manufacturing and Quality Control. He ensures that company operations in his assigned areas of responsibility are carried out in full compliance with established policies and guidelines. He is responsible for producing the desired results within the allocated resources and for reporting of results to the Senior Vice President and General Manager - Nuclear Division.

1.2.1.3.1 Plant Manager, Richland

The Plant Manager, Richland reports to the Vice President, Manufacturing, and is responsible for the overall management of the SPC fabrication plant within the constraints imposed by the product, process, quality assurance, licensing, and safety requirements. In addition to Plant Operations and Machine Shop and Component Fabrication, his responsibilities include the functions of Quality Control, Manufacturing Engineering, Materials and Scheduling, and Safety, Security and Licensing. In the context of quality assurance, he has the responsibility for ensuring that all manufacturing operations, especially those affecting product quality, are carried out in compliance with the SPC Quality Assurance Program. The managers reporting to the Plant Manager, Richland are shown in Figure 1.

1.2.1.3.1.1 Manager, Quality Control

The Manager, Quality Control, reports to the Plant Manager, Richland, and has the responsibility for implementing the Quality Assurance Program in the manufacturing process. The Manager, Quality Control is independent of the Managers, Plant Operations and Components and Support Machining, thereby assuring independence in carrying out the functions of checking, inspection, process surveillance, or otherwise verifying that the work has been performed satisfactorily and that the product conforms to specifications and process parameters. Figure 2 shows the organizational delineation and supervisory personnel reporting to the Quality Control Manager. Specific responsibilities of the Manager, Quality Control include:

a) Developing and operating the analytical laboratory and physical testing laboratory such that they are capable of meeting internal and customer requirements for analytical services and physical testing or, alternatively, securing and auditing outside service vendors.

b) Preparing the Quality Control Program relating to vendor inspection activities and off-site source surveillance.

c) Preparing receiving inspection, in-process, and final inspection Quality Control Standards.

d) Preparing technician certification procedures and monitoring performance of related qualifications.

e) Administering the system of material, component, and production releases.

f) Performing receiving inspection, specified in-process, and final inspections, including nondestructive testing of components and products per issued Quality Control Standards.

g) Performing process control surveillance and follow-up.

h) Withholding from further processing any components, subassemblies, or fuel bundles whose quality is in question and/or to order work stopped when conditions adverse to quality exist.

i) Administering and maintaining the quality control records related to products.

j) Administering and maintaining the inspection gage calibration and control system.

1.2.1.3.1.2 Various Shop Operations Managers

The Managers, Plant Operations and Components and Support Machining, (hereafter referred to as Shop Operations) report to the Plant Manager, Richland, and are responsible for fuel manufacturing and related facilities including responsibilities for UO_2 and special fuels operations, machine shop operations, component fabrication, for executing the Quality Assurance Program related to their activities, and for completion of fabrication operations within established fabrication schedules.

1.2.1.3.1.3 Manager, Safety, Security, and Licensing

The Manager, Safety, Security, and Licensing, reports to the Plant Manager, Richland, and is responsible for plant physical security, radiological and industrial safety, and regulatory compliance.

1.2.1.3.1.4 Manager, Materials & Scheduling

The Manager, Materials & Scheduling, reports to the Plant Manager, Richland. Specific responsibilities include:

a) Scheduling and coordinating the flow of materials, specifically fuel hardware items, from procurement through final assembly and shipping.

b) Preparation of procurement documents which assure that items are procured on schedule and comply with the applicable specifications and Quality Assurance requirements. *

c) Execution of the purchasing and logistics functions to support the manufacturing operation.

d) Approving and executing purchase documents which assure that materials and components are procured on schedule and comply with the applicable specifications and Quality Assurance requirements. *

e) Assisting in the evaluation of vendors' capabilities.

f) Providing an interface between vendors and Siemens Power Corporation - Nuclear Division.

g) Maintaining the Approved Vendor List.

h) Interfacing with other groups on purchased material, vendor schedules, quality, and corrective actions.

i) Maintaining storage facilities and services for purchased material and components.

j) Shipping completed fuel assemblies and other material.

k) Planning of requirements and initiating purchase requisition for fuel hardware.

l) Maintaining inventory control of fuel hardware.

1.2.1.3.1.5 Manager, Manufacturing Engineering

The Manager, Manufacturing Engineering reports to the Plant Manager, Richland, and is responsible for all Process Engineering and Plant Engineering, including Maintenance. Responsibilities of the organization include:

a) Providing engineering support to plant operations in the areas of facilities, equipment/tooling, and maintenance.

b) Performing plant and facility maintenance.

c) Providing revised fabrication processes and Process Specifications.

d) Providing routine process and engineering support in the areas of manufacturing methods and standards and coordinating automation activities.

e) Providing Process Test Authorizations for qualifying new or significantly modified processes.

1.2.1.3.2 Manager, ANFGmbH-Lingen

The Manager, ANFGmbH-Lingen reports to the Vice President, Manufacturing, and is responsible for the overall management of the Lingen fabrication plant within the constraints imposed by the product, process, quality assurance, licensing, and safety requirements. The specific organizational breakdown and responsibilities of the Lingen Plant are described in the Lingen QA Manual, ANFG-4.008. The ANFGmbH Quality Assurance group receives program direction from the SPC Director, Quality Assurance.

1.2.1.4 Vice President, Sales and Marketing

The Vice President, Sales and Marketing reports to the Senior Vice President and General Manager - Nuclear Division, and directs the following activities:

1.2.1.4.1 Contract and Proposal Administration

The Contract and Proposal Administration organization is responsible for providing the primary contractual interface with the customer, coordinating SPC activities to assure that contractual requirements are being met, and reporting to the customer on the status of these activities.

1.2.1.4.2 Customer Services Engineering

Customer Services Engineering reports to North American Marketing, and is responsible for providing technical support to Sales and Marketing, performing the role of primary customer contact on noncommercial matters, and in arranging appropriate technical interaction with the customer.

1.2.1.5 Director, Reactor Services & Systems *

The Director, Reactor Services & Systems reports to the Senior Vice President and General Manager - Nuclear Division, and has authority for the day-to-day conduct of the company within the assigned areas of responsibility, including Reactor Systems Projects, Fuel Services, and Plant Services. He ensures that company operations in his assigned areas of responsibility are carried out in full compliance with established policies and guidelines. He is also responsible for producing the desired results within the allocated resources and for reporting of results to the Senior Vice President and General Manager - Nuclear Division.

1.2.1.5.1 Manager, Plant Services - Chattanooga Facility *

The Manager, Plant Services reports to the Director, Reactor Services & Systems and is responsible for the overall management of the Plant Service Chattanooga Facility within the constraints imposed by the product, process, quality assurance, and safety requirements. In addition to Field Services, Engineered Products & Services, and Technology Applications, his responsibilities include the function of Quality Assurance at the Chattanooga Facility.

1.2.1.5.1.1 Manager, Quality Assurance - Chattanooga Facility *

The Manager, Quality Assurance reports to the Manager, Plant Services for daily activities and to the Director, Quality Assurance for corporate direction, and has the responsibility for implementing the Quality Assurance Program at the Chattanooga Facility. The Director, Quality Assurance delegates to him the overall responsibility of administering the Quality Assurance Program at the Chattanooga Facility. This also includes Quality Control activities performed at the Chattanooga Facility and document control for unique Plant Services procedures. The Manager, Quality Assurance is independent of the Manager, Field Services; Manager, Engineered Products & Services; and Manager, Technology Application, thereby assuring independence in carrying out the quality functions.

1.2.1.5.2 Manager, Fuel Services

The Manager, Fuel Services reports to the Director, Reactor Services & Systems, provides for monitoring of fuel performance during and after irradiation, and supplies important feedback to the fuel design process. Fuel Services provides fuel warranty related inspection and repair and * conducts nondestructive, on-site examination and dimensional measurement of irradiated fuel. Fuel inspection data is analyzed by Fuel Services and is reported to other SPC Engineering and Manufacturing organizations. Fuel Services also maintains the fuel performance and irradiation history data base. On-site rework/repair/reconstitution of fuel assemblies requires acceptance inspection by a designated, qualified individual other than the one who performed the activity being inspected.

1.2.1.5.3 Manager, Reactor Systems Projects *

The Manager, Reactor Systems Projects reports to the Director, Reactor Services & Systems, and is responsible for managing projects and developing business in the reactor systems business area consisting of the delivery of nonfuel-related products and services. These products and services employ KWU technology imported in the U.S. and adapted to the needs of U.S. utilities. Activities include support for the preparation of proposals, program management, customer service, coordination of business strategies with KWU and the negotiation and execution of agreements with third parties as necessary for the development of customers in this business area.

1.2.1.6 Other functions within SPC are responsible for interfacing on design matters and sign-off of design documents as indicated in Document Control QA Procedures.

2.0 QUALITY ASSURANCE PROGRAM

The SPC Quality Assurance Program for Nuclear Fuels and Services includes activities in the design, procurement, fabrication, and inspection testing of nuclear fuel assemblies, and reactor and fuel services, e.g., site repair/reconstitution, irradiated fuel inspection, in-core monitoring software, nuclear plant analyses, reactor plant component inspection and refurbishment, etc. This Quality Assurance Program applies specifically to the activities affecting the safety-related aspects of nuclear fuel and services. The Quality Assurance Program has been established to ensure that the delivered nuclear fuel assemblies and services do not adversely affect the health and safety of the public. This is accomplished through conformance with the requirements of 10CFR50, Appendix B. *

2.1 Related Standards and Regulatory Guides

The SPC Quality Assurance Program for Nuclear Fuels encompasses and satisfies the requirements of Appendix B to 10CFR50, "Quality Assurance Criteria for Nuclear Plants"; NRC Regulatory Guide 1.28, "Quality Assurance Program Requirements (Design and Construction)"; ANSI N45.2 (1977), "Quality Assurance Program for Nuclear Power Plants"; Basic Requirements of ANSI/ASME NQA-1-1989, "QA Program Requirements for Nuclear Facilities"; IAEA Code of Practice No. 50-C-QA, "Quality Assurance for Safety in Nuclear Power Plants" (European customers); KTA 1401, General Requirements for Quality Assurance (German customers); ANSI/ASQC Q91-1987, "Quality Systems - Model for Quality Assurance in Design/Development, Production, Installation, and Servicing"; and ASME Code, Section XI. Additionally, when specified in a contract between SPC and a utility customer, other related ANSI Standards and Regulatory Guides are committed to by SPC on a contract-by-contract basis. The methodology for implementing these requirements is reflected in this QA Manual in general and more specifically in the QA Procedures and any supplements thereto. *

2.2 Applicability to Fuel Assemblies, Parts, and Components

The finished nuclear fuel assemblies furnished by SPC to utilities for their nuclear power plants are classified by utilities as being nuclear safety-related. Therefore, the applicable requirements of 10CFR50, Appendix B apply to the finished fuel assemblies.

In order to place the correct amount of emphasis on the more important characteristics of the various parts and components making up the fuel assemblies, SPC has developed a system of classifying characteristics identified in the product and material specifications as critical, major, or minor. The essential criteria for the classification are as follows:

> Critical - A characteristic of a specification, inspection, test, or defect which, if not properly controlled, could result in a reactor fuel failure. Such a defect, for example, is one that judgement and experience indicate is likely to prevent performance of the function of an end item such as fuel rod, fuel assembly, or fuel reload core.

Major - A characteristic of a specification, inspection, test, or defect other than critical which, if not properly controlled, could result in excessive costs, defect rates, rework, or delays in scheduled shipping dates. Such a defect, for example, is likely to reduce materially the usability of the product or an end item such as a fuel rod or fuel assembly.

Minor - A characteristic of a specification, inspection, test, or defect other than critical or major which, if not controlled, does not materially reduce the usability of the product or an end item, such as a fuel rod, for its intended purpose, or is a departure from established standards having no significant bearing on the effective use or operation of the unit, or affects the appearance in a minor degree where appearance is a significant characteristic.

Based on the above classification criteria, SPC's design and engineering personnel determine the proper classification of characteristics during the design process. These are identified in the Product and Material Specifications, or where not specifically defined, are established by the Project Engineer in the course of evaluating variances. Product inspection/test frequencies take into account the assigned classification to ensure that appropriate importance is given to each characteristic.

2.3 Implementation of Quality Assurance Program

Implementation of the requirements of this Quality Assurance Program and related procedures is considered to be normal practice in the design, fabrication, procurement, engineering, inspection, certifying, and shipping of the nuclear fuel and related products, and execution of services. If special projects are undertaken that are not subject to all requirements of 10CFR50, Appendix B, or do not require all the applicable Quality Assurance system requirements and practices established by this document, a specific exemption may be made within the following contingencies:

a) A Special Project Authorization document is written to include necessary steps and requirements, including design, engineering, manufacturing, quality assurance, quality control, and purchasing.

b) The Special Project Authorization shall be prepared and approved in accordance with Document Control QA Procedures.

2.4 Policies, Procedures, and Instructions

The objectives of the Quality Assurance Program are to provide services and nuclear fuel that will perform satisfactorily in service with a high assurance against failure or malfunction and without undue risk to the health and safety of the public. Compliance with the policies and procedures of the SPC QA Program is mandatory for personnel performing activities affecting the quality of the nuclear fuel and services. This is communicated to personnel through

indoctrination sessions and distribution of the QA Manual. When required, disputes involving quality are referred to the next higher level of management for resolution. The distribution of the QA Manual, including revisions, is controlled as described in Section 6.0, Document Control.

The SPC QA Manual contains three parts, as follows:

Part I - Introduction
Part II - QA Program Description
Part III - QA Procedures

The Introduction, Part I, contains a policy statement, and a brief description of the purpose, scope, implementation, and control of the manual. The QA Program, Part II, contains a description of the program setting forth mandatory requirements, policies, and responsibilities. The QA Procedures, Part III, set forth instructions governing the methods, practices, procedures, and controlled conditions to be employed by SPC in the implementation of the program.

Part II - QA Program, and Part III - QA Procedures, are signed off by members of SPC management as indicated in Document Control QA Procedures. Control of the QA Manual and distribution of copies, including revisions, is the responsibility of the Director, Quality Assurance. Internal QA audits are conducted to ascertain the effectiveness and proper implementation of the QA Program.

2.5 Indoctrination and Training

Indoctrination and training of SPC personnel whose activities affect the quality of products and/or safety-related services shall be provided. Both direct Quality Assurance training and specific job-related training or certification are conducted as necessary, including retraining and/or recertification to assure that desired proficiency is maintained. Quality Assurance is responsible for conducting QA Program and Procedure Training. Managers are responsible for assuring that the personnel within their organizations attend the Quality Assurance training sessions and that they have the necessary training to perform their assigned jobs consistent with Quality Assurance Program requirements.

2.6 Qualification Requirements for Principal Quality Assurance and Quality Control Management Positions

2.6.1 Qualification requirements for the Director, Quality Assurance are:

a) A bachelor's degree in a technical field.

b) At least ten years experience in responsible management of technical or manufacturing activities in the nuclear field, five years of which have been in fields allied to nuclear quality assurance.

c) Knowledge of applicable quality-related codes, standards, and regulatory requirements.

d) Thorough knowledge of the SPC Quality Assurance Program.

2.6.2 Qualification requirements for the Manager, Quality Control are:

a) A bachelor's degree in a technical field.

b) At least six years experience in responsible management of technical or manufacturing activities in the nuclear field, four years of which have been spent in quality-related nuclear activities.

c) Knowledge of applicable quality-related codes, standards, and regulatory requirements.

d) Thorough knowledge of the SPC Quality Assurance Program.

2.7 Management Reviews

Review of the scope, status, implementation, and effectiveness of the Quality Assurance Program to assure that the program is adequate and complies with 10CFR50, Appendix B criteria is conducted by management for the portion for which they have designated responsibilities. These reviews are conducted on an annual basis where major changes have been made, and at a minimum of once every two calendar years.

2.8 Contract Review

Review of customer contracts is performed to transfer requirements to SPC documents. These documents may include work commitment documents, Special Requirements QC Standards, Manufacturing and Examination Sequence Plans, and Project Plans. Specific product requirements are placed in the Characteristic Specifications. *

2.9 Revisions

This Quality Assurance Program document is to be reviewed each calendar year and revised if the need exists. The Director, Quality Assurance is responsible for soliciting comments each calendar year from affected managers on proposed changes. As substantive (including organizational) changes to the Quality Assurance Program are identified, they will be reflected in a revision to this program document. Interim Quality Assurance Program updates providing organizational or other pertinent information, but not reducing commitments in the Program description previously approved by the USNRC, may be distributed within SPC prior to distribution of the revised document. An information copy of the update shall be submitted to the USNRC within 90 days, as an interim program update. New or revised Quality Assurance Program requirements are to be implemented within 90 days following issue unless additional time is approved by the Director, Quality Assurance.

3.0 DESIGN CONTROL

Quality Assurance for design includes assuring that design activities are carried out in a planned, controlled, and correct manner. It also includes design document control, independent verification of calculations, design testing, and auditing with appropriate corrective action to assure that the design program is functioning as planned.

Performance of engineering services, design of fuel assemblies and related components, and the preparation of design documents are performed in accordance with approved procedures and techniques. Customer requirements contained in Design Criteria are translated into Material Specifications, Product Specifications, and Drawings. Wherever practical and applicable, industry standards and specifications (e.g., ASTM) are utilized in design specifications for suitable materials, parts, equipment, and processes. Approved Product or Material Specifications are required to procure or fabricate materials or components for the nuclear fuel manufacturing process.

3.1 Design Planning and Implementation

Overall design planning includes providing a schedule for work completion and identifies the responsibilities for the various phases of design. Where applicable, schedules include tasks, milestones, and control points relating to the design or service.

Factors included in typical design planning, implementation, and evaluation are:

a) Compatibility with reactor and remaining fuel.

b) Reactor physics, stress, thermal-hydraulic, and accident analysis.

c) Optimum balance in fuel enrichment, life, and power costs.

d) Choice and compatibility of materials and suitability for use of standardized materials, parts, and equipment, or those which have been used previously for similar applications.

e) Choice of physical parameters.

f) Mechanical stability under service.

g) Licensability.

h) Choice of design methodology.

3.2 Design Documents

3.2.1 Design Criteria

Design Criteria are prepared which are consistent with the principal technical requirements and needs of the customer as reflected by the contract with SPC and with applicable regulatory requirements. Design Criteria and other design documents described below are approved in accordance with Document Control QA Procedures.

3.2.2 Parts List

The design of production fuel, lead assemblies, "proof-of-fabrication," or special "in-reactor performance evaluations" are defined by a Parts List which displays by number and revision all Product Specifications, Materials Specifications, and Drawings required to define the product. The Parts List is the sole authoritative definition of the product. Approved partial Parts Lists which do not include all fuel bundle components may be issued prior to approval of the complete Parts Lists in order to expedite procurement or fabrication of materials and components for which the design has been completed.

3.2.3 Technical Bases

The design of lead assemblies and product fuel for customers is based upon Technical Bases, which represent the best state-of-the-art at the time of issue.

3.3 Design Interfaces

Interfaces among participating organizations within SPC are defined in Document Control QA Procedures for preparation and approval of design documents. Additional interfaces are defined in Design Control Quality Assurance Procedures.

3.4 Design Change Control

Design changes to previously approved and issued design documents shall be approved in the same manner as the original document, in accordance with the current issue of the document approval matrix. If those required to accept or approve are unable to achieve a unanimous agreement, the items of disagreement are referred to the next higher level of management until resolved.

3.5 Design Verification

The adequacy of product designs may be verified in several ways, including in-reactor experience of similar design, performance of design reviews, alternate calculations, or design testing. The depth of design reviews and verifications depends upon the complexity and end use of the item. The individuals responsible for performing design verification activities should include persons

other than those who performed the original design. Use of the designer engineer's subsection manager for design verification is restricted to special situations where the subsection manager is the only individual within the design organization competent to perform the verification. Design verification activities are performed in accordance with Design Quality Assurance Procedures.

3.5.1 Design Reviews

Reviews of fuel designs and related documentation are performed to determine adequacy of the design, to assure that design parameters can be controlled during manufacture, and that design features can be inspected and tested and that inspection and test criteria are identified. Approval of the design is indicated by signature on the applicable design documents, and Project Design Review Summary Report.

3.5.2 Alternate Calculations

Verification of some types of calculations or analyses may be achieved by comparison with alternate methods of calculation or analysis. When performed, these alternate calculations are performed by persons other than those who performed the original calculation and serve to verify the correctness of the original calculation. Alternate calculations may employ a more simplified approach or be less rigorous and the results may not exactly check with the original calculation; however, they must provide results consistent with the original calculation or analysis. The alternate calculation will also address the appropriateness of assumptions, input data, and the code or other calculation used.

3.5.3 Design Testing

Test programs utilized to verify design adequacy are conducted under design conditions sufficient to demonstrate that the item will withstand in-service use. Design tests are approved and controlled in accordance with Design Control Quality Assurance Procedures. Existing data from tests of previous designs may be valid for current designs provided the designs are adequately similar. In such cases new testing may not be required.

Designs are verified by out-of-reactor testing for basic parameters such as flow, pressure drop, and for the absence of fretting corrosion. Additional tests, such as thermal cycling, velocity distribution, or strength tests, may be performed, if appropriate.

3.6 Document and Records Control

Reproducible copies of design documents (Design Criteria, Product Specifications, Material Specifications, and Drawings) and revisions thereto are maintained in the Document Control central files as discussed in Section 6.0. Documents are controlled in accordance with Quality Assurance Document Control Procedures.

3.7 Customer-Supplied Designs

Exception is made to the normal requirements for design control to accommodate instances in which the fuel design is supplied by the customer. Design requirements applicable to the following areas, as determined by the scope of work and contract, may be deemed not applicable:

a) Preparation and review of Design Criteria, Product Specifications, Materials Specifications, and Drawings.

b) Design reviews.

c) Calculational checks.

d) Design testing.

In such instances, approval of the Parts List constitutes approval of the design package by affected organizational components.

4.0 PROCUREMENT DOCUMENT CONTROL

Procedural controls are established to assure that applicable regulatory requirements, design bases, fabrication requirements, and other requirements are included or referenced in procurement documents for material, equipment, and services.

4.1 Procurement Documents

Design requirements set forth in approved Product Specifications, Material Specifications, Characteristics Specifications, and Drawings are transferred into procurement documents in the form of Purchase Requisitions. Additionally, the procurement documents must be technically compatible with applicable approved Quality Control Standards, Process Specifications, and Quality Assurance requirements. Acceptance of purchase documents by Quality Control is intended to assure that quality requirements are adequate, correctly stated, and are controllable. Purchase Requisitions and Purchase Orders are prepared and approved as described in Procurement Control QA Procedures. *

4.2 Content of Procurement Documents

Procurement documents for the purchase of quality-related material, equipment, and services include or reference the following provisions as applicable: *

a) A statement of work to be performed.

b) Technical requirements regarding specific drawings, specifications, codes, regulations, procedures, or instructions including test and inspection requirements, and special process instructions.

c) Quality Assurance Program requirements, including applicable requirements of 10CFR50, Appendix B.

d) Submittal of vendor's Quality Assurance Program (Manual) and access to the vendor's QA/QC Procedures.

e) Standard clauses for access to their plant and records, performance of source inspection, and auditing their QA system and those of their sub-vendors.

f) Identification of documentation required to be submitted, including Quality Assurance records, for information, review, or approval of the Purchaser.

g) Retention and disposition requirements of Quality Assurance records not delivered to the Purchaser.

h) Submittal of Process Outline and QC Inspection Plan to the Purchaser, including process hold points.

i) Requirements for control and approval of vendor nonconformances.

j) Source inspection requirements.

k) Requirements for extension of applicable Quality Assurance requirements to subtier procurements.

4.3 Control of Contract Changes with Vendors

The procurement documents state the controls which will exist between SPC and vendors in requesting and accepting changes in the purchase contracts, changes in product or service specified, including revisions of design and specifications, changes in processes used and, where applicable, changes in sources of supply and/or subcontractors.

Quality-related changes to procurement documents, changes to drawings and quality assurance program requirements for product components and materials are reviewed and approved by the same authorities reviewing and approving the original documents.

SPC acceptance of vendor-supplied material known to be nonconforming to procurement documents requires an approved Variance Report. Nonconforming material shipped to SPC is identified as nonconforming by the supplier.

5.0 INSTRUCTIONS, PROCEDURES, AND DRAWINGS

The Quality Assurance Program and associated quality-related design, procurement, fabrication, inspection, handling, and shipping activities are prescribed by documented instructions, procedures, and drawings, as appropriate, to assure adequate definition of the inspections for satisfactory completion of activities. The instructions, procedures, and drawings include appropriate quantitative or qualitative acceptance criteria to verify that important activities have been satisfactorily accomplished.

5.1 Quality Assurance and Quality Control Documents

5.1.1 Quality Assurance Program

The SPC Quality Assurance Program described herein establishes the reactor and fuel services and fuel manufacturing quality system which inter-relates with design, process, fabrication, procurement, and customer requirements to assure that the quality-related work elements are identified and controlled. *

The various types of documents addressing activities and associated responsibilities for preparation, concurrence, and approval are defined in Document Control QA Procedures. Provisions for the preparation, approval, and control of instructions, procedures, and drawings are discussed in Section 6.

5.1.2 Quality Assurance Procedures

The Quality Assurance Procedures contained in Part III of the QA Manual provide instructions for carrying out Quality Assurance Program requirements.

5.1.3 Quality Control Procedures

The Quality Control Procedures provide written inspection instructions and techniques, nondestructive testing procedures, equipment operating procedures, and other Quality Control methodology employed to implement the Quality Control Standards and the Quality Control portion of the Quality Assurance Program requirements.

5.1.4 Quality Control Standards

The Quality Control Standards identify the Quality Control requirements and methods for assuring conformance to the Process and Product Specifications for each step of the manufacturing process, including receiving inspection, releases to manufacturing, in-process inspection steps and hold points, final inspection, and shipment to the customer. Once approved, the Quality Control Standards reflect the minimum inspection plan required to meet the intent of the Product Specifications, Material Specifications, and Drawings.

5.1.5 Analytical Procedures

Analytical Procedures are operating procedures written for use in the analytical laboratories.

5.1.6 Metallurgical Procedures

Metallurgical Procedures are operating procedures for the physical and metallurgical testing of samples.

5.2 Product Definition

5.2.1 Design Criteria

Design Criteria combine contract, regulatory, and SPC-imposed requirements which unite technical, material choice, economic, Quality Assurance, and compatibility factors, and serve as the basis for product design.

5.2.2 Design Reports

Design Reports provide the final expression of the design combining relevant factors such as contract requirements, reactor compatibility, Design Criteria, product life and warranties, applicable codes and standards, choice of materials, reactor safety and licensability, inspectability, and product quality.

5.2.3 Product Specifications, Material Specifications, and Drawings

Product Specifications, Material Specifications, and Drawings identify the "end function" requirements for product components and final product. They serve as the basis for procurement documents, Process Specifications, and Quality Control Standards, and must meet the requirements of the Design Criteria. The Product and Material Specifications establish limiting physical and chemical properties of materials and related products. The Parts List identifies the specific Product and Material Specifications and Drawings applicable to a particular reload and thus constitutes the authoritative definition of the product. Product Specifications include the required characteristics and the standards or tolerances applicable to each part and a classification of characteristics as to importance. This "importance" statement (critical, major, or minor) establishes the basis for inspection and testing requirements.

5.2.4 Technical Bases

Technical Bases provide the technical foundation and material limits for the product, consistent with the present state-of-the-art.

5.3 Process Specification Documents

5.3.1 Process Specifications

Process Specifications establish the step-by-step requirements for manufacturing the product and also provide an indirect means of specifying product quality. Conformance to Process Specifications is also indirect evidence of conformance to Product Specifications.

5.3.2 Flow Sheets

Flow Sheets identify the basic flow streams and the component preparation, process steps, and inspection steps from the receipt of materials and components through final acceptance of the product.

5.4 Procurement

5.4.1 Procurement Documents

Procurement documents are prepared from Purchase Requisitions, and serve as the actual purchase documents and encompass technical requirements identified in applicable approved Product and Material Specifications, Process Specifications, and Quality Control Standards. Procurement documents also specify necessary Quality Assurance certification and inspection and test requirements to assure receipt of acceptable quality material or services. *

5.4.2 Vendor Quality Assurance Requirements

Vendor Quality Assurance requirements establish the Quality Assurance requirements of a vendor and his subvendors to assure there is objective evidence that they have in effect a Quality Assurance Program capable of conforming to the procurement documents. Routine assessment of vendor's control of quality is established at intervals consistent with the importance, complexity, and quality of the product or service.

5.4.3 Purchase Orders

Purchase Orders establish the legal contract between the vendor and SPC. Included in Purchase Orders are the purchase requisitions, quality requirements, quantity, terms and conditions, and other procurement requirements.

5.5 Manufacturing

5.5.1 Operator Certification Procedures for Special Processes

Operator certification procedures for special processes are contained in the Quality Control procedures, Process Specifications, and Reactor & Fuel Services procedures, and specify the *

qualification procedures, training, and certification examination requirements for those personnel to be qualified for work in the special processes of welding, heat treating, and nondestructive examination. *

5.5.2 Standard Operating Procedures

Standard Operating Procedures provide the detailed operating instructions required to control shop operations and serve as training guides for manufacturing personnel.

5.6 Fuel Services Documents

5.6.1 Fuel Services Procedures and Practices

Procedures and Practices define requirements and practices used to implement QA Program and administrative activities.

5.6.2 Fuel Services Cover Procedures

Cover Procedures define the detailed activities performed during at-reactor fuel inspection and fuel repair/reconstitution.

5.6.3 Fuel Services Standard Operating Procedures

Standard Operating Procedures (SOPs) provide instructions for equipment operation and related generic support activities.

5.6.4 Performance Evaluations

Performance Evaluations from in-reactor tests, post-irradiation data, and ex-reactor tests and data are contained in Fuel Services technical reports issued to utility customers and to SPC Engineering and Manufacturing organizations. *

5.6.5 Failure Analyses

Failure Analyses provide for the detailed evaluation of any fuel failure, with specific emphasis on comparing pre- and post-irradiation physical measurements, reactor operating transients, fuel management, and any other specific observations that will assist in isolating the specific failure mechanism.

5.7 Plant Services *

5.7.1 Practices and Procedures

Practices and Procedures define requirements and practices used to implement QA Program and administrative activities.

5.7.2 Project Plans *

Project Plans define the detailed activities performed during site inspection, test, and repair. Project Plans are generated when Plant Services works to SPC's QA Program on site and the scope of work warrants such detail.

5.7.3 Standard Operating Procedures *

Standard Operating Procedures (SOPs) provide instructions for equipment operation and related support activities (i.e., Calibration, Automated UT, Examination, Maintenance, etc.).

5.8 Temporary Deviations

Temporary Deviations from procedures or instructions may be approved, provided the following conditions are met:

a) The designated responsible engineer or supervisor shall be responsible for assuring that any Temporary Deviations will be acceptable to those individuals who are required to approve/concur with the document being changed.

b) The Temporary Deviations are not used for deleting license requirements and do not decrease assurance of product quality.

c) The Temporary Deviation is documented prior to use and a description of the change is distributed to all signators of the original document, Document Control, and Director, QA within one working day of effectivity of the change. Any one of the individuals who signed the original document may ask for a full review of the change. Material traceability shall be maintained such that items processed per Temporary Deviations are identified.

d) The Temporary Deviation includes the effective dates, not to exceed 30 days unless specially extended per QA Procedure.

e) The use of Temporary Deviations is controlled per the requirements delineated in QA Procedure #5, Temporary Document Revisions and Interim Procedures.

6.0 DOCUMENT CONTROL

Document Control is required to assure that documents (which include drawings by definition) affecting quality and revisions thereto are identified and approved for release by authorized personnel, and properly distributed, stored, recalled, and disposed of. Document Control requirements are defined in Quality Assurance Procedures.

6.1 Procedure for Document Identification and Control

The Document Identification and Control Procedure provides for identification, review, approval, and control of documents issued by SPC. This includes preparation and revision, review and comment, approval, distribution, and storage of documents which affect quality, or are controlled for other reasons.

6.2 Controlled Documents

Controlled documents are defined as documents which either contain information which must be periodically updated or replaced to maintain accuracy, or which contain information which is intended for limited distribution because of its nature. The instructions, procedures, specifications, standards, drawings (tracings and reproductions), reports, manuals (such as QA Manuals), and other materials which define or affect the product line or services quality, are controlled documents. *

6.3 Responsibilities

The originator of a document is responsible for the preparation of the document in accordance with document identification and format requirements, obtaining required review and approvals, determining the original distribution list, and revising, as necessary. Document Control is responsible for issuance and distribution of documents and revisions including retention of the copies in accordance with the Document Identification and Control Procedure. Documents which are unique to the Chattanooga Facility may be issued and distributed from there under the direction of the Plant Services QA Manager. *

6.4 Control of Document Generation and Issuance

Document Control assigns numbers for documents upon request, maintains distribution lists of controlled documents, issues copies of approved documents and revisions, and maintains file copies. Approved changes to documents are included in documents prior to implementation of the change and commencement of work. Document Control is responsible for physically entering the revisions in the Shop Operation and Quality Control copies used for fabrication; however, individual groups may physically enter the revisions in these copies, subject to controls described in Quality Assurance Procedures.

6.5 Special Control Provisions

In order to avoid the unnecessary shutdown of key shop operations, Quality Assurance Procedures provide for the distribution of "advanced copies" and "Temporary Document Revisions." Copies of fully approved documents may be distributed in advance of the normal distribution ("advance copies") provided they are identified and controlled per the applicable Quality Assurance Procedure. Minor interim revisions to documents may be approved by a limited number of signatures, provided documents are approved and controlled per the applicable Quality Assurance Procedure governing temporary document revisions.

6.6 Approval of Changes

Changes to previously issued documents are approved in the same manner as original versions. Management affected by changes are required to approve revisions. Approvers of previous document versions are not required to approve revisions where the changes do not affect their organizations(s). The document originator is responsible for determining which organizations are affected by the changes.

7.0 CONTROL OF PURCHASED MATERIAL, EQUIPMENT, AND SERVICES

SPC maintains a program for the control of quality-related purchased material, equipment, and services consistent with the importance, complexity, and quality of the product or services. SPC delegates to fuel component vendors the task of establishing and executing Quality Assurance subprograms, but retains responsibility for overall program effectiveness. Quality Assurance Programs established by vendors are approved by SPC. To assure that purchased material, equipment, and services conform to procurement documents, evaluations of vendors' capabilities are made by Materials and Purchasing, Quality Assurance, and Quality Control. *

7.1 Vendor Evaluation

The selection of vendors is based on evaluation of their capability to provide items or services in accordance with procurement requirements. Determination of vendor capability involves an integrated evaluation by Materials and Purchasing, Quality Assurance, and Quality Control or some combination of these, based upon the classification and complexity of the item or service being procured. Results of vendor evaluations are documented and filed. Evaluation of vendor sources include any one or combination of the following methods:

a) Evaluating the vendor's history of providing a quality product based on analysis of vendor survey records, audit reports, or other appropriate methods.

b) Evaluating vendor's current quality records, including the vendor's QA program, manual, and procedures, as appropriate.

c) Performing pre-award surveys at the vendor's plant to determine current capability to satisfy procurement document requirements.

Prior to qualification of vendors who supply quality-related components or services, a source evaluation is conducted to assure that the vendor maintains a Quality Assurance Program and organization, and that he can effectively demonstrate the controls within his own plant and those of his subvendors to provide the quality that is required. In addition, their technical capabilities and adequacy of facilities are surveyed. Vendors are required to demonstrate qualification by production of acceptable products. *

7.2 Vendor Audits

Vendor Quality Assurance system audits are conducted by the Director, Quality Assurance or his designee. These audits are performed in accordance with the Quality Assurance Audit Procedure and are conducted based on vendor activity and required quality. For major components (i.e., UO_2, cladding, tie plates, spacer components, neutron absorber pellets, zircaloy), these audits are normally conducted once each calendar year when the vendor is active. Other vendors are audited on a triennial basis as a minimum. Audit results written by the auditing organization are transmitted to the vendor in writing requesting formal corrective action response to deficiencies.

7.3 Vendor Source Surveillance

Vendor product source surveillance is conducted by Quality Control, in accordance with written procedures, to assure the purchase order requirements are being met. These activities may be delegated to Quality Assurance by the Manager, Quality Control. The frequency depends on vendor activity, vendor quality experience, importance of the components, ability to verify conformance to quality requirements upon receipt of product, and the receiving inspections to be performed. Product source surveillance is normally conducted at least once each year when the vendor is supplying major components, as defined in Section 7.2. If possible, the surveillance * is conducted while the material is being fabricated or inspected and tested. Product source surveillance may be performed in conjunction with audits of the vendor's Quality Assurance Program.

7.4 Approved Vendor List

An Approved Vendor List is prepared and maintained by the Manager, Materials and Purchasing, and approved by the Manager, Quality Control and Director, Quality Assurance. A vendor may be added to or deleted from the list in accordance with the requirements defined in the applicable QA Procedure. Bid proposals may be withheld from vendors not demonstrating adequate performance. As a minimum, the Approved Vendor List is reviewed and reissued, if appropriate, with approvals once a year.

7.5 Purchased Material Receipt Inspection and Release

Purchased material is received, identified, tagged, and stored in accordance with Logistics Procedures and/or other Quality Assurance Procedure requirements. Vendor certifications are required for fuel product line related procured components and materials. Purchased material is inspected by Quality Control in accordance with approved procedures and is returned to the * warehouse for storage and physical release to the shop after formal release by Quality Control. Nonconforming material is segregated and controlled in accordance with written procedures. Quality Control reviews vendor certifications, records, and receiving inspection results, and releases material in accordance with approved procedures. Continuing assessment of the * effectiveness of vendors control of quality is conducted by reviewing incoming product quality during the release process.

7.6 Control of Vendor Nonconforming Items

Items known to be nonconforming to SPC purchase requirements are not shipped to SPC without prior approval. Allowable manufacturing operations are either specifically identified in procurement documents or are approved by SPC prior to commencement of the operations.

7.7 Records

Certification and receiving inspection records are maintained in accordance with Section 17.

8.0 IDENTIFICATION AND CONTROL OF MATERIALS, PARTS, AND COMPONENTS

Measures are established to assure that materials, components, subassemblies, and assemblies are adequately identified to allow traceability to purchase documentation, manufacturing documents, and nonconforming material reports. These measures are also established to prevent the use of incorrect or defective items.

8.1 Identification

Quality Assurance Procedures, Quality Control Standards, and Standard Operating Procedures and other pertinent procedures are established to assure control of product or process materials and to maintain traceability from receipt of material to final shipment. The procedures require that identification be maintained either on the item or on the records traceable to the items. Stamping, tags, labels, and manufacturing order routers are the normal means of identification. In instances where the identification is located on the item, the location and method of inspection are such that the function, fit, and quality of the item are not adversely affected.

8.2 Controls

Physical identification requirements for materials, components, fuel rods, and fuel bundles, when applicable, originate in the design stage with specific identification and lot definition requirements set forth in the specifications and drawings.

At Receiving, product components and material are identified with date of receipt, vendor, reference Purchase Order number, and lot number. Quality Control verifies the correct identification and certification of the items. If the item passes receiving inspections, Quality Control indicates acceptance of the item and a release number is assigned. The identification remains with the item until used. The release number is then transferred to a manufacturing order router, if further processing is required, which provides traceability of identification throughout the manufacturing process. The manufacturing order router is checked at the final certification operation for completeness; it documents the manufacturing history of the fuel element, including the date it passed key manufacturing steps and the identification of the inspector.

Preceding steps are required to be signed off as completed on the manufacturing order router before the next step can begin, except as specifically waived by approved conditional releases or out of sequence operations as defined in the Quality Control Standards or other controlling procedure.

The Production Control Center unit of Master Scheduling & Uranium Management is responsible for issuance and control of manufacturing order routers, while the use and control of hold tags and inspection data forms is the responsibility of the Quality Control Manager. Plant Operations and Master Scheduling & Uranium Management Managers are responsible for controlling the flow of materials as specified in QA Procedures, Process Specifications, QC Standards and Procedures, Shop Operating Procedures, and Logistics Procedures.

For off-site activities, such as reconstitution of fuel assemblies or plant services, identification and control activities are defined in specific Services Procedures. These procedures include checklist signoffs of key activities and ensure that the completed work meets product or service quality requirements and that appropriate traceability to starting material is maintained. Product certification and/or re-release may be performed based on completion of procedures and checklists. *

8.3 Conditional Releases

During manufacture, conditional releases of material beyond designated process Quality Control hold points may be initiated by completion of a Conditional Release which is requested by Shop Operations, prepared by Quality Control, and approved in accordance with Document Control QA Procedures. The purpose of a Conditional Release is to facilitate continued processing when the required analyses or overchecks have not been completed and still assure physical identity and control of material in order to be able to reject, segregate, or otherwise disposition the affected material should the analyses or overchecks be unacceptable. Any conditionally released material is required to be identified until full release of the material is granted or other disposition is directed. Conditional releases are not to be used to waive Process or Product Specification requirements. *

8.4 Confirmation of Material Identification and Control from Inspection Records

A comprehensive system of inspection records is maintained to assure that material identification, inspection status, and fabrication status are explicitly identified, including, as appropriate:

a) Vendor inspection and test data and certification.

b) Results of tests and inspections.

c) Releases of material.

d) Status and disposition of "hold," "nonconforming," or "reject" items.

e) Manufacturing Order Routers, or activity checklist.

8.5 Loss of Identification

Any material, component, subassembly which loses its identification is considered nonconforming until such time as the identity can be established or the item is dispositioned by the Control of Nonconforming Items Procedure.

8.6 Control of Prohibited Material

Controls are established to assure that materials detrimental to fuel performance are not used. The measures include control of essential material purchases and evaluation of the process via appropriate analyses, as required to assure that adequate control is maintained over the use of such materials.

8.7 Enrichment Control

Measures are established to assure that nuclear materials of varying enrichment and form are positively identified and physically segregated as required to assure no inadvertent intermixing of enrichment or forms. These measures include, as appropriate, identification of storage and processing containers, gamma scan verification of powder, nuclear rod assay, analytical examinations, in-process inspections, cleanouts of processing equipment between enrichments, administrative controls on the handling of materials, and audits of processing and product.

8.8 Nonconforming Material

Control of nonconforming material is addressed in Section 15.

8.9 Situations Requiring Special Controls

In addition to other required documentation, special manufacturing order routers are prepared for those rework or repair situations requiring special control in areas where Manufacturing has responsibility for control. These situations include, but are not limited to, rework or repair operations of a nature involving more than two process and/or inspection steps performed in a sequence different from the normal process for the material being processed.

9.0 CONTROL OF SPECIAL PROCESSES

Controls over manufacturing and inspection processes are implemented to an extent consistent with process complexity and importance to product quality and safety. These controls assure that equipment and procedures are adequately evaluated and personnel are adequately qualified to perform their assigned tasks.

9.1 Special Processes and Tests

Applicable special processes and tests are welding, heat treating, nondestructive examination (NDE), and nuclear rod assay. These special processes and tests are subject to the following general criteria, as required by supplementary procedures: *

a) Qualified operators are used.

b) Qualification of operators is documented.

c) Special process qualification procedures are reviewed and approved.

d) Practices are consistent with approved procedures and appropriate codes and standards.

e) Test results are documented and reviewed for acceptability.

f) Records of test results and qualifications are maintained.

g) Controls are provided to assure that personnel qualification records are regularly reviewed and appropriate requirements for requalification are implemented.

9.2 Welding Qualification

Weld qualification procedures are included as part of the Process Specifications, which define qualification requirements for the process parameters, equipment, and operator, including number of welds required, inspection and testing requirements, and acceptance criteria. Operators are certified in accordance with the Process Specifications, Weld Procedures, and the Quality Control Procedures.

9.3 Heat Treating

Heat treating, whether performed in-house or by vendor, shall be controlled and accomplished by qualified personnel using qualified procedures. Bases for qualification shall be documented and approved.

9.4 NDE *

Liquid penetrant, radiography, helium leak, ultrasonic and eddy current testing, and nuclear rod assay are controlled by written operating procedures and operator qualifications. Operators successfully completing the qualifications are certified in accordance with the approved procedures.

9.5 Certification Records

Evidence that special processes are performed by qualified personnel exists in the form of Manufacturing Order Routers, inspection report or checklist signoffs which are traceable to certification records. Qualification and certification records are part of the Quality Assurance Records and are maintained in accordance with Section 17.

9.6 Manufacturing Process Control

9.6.1 Essential Material Specifications

Essential Material Specifications are prepared and approved in accordance with Document Control QA Procedures. These define the requirements for critical materials used and consumed in the process, such as weld gas, furnace gas, cleaning solutions, etc.

9.6.2 Process Parameters

In many instances, the Process Specifications and other process-related documents (Operating Procedures, Quality Control Standards, etc.) provide a range of operating parameters as limits. Process Specification requirements are met if the product is produced within this range. However, tighter control within the approved range is sometimes desirable for optimum product quality and/or throughput. To define these operating controls, process parameter sheets (including welding procedures) are prepared by Process Engineering (or other cognizant engineering component) and approved by the supervision of the implementing shop component.

10.0 INSPECTION

Inspections performed for the purpose of certifying acceptance of items to product and process requirements are performed using approved procedures and by personnel who are independent of the activities being inspected. Inspectors report to supervisors who are not responsible for performance of the work being inspected.

10.1 Standards and Procedures

Quality Control Standards, or other appropriate procedures, are prepared for receiving, in-process, and final inspections. These identify the inspection requirements and associated means of assuring conformance to the pertinent Product Specifications, Material Specifications, Process Specifications, and Drawings. The Standards are supplemented by Quality Control Procedures, Analytical Procedures, Metallurgical Procedures, Product, Material, and Process Specifications, Drawings, Manufacturing Order Routers, inspection forms, and other documents as required during the inspections. In-process inspection and Process Specifications and their supporting documentation include indirect control by monitoring processing methods, equipment, and personnel where direct inspection is not practicable. The Standards or supporting documentation include the following information where applicable: *

a) Identification of the item to be inspected and the individuals or groups responsible for performing the inspection.

b) Equipment and/or method to be used, as appropriate, for the inspection or analyses.

c) Prerequisites to be satisfied prior to the inspection, including operator qualifications and equipment calibration checks.

d) Acceptance and rejection criteria.

Off-site inspections of fuel and related components and plant services activities are done according to approved procedures by personnel who have been appropriately trained and certified, and the results are documented and retained as QA Records. Inspection of reconstituted fuel is performed by personnel who are independent of the fabrication activity. *

10.2 Records Requirements

Identification of the person performing the inspection and the inspection results are recorded on the applicable inspection record sheet. Manufacturing Order Routers and Inspection record sheets become part of the Quality Control records as described in Section 17.

10.3 Hold Points

Hold points may be established at specified points in the process whereby material may not proceed until formally inspected and released by Quality Control and/or the customer. Release points are designated in the Quality Control Standards or associated implementation procedure. Releases become part of the Quality Assurance Records as described in Section 17. *

10.4 Inspector Qualifications

Inspectors and special test operators are qualified in accordance with applicable procedures and Section 9. *

10.5 Reworked, Repaired, or Replacement Items

Items which are reworked, repaired, or replaced are inspected in accordance with applicable design and/or inspection requirements applied to the original items or as specified in applicable rework or repair procedures.

10.6 Statistical Techniques

Statistical techniques are utilized, as applicable, as in-process control methods, as well as in final inspections. Quality Control procedures and inspection plans define the use of statistical sampling methods. Statistical techniques are based on conventional statistical methods such as use of Mil. Standard 105.

11.0 TEST CONTROL

Test programs are established for new fuel designs, new processing methods, new or extensively modified product processing equipment, and systems and components related to plant services. * Test authorization procedures are prepared in accordance with Design Control QA Procedures for significant tests and are discussed below. Test results are analyzed by qualified personnel * prior to issuing the final product and process specifications or project report.

For complex testing, such as evaluating spacer flow characteristics under simulated reactor conditions, fuel assembly mock-up tests, or fuel license testing, a written test procedure is prepared which includes instructions for performing the tests, the test conditions to be achieved, test duration, accuracy, detailed schedule of measurements to be recorded, and the specific responsibilities for the test preparation, approval, operation, data collection, audit, and data evaluation.

Where other than SPC facilities are utilized, the person assigned responsibility for the test is responsible for reviewing the capabilities of the facility to be used and for establishing the procedures, controls, and measurements required to assure conformance within the required limits. Quality Assurance may audit any or all phases of the test depending on the test complexity and data usage.

The test results are documented and evaluated for acceptability by appropriate personnel. The test report is distributed to test program signees and others who have a technical interest, and a copy is filed with Document Control as a permanent record.

11.1 Special Test Authorizations

Special Test Authorizations (STAs) for complex testing are required to be documented and approved before work is initiated. The following items shall be considered and included, as applicable, in the STA:

a) Introduction/purpose/scope.

b) Justification.

c) Identification of material and equipment to be used.

d) Requirements or acceptance limits contained in applicable design documents.

e) Duration of test.

f) Instructions for required activities.

g) Effect on product material or processes, including provisions for controlled environmental conditions.

h) Calibrations required.

i) Mandatory inspection or hold points, if required.

j) Assignment of responsibilities including use of appropriately trained or qualified personnel.

k) Record requirements and recording of results.

l) Disposition of material and equipment.

m) Return of work areas to original condition.

In addition, the following items should be considered for inclusion, if appropriate:

- Applicable appendixes; e.g., drawings, charts, tables, etc.
- Applicable references.
- Archive requirements.

Special Test Authorizations are prepared by the engineer responsible for the test and approved in accordance with Document Control QA Procedures.

Special Test Authorizations and test results are documented in report form and a copy is retained in the central files. Special Test Authorization changes require the same approval signatures as required for the original test authorization. PTA results summaries require concurrence by the Managers, Product Mechanical Engineering and Quality Control.

Special Test Authorizations may be several types:

a) Process Test Authorizations (PTAs)

b) Design Test Authorizations (DTAs)

c) In-reactor Performance Evaluation Authorizations (IPEAs)

11.1.1 Process Test Authorizations

Process Test Authorizations are prepared per Manufacturing Engineering procedures for tests using new or different manufacturing parameters, processing techniques, or new/extensively modified product processing equipment. Completed Process Test Authorizations serve as one means of process qualification.

11.1.2 Design Test Authorizations

Design Test Authorizations are prepared for tests designed to improve or verify the design, exclusive of tests involving irradiation in customer reactors. Thermal hydraulic DTAs which do not involve fuel production equipment may be called Test Specifications.

11.1.3 In-reactor Performance Evaluation Authorizations

In-reactor Performance Evaluation Authorizations (IPEAs) are prepared for tests or characterizations involving irradiation of fuel in a customer's reactor. In addition, the following conditions must be met:

a) The evaluation shall be requested by or discussed with and approved by the customer before starting fabrication.

b) The mechanism for review and approval shall be via an IPEA.

11.2 Process Qualification

Process qualification is accomplished in accordance with Manufacturing Engineering and Quality Control procedures. Qualification records contain the following, as applicable:

a) Basis for qualification, such as a completed Process Test Authorization including Quality Control verification, other testing programs, or operating experience.

b) Listing of supporting documentation.

c) Parameters and/or ranges qualified.

d) Requalification results following major repairs or changes.

11.3 Plant Services *

Tests performed for customers by Plant Services shall be documented and approved, and shall consider the pertinent items listed in Section 11.1. Customer approval is generally required for work done at customer's site.

11.4 Qualification of Manufacturing Computer Software *

New and modified computer codes used in the manufacture and inspection of fuel assemblies and components shall be subjected to testing to demonstrate satisfactory applicability for the intended purpose. This shall be conducted per sub-tier procedure(s).

12.0 CONTROL OF MEASURING AND TEST EQUIPMENT

Procedures are established for the control of measuring and test equipment (M&TE) used in activities affecting product and services quality. *

Measuring and test equipment are defined as those devices used to measure characteristics for the purpose of determining acceptance of items to specified product or services requirements and process requirements where subsequent inspection is not performed. *

12.1 Procedures

Approved gage control procedures describe the calibration program for Quality Control and process control measuring and test equipment. *

12.2 Calibration and Control of Measuring and Test Equipment

The SPC QA Program requires the following, as appropriate:

a) Traceability of calibration standards is to the National Institute of Standards and Technology, where such standards exist. In the event there are not national standards, the basis of the calibration is documented.

b) Equipment falling within the scope of this program is procured, controlled, and used to ensure the required degree of accuracy, reproducibility, and traceability.

c) Purchase Orders for M&TE are reviewed to ensure that the equipment is sufficient for its intended use and that the specifications, certified calibration by the vendor or SPC, and the shipping requirements have been identified. *

d) Frequencies of recalibration are established, based on required accuracy, usage, stability of the equipment and, where feasible, the calibration status is identified by tag or label.

e) Nonconforming equipment is clearly labeled and its use prohibited or suitably restricted until repaired or calibrated.

f) Records are maintained which indicate the calibration status and dates of previous calibrations.

g) Where practical, M&TE are calibrated against working standards having an accuracy at least four times better than the allowable accuracy of the M&TE. Accuracies of working standards less than this are acceptable when limited by the state-of-the-art, or when the end use of the M&TE being calibrated does not require this accuracy. Additionally, M&TE used to measure characteristics classified as "major" or "minor" characteristics, i.e., nonsafety-related characteristics, may be calibrated against working standards which are less than four times better than the allowable accuracy of the M&TE being calibrated.

12.3 Out-of-Calibration Equipment

Measuring and test equipment actively being used to determine product or service acceptance that is found to be out of calibration will be removed from service and recalibrated. The degree out of calibration is determined during recalibration. An evaluation is made on a case-by-case basis to determine the validity of previous inspections during the period in which the measuring and test equipment was suspect of being out of calibration. Only when the evaluation reveals that the degree out of calibration impacts on the validity of previous inspections will action be taken regarding previous inspections. *

12.4 Calibration Records

Records are maintained for M&TE showing the equipment identification number, calibration status, and results of calibrations.

13.0 HANDLING, STORAGE, AND SHIPPING

Procedural controls are established to assure that purchased materials, shipping containers, equipment, fuel fabrication components, and completed fuel assemblies are stored, shipped, and preserved in a manner such that quality is not adversely affected. Special handling, storage, and preservation requirements are established in the Process Specifications, Product Specifications, and Material Specifications or other applicable approved procedure. Qualified individuals accomplish the special handling, storage, and preservation in accordance with predetermined work and inspection instructions contained in Quality Assurance Procedures, Logistics Procedures, Standard Operating Procedures, QC Standards, QC Procedures, or other applicable approved procedures. Where special controls are not required for handling, storage, and preservation, standard material handling and transportation methods are used to protect against physical damage. *

13.1 Responsibility

The Managers of Quality Control, Process Engineering, Product Mechanical Engineering, Materials and Scheduling, Shop Operations, Fuel Services, and Plant Services are responsible for including in their respective procedures those quality requirements which relate to preservation, handling, storage, and shipping. The respective managers are responsible for appropriately training their personnel in these matters.

13.2 Preservation and Packaging

Written instructions for preservation assure that quality-related items, such as fuel bundles and shipping containers, which are subject to deterioration or damage through exposure to air, moisture, and other environments, are protected during procurement, fabrication, processing, assembly, interim storage, and shipping. Packaging of fuel assemblies is inspected by Quality Control per written instructions prior to shipping. *

13.3 Handling

Special handling instructions are prepared, where necessary, for critical items that are susceptible to handling damage. Use is made of special carts, cranes, boxes, containers, and methods of transportation. Handling instructions for inspection equipment, fuel components, rods, and assemblies in the shops are included in appropriate Standard Operating Procedures, Quality Control Standards, Quality Control Procedures, or Process Specifications Handling instructions for both systems and physical handling of components at receipt are to be in accordance with Material Instructions or other approved applicable procedures. * *

13.4 Storage

Instructions provide requirements to prevent deterioration and damage and also include requirements for adequate safety, periodic inspection, and accountability. In addition, instructions or procedures include requirements for segregation and control of nonconforming items.

13.5 Shipping

13.5.1 Quality Assurance Product Certificate

A final Quality Assurance Product Certificate is prepared and approved for the finished fuel rods, fuel bearing assemblies, and assemblies containing neutron absorber materials leaving the SPC facilities and is provided to the customer. The certificate assures that the following requirements were reviewed and met:

a) The items have been produced in accordance with approved specifications or approved nonconformance reports thereto.

b) The items have been subjected to and have satisfactorily passed applicable inspections and tests and have been released by Quality Control.

c) The items are complete and fully assembled as required.

d) The items were designed, procured, fabricated, and packaged in accordance with the Quality Assurance Program.

13.5.2 Formal Shipping Release

The finished fuel assemblies containing special nuclear material or neutron absorber material shipped from the SPC facilities are formally released and approved for shipping in accordance with approved Quality Assurance Procedures.

14.0 INSPECTION, TEST, AND OPERATING STATUS

Controls are established to assure that the inspection and processing status of services activities, or items which will become part of the product or are important to the manufacturing process, are adequately identified from receipt of the items to end use in order to prevent inadvertent bypassing of operations or inadvertent use. *

The following controls are employed to assure that the status of services activities or materials, components, and assemblies are adequately identified: *

a) Lot cards, manufacturing order routers, station reports, or checklists are utilized to identify and control lots or items and to transfer identification when several items are joined into a single unit.

b) Inspector or operator initials are entered on the identity/control documentation to signify the completion of operations or inspections.

c) Inspection forms and lot cards are controlled in accordance with Quality Control Procedures. Manufacturing order routers are controlled in accordance with Production Control Center Procedures. Off-site fuel reconstitution checklists are generated for each specific project. These forms, plus Quality Control releases, assure that traceability to starting material is maintained.

d) Quality Control release points are required at several points in the manufacturing process; components, sub-assemblies, and assemblies are not permitted to pass a release point unless required inspection, tests, and operations have been completed, except by approved conditional release.

e) Rejected items are tagged and separated from acceptable items per nonconforming Material Control Procedures to prevent their inadvertent use.

f) The removal of hold tags is authorized only by the Quality Control organization or by other appropriate personnel designated in Quality Assurance Procedures.

g) Small parts, for which it is not practical to uniquely mark each item, are identified and controlled by appropriate means, such as attaching inspection labels or tags to the container, bin, or carton in which the parts are stored.

15.0 NONCONFORMING MATERIAL, PARTS, OR COMPONENTS

Materials, parts, components, subassemblies, and assemblies or activities that deviate from services or product requirements of approved specifications, standards, or drawings are considered to be nonconforming items. The SPC Quality Assurance Program requires that nonconforming items discovered during procurement, receiving inspection, manufacture, fabrication, or inspection/test activities be controlled and documented in accordance with written procedures. *

15.1 Nonconforming Material Control System

Items found to be nonconforming are identified and segregated, as practicable, to prevent their inadvertent use. They are withheld from further use unless they can be reworked to approved rework procedures, or are processed in accordance with the applicable QA Procedure. Nonconforming material reports, if required, are originated by Quality Control. The details of the nonconforming material report system, including distribution of nonconforming material reports to affected organization management, are described in Quality Assurance Procedures. Processing of nonconforming material and nonconforming material reports is subject to the following controls: *

a) The nonconforming item is segregated from acceptable items and is identified with a hold tag, rework router, or nonconforming material report.

b) The nonconformance is documented, including item name and description, description of nonconforming conditions and identification of requirements violated, and signature of the originator and date.

c) The nonconformance is evaluated by Engineering and Quality Control and a disposition is recommended. *

d) Acceptance of nonconformances involving critical characteristics to existing specifications and repair of items requires approval in accordance with approved Quality Assurance Procedures. These approvals signify that any areas of concern within engineering or related to the customer contract are resolved.

e) Copies of approved nonconformance reports are placed in the Quality Control Release Files for the affected material. In addition, a final product nonconformance report for nuclear fuel projects is sent to customers in accordance with the applicable Quality Assurance Procedure. *

f) Items rejected are physically separated from acceptable items when practicable, and are either returned to the vendor for credit, held in a clearly marked storage area for future disposition, altered to prevent uncontrolled usage, or scrapped.

g) Preventive action is initiated, as appropriate, to assure that the causes of quality problems are identified and corrected. Any recommended preventive action is indicated in the nonconformance report or attachments thereto; the manager of the group responsible for the preventive action signs as accepting the preventive action and verifying its completion. *

h) Rework and repair operations are conducted in accordance with documented procedures, which are either a part of the nonconformance report or approved Process Specifications; the acceptability of rework or repair operations is verified by reinspection or retesting of the items, as required, to assure adequacy of the product or service. *

i) If agreement on disposition and/or preventive action is not reached by persons approving the nonconformance report, the matter is brought to the attention of the next higher level of management and the Director, Quality Assurance for resolution.

16.0 CORRECTIVE ACTION

Nonconforming conditions, significant processing incidents, inspection or design inadequacies, or other events which can adversely affect product or services quality, are reported to appropriate levels of management for review and assessment. Formal corrective action is promptly taken for significant incidents adverse to quality and the results are documented and reviewed for effectiveness. *

16.1 Nonconforming Material

Technical review and preventive action recommendations on nonconforming material are made by those responsible for approving nonconforming material reports as specified in Section 15. Preventive action and control of nonconforming materials are also as described in Section 15. Requests for corrective action by vendors are submitted in writing by Materials and Purchasing or QA to the responsible vendor. Follow-up action to obtain vendor corrective action commitments is also the responsibility of the Manager, Materials and Purchasing. Follow-up audits for vendor Quality Assurance system deficiencies are performed by Quality Assurance when required. Follow-up actions are documented to identify that the corrective actions were implemented and effective. *

16.2 Incident Reviews

16.2.1 Incident Review Boards

Incident Review Boards (IRBs) are convened to investigate significant incidents involving unusual events that are determined to have a potential major adverse impact on product quality. The IRB is chaired by the Director, Quality Assurance. Members serving on an IRB are appointed by the chairman and should have no direct responsibilities in the area(s) being investigated. The IRB evaluates facts relating to the incident to identify probable causes and to recommend corrective action, as appropriate, to minimize recurrence. As fact-finding bodies, IRBs are authorized to interview appropriate personnel and to review pertinent hardware and documentation relating to the incident. Potentially significant incidents should be promptly reported to the IRB Chairman by the responsible manager; however, such reporting is not a prerequisite for convening an IRB. IRB meetings should be convened whenever the Quality Assurance Director becomes aware of product/services-related significant events and determines that these events have a potential for major impact on product/services quality. *

16.2.2 Incident Review Board Reports and Follow-up

Minutes of IRB meetings are recorded by a secretary appointed by the IRB Chairman. A final IRB report, signed by each member, is issued and distributed to appropriate management responsible for directing implementation of corrective action. The IRB Chairman is responsible for taking any follow-up necessary to verify that the appropriate corrective action has been taken and that it is effective. Reports on IRBs conducted at the Lingen, Germany plant shall include Director, Quality Assurance - SPC, on distribution.

16.3 Audits

Corrective action, in response to customer and NRC Quality Assurance audits or inspections, is documented by the Director, Quality Assurance or his designated representative. Internal audits are documented in accordance with Quality Assurance Procedures and Quality Control Procedures. Follow-up reviews are conducted, as required, to verify the implementation of corrective action. Corrective action resulting from audits is discussed further in Section 18.

17.0 QUALITY ASSURANCE RECORDS

Documents and records sufficient to characterize the services performed, product design, materials used, and process by which the product was fabricated, material and fabrication history, and the quality achieved are maintained for each contract to furnish evidence of activities which affect quality. The records are consistent with applicable codes, standards, specifications, and contracts. QA records include results of reviews, inspection, tests, audits, and material analyses; monitoring of work performance; qualification of personnel, procedures, and equipment; and other documentation such as drawings, specifications, procurement documents, calibration procedures and reports; nonconformance reports; and corrective action reports.

17.1 Record System

Quality Assurance records which furnish documentary evidence of the quality of nuclear fuel or of activities affecting quality, provide sufficient information to permit identification between the record and the items or activities to which it applies. This includes the following types of information, as applicable: document title, number, revision, date, references to appropriate contract, purchase order, work order, drawing, specifications, and/or procedures. Records of inspection and testing of products contain the following information, as applicable:

a) Identification of the record and the item to which it applies.

b) Description or identification of the observation.

c) Evidence of completion of the inspection or test.

d) Date of the inspection or test.

e) Inspector.

f) Evidence of acceptability or conditions adverse to quality.

17.2 Record Storage and Retention

Documents designated as Quality Assurance records are transmitted to and retained by Central Files (Document Control) or are maintained in satellite files. Satellite file stations include the Quality Control records area controlled by Quality Control, the vendor documentation records area controlled by Materials and Purchasing and Quality Control, the Quality Assurance audit and certification records area controlled by Quality Assurance, design records area controlled by Engineering, and the Chattanooga office controlled by Plant Services Quality Assurance. Measurement, test equipment, and calibration equipment records are maintained by Quality Control, or the user organization. *

Designated Quality Assurance records not stored in the Central Files vault are stored either in two physically separated locations or in fire-resistant file cabinets.

Designated Quality Assurance records are transferred from satellite files to Central Files within the time interval specified in the applicable QA Procedure. Either the Quality Assurance Director, Corporate Information Services Manager, or Quality Control Manager may authorize reducing the records to microfilm for storage in a safe repository.

Designated Quality Assurance records are stored so as to provide for timely retrieval of information. Retention periods are indicated in Quality Assurance Procedures.

18.0 AUDITS

A comprehensive program of planned and periodic audits is carried out to verify compliance with all aspects of the Quality Assurance Program and to determine the effectiveness of the program. The audits include the evaluation of work areas, activities, quality-related practices, items, and reviews of documents and records. The program includes external audits of vendor activities, as well as internal audits of SPC activities. Audit reports are documented and distributed to appropriate management and necessary corrective actions are taken to correct noted deficiencies.

18.1 Categories of Audits

18.1.1 Quality Assurance Audits

The Quality Assurance Audit Program is documented in a Quality Assurance Procedure. The audit program includes:

a) Quality Assurance system audits of the adequacy and implementation of criteria of the Quality Assurance Program, such as document control and identification and control of materials.

b) Documentation review audits of the adequacy and consistency of Quality Assurance Program documentation.

c) Processing/inspection audits of manufacturing and inspection operations. *

d) Audits of vendor Quality Assurance Programs. *

e) Special audit of non-routine activities as deemed necessary.

18.1.2 Vendor Audits

The Vendor Audit Program is described in Section 7. The responsibility for auditing vendor Quality Assurance system activities may be delegated to off-site inspector services, Quality Control, or other qualified personnel as designated by the Director, Quality Assurance; however, he still retains full responsibility for the effectiveness of the audits. The Manager, Quality Control is similarly responsible for vendor Quality Control inspection activities and may delegate this responsibility to other independent groups or organizations.

18.2 Procedures

Requirements governing the performance of audits are delineated in audit procedures addressing the following:

a) Types and frequency of audits.

b) Responsibility and training of Lead Auditors (Quality Assurance system audits only).

c) Planning and scheduling of audits.

d) Preparation of audits, including notification.

e) Conduct of audits, including conferences as required.

f) Preparation, issuance, and distribution of audit reports.

g) Follow-up, including commitments, status, and reporting of open items and re-audits.

h) Audit records.

18.3 Audit Performance and Reports

Audits are conducted by appropriately trained, experienced personnel who have no responsibilities in the areas being audited. They are performed in accordance with written procedures or checklists. Audit personnel have access to contract requirements, technical data, design data, fabrication data, facilities, products, tooling, work instructions, materials, and data directly related to the work.

Audit results are documented in audit reports, which are distributed to appropriate management personnel. Results of external audits are issued to management of the organization audited.

Audit frequencies are based on the status and safety importance of the activities performed and are adjusted, based on such things as the results of previous audits, current problem areas identified by management, scrap and rework losses, nonconforming material reports, and quality cost data. Each QA Program criterion (element) is internally audited at least once each calendar year during the performance of functional area audits. As a minimum, suppliers of nuclear fuel hardware items are audited annually if the hardware item is considered to be a major component and triennially for suppliers of other items and services.

18.4 Corrective Action/Follow-up

Audit results are reviewed with responsible supervision or management and corrective actions established. Managers or supervisors responsible for the areas in which deficiencies are found are responsible for providing corrective actions with dates of completion to the auditors.

Each manager responsible for corrective action performs follow-up on his outstanding commitments. Periodic reports on the status of the outstanding corrective actions are sent to appropriate management until the commitment is completed and verified to be effective.

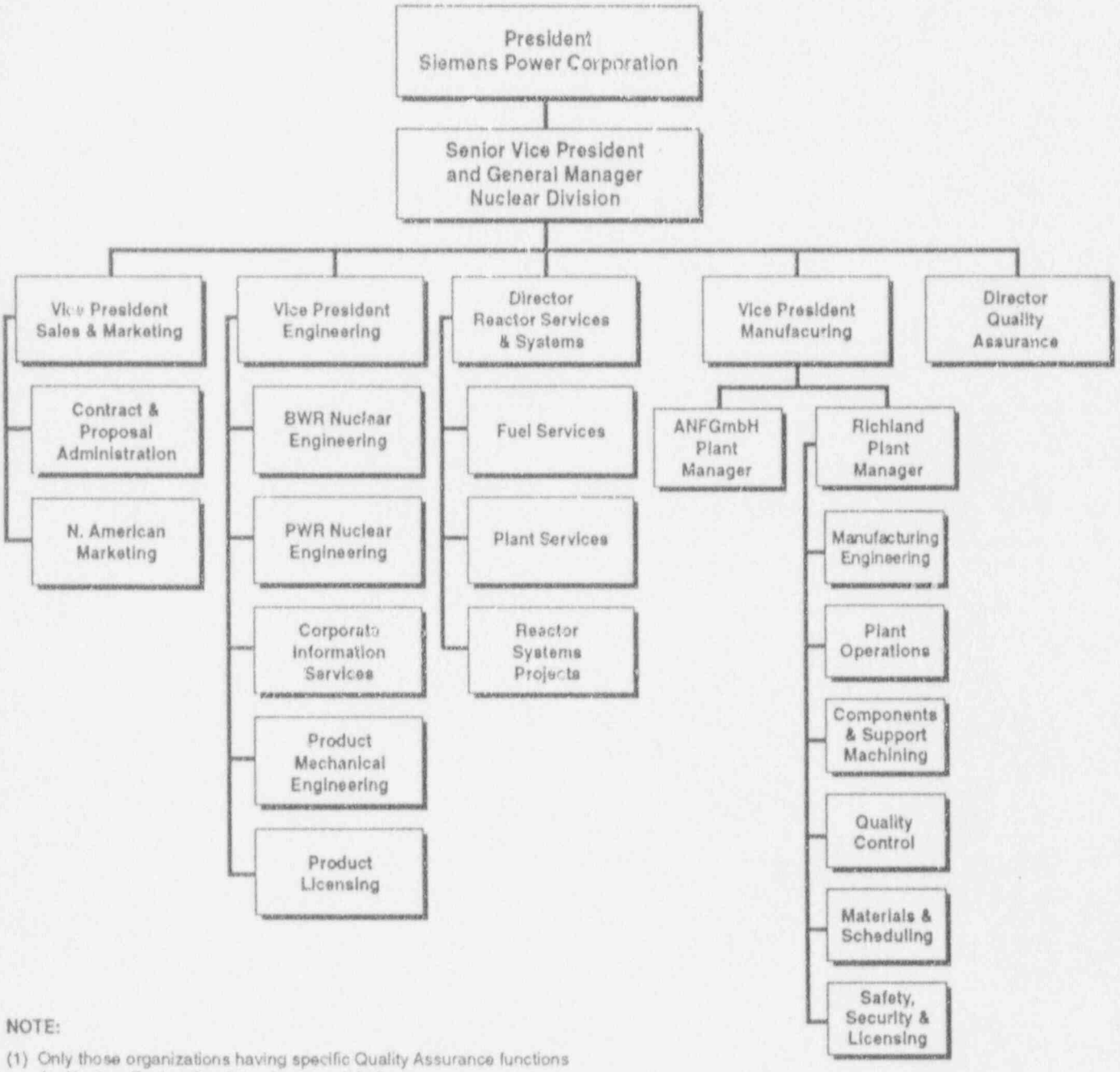
The Manager, Materials and Purchasing is responsible for follow-up on vendor deficiencies. The status of outstanding corrective actions is periodically reviewed and reported until the corrective action has been satisfactorily implemented.

Re-auditing is conducted as determined by the Director, Quality Assurance to verify implementation of corrective action from earlier audits.

Figure 1

Siemens Power Corporation Organizations

(Related to Nuclear Fuel Design and Fabrication, and Services)



NOTE:

(1) Only those organizations having specific Quality Assurance functions for Nuclear Fuel or Services shown on this figure.

(2) This chart is representative. Minor organizational changes which do not impact on effectiveness of the QA Program will not be cause for revision of this document.

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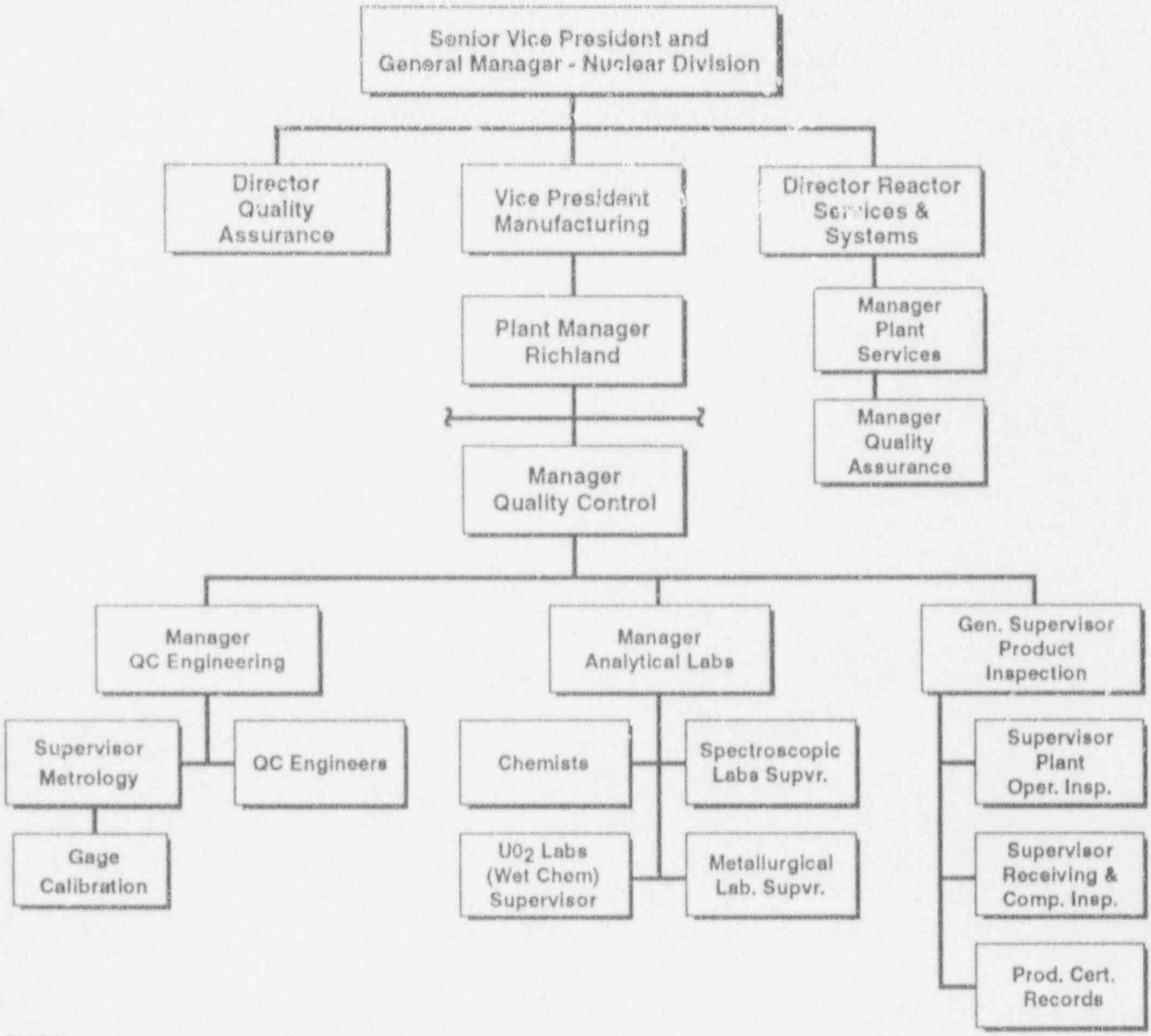
Figure 2

Siemens Power Corporation - Nuclear Division
QA/QC Organizations

(Related to Nuclear Fuel Fabrication, and Services)



NOTE:

This chart is representative. Minor organizational changes which do not impact on effectiveness of the QA program will not be cause for revision of this document.

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APPENDIX I

APPLICABILITY OF ANSI STANDARDS AND REGULATORY GUIDES

As noted in Section 2, the SPC Quality Assurance Program satisfies the requirements of Appendix B to 10CFR50, "Quality Assurance Criteria for Nuclear Power Plants"; NRC Regulatory Guide 1.28, "Quality Assurance Program Requirements"; and ANSI 45.2 (1977), "Quality Assurance Program for Nuclear Fuel Power Plants."

Since the Quality Assurance requirements and guidelines of the Regulatory Guides and ANSI Standards were initiated to apply to nuclear power plants, interpretation is required to determine their applicability to services, and the design and manufacture of a plant component such as nuclear fuel. The SPC Quality Assurance Program follows the guidelines set forth in Section 17.1 of the NRC Standard Review Plan insofar as it applies to fuel design and fabrication activities performed by SPC. The extent to which the ANSI Standards and Regulatory Guides referenced in the Standard Review Plan are deemed to be applicable to SPC-ND activities is summarized in the table which follows. The listed ANSI Standards apply only to nuclear safety-related activities. Specific exceptions to the documents are included with appropriate justification. Standards or Guides referenced by the Standard Review Plan which are deemed not applicable to fuel design and fabrication have been omitted.

APPLICABILITY OF ANSI STANDARDS AND REGULATORY GUIDES		
ITEM NO.	DOCUMENT NUMBER & DATE	SUBJECT AND APPLICABILITY
1.	Reg. Guide 1.28 (Rev. 3, Aug. 1985)	Quality Assurance Program Requirements (Design Construction)
	ANSI N45.2, 1977	Quality Assurance Program Requirements for Nuclear Power Plants Applicability: Fully applicable.
	ANSI/ASME NQA-1	Quality Assurance Requirements for Nuclear Facilities Applicability: Applicable with same comments as described below for corresponding Supplements.
2.	Reg. Guide 1.38 (Rev. 2, May 1977)	Quality Assurance Requirements for Packaging, Shipping, Receiving, Storage, and Handling of Items for Water-Cooled Nuclear Power Plants
	ANSI N45.2.2 - 1972	Packaging, Shipping, Receiving, Storage, and Handling of Items for Nuclear Power Plants Applicability: ANSI N45.2.2, Section 2.7.1 (3), defines nuclear fuel as a Level A item. As such, ANSI N45.-2.2, Section 3.2.1, Items 1-9, apply with the following exceptions: 1) ANSI N45.2.2, Section 3.2.1, Item 1 is amended to eliminate the need for temperature and humidity controls. 2) The serial number of the fuel assembly constitutes adequate item identification as required by Section 3.2.1, Item 9 of ANSI N45.2.2. Shipping container marking shall comply with the requirements of applicable state and federal regulations governing nuclear fuel shipments. Additionally, the following sections of ANSI N45.2.2 are deemed to apply: 4.6, 5.1, 5.2.1 (5), 5.2.2. (7), 5.2.2 (8), 5.2.2 second paragraph (2) and (4), 5.3, 5.4, 5.5, 5.7, 6.1 (at fuel fabrication site only, and with exception of temperature and humidity controls). Storage in shipping containers may satisfy the requirements of Section 6.1 of ANSI N45.2.2, and 7.1

APPLICABILITY OF ANSI STANDARDS AND REGULATORY GUIDES		
ITEM NO.	DOCUMENT NUMBER & DATE	SUBJECT AND APPLICABILITY
3.	Reg. Guide 1.58 (Rev. 1, Sept. 1980)	Qualification of Nuclear Power Plant Inspection, Examination, and Testing Personnel
	ANSI N45.2.6, 1978	Qualification of Inspection, Examination, and Testing Personnel for the Construction Phase of Nuclear Power Plants Applicability: Applicable with the following clarifications: 1) Levels of capability, as specified by Sections 3.1 and 4 of ANSI N45.2.6, are applicable only to special processes, as defined by ASNT-TC-1A. 2) Formal levels of qualification are not assigned for nuclear fuel ultrasonic test and helium leak check personnel. However, formal training programs for all inspectors are conducted and documented in accordance with ASNT-TC-1A recommended practice. The degree of evaluating acceptability of test results is limited by procedure, to comparing chart or dial readings of product tests versus acceptance limits established using approved standards. 3) Practical experience and on-the-job training times may vary from the ASNT-TC-1A classifications. Other inspections and testing qualifications, while formalized, are not deemed to require designation of levels of capability. In addition, physical examinations after initial certification are verified biennially in lieu of annually per Section 3.2.1, since this is company policy. 4) A special category, "Level II Rod Film Reader Only", is defined to evaluate acceptability of fuel rod weld radiographs only. This classification requires less extensive general training and experience than "Level II", and limits qualification to an in-depth ability to read and interpret film only. Special training with demonstration of ability to consistently detect defects is required and is documented in training files.

APPLICABILITY OF ANSI STANDARDS AND REGULATORY GUIDES		
ITEM NO.	DOCUMENT NUMBER & DATE	SUBJECT AND APPLICABILITY
4.	Reg. Guide 1.64 (Rev. 2, June 1976)	Quality Assurance Requirements for the Design of Nuclear Fuel Power Plants
	ANSI N45.2.11 - 1974	(Same title of Reg. Guide 1.64) Applicability: Applicable with the following clarifications and exceptions which make the standard more consistent with Nuclear Fuel Design: (1) Paragraph 3.2 of ANSI N45.2.11 is changed to read as follows: "The design shall be such as to be capable of accommodating the following where applicable: 1) Basic functions of each structure and component. 2) Performance requirements. 3) Codes, standards, and regulatory requirements including the applicable issue and/or addenda. 4) Design conditions such as pressure and temperature. 5) Loads such as seismic, thermal, and dynamic where required. 6) Environmental conditions anticipated during fabrication, storage, and operation, such as pressure, temperature, humidity, corrosiveness, and nuclear radiation. 7) Interface requirements, including definition of the functional and physical interfaces involving structures and components. 8) Material requirements, including such items as compatibility and corrosion resistance. 9) Mechanical requirements, such as vibration, etc. 10) (Not applicable) 11) Hydraulic requirements such as allowable pressure drops and fluid velocities. 12) (Not applicable) 13) (Not applicable) 14) Layout and arrangement requirements.

APPLICABILITY OF ANSI STANDARDS AND REGULATORY GUIDES		
ITEM NO.	DOCUMENT NUMBER & DATE	SUBJECT AND APPLICABILITY
		15) Operational requirements under various conditions, such as plant startup, normal plant operation, plant shutdown, plant emergency operation, special or infrequent operation and system abnormal or emergency operation. 16) Provision for accommodating installation of necessary instrumentation. 17) (Not applicable) 18) (Not applicable) 19) Failure effects requirements of structures, and components, including a definition of those events and accidents which they must be designed to withstand. 20) Test requirements including in-plant tests and conditions under which they will be performed. 21) Accessibility, maintenance, repair and in-service inspection requirements for the fuel, including the conditions under which these will be performed. 22) Personnel requirements and limitations, including qualification and number of personnel available for testing and inspection and permissible personnel radiation exposures for specified areas and conditions. 23) Transportability requirements such as size and shipping weight, limitations, and DOT regulations. 24) Handling, storage, and shipping requirements. 25) Other requirements to prevent undue risk to the health and safety of the public. 26) Materials, processes, parts, and equipment suitable for application. 27) Safety requirements for preventing personnel injury, including such items as radiation hazards, and restricting the use of dangerous material.*

APPLICABILITY OF ANSI STANDARDS AND REGULATORY GUIDES		
ITEM NO.	DOCUMENT NUMBER & DATE	SUBJECT AND APPLICABILITY
		(2) If, in an exceptional circumstance, the designer's immediate supervisor is the only technically qualified individual available, this review can be conducted by the supervisor, provided that: a) The provisions of the Regulatory Guide are satisfied. b) The justification is individually documented and approved in advance by the supervisor's management. c) Quality Assurance audits will cover the frequency and efficiency of the use of immediate supervisors as design verifiers to guard against abuse.
		(3) The requirements of Section 6.3.3 for incorporation of design test acceptance limits into test procedures is not deemed applicable if the purpose of the test is to produce data for design inputs. Additionally, not all qualification tests are conducted under the worst conceivable design conditions.
5.	Reg. Guide 1.74 (Feb. 1974) ANSI N45.2.10-1973	Quality Assurance Terms and Definitions (Same title as Reg. Guide 1.74) Applicability: Fully applicable.

APPLICABILITY OF ANSI STANDARDS AND REGULATORY GUIDES		
ITEM NO.	DOCUMENT NUMBER & DATE	SUBJECT AND APPLICABILITY
6.	Reg. Guide 1.88 (Rev. 2, Oct. 1976)	Collection, Storage, and Maintenance of Nuclear Power Plant Quality Assurance Records
	ANSI N45.2.9-1974	Requirements for Collection, Storage, and Maintenance of Quality Assurance Records for Nuclear Power Plants Applicability: Applicable with the following exceptions: 1) The SPC vault has no provision for drainage, as recommended by Section 5.6 (6); however, there is no credible mechanism (e.g., sprinkler system) for entry of water into the vault. 2) Calibration records are maintained in the calibration laboratory as these are not subject to vault storage until reasonable time after fuel shipment. 3) Quality Control records and procurement records need not be transferred to vault storage. 4) Radiographs of fuel assembly components are not retained as QA Records. Results of the review are recorded on Inspection Report and/or routing cards and these are saved as lifetime QA Records. 5) Certain nonpermanent QA Records, not directly product-related, e.g., personnel certification records, are kept in satellite file cabinets rated at one hour minimum fire protection. These satellite files are located in office areas where a credible fire would be extinguished within one hour.

APPLICABILITY OF ANSI STANDARDS AND REGULATORY GUIDES		
ITEM NO.	DOCUMENT NUMBER & DATE	SUBJECT AND APPLICABILITY
7.	Reg. Guide 1.144 (Rev. 1, Sept. 1980) ANSI N45.2.12-1977	Auditing of Quality Assurance Programs for Nuclear Power Plants Applicability: Applicable with the following exceptions: 1) With respect to the annual audit frequency requirements of Paragraph 3.5.2, the term "Applicable elements..." is interpreted within the following context. SPC conducts comprehensive internal QA Audits of important quality functional areas. Each functions area audit may address implementation of one or more of the QA program criteria (elements) applicable to the area. Each QA program criterion is audited at least once every calendar year during the performance of functional area audits. In determining the audit scope, an evaluation of the area being audited is done. The evaluation may include some or all of the following: prior quality assurance program audits, results of audits from other sources, nature and frequency of identified discrepancies, significant changes in the organization or quality assurance program, and the corrective actions taken to correct discrepancies. Suppliers of nuclear fuel hardware items are audited annually if the hardware item is considered to be a major component and triennially for suppliers of other items. Where a current supplier having an active contract with SPC is not audited within a calendar year, a documented interim evaluation of the supplier will be performed annually. As an exception to the foregoing, audits of suppliers are not necessarily performed for procurement actions where acceptance of the product is in accordance with Section 10.3.2 of ANSI N45.2.13 - 1976. In the case of both internal and external audits, audit frequency is adjusted as necessary from these minimum requirements depending on the importance and status of the organization/area being audited. 2) Concerning Paragraph 4.5.2.1, a written reply to the audit report is obtained only if required by the audit report or the audit report transmittal. Written responses to individual adverse findings (Corrective Action Requests) are obtained in accordance with Paragraph 4.5.1.
8.	Reg. Guide 1.123 (Rev. 1, July 1977) ANSI N45.2.13 - 1976	Quality Assurance Requirements for Control of Procurement Items and Services for Nuclear Power Plants (Same title as Reg. Guide 1.123.) Applicability: Fully applicable.

APPLICABILITY OF ANSI STANDARDS AND REGULATORY GUIDES		
ITEM NO.	DOCUMENT NUMBER & DATE	SUBJECT AND APPLICABILITY
9.	Reg. Guide 1.146 Aug. 1980 ANSI N45.2.23 - 1978	Qualification of Quality Assurance Program Audit Personnel for Nuclear Power Plants (Same title as Reg. Guide 1.146.) Applicability: Applicable with the following exception: Calibration and lab services supplier audits are performed by QC auditors, rather than QA auditors, due to the specialized and limited scope of these audits. QC auditors are appropriately trained and qualified in accordance with approved procedures, but are not required to be formally designated Lead Auditors, as defined by ANSI N45.2.23.

APPENDIX II

MATRIX CHART OF SPC-ND
QA PROGRAM AND QA PROCEDURES
RELATED TO QA CRITERIA

10CFR50, APPENDIX B QA CRITERIA		SPC - NUCLEAR FUELS	
		QA PROGRAM Topical Report Sections	QA PROCEDURES By Number
I	Organization	1	All listed QA Procedures
II	QA Program	2	EMF-P00,019 and 036
III	Design Control	3	EMF-P00,002
IV	Procurement Document Control	4	EMF-P00,018
V	Instructions, Procedures, and Drawings	5	All listed QA Procedures
VI	Document Control	6	EMF-P00,001; EMF-365
VII	Control of Purchased Material	7	EMF-P00,018
VIII	Identification and Control of Materials and Parts	8	EMF-P00,027
IX	Control of Special Processes	9	EMF-P00,001
X	Inspection	10	EMF-P00,020
XI	Test Control	11	EMF-P00,020
XII	Calibration of Equipment	12	EMF-10
XIII	Handling, Storage, and Shipping	13	EMF-P00,001, 002, & 028
XIV	Inspection, Testing, and Operating Status	14	EMF-P00,027 & 020
XV	Nonconforming Material	15	EMF-P00,002, 039, & 027
XVI	Corrective Action	16	EMF-P00,021
XVII	QA Records	17	EMF-P00,023
XVIII	Audits	18	EMF-P00.004

NOTE: QA Procedure prefixes will be changed from ANF to EMF as procedures are changed.