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Siemens Power Corporation

Nuclear Division
Engineering & Manufacturing

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UNITED STATES
NUCLEAR REGULATORY COMMISSION
WASHINGTON, D.C. 20555-0001

January 16, 1996

Mr. Chris M. Powers, Director, Quality
Siemens Power Corporation
Nuclear Division
2101 Horn Rapids Road
Post Office Box 130
Richland, Washington 99352-0130

Subject: ACCEPTANCE OF SIEMENS POWER CORPORATION QUALITY ASSURANCE PROGRAM TOPICAL REPORT, REVISION 28

Dear Mr. Powers:

We have completed our review of the subject topical report, EMF-1, "Quality Assurance Program for Nuclear Fuels and Services", Revision 28, submitted by your letter of October 18, 1995. Our review included your original submittal of Revision 28 of the topical report by letter dated February 10, 1995, additional information provided by your letter dated April 4, 1995, supplemental information by your fax transmittal dated October 4, 1995, your submittal that included your new company organization dated October 18, 1995, and the supplemental information by your fax transmittals dated November 13, 1995 and November 28, 1995.

The latter submittal provided further information regarding your internal auditing program. The NRC finds that Siemen's reliance on the numerous audits performed by licensee customers and the Nuclear Fuel Users Forum (NFUF) to assist in fulfilling the requirements for internal audits to be acceptable providing that in addition to the discussion of the exception to Regulatory Guide 1.44 as discussed on page 81 of your topical quality assurance program that 1) the audits conducted by the licensee customers and NFUF are subject to oversight and involvement by Siemens quality assurance personnel, 2) the audits conducted by the licensee customers and NFUF are evaluated on an annual basis by SPC-ND and supplemented as necessary by Siemen's internal audits for those areas of activity not addressed in sufficient depth or not encompassed by the licensee and NFUF audits, 3) that areas of weakness identified by the licensee customer and NFUF audits will receive emphasis in your internal audits and be audited on an accelerated basis as warranted, and 4) that your licensee customers and NFUF are informed of your intent to rely upon their audits as outlined in Appendix II of your quality assurance topical report.

Based on our review of this information and your implementation of the additional conditions discussed above, we have determined that your quality assurance program description is acceptable in that it will continue to satisfy the requirements of 10 CFR Part 50, Appendix B.

Sincerely,

Suzanne C. Black

Suzanne C. Black, Chief
Quality Assurance and Maintenance Branch
Division of Reactor Controls and
Human Factors
Office of Nuclear Reactor Regulation

EMF-1, PART II

Siemens Power Corporation - Nuclear Division

QUALITY ASSURANCE PROGRAM FOR NUCLEAR FUELS & SERVICES

	Organization	Signature	Date
Prepared by:	Quality Assurance	C.M. Bourne for R.H. Nelson	2/8/95
Approved by:	Director, Quality	C.M. Bourne	2/8/95
Approved by:	Vice President, Engineering	J.F. Mallay	10 Feb 95
Approved by:	Plant Manager, Richland	T.J. Lagarde	2/8/95
Approved by:	Vice President, Sales & Marketing	J.A. Lockard	2/10/95
Approved by:	Director, Reactor Services & Systems	D.A. Lemmon	2/10/95

SUMMARY OF CHANGES:

Complete revision including format change to incorporate SFG-1, "Siemens Nuclear Fuels Business Global Quality Assurance Program."

Changed Section 1.2.1.5 and Figure 6 to incorporate Reactor Services & Systems organizational changes.

Note: Since Revision 28 is a complete rewrite of the Program description, the use of asterisks to denote changes has not been employed. Future revisions will resume the identification of changes in the margins.

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QUALITY ASSURANCE PROGRAM FOR NUCLEAR FUELS & SERVICES

0.0 INTRODUCTION

The world-wide Siemens nuclear fuels business is executed under a strongly coordinated, global operating arrangement between several legal entities, all of which are wholly owned subsidiaries of Siemens AG, Germany. These legal entities are called affiliates of the operating arrangement. Known as the Siemens Nuclear Fuels Business, the operating arrangement is comprised of three main segments under the direction of a common chief executive officer. These include the European Business Unit, the U.S. Business Unit, and a jointly operated Research and Technology unit which performs research and development activities for both business units. Figure 1 depicts the functional relationships within the nuclear fuels business operating arrangement.

The European Business Unit is comprised of the Nuclear Fuel Cycle Division (KWU-B) (exclusive of the European portion of the Research and Technology Unit) of the KWU Power Generation Group, Siemens AG, and the Siemens subsidiary, Advanced Nuclear Fuels GmbH (ANF), Lingen, Germany. ANF operates a fuel assembly plant in Lingen, a tubing manufacturing plant in Duisburg, Germany, and a component machining facility in Karlstein, Germany.

The U.S. Business Unit is comprised of the Nuclear Division, Siemens Power Corporation (SPC-ND) (exclusive of the U.S. portion of the Research and Technology Unit), a subsidiary of Siemens U.S. Corporation, New York, New York. Siemens U.S. is a subsidiary of Siemens AG.

The Research and Technology Unit is comprised of employees from both the KWU-B and SPC-ND organizations. It is divided in its activities with fuel assembly development, testing, and materials functions performed in Europe, while methods and codes development and associated testing is performed in the U.S. A common manager integrates the Unit to support both Business Units.

Within the operating arrangement, the Chief Executive Officer (CEO) is accountable to the KWU Power Generation Group Board of Directors, a major Business Group of Siemens AG, and has overall responsibility for all aspects of the Nuclear Fuels Business. The CEO functions in a dual management role; as Executive Director of KWU-B and Senior Vice President/General Manager of SPC-ND. By virtue of this dual position, the CEO integrates the activities of the various legal entities and makes the operating arrangement effective.

To define overall quality requirements, the CEO has established a Global Quality Policy and a Global Quality Assurance Program for the Siemens Nuclear Fuels Business. These are applicable to all products and services provided by the Siemens Nuclear Fuels Business and compliance with policy and program requirements is mandatory.

The basis for the Global Quality Assurance Program is the European Quality Standard, DIN ISO-9000. Within the United States, Siemens Power Corporation - Nuclear Division has elected to restructure its Quality Assurance Program to be consistent with this standard. SPC-ND is also committed to comply with United States regulations, 10 CFR 50, Appendix B. It is the intention of SPC-ND to implement the more stringent requirements from either set of requirements to form a complete Quality Assurance Program. Appendix I has been provided to relate 10 CFR 50, Appendix B criteria with the corresponding ISO-9001 requirements and appropriate sections within the Topical Report.

The SPC-ND 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-ND in the implementation of the program.

Part II - QA Program, and Part III - QA Procedures, are signed off by members of SPC-ND 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. Internal QA audits are conducted to ascertain the effectiveness and proper implementation of the QA Program.

In several instances, SPC-ND has described requirements that are not contained in the Standard Review Plan or 10 CFR 50, Appendix B. SPC-ND reserves the right to modify the imposition of these additional requirements without NRC approval. In addition, compliance inspection should be limited to 10 CFR 50, Appendix B requirements exclusive of any additional requirements SPC-ND has elected to incorporate at its discretion.

1.0 MANAGEMENT RESPONSIBILITY AND ORGANIZATION

1.1 Quality Policy

1.1.1 General

It is the policy of the Siemens Nuclear Fuels Business to provide products and services that are sound, achieve customer satisfaction, and meet or exceed the established norms of the industry for the use intended. All products are to be provided with a high assurance against failure or malfunction, and without risk to the health and safety of the public. The use of a systematic, disciplined, and uniform approach to Quality Assurance is established to effectively comply with regulatory and customer requirements. Objective evidence must be provided to achieve confidence and to assure that the required quality standards are met.

1.1.2 Principles

In order to achieve the above objectives, the following quality principles are implemented throughout the global Siemens Nuclear Fuels Business:

- Quality Assurance requirements shall be established in all activities including development, marketing, design, procurement, manufacturing, inspection, delivery, and services. The quality of all activities in these areas shall be reviewed with the goal of continuous quality improvement.

- Emphasis shall be given to achieving the required quality by controlled processes, whereas inspection is performed to assure that the quality level has been met.

- Special consideration shall be placed on problem prevention rather than on problem detection and solution.

- All organizational units shall operate in compliance with this Global QA Program.

1.1.3 Directive

The management of the Siemens Nuclear Fuels Business shall cause their units to operate in compliance with the approved Global Quality Assurance Program. All personnel are required to strictly follow the objectives and principles of the Global QA Program, and associated affiliate-specific implementing procedures.

All employees shall be responsible to execute their individual assignments with specific attention to quality performance and its importance to their customers, whether they be end users or otherwise.

1.2 Organization

The responsibility and authority of all personnel who manage, perform, and verify work affecting quality shall be defined for the global and for the affiliate organizations.

1.2.1 General

The Siemens Nuclear Fuels Business operating arrangement is comprised of the following main segments:

- The European Business Unit, headquartered in Erlangen, Germany, and consisting of the Nuclear Fuel Cycle Division (KWU-B) of KWU Power Generation Group (exclusive of the European portion of the Research and Technology Unit), Siemens AG, and Advanced Nuclear Fuels, GmbH (ANF). (Figure 2)

- The U.S. Business Unit, headquartered in Richland, Washington, and consisting of the Nuclear Division of Siemens Power Corporation (exclusive of the U.S. portion of the Research and Technology Unit). (Figure 3)

- The Research and Technology Unit, co-located in Erlangen, Germany and Richland, Washington, jointly operated and staffed by KWU-B and SPC-ND personnel. (Figure 4)

Each affiliate maintains its own organizational and management structures. Management accountabilities and responsibilities within the operating arrangement are defined, in part, by provisions within the Global Quality Assurance Program, which defines integrated quality requirements applicable to the operating arrangement activities. Requirements within each affiliate's specific Quality Assurance program further define unique aspects of local authority regulations. The CEO has overall responsibility for Quality within the Nuclear Fuels Business and has delegated program definition, administration, and implementation to the Global Quality Assurance management function and affiliate Quality Assurance managers. These managers report directly to the CEO or affiliate General Managers and are independent from the line-operating organizations.

1.2.2 Global Quality Management

A senior manager within the operating arrangement is appointed to perform in the Global Quality Manager function by the Chief Executive Officer. The Global Quality Manager advises the Chief Executive Officer and coordinates the common quality activities of the various affiliates. This individual is charged with no global responsibility for engineering or manufacturing. This position is responsible for supervising the implementation of the global

quality assurance related activities including the interpretation of quality requirements, and for defining, developing, administering, executing, and auditing the Global Quality Assurance Program for the Siemens Nuclear Fuels Business. Specific responsibilities of the Global Quality Manager include:

- Preparation and maintenance of the Global QA Program.
- Coordination of QA procedures in cooperation with affiliate QA programs.
- Quality management reviews on the global level.
- Reporting of quality trends and quality related costs to the Chief Executive Officer.
- Coordination of quality and quality improvement programs between affiliates.
- Coordination of audits of each affiliate to verify implementation of the global Quality Assurance requirements.
- Definition of continuous improvement measures of quality management on the global level.

The Global Quality Manager function is supported by the Quality Assurance Managers within the affiliates. The Global Quality Manager may delegate specific tasks and responsibilities to be performed under his supervision to the respective QA organizations. The Global Quality Manager has the overall authority to make decisions on interfacing QA matters within the operating arrangement. This position has the authority to submit quality-related matters directly to the CEO. The Global Quality Manager has the organizational freedom and authority to identify and report quality problems; recommend, initiate, and provide solutions; verify implementation of solutions and initiate actions to prevent the recurrence of quality problems. The Global Quality Manager shall report audit results to the appropriate affiliate Manager and any significant deviations to the CEO. The Global Quality functional organization is depicted in Figure 5.

1.2.3 Affiliate Quality Assurance Management

The Quality Assurance Managers within the various affiliates are charged with no direct product, engineering, or manufacturing responsibilities. They are responsible for interpreting quality requirements and for the preparation and maintenance of Quality Assurance management systems within their respective organizations. These systems integrate the inter-organizational functions required to implement the Global QA Program, as well as define program elements which address local authority regulations. These systems are approved by the affected management. The Quality Assurance Manager of each affiliate is responsible for

implementing a comprehensive audit program to verify compliance with and determine the effectiveness of all aspects of the approved Global Quality Assurance Program. They have stop work authority for the affiliate and report the audit results, as well as any significant deviations, to their responsible management and to the Global Quality Manager.

With respect to Quality Assurance Program applicability to the Research and Technology functions, the location of the work activity determines which specific program is invoked. That is, the activities performed in Europe are conducted in accordance with the KWU-B affiliate specific QA Program, while the activities performed in the United States are controlled by the SPC-ND affiliate specific QA Program.

Specific responsibilities include:

- Preparation, interpretation, and administration of the affiliate QA program.
- Preparation, interpretation, and administration of QA procedures in compliance with the Global QA Program.
- Providing QA indoctrination and training covering the global and affiliate requirements.
- Providing program and executing audits within the affiliates.
- Performing vendor QA audits in compliance with the global requirements of the Global QA Program and affiliate QA procedures.
- Conducting and monitoring corrective actions.
- Interfacing with the other affiliates on QA matters.
- Conducting management reviews within the affiliate.
- Performing contract review as required to assure compliance to affiliate and Global QA requirements.
- Reporting regularly to senior management of the affiliate and to the Global Quality Manager on QA program status and quality trends.
- Participating in or performing QA audits in other affiliates upon request of Global Quality Manager.

1.2.4 Siemens Power Corporation - Nuclear Division Organization

1.2.4.1 Corporate Organization

Siemens Power Corporation is composed of a Fossil Division and a Nuclear Division, and is wholly owned by Siemens Corporation which, in turn, is wholly owned by Siemens AG. Siemens Power Corporation is incorporated in the State of Delaware and has its principal offices in Richland, Washington, with Sales support at Bellevue, Washington.

1.2.4.2 Company Organization

Siemens Power Corporation - Nuclear Division, hereafter referred to as SPC-ND, is responsible for the establishment and execution of the Quality Assurance Program applicable to reactor and fuel services, and nuclear fuel assembly design, procurement, and fabrication. The SPC-ND Quality organization is shown in Figure 6, while the balance of the SPC-ND Engineering and Manufacturing, as well as the Sales and Marketing, Projects and Services organizations are depicted in Figures 7 and 8, respectively. The Director, Quality is responsible for the establishment and execution of the Quality Assurance Program. This position reports to the CEO and has the authority to identify quality problems, to initiate remedial action, and to verify implementation of corrective action.

Responsibilities of key individuals who manage quality affecting activities within the scope of the QA Program are as follows:

1.2.4.2.1 Chief Executive Officer, Nuclear Fuels Business

The Chief Executive Officer, Nuclear Fuels Business reports to the KWU Power Generation Group Board of Directors, and holds the position of Senior Vice President/General Manager within SPC-ND. The CEO is responsible for establishing the Corporate SPC-ND Quality Assurance Policy, including goals and objectives, and ensuring that Corporate operations are carried out in full compliance with the policy. The CEO is also 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 CEO include establishing the Division's organizational structure and defining the participating management roles, as well as providing adequate resources to accomplish assigned objectives.

1.2.4.2.1.1 Director, Quality

The Director, Quality reports to the Senior Vice President and General Manager - Nuclear Division, and is responsible for providing Quality Assurance and Quality Control program management for all SPC-ND activities. The Director, Quality 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. The Director, Quality is responsible for interpreting quality requirements, and for defining, developing, administering, executing, and auditing the Quality Assurance Program in accordance with quality requirements. The Director, Quality has responsibility for the implementation of the quality assurance-related activities, including stop work authority. The Director, Quality also has responsibility for the overall establishment and execution of the Quality Control Program applied in the manufacturing process. In matters pertaining to Quality Assurance and/or Quality Control, the Director, Quality also has direct lines of communication to the Vice President, Sales and Marketing, Projects, and Services; to the Vice President, Engineering and Manufacturing; and to the Director, Research and Technology. Specific responsibilities include:

- Interpreting and administering the Quality Assurance Program.
- Ordering work stopped when the seriousness of a condition adverse to quality warrants such action in order to maintain the requisite quality.
- Developing 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.
- Developing and implementing quality enhancement initiatives and/or training programs in Quality Assurance requirements and practices to promote the understanding of quality requirements throughout the organization.
- Formulating and implementing Quality Control Programs to ensure adequate product quality.
- Monitoring and conducting corrective action follow-ups for Quality Assurance activities.
- Providing the necessary organization and qualified personnel to carry out the required Quality Assurance/Quality Control functions.

1.2.4.2.1.1.1 Manager, Quality Engineering

The Manager, Quality Engineering reports to the Director, Quality, and has responsibility for the quality assurance program and associated engineering functions, the quality control engineering functions, as well as the inspection gage calibration and control functions.

1.2.4.2.1.1.2 Manager, Analytical Services

The Manager, Analytical Services reports to the Director, Quality, and has responsibility for operating the analytical, physical testing, environmental, and bio-assay laboratories which support Uranium Operations, Environmental Monitoring, and Health Physics programs.

1.2.4.2.1.1.3 Manager, Inspection Services

The Manager, Inspection Services reports to the Director, Quality, and has responsibility for product/component inspection and certification to design requirements activities, as well as records review and release functions.

1.2.4.2.1.2 Vice President, Engineering and Manufacturing

The Vice President, Engineering and Manufacturing reports to the Senior Vice President and General Manager - Nuclear Division, and is responsible for the overall management of Engineering and Manufacturing activities 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, the Vice President's responsibilities include the functions of Materials and Scheduling; Safety, Security and Licensing; Manufacturing Engineering; Nuclear Engineering; and Product Mechanical Engineering. In the context of quality assurance, the Vice President also has the responsibility for ensuring that all manufacturing operations and engineering, especially those affecting product quality, are carried out in compliance with the SPC-ND Quality Assurance Program. The managers reporting to the Vice President, Engineering and Manufacturing are shown in Figure 7.

1.2.4.2.1.2.1 Various Shop Operations Managers

The Managers, Plant Operations and Components and Support Machining (hereafter referred to as Shop Operations) report to the Vice President, Engineering and Manufacturing, 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.

1.2.4.2.1.2.2 Manager, Materials & Scheduling

The Manager, Materials & Scheduling reports to the Vice President, Engineering and Manufacturing. Specific responsibilities include:

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

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

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

- 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.

- Development and implementation of Corporate Information Services related capabilities such as computing tools, facilities and support for fuel design and engineering analyses, as well as manufacturing and financial systems including Document Control.

- Assisting in the evaluation of vendors' capabilities.

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

- Maintaining the Approved Vendor List.

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

- Maintaining storage facilities and services for purchased material and components.

- Shipping completed fuel assemblies and other material.

- Planning of requirements and initiating purchase requisitions for fuel hardware.

- Maintaining inventory control of fuel hardware.

1.2.4.2.1.2.3 Manager, Safety, Security and Licensing

The Manager, Safety, Security and Licensing reports to the Vice President, Engineering and Manufacturing, and is responsible for plant physical security, radiological and industrial safety, and regulatory compliance.

1.2.4.2.1.2.4 Manager, Manufacturing Engineering

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

- Providing engineering support to plant operations in the areas of facilities, equipment/tooling, and maintenance.
- Performing plant and facility maintenance.
- Providing revised fabrication processes and Process Specifications.
- Providing routine process and engineering support in the areas of manufacturing methods and standards and coordinating automation activities.
- Providing Process Test Authorizations for qualifying new or significantly modified processes.

1.2.4.2.1.2.5 Manager, Nuclear Engineering

The Manager, Nuclear Engineering reports to the Vice President, Engineering and Manufacturing, and is responsible for providing neutronics, safety, and thermal-hydraulic analyses of fuel assemblies, cores, reactors, and their protective systems. This includes technical support to customers, as needed, for licensing of SPC-ND fuel and computer software and related services as required for on-line monitoring of BWR and PWR reactor power distribution and limits.

1.2.4.2.1.2.6 Manager, Product Mechanical Engineering

The Manager, Product Mechanical Engineering reports to the Vice President, Engineering and Manufacturing, and is responsible for preparation and integration within SPC-ND of the mechanical design drawings and specifications, stress analysis, fuel rod analyses, and Parts Lists.

1.2.4.2.1.3 Vice President, Sales and Marketing, Projects and Services

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

1.2.4.2.1.3.1 Bid/Proposal Preparation

The Bid/Proposal Preparation organization is responsible for the development of proposals in response to customer requirements and communication of design commitments to appropriate functional organizations within SPC-ND.

1.2.4.2.1.3.2 Project Management

The Manager, Project Management reports to the Vice President, Sales and Marketing, Projects and Services, and is responsible for project management of reload contracts in accordance with customer requirements and the SPC-ND QA Program.

1.2.4.2.1.3.3 Uranium Operations

The Manager, Uranium Operations reports to the Vice President, Sales and Marketing, Projects and Services, and is responsible for uranium procurement, inventory management, and delivery for customer utilization as required.

1.2.4.2.1.3.4 Far East Marketing

Far East Marketing reports to the Vice President, Sales and Marketing, Projects and Services, and is responsible for business development in Asia, including joint ventures, licensed activities, and direct contract scopes of supply utilizing SPC-ND Quality Assurance Programs.

1.2.4.2.1.3.5 Manager, Reactor Services and Systems

The Manager, Reactor Services and Systems reports to the Vice President, Sales and Marketing, Projects and Services, and has responsibility for Projects, Support, Site Services, Reactor Services and Systems Engineering, and affiliate programs. The manager ensures that company operations in assigned areas of responsibility are carried out in full compliance with established policies and guidelines. The manager is also responsible for producing the desired results within the allocated resources and for reporting of results to the Vice President, Sales and Marketing, Projects and Services.

1.2.4.2.1.3.5.1 Manager, RS&S Richland Support

The Manager, RS&S Richland Support reports to the Manager, Reactor Services and Systems, provides for monitoring of fuel performance during and after irradiation, and supplies important feedback to the fuel design process. Fuel inspection data is collected and is reported to other SPC-ND Engineering and Manufacturing organizations. RS&S Richland Support also maintains the fuel irradiation history data base.

1.2.4.2.1.3.5.2 Manager, RS&S Engineering

The Manager, RS&S Engineering reports to the Manager, Reactor Services and Systems, and is responsible for all engineering activities within the RS&S organization. Responsibilities of the organization include:

- Design control of new and modified test equipment/tooling.
- Software control and validation.
- Providing specifications for the calibration of test equipment.
- Providing NDE primary Level IIIs responsible for the certification/qualification program.

1.2.4.2.1.3.5.3 Manager, Site Services

The Manager, Site Services reports to the Manager, Reactor Services and Systems, and is responsible for the overall readiness of field personnel and equipment within the RS&S organization.

1.2.4.2.1.3.5.4 Manager, Projects

The Manager, Projects reports to the Manager, Reactor Services and Systems, and is responsible for the overall management of RS&S projects.

1.2.4.2.1.3.5.5 Manager, Affiliate Programs

The Manager, Affiliate Programs reports to the Manager, Reactor Services and 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.

1.2.4.2.1.4 Director, Research and Technology

The Director, Research and Technology reports to the Senior Vice President and General Manager - Nuclear Division, and is responsible for the following quality affecting activities: methods and codes development, fuel assembly development, and related testing.

1.2.4.2.1.4.1 Methods and Codes

The Manager, Methods and Codes reports to the Director, Research and Technology, and is responsible for the development of innovative and competitive engineering methods and codes which fulfill the needs of both Business Units. In addition, the Manager is responsible for code installation maintenance of existing products and testing programs which support methods development.

1.2.4.2.1.4.2 Fuel Assembly Development

The Manager, Fuel Assembly Development reports to the Director, Research and Technology, and is responsible for the development of innovative and competitive fuel assembly designs, related components, and testing methods/facilities. The Manager also directs related mechanical testing in support of fuel assembly development.

1.2.4.2.1.4.3 Materials and Technology Laboratories

The Manager, Materials and Technology Laboratories reports to the Director, Research and Technology, and is responsible for the development of advanced structural and cladding materials, as well as advanced manufacturing processes. The Manager also develops and performs related laboratory and irradiation testing.

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

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

1.3.1 Qualification requirements for the Director, Quality are:

- A bachelor's degree in a technical field.
- 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.
- Knowledge of applicable quality-related codes, standards, and regulatory requirements.
- Thorough knowledge of the SPC-ND Quality Assurance Program.

1.3.2 Qualification requirements for the Manager, Quality Engineering are:

- A bachelor's degree in a technical field.

- 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.

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

- Thorough knowledge of the SPC-ND Quality Assurance Program.

1.4 Verification of Resources and Personnel

In-house verification requirements are defined throughout the Global QA Program and in sub-tier documents.

Procedures require that verifications be performed by personnel independent of the function being verified.

1.5 Management Reviews

In all affiliates of the Siemens Nuclear Fuels Business, an annual review of the scope, status, implementation, and effectiveness of the QA program shall be conducted by the responsible management to assure that the program is adequate and complies with the applicable standards. The results are documented and reported to the CEO, the Global Quality Manager, and the respective QA Managers of the other affiliates.

At least every two years, the Global Quality Manager initiates a review of the adequacy and implementation of the Global QA Program. The results of the individual affiliate reviews, internal audits, customer satisfaction, and quality performance of the Siemens Nuclear Fuels Business are the basis of the review. The results of the management review are documented.

1.6 Management Team

In order to integrate the activities of the Siemens Nuclear Fuels Business, a management team of the principle line functions has been chartered to meet operating objectives established by the CEO. This group is comprised of the following functions:

- U.S. Business Unit
  - Sales & Marketing, Projects & Services
  - Engineering & Manufacturing

- European Business Unit
  - Sales & Marketing
  - Engineering
  - Manufacturing
  - Business Administration
- Research & Technology Unit
  - Research & Technology

This group meets periodically to formulate policies, adopt operating objectives, authorize projects, and review progress on a variety of business activities.

2.0 QA SYSTEM

2.1 Scope

The Global Quality Assurance Program is applicable for the sales and marketing, design, procurement, fabrication, inspection and testing of nuclear fuel assemblies, core components and related engineering services including irradiated fuel inspection, repair or reconstruction of irradiated fuel, in-core monitoring software and nuclear plant analyses. The program is also applicable to reactor systems and other fuel/reactor services. The QA Program ensures that the delivered nuclear fuel, systems, and services do not adversely affect the health and safety of the public.

This Global QA Program is applied in all affiliates of the Siemens Nuclear Fuels Business and is mandatory for all employees who perform work that will affect the quality of the product or the service. Implementation is achieved through QA procedures and sub-tier documents.

2.2 Related Regulatory Guides and National or International Standards

This Global QA Program is designed to satisfy the regulatory guides and standards, latest revision, listed below:

- ISO 9001 or ISO 9002, as applicable.
- 10 CFR 50, Appendix B, "Quality Assurance Criteria for Nuclear Plants."
- IAEA 50-C-QA, "Quality Assurance for Safety in Nuclear Power Plants" (European customers).
- KTA 1401 "General Requirements for Quality Assurance" (German customers).
- ANSI Standards and Regulatory Guides -- The applicability of ANSI Standards and Regulatory Guides is addressed in Appendix II. Exceptions to the ANSI requirements are as noted.

The applicability of ANSI Standards and Regulatory Guides is addressed in Appendix II. Exceptions to the ANSI requirements are as noted.

Additionally, when specified in a contract between an affiliate and a customer, other related standards or regulatory guides are committed to on a contractual basis. The principles for implementation of these requirements are reflected in this QA Program and more specifically in sub-tier documents. Revisions to the above documents shall be incorporated into the Global QA Program within 120 days.

2.3 Implementation of the Global QA Program

This QA Program defines the basic requirements to be fulfilled by all affiliates of the Siemens Nuclear Fuels Business. Each affiliate establishes and maintains Quality Assurance procedures which are in compliance with this Global QA Program. Procedures take into account the specific organization of the affiliate, the scope of activities, and regulatory requirements of the country where the affiliate is located.

For QA criteria which are to be treated in all affiliates in the same manner, affiliate QA procedures are coordinated to ensure that those activities are performed and controlled on an equal level within the Siemens Nuclear Fuels Business. To assure compliance with these global objectives, the QA procedures are reviewed and concurred or approved by the Global Quality Manager or his designee.

For SPC-ND, the Director, Quality is responsible for defining the content and changes to the QA program and manual. Review and approval and distribution responsibilities are defined in sub-tier QA procedures.

A matrix chart of SPC-ND QA procedures related to 10 CFR 50, Appendix B criteria is shown in Appendix III.

If special projects are undertaken that are not subject to all requirements of 10 CFR 50, 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 Special Project Authorization document is written to include necessary steps and requirements, including design, engineering, manufacturing, quality assurance, quality control, and purchasing.

- The Special Project Authorization shall be prepared and approved in accordance with Document Control QA procedures.

2.4 Classification of Characteristics

The products delivered by affiliates of Siemens Nuclear Fuels Business to utilities for their nuclear power plants are designated as being safety related.

In order to place the correct amount of emphasis on the more important materials, parts and components of the fuel assembly, or other reactor core components, the affiliates of Siemens Nuclear Fuels Business will implement a system of classifying quality characteristics in the design documents. The essential criteria for the classification are as follows:

Critical	A quality characteristic of a product, determined in the design documents or during the judgement of nonconformances, which, if the requirements are not met, could result in a reactor fuel failure. Such a deviation from the requirements, for example, could affect the reliability of a major component or a complete product.
Major	A quality characteristic of a product, determined in the design documents or during the judgement of nonconformances, other than Critical, which, if the requirements are not met, could result in excessive rework rates, costs or delays in delivery. Such a deviation from the requirements, for example, could reduce the usability of a component or the product.
Minor*	A quality characteristic of a product, other than Critical or Major, which, if the requirements are not met, does not reduce the reliability or usability of the component or product.

Based on the above classification criteria, the classification of characteristics is determined during the design process. They are identified in the product and material specifications and/or drawings, or where not specifically defined, are established by the design engineers in the course of evaluating nonconformances.

Product inspection or test frequencies take into account the assigned classification to ensure that appropriate importance is given to each characteristic.

2.5 Policies, Procedures, Instructions, and Drawings

In each of the affiliates, QA procedures are issued which cover all quality related activities of the affiliate. QA procedures in the affiliates give more detail for the implementation of the applicable criteria from the Global QA Program.

For all activities affecting quality including design, fabrication, inspection tests and service, adequate written procedures, instructions, and drawings are established, which include appropriate quantitative and/or qualitative acceptance criteria.

Compliance with the policies and procedures of the SPC-ND QA Program is mandatory for personnel performing activities affecting the quality of the nuclear fuel, systems, and services.

2.6 Revisions of the Global QA Program

This Quality Assurance Program document is to be reviewed each calendar year and revised if needed. The Global Quality Manager is responsible for collecting proposed changes from the affiliates and incorporating appropriate changes into the program. New or revised

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*Equivalent to "Standard" per DIN ISO 10205.

requirements of the Global QA Program requirements are to be implemented by the affiliates within 120 days following the issue of the revision, unless otherwise specified.

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-ND 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.

2.7 Overall Objective

It is the global objective of all affiliates of the Siemens Nuclear Fuels Business to coordinate efforts to meet requirements of all customers and regulatory agencies. This includes mutual acceptance of items such as:

- Process Qualifications.
- Design Verification.
- Acceptance Testing.
- Nonconformances.
- Audits.
- Computer Codes.

2.8 Quality Disputes

When required, disputes involving quality are referred to the next higher level of management for resolution.

3.0 CONTRACT REVIEW

New contracts or revisions to existing contracts shall be reviewed before they are signed. The review is conducted to verify that the requirements are adequately defined, and that the technical and organizational capability is provided or can be established.

The details of the scope of the review, the responsibilities, and the requirement for documentation are established in appropriate QA procedures. These procedures also delineate the requirements for transferring contract requirements to documentation.

4.0 DESIGN CONTROL

4.1 General

Quality Assurance measures for 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 QA procedures and supplementary 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 are utilized in design specifications for suitable materials, parts, equipment, and processes. Approved Product or Material Specifications are required to procure or fabricate materials for components for the nuclear fuel manufacturing process.

4.2 Design and Development Planning

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:

- Compatibility with reactor and co-resident fuel.
- Reactor physics, stress, thermal-hydraulic, and accident analysis.
- Optimum balance in fuel enrichment, life, and power costs.
- 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.
- Choice of physical parameters.
- Mechanical stability under service.
- Licensability.
- Choice of design methodology and Quality Assurance review approach.

4.2.1 Activity Assignment

Design and verification activities are planned and assigned to qualified personnel in accordance with affiliate QA procedures.

4.2.2 Organizational and Technical Interfaces Between Affiliates of the Siemens Nuclear Fuels Business

Organization and technical interfaces are covered in QA procedures and/or lower tier documents for design control by the involved affiliates.

4.3 Design Input

Technical requirements are defined in a design data package or in a set of design documents and are transferred into the design process via Design Criteria and, if necessary, additional documents. For lead assemblies, Design Criteria can be replaced by Technical Bases.

4.3.1 Design Criteria

Design Criteria are prepared in such a way that they are consistent with the principal technical requirements of the products for their intended use (boundary conditions and results of the underlying development activities), if necessary, with additional provisions resulting from special requirements and needs of the customer as reflected by the contract and with all applicable regulatory requirements. Design Criteria and other design documents described below are approved as stated in the applicable QA procedures.

4.3.2 Technical Bases

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

Technical Bases consist of theoretical or empirical information and data which identifies the specific technical foundation for selection of materials, items, processes, or of calculation methods and analyses to be used to establish and support the design criteria.

4.4 Design Output

Design output will be documented and expressed in terms of dimensional, material, testing and manufacturing requirements (drawings and specifications), design calculations, and analyses.

Design reports shall be prepared which describe or reference design and or acceptance criteria, show that these have been properly transferred into specifications and drawings, and evaluate and confirm that the design input requirements are met. The design output documents shall also demonstrate that the appropriate regulatory requirements are met, and they shall identify those characteristics that are essential to the safe and proper functioning of the product.

4.4.1 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, Material 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.

4.5 Design Verification

The adequacy of product designs may be verified in several ways, including in-reactor experience of similar design, performance of design reviews, alternative calculations, or design testing. The depth of design reviews and verifications depends upon the complexity and end use of the item. The extent of design verification or Quality Assurance review will be determined by the degree of deviation from previous design work activities. A graded approach to review scopes which recognizes differences in routine versus newly developed analytical techniques will be utilized. The type of review and basis for selection will be documented for each design product. The individuals responsible for performing design verification activities should include persons other than those who performed the original design. Use of the design engineer's manager for design verification is restricted to special situations where the manager is the only available individual within the design organization competent to perform the verification. Design verification activities are performed in accordance with sub-tier Quality Assurance and Engineering procedures.

4.5.1 Design Reviews

Reviews of fuel designs and related documentation are performed to determine adequacy of the design, to assure customer requirements are met, to assure that design parameters can be controlled during manufacture, 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 or project design review summary reports. The results of design review are documented and recorded according to the provisions of Section 16 of this program.

4.5.2 Alternative 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 agree 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.

4.5.3 Qualification Tests and Demonstrations

If necessary or appropriate, test programs are utilized to verify design adequacy; these 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. Comparing the new design with a similar proven design or the use of existing data from previous tests may also be valid for a verification of new designs provided the designs are adequately similar. In such cases new testing may not be required.

4.5.4 Design Errors

Design errors and deficiencies that adversely affect quality are dispositioned as per sub-tier QA and Engineering procedures.

4.6 Design Change Control

Design changes to previously approved and issued design documents shall be reviewed and approved in the same manner as the original document, in accordance with the current issue of a 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.

4.7 Experience Feedback from Reactor Services and Fuel Manufacturing

Experience from fuel manufacturing and results of reactor service or problems discovered during manufacturing or service activities are reported to the fuel design organizations. This information shall be considered during the fuel design process.

4.8 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:

- Preparation and review of Design Criteria, Product Specifications, Materials Specifications, and Drawings.
- Design reviews.
- Calculational checks.
- Design testing.

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

5.0 DOCUMENT CONTROL

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, parts lists, drawings (tracings and reproductions), reports, manuals (such as QA manuals), and other materials which define the nuclear fuel products or affect fuel or engineering services quality are controlled documents.

5.1 Document Approval and Issue

Document Control is required to assure that documents (which include drawings by definition) affecting quality and changes thereto are identified and approved by authorized personnel, and properly distributed, stored, recalled, and disposed of. Details of the document control system are defined in affiliate QA procedures.

5.1.1 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 distribution list, and revising as necessary.

Affiliate document control functions are responsible for distributing documents to essential operations and for recalling obsolete documents.

5.1.2 Special Control Provisions

In order to avoid the unnecessary shutdown of key production operations, affiliate Quality Assurance procedures may 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 an 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.

5.2 Approval of Changes

Changes to previously issued documents are approved in the same manner as original versions. Management organizations 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.

Document Control procedures require that information on the latest or applicable revision be available to the user and that the nature of changes in revisions be available where applicable.

5.3 Document Availability

Documents are available at controlled mini-library locations where the activity is performed.

5.4 Obsolete/Superseded Documents

Obsolete or superseded documents are controlled in accordance with sub-tier procedures.

6.0 PURCHASING

6.1 General

Procurement documents are established for material, equipment, and services which are safety related. The details for the procurement documents are established in QA procedures and implementing documents. Requirements from the approved Product Specifications, Material Specifications, and Drawings are transferred into procurement documents. Additionally, the procurement documents shall be in compliance with internal instructions, manufacturing and testing procedures, and Quality Assurance requirements.

6.2 Selection of Sub-Contractors Within the Siemens Nuclear Fuels Business

The individual manufacturing plants select their sub-suppliers (vendors) based on evaluation of their capability to provide items or services in accordance with all applicable (global and affiliate specific) procurement requirements. Determinations of vendor capacity involves an integrated evaluation by a group, the makeup of which is 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 a combination of the following methods:

- Evaluating the vendor's history of providing a quality product based on analysis of vendor survey records, audit reports, or other appropriate methods.
- Evaluating vendor's current quality records, including the vendor's QA program, manual, and procedures, as appropriate.
- 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 major components used in production fuel or other safety related applications, a source evaluation is conducted to assure that the vendor maintains a Quality Assurance Program and an appropriate organization, and that they can effectively demonstrate the controls within their own plant and those of their 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.

A Global Approved Vendors List is maintained and is applicable to all affiliates.

6.2.1 Vendor Audits

The Global Quality Manager shall determine the affiliate to perform the qualification of the individual vendor (see list of approved vendors).

These audits are performed in accordance with Quality Assurance audit procedures 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, though discretion to perform audits on a two year frequency based upon vendor quality performance is retained by the Director, Quality. 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. Audits by one of the affiliate's QA organizations are valid for all of the Siemens Nuclear Fuels Business unless otherwise indicated.

6.3 Purchasing Data

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

- A statement of work to be performed.
- Technical requirements regarding specific drawings, specifications, codes, regulations, procedures, or instructions including test and inspection requirements, and special process instructions.
- Quality Assurance Program requirements.
- Submittal of vendor's Quality Assurance Program (manual) and access to the vendor's QA/QC procedures.
- Standard clauses for access to their plant and records, performance of source inspection, and auditing their QA system and those of their subvendors.
- Identification of documentation required to be submitted, including Quality Assurance records, for information, review, or approval of the purchaser.
- Retention and disposition requirements of quality related records not delivered to the Purchaser.
- Submittal of Process Outline and QC Inspection Plan to the purchaser, including process hold points.
- Requirements for control and approval of vendor nonconformances.
- Source inspection requirements.
- Requirements for extension of applicable Quality Assurance requirements to sub-tier procurements.

Specific review and approval of quality requirements in procurement documents are conducted in accordance with sub-tier procedures.

Procurement documents showing review and approval shall be maintained as QA records and available for verification.

Procurement document changes receive the same approval as the original for the specific requirements that are changed.

6.4 Verification of Purchased Product

Purchased product verification is performed at receipt inspection and/or at source inspection. Source inspection does not, however, replace vendor inspection of the final product.

6.4.1 Vendor Source Surveillance

Vendor product source surveillance is the responsibility of Quality Control, in accordance with written procedures, to assure the purchase order requirements are being met. Performance may be delegated, as applicable. 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. 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.

Vendor process audits and product related qualifications are conducted, as applicable, or as required by contract.

6.4.2 Purchased Material Receipt Inspection and Release

Purchased material is received, identified, and stored in accordance with written procedures. Vendor certifications are required for fuel product line related procured components and materials. Purchased material is inspected by Quality Control in accordance with Quality Control Standards and released 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 Quality Control procedures. Continuing assessment of the effectiveness of vendors control of quality is conducted by reviewing incoming product quality during the release process.

6.5 Product and Service Transfer Between Affiliates

For the product and service transfer between the affiliates of Siemens Nuclear Fuels Business, a written inter-affiliate order is used.

Material received from another affiliate is inspected for completeness and possible shipment damage. The certificates are reviewed for compliance with the requirements from the internal order.

The ultimate responsibility for quality of the product and service remains with the affiliate, who delivers the final product or service to the customer.

7.0 PURCHASER SUPPLIED PRODUCT

In the Siemens Nuclear Fuels Business, Uranium hexafluoride (UF_6) is an example of purchaser supplied product. The material is tested and stored using affiliate procedures for the site involved.

Engineering analyses and software are examples of non-hardware types of purchaser provided products.

7.1 Purchased Material Certifications

Quality Control reviews vendor certifications, records, and receiving inspection results, and releases material in accordance with approved procedures.

If the purchaser supplied product is found to be nonconforming, a written notification shall be issued to the purchaser and work shall not proceed until the nonconformity is satisfactorily resolved.

8.0 PRODUCT IDENTIFICATION AND TRACEABILITY

8.1 Identification

Procedures are established to assure control of product or process materials and to maintain traceability through receipt of material to final shipment. The procedures require that identification be maintained either on the item or on the records traceable to the item. Stamping, tags, labels, and lot follower cards 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 is 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 in the specifications and on drawings, respectively.

8.3 Records

A comprehensive system of fabrication and inspection records is maintained by the originating affiliate to assure that material identification, inspection status, and fabrication status are explicitly identified, including:

- Vendor certification.
- Results of test and inspections obtained on-site (receiving, in-process, and final inspections).
- Releases of material.
- Status and disposition of "hold," "conditionally released," "nonconforming," or "reject" items.
- Follower cards or activity check lists.

8.4 Loss of Identification

Any material, component, subassembly, or assembly which loses its identification is considered nonconforming until such time as the identity can be established or the item is dispositioned by the nonconforming material control system.

9.0 PROCESS CONTROL

9.1 General

9.1.1 Instructions and Parameter Sheets

Approved instructions and parameter sheets are issued on the basis of qualification. The instructions include requirements for in-process control of process and product characteristics in order to monitor that the process is in the specified conditions. The overall manufacturing process may be defined by a Manufacturing and Examination Sequence Plan (MESP), as applicable.

9.2 Process and Equipment Qualification

Production and inspection and test equipment is procured and constructed on the basis of approved design specifications and drawings. New equipment or major changes to existing equipment require qualification prior to their application.

Approved qualification programs are established for the production and inspection processes which may affect the product quality. Applicable codes and standards are implemented into the qualification program. The qualification programs include, if applicable:

- Qualification objectives.
- Instructions for the qualification.
- Required tests and inspections.
- Required documentation.
- Qualification requirements for personnel.

When the qualification is performed, a qualification report is issued which summarizes the results of the qualification and defines the parameters and conditions for the process.

9.3 Control of Prohibited Material

Controls are established to assure that materials detrimental to fuel performance are sufficiently controlled or 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.

9.4 Special Processes

Processes in which the quality achieved depends on the performance of the process and the results cannot be fully verified by subsequent inspections and tests are considered as special processes and are covered by more in-depth controls. These controls assure that equipment and procedures are adequately evaluated and personnel are adequately qualified to perform their assigned tasks.

Applicable special processes and tests include welding, heat treating, liquid penetrant testing, radiography, helium leak testing, ultrasonic testing, eddy current testing, and nuclear rod assay. These special processes and tests are subject to the following general criteria, as required by implementing documents:

- Qualified operators are used.
- Qualification of operators is documented.
- Special process qualification procedures are reviewed and approved.
- Practices are consistent with approved procedures and appropriate codes and standards.
- Test results are documented and reviewed for acceptability.
- Records of test results and qualifications are maintained.
- Controls are provided to assure that personnel qualification records are regularly reviewed and appropriate requirements for requalification are implemented.
- Controls or requirements are placed upon critical materials used in the manufacturing process such as weld gas, furnace gas, cleaning solutions, etc., through the use of Essential Material Specifications.
- In-process inspection and testing.

9.5 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.

9.6 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.

9.7 Computer Code Control

Before their application, new and modified computer codes used in the functional and mechanical design of fuel assemblies and other core components, as well as for their manufacture and inspection, shall be subjected to extensive testing and re-testing to demonstrate their satisfactory applicability for the intended purpose.

10.0 INSPECTION AND TESTING

Inspections are performed for the purpose of verifying conformance of items or activities to specified requirements using approved procedures. Inspection hold points are established in approved procedures whereby material may not proceed until inspected and released.

Approved plans, instructions, and procedures are issued and include the following information where applicable:

- Identification of the item and/or the characteristics to be inspected or tested.
- Sampling plan to be applied.
- Equipment and/or method to be used for the inspection, test, or analysis.
- Acceptance and rejection criteria.
- Record requirements.

10 1 Receiving Inspection and Testing

Incoming material or components are inspected and/or tested for compliance with the specified requirements in accordance with approved procedures, which include the review of certificates provided by the supplier. Materials or components are only released for further production if those are acceptable according to established criteria. The results of the receiving inspections are documented. Materials supplied by an affiliate of the Siemens Nuclear Fuels Business are processed per the Purchasing Section.

10.1.1 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 procedures. Releases become part of the Quality Assurance Records as described in Section 16.

10.1.2 Conditional Release

Conditional release of material beyond Process Quality Control hold points may be initiated by completion of a Conditional Release. 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. Conditional Releases shall be converted to Full Releases, at the latest, prior to product shipment.

10.1.3 Inspector Qualifications

Inspectors and special test operators are qualified in accordance with applicable procedures and as specified in Section 9.4.

10.1.4 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.

10.2 In-Process Inspection and Testing

Procedures for in-process inspections are established and include indirect control by monitoring processing methods and parameters, equipment, and personnel where direct inspection is not practicable.

In-process inspections are documented on manufacturing routers/travellers, computer systems, etc. Preceding steps are required to be signed off as completed 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.

Nonconforming items or products are tagged when identified in the course of inspection.

10.3 Final Inspection and Testing

Final inspection and testing is performed in accordance with approved procedures and is documented on the manufacturing routers/travellers or on other inspection records.

10.4 Inspection and Test Records

Identification of the person performing the inspection and the inspection results are recorded on the applicable inspection record sheet. Manufacturing routers/travellers, inspection record sheets, and computer data become part of the Quality Control records.

11.0 INSPECTION, MEASURING, AND TEST EQUIPMENT

Procedures are established for the control of inspection, measuring, and test equipment, which can directly affect product quality, used in the fabrication and inspection of fuel and fuel components.

Inspection, measuring, and test equipment is defined as those devices used to measure characteristics for the purpose of determining acceptance of items to specified product requirements and process requirements where subsequent inspection is not performed.

11.1 Procedures

Approved procedures describe the control, calibration, and maintenance program for inspection, measuring, and test equipment.

11.2 Calibration and Control

This QA program imposes the following requirements which are specified in sub-tier Quality Control procedures:

- Traceability of calibration standards according to national or international standards, where such standards exist. In the event there are no national or international standards, the basis of the calibration is documented.
- Equipment within the scope of this program is procured, controlled, and used to ensure the required degree of accuracy, reproducibility, and traceability.
- Purchase Orders for equipment are checked to ensure that the accuracy of the equipment is sufficient for its intended use and that the specifications, certified calibration by the vendor or use of an approved vendor if applicable, and the shipping requirements have been identified.
- 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.
- Nonconforming equipment is clearly labeled and its use prohibited or suitably restricted until repaired or calibrated.
- Records are maintained which indicate the calibration status and dates of previous calibrations.

- Environmental conditions for calibration.
- Handling and safeguarding of equipment.
- Use of test hardware (fixtures, templates).

11.3 Out-of-Calibration Equipment

Inspection, measuring, and test equipment actively being used to determine product 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 equipment was suspected of being out of calibration. Only when the evaluation reveals that the degree out of calibration impacts the validity of previous inspections will action be taken regarding previous inspections.

11.4 Calibration Records

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

12.0 INSPECTION AND TEST STATUS

Controls are established to assure that the inspection and processing status of 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 materials, components, and assemblies are adequately identified:

- 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.

- Inspector or operator identification is entered on the identity/control documentation to signify the completion of operations or inspections.

- Inspection forms and lot cards are controlled in accordance with established procedures. Manufacturing routers/travellers are controlled in accordance with manufacturing procedures. Fuel reconstruction checklists are generated for each specific project. These forms, plus Quality Control releases, assure that traceability to starting material is maintained.

- 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.

- Rejected items are tagged and separated from acceptable items per nonconforming material control procedures to prevent their inadvertent use.

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

- 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.

13.0 CONTROL OF NONCONFORMING PRODUCT

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

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 by repeating an approved process step, in accordance with approved rework procedures, or are processed in accordance with the applicable QA procedure. Nonconforming material reports are originated, if required. 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 is subject to the following controls:

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

13.1 Nonconformity Review and Disposition

Processing of nonconforming material reports is as follows:

- The nonconformance is evaluated by representatives from Engineering, Manufacturing, and Quality Control, sometimes referred to as the Material Review Board, and a disposition is recommended. Description may be:
  - Use-as-is.
  - Rework to meet specified requirements.
  - Accept with repair.
  - Reject as scrap.
- Use or accept with repair dispositions of nonconformances involving critical characteristics 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.

- Copies of approved nonconformance reports are placed in the Quality Control release files for the affected material. In addition, a final product nonconformance report is sent to customers in accordance with the applicable Quality Assurance procedure.

- Items dispositioned "reject" 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.

- Corrective action is initiated and verified for implementation, as appropriate, to assure that the causes of quality problems are identified and corrected.

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

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

13.2 Trend Analysis

Quality Control reviews, evaluates, and reports trends on nonconforming items in accordance with sub-tier procedures.

14.0 CORRECTIVE AND PREVENTIVE ACTION

Nonconforming conditions, significant processing incidents, inspection or design inadequacies, or other events which can adversely affect product quality, are reported to appropriate levels of management for review and assessment. Formal disposition of nonconformances and corrective action is promptly taken for significant conditions adverse to quality, the results are documented and reviewed for effectiveness. Preventive actions are established to deal with generic implications of quality problems to preclude recurrence.

14.1 Disposition of Nonconformances

Disposition of nonconformances involves a determination of actions to deal with the known condition of items which deviate from acceptance criteria. Typical dispositions include use-as-is, repair, rework, or scrap.

14.2 Corrective Action for Nonconformances

The development of corrective actions involves resolution of the causes of nonconformances to prevent recurrence. Technical review and corrective action recommendations on nonconformances are made by those responsible for approving nonconformances. Requests for corrective action by vendors are submitted in writing to the responsible vendor. Follow-up actions are documented to identify that the corrective actions were implemented and effective.

14.3 Preventive Action for Generic Implications

To support continuous quality improvement, preventive actions are established when formal evaluations of adverse conditions identify weaknesses in process or program controls which could affect product quality under different circumstances. The extent of preventive action is determined by the magnitude of the potential problem and is commensurate with the commercial risks involved.

14.4 Incident Reviews

14.4.1 Incident Review Boards

Incident Review Boards (IRBs) are convened to investigate significant conditions adverse to quality that are determined to have a potentially major impact on product or process quality. The majority of members serving on incident reviews shall 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 or preventive action, as appropriate, to minimize recurrence.

14.4.2 Incident Review Board Reports and Follow-up

A final incident review report is issued and distributed to appropriate management responsible for directing implementation of corrective or preventive action. The Quality Assurance or Quality Control function, as defined on a case-by-case basis, is responsible for taking any follow-up action necessary to verify that the appropriate corrective or preventive action has been taken and that it is effective.

14.5 Audits

Corrective or preventive action, in response to customer and regulatory agency Quality Assurance audits or inspections, is documented. Internal audits are documented in accordance with Quality Assurance procedures and lower tier documents. Follow-up reviews are conducted, as required, to verify the implementation of corrective or preventive action.

14.6 Procedures

Approved procedures are established for the disposition of nonconformities, control of corrective actions, preventive actions, and treatment of incidents.

The procedures for disposition of nonconformances and corrective action address:

- Responsibilities for identification and disposition of nonconformances, initiation of corrective actions, and follow-up.
- Requirements for investigation of root causes of nonconformances using formal cause determination methodologies.
- Requirements for analysis of nonconformances, process deviations, audit findings and customer complaints for the need of corrective actions to address conditions adverse to quality.
- Initiation and implementation of formal corrective actions.
- Verification of the implementation and effectiveness of corrective actions.
- Documentation requirements.

The procedures for preventive action address:

- Responsibilities for initiation and implementation of preventive actions and follow-up.
- Verification of the implementation and effectiveness of preventive actions.

- Documentation requirements.

The procedures for the treatment of incidents address:

- Responsibilities for the establishment and make-up of Incident Review Boards.
- Requirements for the development and implementation of corrective or preventive actions, as well as follow-up to verify implementation and effectiveness.
- Documentation requirements.

15.0 HANDLING, STORAGE, PACKAGING, AND DELIVERY

15.1 General

Procedural controls are established to assure that purchased materials, shipping containers, equipment, fuel fabrication components, and completed fuel assemblies are handled, stored, shipped, and preserved in a manner such that quality is not adversely affected. Trained individuals accomplish the special handling, storage, and preservation in accordance with predetermined work and inspection instructions. Where special controls are not required for handling, storage, and preservation, standard material handling and transportation methods are used to protect against physical damage.

15.2 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 fuel components, rods, and assemblies in the shops are included in appropriate procedures. Handling instructions for both systems and physical handling of components at receipt are to be in accordance with established procedures.

15.3 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 on nonconforming items.

15.4 Packaging and Preservation

Written instructions for preservation assure that items intended for incorporation into 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 final shipping. Packaging of fuel assemblies is inspected by Quality Control per written instructions prior to shipping.

15.5 Delivery

Shipping of nuclear material is performed in accordance with national and international regulations. For shipments of non-nuclear reactor components common carriers are selected.

Upon receipt of nuclear fuel at the customer's plant, receiving inspection is performed by affiliate inspectors with the assistance of customer personnel, unless otherwise specified. The inspection criteria are based on a written procedure, which is mutually agreeable to both parties. The procedure provides for the formal customer acceptance of the fuel after the inspection.

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-ND facilities and is provided to the customer. The certificate assures that the following requirements were reviewed and met:

- The items have been produced in accordance with approved specifications or approved nonconformance reports thereto.
- The items have been subjected to and have satisfactorily passed applicable inspections and tests and have been released by Quality Control.
- The items are complete and fully assembled as required.
- The items were designed, procured, fabricated, and packaged in accordance with the Quality Assurance Program.

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

16.0 QUALITY RECORDS

Quality Assurance procedures address identification, collection, indexing, filing, storage, maintenance, and disposition of quality records.

Documents and records sufficient to characterize the product design, materials used, and process by which the product was fabricated, material and fabrication history, and the quality achieved are maintained 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, inspections, tests, audits, and material analyses.
- Monitoring of work performance.
- Qualification of personnel, procedures, and equipment.
- Other documentation such as drawings, specifications, procurement documents, calibration procedures and reports, nonconformance reports, and corrective action reports.
- Logbooks are utilized for in-process record keeping and are not considered QA records.

16.1 Records System

Quality 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, reference to appropriate contract, purchase order, work order, drawing, specification, and/or procedures. Records of inspection and testing of products contain the following information, as applicable:

- Identification of the record and the item to which it applies.
- Description or identification of the observation.
- Evidence of completion of the inspection or test.
- Date of the inspection or test.
- Inspector identification.
- Evidence of acceptability or condition adverse to quality.

16.2 Record Storage and Retention

Documents designated as quality records are transmitted to and retained in permanent storage to protect against deteriorating damage or loss, or are maintained in temporary satellite files. Designated Quality records not stored in the Central Files vault are stored either in two physically separated locations or in fire-resistant file cabinets.

Designated quality records are transferred from satellite files to controlled storage within the time interval specified in the applicable QA Procedure. Designated Quality records are stored so as to provide for timely retrieval of information. Retention periods are indicated in Quality Assurance procedures.

16.3 Customer Records

Customer records are provided in accordance with contract requirements at completion of the individual projects.

17.0 QUALITY 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 QA procedures. The audits include the evaluation of work areas, activities, quality-related practices, and review of documents and records. The audit program includes external audits of vendor activities, as well as internal audits. Audit reports are documented and distributed to appropriate management and necessary corrective actions are taken to correct noted deficiencies.

17.1 Categories of the Audits

17.1.1 Internal Audits

Global QA Audits -- The program for the audits of the affiliates for compliance with this Global QA Program is documented. Audits of the affiliates are conducted by an audit team which consists of the Global Quality Manager or his designee and qualified auditors from selected affiliates, except for the affiliate being audited. Applicable criteria from this Global QA Program are covered in the audits which are performed at least every two years.

Affiliate QA Audits -- Internal audits within the affiliates are established in QA procedures and are directed by qualified personnel who have no responsibilities in the area being audited. Subject matter experts may be included on audit teams to enhance the effectiveness of the audits. All applicable criteria from the QA procedures of the affiliate are covered by this audit program.

The audit programs or procedures include:

- Quality Assurance system audits of the adequacy and implementation of criteria of this Global Quality Assurance Program and the affiliate QA procedures, such as document control and identification and control of materials.
- Processing/inspection audits of manufacturing and inspection operations.
- Special audit of non-routine activities as deemed necessary.
- Process and product audits if required by customer or management.
- Audit frequencies.
- Documentation review audits of the adequacy and consistency of Quality Assurance Program documentation.

17.1.2 Quality Assurance Vendor Audits (External Audits)

The program for vendor audits is established in QA procedures. The program provides:

- Criteria for vendor audits based on vendor activity and required quality.
- Audit frequencies.
- Requirements for reporting of audit results to the vendor.

17.1.3 Customer or Authority Audits

Audit findings with global implications performed at affiliates shall be distributed to all affiliates.

The responsibility for coordinating customer and authority audits is with the QA Manager of each involved affiliate.

The respective QA Managers of each affiliate, and the Global Quality Manager, shall inform each other about scheduled audits if the affiliate is directly concerned with audits performed by customers or authorities.

This information shall contain:

- Schedule of the audit (audit program).
- Scope of the audit (system, product, or process related).
- Results and possible corrective actions to be taken.

17.2 Procedures

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

- Types and frequency of audits.
- Responsibility and training of Lead Auditors.
- Planning and scheduling of audits.
- Preparation of audits, including notification.
- Conduct of audits, including conferences as required.

- Preparation, issuance, and distribution of audit reports.
- Follow-up, including commitments, status, and reporting of open items and re-audits.
- Audit records.

17.3 Audit Performance and Reports

Audits are conducted by appropriately trained, experienced personnel. Audit Team Leaders are generally from the QA organization and have no responsibility 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 audits are issued to the management of the organization audited.

Audit frequencies are based on the status and safety related 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.

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; however, the Director, Quality still retains full responsibility for the effectiveness of the audits. The Director, Quality is also responsible for vendor Quality Control inspection activities and may delegate this responsibility to other independent groups or organizations.

17.4 Corrective Action/Follow-up

Audit results are reviewed by the responsible supervisor 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.

Re-auditing is conducted as applicable to verify implementation of corrective action from earlier audits.

18.0 **TRAINING**

Comprehensive training programs for all personnel whose activities affect the quality of products or services are established in procedures in each of the affiliates.

These procedures address:

- Responsibilities for performing the training.
- Indoctrination and training on the Global Quality Assurance program and procedures.
- Job related training for the different tasks.
- Special training and certification for special processes in accordance with applicable recognized codes and standards.
- Auditor qualification training.
- Requirements for retraining and recertification.
- Requirements for establishing and maintaining training records.

18.1 Indoctrination

A general indoctrination session is presented to all personnel who perform activities affecting quality. This session is presented to new personnel shortly after they begin work. The purpose of the indoctrination session is to familiarize personnel with the Quality Assurance program requirements and the manner in which it is implemented. Retraining is performed periodically.

18.2 Job-Related Training

Assessment of education and experience is used to determine the type and extent of training necessary to perform a specific job. Highly technical jobs (for example, in Engineering) may require extensive education and prior experience before an individual is qualified to perform work without oversight or assistance. Qualifications for entry-level jobs (for example, in manufacturing operations) emphasize on-the-job training with supervisory oversight until sufficient skill/knowledge is demonstrated.

The respective supervisor/manager is responsible for defining, implementing, and documenting appropriate training to assure that employees achieve and maintain proficiency needed to carry out their assignments. Activities which may be used to accomplish this training include:

- On-the-job training.

- In-house training programs.
- Specialized training by industry, professional societies, universities, or outside consultants.

19.0 SERVICING

Servicing activities are performed in accordance with the applicable portions of the Siemens Nuclear Fuels Business QA program.

Activities include but are not limited to:

- Fuel post-irradiation analysis.
- Irradiated fuel examination and failure detection.
- Irradiated fuel repair/reconstitution.
- Plant Component Inspection.

Approved procedures are utilized and include:

- Qualification requirements for service personnel.
- Purchasing and qualification of service equipment.
- Instructions and procedures for performing the service or analysis.
- Requirements for documentation of the service activities.

20.0 STATISTICAL TECHNIQUES

It is the intent of the Siemens Nuclear Fuels Business to develop and apply manufacturing processes which demonstrate a minimum of variability to ensure consistent, high quality product characteristics. Further, our intention is to build quality into our products by monitoring and taking control action as close to the source of variability as possible. To provide timely response actions and firm technical bases for the qualification/control of processes and product/component certification, Siemens Nuclear Fuels Business shall maximize the application of statistical techniques, especially statistical process control (SPC). Procedures shall be established, where appropriate, in the areas of engineering, production, and inspection which utilize statistical techniques to verify/control process capability and to certify acceptable product/component characteristics.

Examples where statistical techniques should be considered include:

- Statistical Process Control for key manufacturing processes and/or component attributes in the following areas:
  - UF_6 Conversion
  - UO_2 Powder Preparation - Isotopic Blend
  - Pellet Attributes
    - Chipping
    - Diameter
    - Surface Finish
    - Grain Size
    - Density
    - Land/Dish Dimensions
  - Spacer Envelope
  - Rod Length, Diameter, and Wall Thickness
  - End Cap Dimensions
  - Rod Welding Parameters
  - Tie Plate Dimensions
- Product/Component Certification.
- Inspection planning and sampling of important characteristics.
- Process of Equipment Qualification.
- Analysis of inspection data/determination of defect rates.

21.0 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 are controlled QA documents, and include appropriate quantitative or qualitative acceptance criteria to verify that important activities have been satisfactorily accomplished. Preparation, review, and approval are conducted in accordance with sub-tier procedures.

21.1 Quality Assurance and Quality Control Documents

21.1.1 Quality Assurance Program

The SPC-ND 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 5.

21.1.2 Quality Assurance Procedures

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

21.1.3 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.

21.1.4 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.

21.1.5 Analytical Procedures

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

21.1.6 Metallurgical Procedures

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

21.2 Product Definition

21.2.1 Design Criteria

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

21.2.2 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.

21.2.3 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.

21.2.4 Technical Bases

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

21.3 Process Specification Documents

21.3.1 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.

21.3.2 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.

21.4 Procurement

21.4.1 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.

21.4.2 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.

21.4.3 Purchase Orders

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

21.5 Manufacturing

21.5.1 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.

21.5.2 Standard Operating Procedures

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

21.6 Reactor Services and Systems Documents

21.6.1 Reactor Services and Systems Procedures and Practices

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

21.6.2 Reactor Services and Systems Cover Procedures

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

21.6.3 Reactor Services and Systems Standard Operating Procedures

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

21.6.4 Performance Evaluations

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

21.6.5 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.

21.7 Temporary Deviations

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

- 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.

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

- The Temporary Deviation is documented prior to use and a description of the change is distributed to all signataries of the original document, Document Control, and Director, Quality within one working day of affectivity 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.

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

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

22.0 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 site 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-ND 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 signers and others who have a technical interest, and a copy is filed with Document Control as a permanent record.

22.1 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:

- Introduction/purpose/scope.
- Justification.
- Identification of material and equipment to be used.
- Requirements or acceptance limits contained in applicable design documents.
- Duration of test.
- Instructions for required activities.

- Effect on product material or processes, including provisions for controlled environmental conditions.
- Calibrations required.
- Mandatory inspection or hold points, if required.
- Assignment of responsibilities including use of appropriately trained or qualified personnel.
- Record requirements and recording of results.
- Disposition of material and equipment.
- 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 result summaries require concurrence by the Managers, Product Mechanical Engineering and Quality Control.

Special Test Authorizations may be several types:

- Process Test Authorizations (PTAs).
- Design Test Authorizations (DTAs).
- In-Reactor Performance Evaluation Authorizations (IPEAs).

22.1.1 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.

22.1.2 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.

22.1.3 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:

- The evaluation shall be requested by or discussed with and approved by the customer before starting fabrication.
- The mechanism for review and approval shall be via an IPEA.

Figure 1

Siemens Nuclear Fuels Business
Operating Arrangement
Functional Relationship

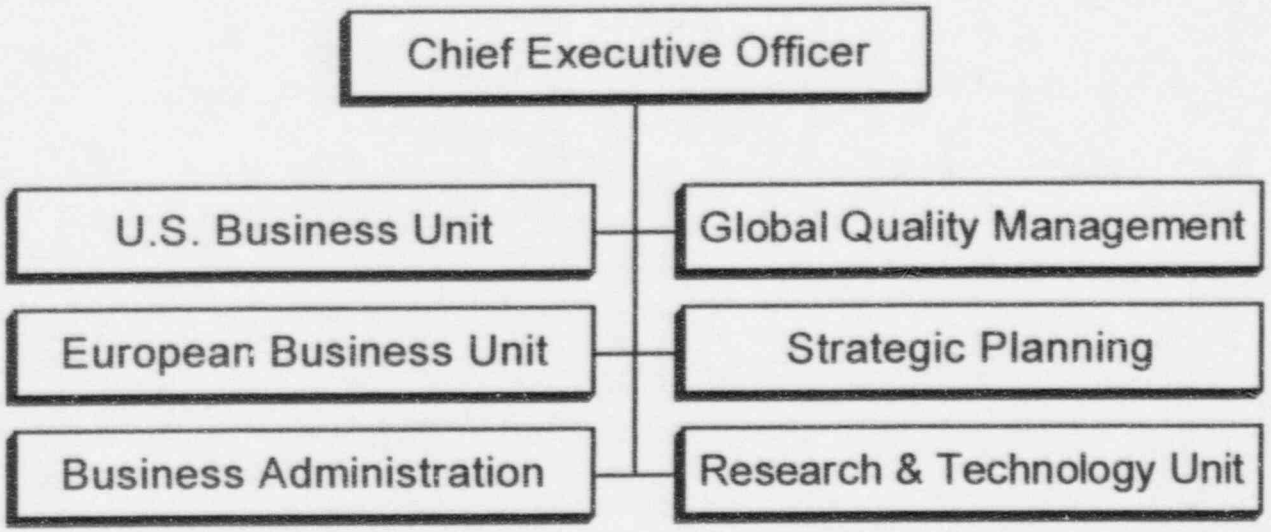


Figure 2

European Business Unit
Functional Relationship

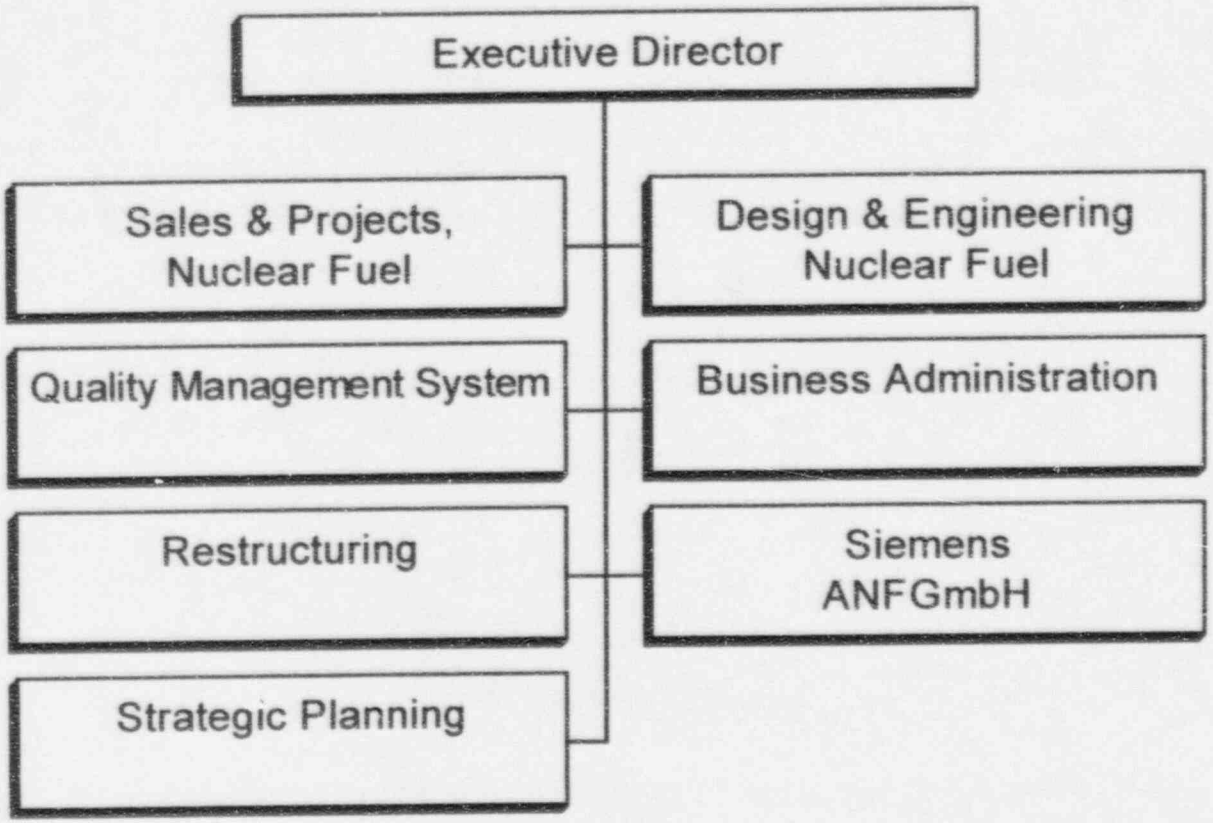


Figure 3

U.S. Business Unit
Functional Relationship

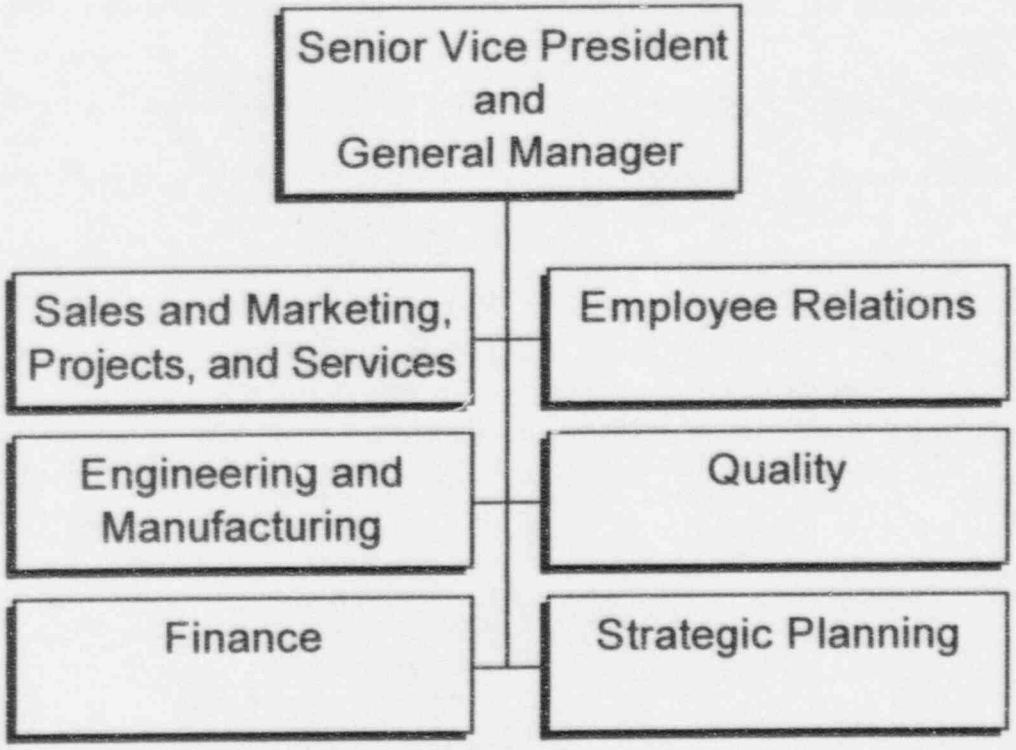


Figure 4

Research and Technology Unit
Functional Relationship

Figure 5

Siemens Nuclear Fuels Business
Global Quality Coordination
Functional Relationship

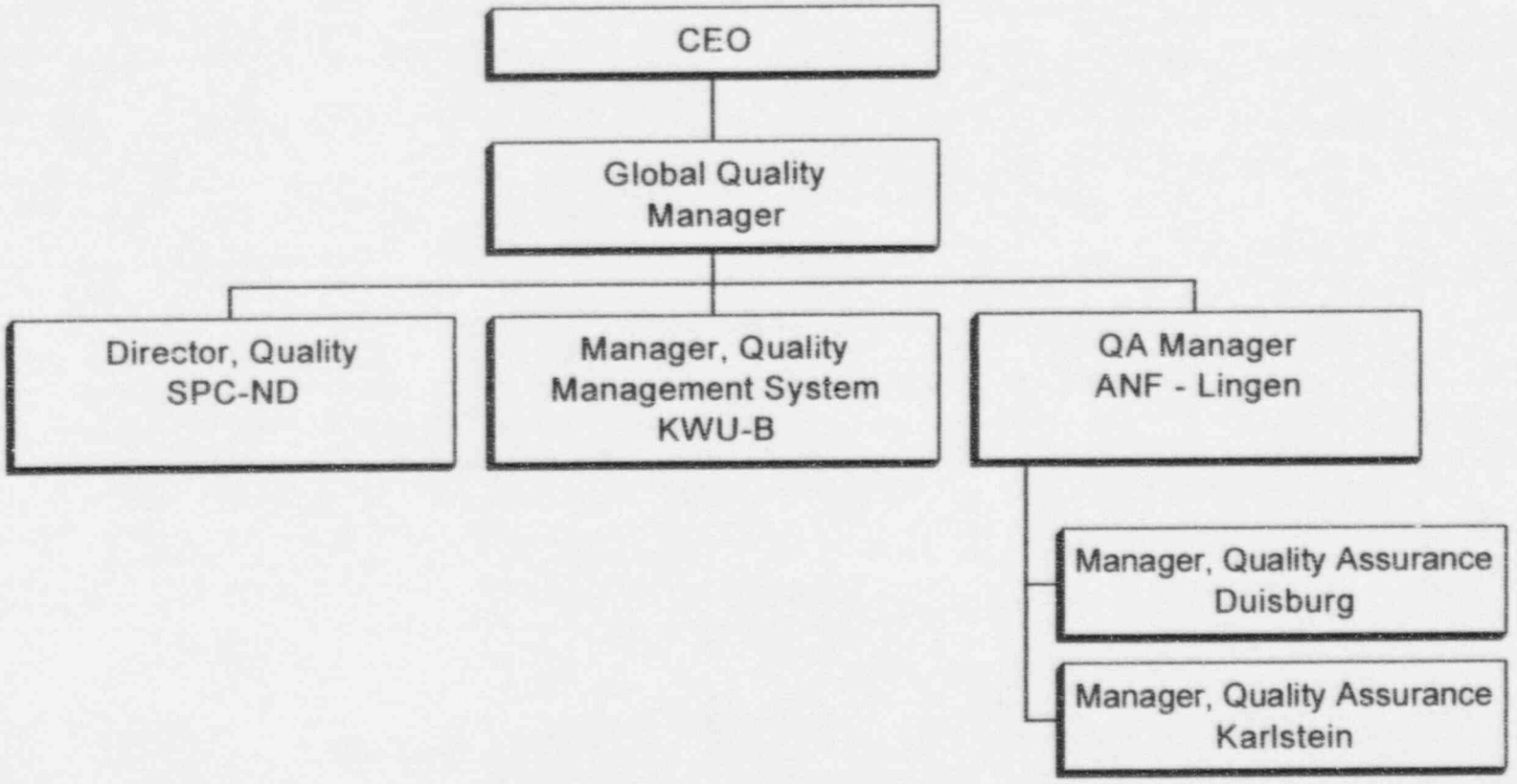


Figure 6

SPC-ND Quality Organization

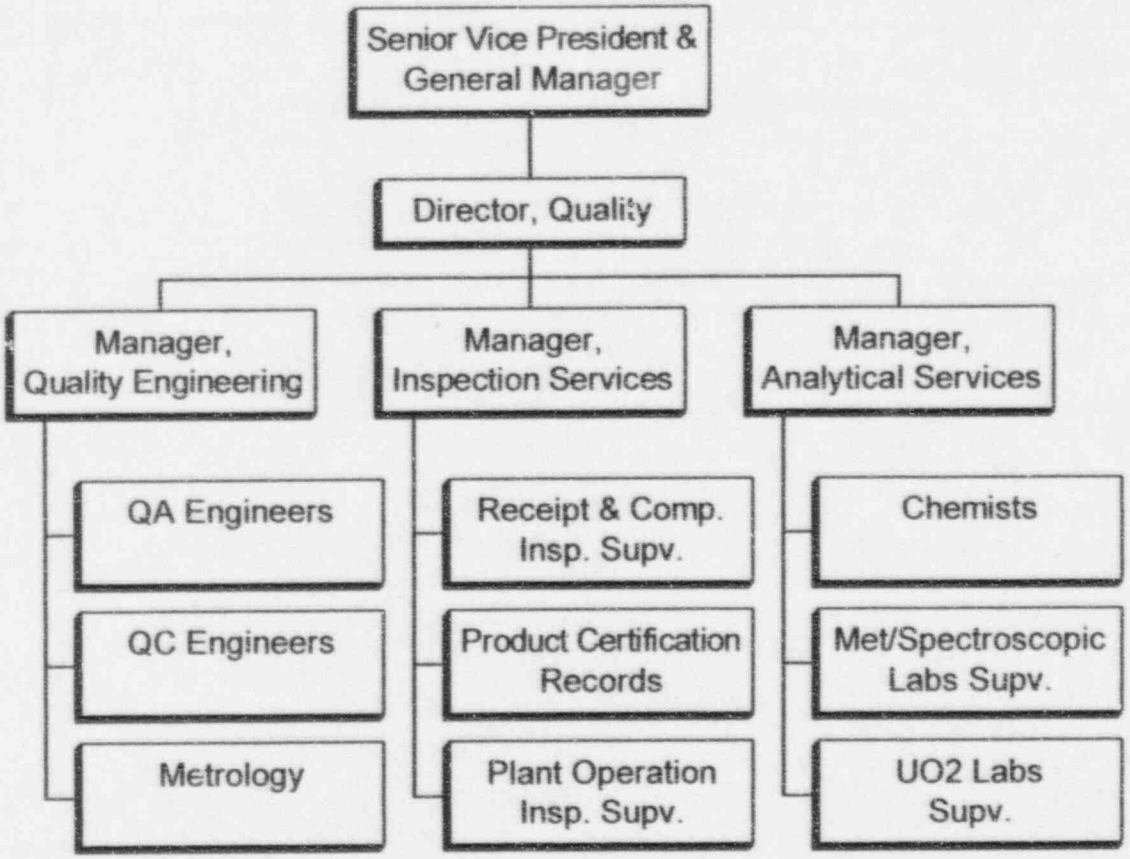


Figure 7

SPC-ND Engineering and
Manufacturing Organization

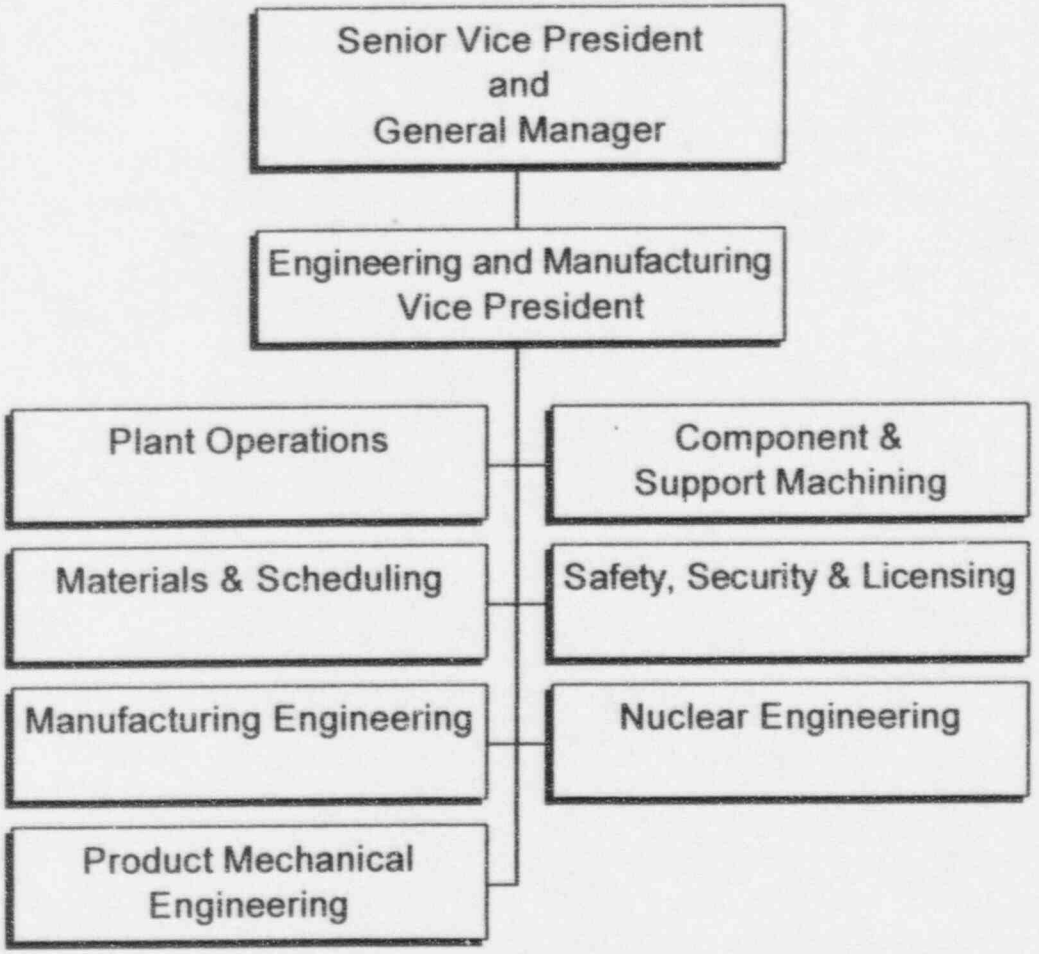
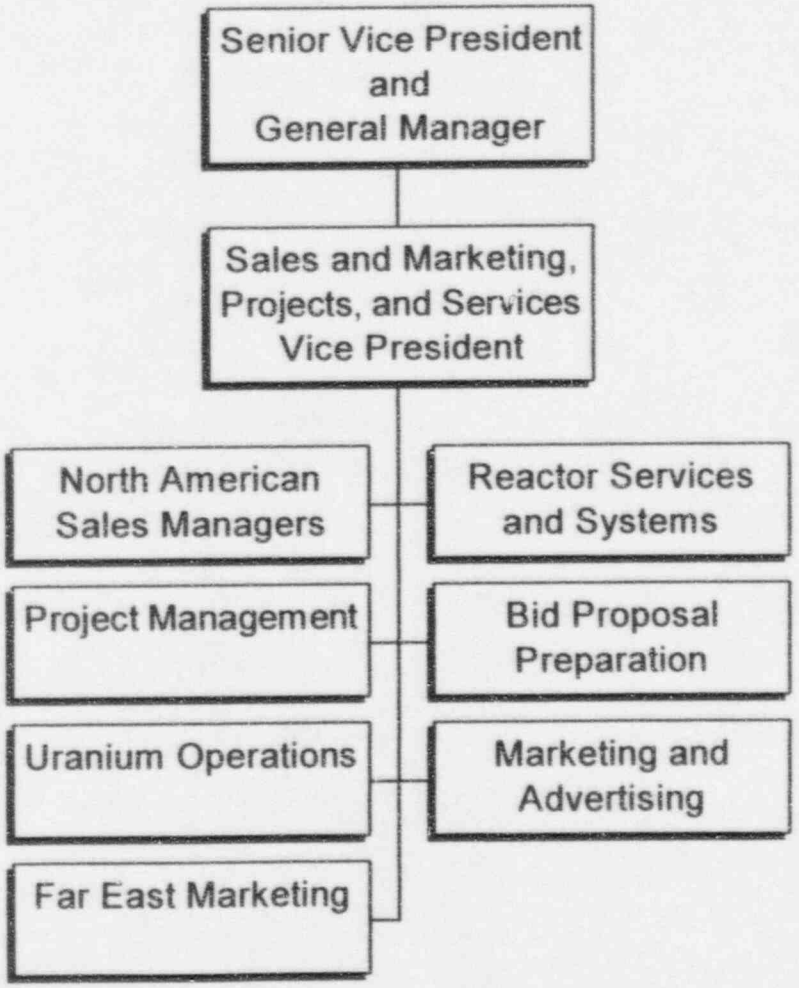


Figure 8

SPC-ND Sales and Marketing,
Projects, and Services Organization



APPENDIX I

CORRELATION OF 10 CFR 50, APPENDIX B CRITERIA
WITH ISO-9001 REQUIREMENTS

10 CFR 50, APPENDIX B QA CRITERIA		CORRESPONDING ISO-9001 REQUIREMENTS	PART II SECTION WHICH IMPOSES CRITERIA/REQUIREMENT	REVISIONS PERMISSIBLE AT SPC'S DISCRETION
I	Organization	Management Responsibility	1.0	
II	QA Program	QA System & Management Responsibility, Training	1.0, 2.0, & 18.0	
III	Design Control	Design Control	4.0	
IV	Procurement Document Control	Purchasing	6.0	
V	Instructions, Procedures, and Drawings	Not Applicable	21.0	
VI	Document Control	Document Control	5.0	
VII	Control of Purchased Material	Purchasing, Purchaser Supplied Product, Quality Audits	6.0, 7.0, & 17.0	
VIII	Identification and Control of Materials and Parts	Product Identification and Traceability, Inspection & Testing	8.0 & 10.0	
IX	Control of Special Processes	Process Control	9.0	
X	Inspection	Inspection and Testing	10.0	
XI	Test Control	Not Applicable	22.0	
XII	Calibration of Equipment	Inspection, Measuring, and Test Equipment	11.0	
XIII	Handling, Storage, and Shipping	Handling, Storage, Packaging, and Delivery	15.0	
XIV	Inspection, Testing, and Operating Status	Inspection and Test Status	12.0	
XV	Nonconforming Material	Control of Nonconforming Product	13.0	
XVI	Corrective Action	Corrective Action	14.0	
XVII	QA Records	Quality Records	16.0	
XVIII	Audits	Quality Audits	17.0	
N/A	N/A	Contract Review	3.0	X
N/A	N/A	Servicing	19.0	X
N/A	N/A	Statistical Techniques	20.0	X

APPENDIX II

APPLICABILITY OF ANSI STANDARDS AND REGULATORY GUIDES

The SPC-ND Quality Assurance Program satisfies the requirements of Appendix B to 10 CFR 50, "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-ND 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-ND. 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 (2), 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)

APPLICABILITY OF ANSI STANDARDS AND REGULATORY GUIDES		
ITEM NO.	DOCUMENT NUMBER & DATE	SUBJECT AND APPLICABILITY
		13) (Not applicable) 14) Layout and arrangement requirements. 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-ND 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-ND 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 three years during the performance of functional area audits. The basis for this frequency is the considerable QA involvement in support of customer program audits which occur numerous times yearly. 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 normally audited annually if the hardware item is considered to be a major component and triennially for suppliers of other items. Based upon performance, vendor audits may be scheduled on a biennial frequency at the discretion of the Director, Quality. 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 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 III

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

10 CFR 50, APPENDIX B QA CRITERIA		SPC-ND QA PROCEDURES By Number
I	Organization	All listed QA Procedures
II	QA Program	EMF-P00,019 and 036
III	Design Control	EMF-P00,002
IV	Procurement Document Control	EMF-P00,018
V	Instructions, Procedures, and Drawings	All listed QA Procedures
VI	Document Control	EMF-P00,001; EMF-365
VII	Control of Purchased Material	EMF-P00,018
VIII	Identification and Control of Materials and Parts	EMF-P00,027
IX	Control of Special Processes	EMF-P00,001
X	Inspection	EMF-P00,020
XI	Test Control	EMF-P00,020
XII	Calibration of Equipment	EMF-10
XIII	Handling, Storage, and Shipping	EMF-P00,001, 002, & 028
XIV	Inspection, Testing, and Operating Status	EMF-P00,027 & 020
XV	Nonconforming Material	EMF-P00,002, 039, & 027
XVI	Corrective Action	EMF-P00,021
XVII	QA Records	EMF-P00,023
XVIII	Audits	EMF-P00.004