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Constellation Energy
Generation Group

December 9, 2005

U. S. Nuclear Regulatory Commission
Washington, DC 20555

ATTENTION: Document Control Desk

SUBJECT: **R.E. Ginna Nuclear Power Plant**
Docket No. 50-244

Annual Submittal of Quality Assurance Program Changes

Reference:

a) Letter, R.E. Ginna Nuclear Power Plant to USNRC, "Annual Submittal of Quality Assurance Program Changes," dated December 22, 2004.

R.E. Ginna Nuclear Power Plant, LLC is submitting Revision 33 to the R.E. Ginna Nuclear Power Plant Quality Assurance Program for Station Operation (QAPSO) in accordance with 10CFR50.54(a)(3) and 10CFR50.71(e). Revision 33 of the QAPSO (Enclosure 1) incorporates changes made to the quality assurance program since the last update (Revision 32) submitted with reference (a). Each change is supported by a written evaluation in accordance with 10CFR50.54(a)(3), demonstrating that the change does not constitute a reduction in commitment contained in the quality assurance program as previously approved by the NRC. There were no changes requiring NRC approval prior to implementation during the period covered by this submittal.

For ease of document administration, the entire QAPSO is updated. A single revision bar in the left margin denotes changes made from Revision 32 to Revision 33 of the QAPSO. Attachment 1 provides a description of the changes made, the reason for the changes, and the basis for the changes not involving a reduction in quality assurance program commitments. Attachment 2 provides, for reference only, a strikeout version of the QAPSO, highlighting the differences between Revisions 32 and 33.

Should you have questions regarding the information in this submittal, please contact Mr. George Wrobel at (585) 771-3535 or George.Wrobel@constellation.com.

Very truly yours,

Mary G. Korsnick

Q004

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Attachments: 1. Summary of Changes.
2. Copy of Enclosure with changes highlighted or struck out.

Enclosure: 1. Quality Assurance Program for Station Operation, Revision 33.

cc: S. J. Collins, NRC
P.D. Milano, NRC
Resident Inspector, NRC (Ginna)
J. P. Spath, NYSERDA
P.D. Eddy, NYSDPS

ATTACHMENT 1
SUMMARY OF CHANGES

Organization Changes

Section 17.1.2 Organization and 17.3.2 Assessment

Description of Change: Constellation Generation Group, LLC (CGG) established corporate organization positions for operations support, technical services, Quality and Performance Assessment, project management, supply chain, and information technology. These functional positions assumed corresponding responsibilities from the site organization. The new responsibilities and reporting relationships for these position functions are described.

Reason for Change: To reflect new reporting relationships and responsibilities with establishing a fleet organization.

Basis for Change: The changes are administrative organization changes and do not impact quality or represent a reduction in commitment per 10CFR50.54(a)(3). Titles and position functions for responsible individuals are described consistent with 10 CFR 50.54(a)(3)(iii), which allows "The use of generic organizational position titles that clearly denote the position function, supplemented as necessary by descriptive text, rather than specific titles." Persons and organizations performing quality assurance functions continue to have the requisite authority and organization freedom, including sufficient independence from cost and schedule when opposed to safety considerations, consistent with the requirements of 10 CFR 50.54(a)(3)(vi).

Assessment Change

Section 17.3.2 Assessment

Description of Change: Added that audits may be used to meet the periodic review requirements of the code for the Radiological Protection program

Reason for Change: To clarify a requirement that is currently described in a Nuclear Directive.

Basis for Change: The change is an administrative improvement and does not represent a reduction in commitment per 10CFR50.54(a)(3).

Attachment II

R.E. GINNA NUCLEAR POWER PLANT, LLC

R.E. GINNA NUCLEAR POWER PLANT

Quality Assurance Program for Station Operation

Revision 33~~2~~

DOCKET NO. 50-244

December 6~~21~~, 2005~~4~~

QUALITY ASSURANCE PROGRAM FOR STATION OPERATION

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QUALITY ASSURANCE PROGRAM FOR STATION OPERATION

17.1 MANAGEMENT

17.1.1 Methodology

The R.E. Ginna Nuclear Power Plant, LLC ("Ginna LLC") quality assurance policy is established by the Senior Vice President and Chief Nuclear Officer of Constellation Generation Group, LLC. This policy is set forth in the R.E. Ginna Nuclear Power Plant, LLC Corporate Statement of Quality Assurance Policy, shown in Table 17.1.1-1, and is binding on all organizations and individuals performing Ginna Station quality affecting activities. The policy is implemented under the overall direction of the Vice President, Ginna.

The Quality Assurance Program has been developed by Ginna LLC to assure safe and reliable operation of the R. E. Ginna Nuclear Power Plant. The program covers all existing Seismic Category I and Class 1E structures, systems, and components (SSCs) including their foundations and supports. It applies to all activities affecting the safety-related functions of these structures, systems, and components that prevent or mitigate the consequences of postulated accidents that could cause undue risk to the health and safety of the public.

These activities include designing, operating, maintaining, repairing, fabricating, handling, shipping, storing, procuring, refueling, modifying, cleaning, erecting, installing, testing, inspecting, and inservice inspection. Quality affecting activities are controlled to an extent consistent with their safety significance. In addition, the Quality Assurance Program applies to the activities associated with the packaging of licensed radioactive materials to be shipped in accordance with 10CFR Part 71, excluding design and fabrication of shipping casks.

A classification process is established to identify SSCs that are safety related (SR), safety significant (SS), or Non-Nuclear Safety (NS). Criteria are based on information contained in the Updated Final Safety Analysis Report (UFSAR), licensing commitments, guidelines contained in NRC regulatory guides, and functional guidance derived from ANSI/ANS 51.1-1983. For changes to Ginna Station, safety classification and corresponding QA program applicability are determined using approved procedures.

The Nuclear Policy Manual provides a method of applying a graded QA Program to systems, components, items, and services which are not classified as safety related (SR), but are considered necessary for reliable plant operation.

Special terms used in this document which are not found in ANSI N45.2.10 "Quality Assurance Terms and Definitions" are defined in Table 17.1.1-2, Supplementary Glossary.

17.1.2 Organization

The organizational structure responsible for implementation of the Quality Assurance Program is under the leadership of the President, ~~and Chief Executive Officer of~~ Constellation Generation Group, LLC (CGG). Specific details for the quality assurance functions described are identified in procedures. The authority to accomplish the quality assurance functions described is delegated to the incumbent's staff as necessary to fulfill the identified responsibility.

Corporate Organization

The following positions have the described corporate functional responsibilities:

President ~~and Chief Executive Officer (CEO)~~, CGG

The President ~~and Chief Executive Officer~~, CGG is responsible for establishing the overall corporate policy and implementation of the Quality Assurance Program (QAP). The President ~~CEO~~ provides executive direction and guidance for the corporation as well as promulgates corporate policy through Constellation Generation's senior management staff. Overall responsibility for the implementation of the QAP is delegated to the Senior Vice President and Chief Nuclear Officer, CGG.

Senior Vice President and Chief Nuclear Officer (CNO), CGG

The Senior Vice President and Chief Nuclear Officer, CGG has responsibility for establishing the Quality Assurance Program and issuing the governing policy statement. The CNO oversees all organizations involved in the operation and support of Ginna Station, including the Quality Assurance Program, and establishes the Nuclear Safety Review Board (NSRB) to review and audit plant operations. The Chairman of the NSRB is responsible to the CNO on all activities of the NSRB.

Operations Support, CGG

An executive management position for operations support reports to the CNO and provides direction to the nuclear security, emergency preparedness, training, and fleet procedures departments. Responsibilities for nuclear security include facility physical security, nuclear access programs, and fitness for duty programs. Emergency preparedness responsibilities include development and maintenance of the company radiological emergency plans and coordination with off-site radiological emergency response groups for the nuclear facilities. Training ensures qualified personnel operate and support the nuclear facilities and administers the fleet corrective action, self-assessment, and industry operating experience programs. The fleet procedures department ensures that fleet procedures are prepared in accordance with applicable regulatory requirements, industry quality standards, and this QAP. Additionally, corporate oversight and support is provided in the areas of operations, maintenance, refueling services, radiation protection, chemistry, and work management. Some of these

responsibilities may be assigned to the Vice President, Ginna at the discretion of the CNO.

Technical Services, CGG

An executive management position for technical services reports to the CNO and provides direction to corporate engineering, licensing, nuclear fuel services, and probabilistic risk assessment (PRA) departments. Additionally, corporate oversight and support is provided for site engineering. This position is responsible for the engineering functions supporting design and construction activities and long-term nuclear operations, providing for regulatory compliance and licensing support through NRC communications, and activities related to safety and management of nuclear fuel. Some of these responsibilities may be assigned to the Vice President, Ginna at the discretion of the CNO.

Quality and Performance Assessment (Q&PA), CGG

A senior management position reporting to the CNO is responsible for the verification of effective Company and Supplier quality assurance program development, documentation, and implementation. This position is independent of cost and scheduling concerns associated with construction, operations, maintenance, modification, and decommissioning activities for performing quality assurance program verification. Where implementation of any or all of these functions is delegated to Suppliers, procedures require the establishment of interface documents including defining lines of communication and authorities as appropriate for the delegated functions. However, this senior management position retains responsibility for the scope and effective implementation of the quality assurance program for those functions. This management position has the necessary authority and responsibility for verifying quality achievement; identifying quality problems, recommending solutions and verifying implementation of the solutions; and escalating quality problems to higher management levels. This position has the authority to suspend unsatisfactory work and control further processing or installation of non-conforming materials. The authority to stop work delegated to Q&PA personnel is delineated in procedures.

Q&PA is responsible for the evaluation of Suppliers' quality programs through a system of external audits, evaluations, and reviews of Supplier performance in accordance with quality assurance requirements. A list of approved Suppliers is maintained. Q&PA is responsible for assuring Company compliance with this QAP through administration of a comprehensive and systematic internal audit program. Q&PA is also responsible for the Employee Concerns Program, and developing and maintaining an appropriate quality verification inspection program where not provided for in the facility construction or operating organization functions.

Project Management, CGG

A senior management position reporting to the CNO is responsible for the implementation of large projects for the nuclear facilities. Implementation includes development of the detailed scope, estimate, schedule, cost, design procurement, construction, testing, and closeout of each project. Project management also oversees siting and construction activities. Focus is on defined projects separate from ongoing routine engineering projects. Some of these responsibilities may be assigned to the Vice President, Ginna at the discretion of the CNO.

Supply Chain, CGG

Supply Chain is responsible for material management, purchasing, procurement engineering, and receipt inspection. This position has the authority to control further processing or installation of nonconforming materials. This authority is delegated to inspection personnel as delineated in procedures.

Information Technology, CGG

Information Technology is responsible for network infrastructure maintenance and upgrade, network and application security, network operations; automation strategy, application development and support, automation training; development and maintenance of the software control program; and oversight, maintenance, and repair of the Emergency Offsite Facility Computer System.

Site Organization

The following positions have the described site functional responsibilities:

Vice President, Ginna

The Vice President, Ginna is responsible to the CNO ~~Senior Vice President and Chief Nuclear Officer, CGG~~ and has corporate responsibility for operation of Ginna Station in accordance with applicable regulatory requirements. In addition, the Vice President, Ginna has overall responsibility and authority for directing the Quality Assurance Program and is responsible for the approval of the Nuclear Policy Manual. The Vice President, Ginna is responsible for those items delineated in the Administrative Controls section of the Technical Specifications, for establishing the policies and requirements necessary to assure safe and reliable operation of Ginna Station, and for oversight of Ginna Station and those support activities associated with ~~Nuclear~~site eEngineering ~~Services, Nuclear Assessment, Quality and Performance Assessment,~~ and ~~Nuclear T~~ training.

Plant General Manager, Ginna Station

The Plant General Manager, Ginna Station is responsible to the Vice President, Ginna for the overall on-site safe operation of Ginna Station. The Plant General Manager, Ginna Station is

responsible for:

- the performance of all Ginna Station quality affecting activities in accordance with the requirements of the Quality Assurance Program
- providing qualified personnel to perform quality affecting activities in accordance with approved drawings, specifications, and procedures
- implementation of those items delineated in the Administrative Controls Section of Technical Specifications
- timely referral of appropriate matters to management and the NSRB
- assuring that significant conditions adverse to quality are identified and corrected

The Plant General Manager, Ginna Station assigns responsibility to Managers, Directors, and designated staff members for the control of all activities involving operation, maintenance, repair, refueling, implementation of modifications, radiation protection, chemistry, and fire protection. ~~and plant security.~~ Responsibility is delegated for the implementation of Quality Assurance Program requirements at the plant for testing, operation and test status control, and calibration and control of measuring and test equipment.

Manager, Nuclear Engineering Services

The Manager, Nuclear Engineering Services ~~is responsible~~reports to the Vice President, Ginna and functionally to a Corporate Vice President (offsite), and is responsible for day-to-day engineering support activities including design engineering, engineering programs, equipment reliability, and system engineering.

- ~~design of modifications to the facility in accordance with applicable design bases, regulatory requirements, codes, and standards~~
- ~~maintenance of Ginna Station design and licensing basis~~
- ~~nuclear fuel management~~
- ~~technical support for Ginna corrective action~~
- ~~technical support for Ginna operations~~
- ~~inservice inspection~~
- ~~welding~~

~~Director, Nuclear Assessment~~

~~The Director, Nuclear Assessment is responsible to the Vice President, Ginna for:~~

- ~~Providing Performance Improvement Services~~
- ~~Coordinating the implementation of the Corrective Action and Self Assessment Programs~~
- ~~Supporting root cause investigations and corrective action for significant conditions adverse to quality~~
- ~~Coordinating human performance event investigations~~
- ~~Evaluating and disseminating industry and Ginna operating experience information~~
- ~~Ensuring that relevant and timely recommended actions are provided to management that will eliminate precursors of~~

~~similar problems at Ginna Station~~
- ~~Trending and analysis of corrective action program data~~
- ~~Records Management~~

Director, Quality and Performance Assessment (Q&PA)

The Director, Q&PA reports to the corporate management position (offsite) responsible for Q&PA and functionally to the Vice President, Ginna and is responsible for site Q&PA activities ~~all Quality Assurance and most Quality Control functions. The Director, Q&PA is also responsible for nondestructive examinations, inservice inspection examinations, and the inspection and maintenance of material handling equipment.~~ The Director, Q&PA and staff are responsible to the NSRB for:

- Establishing the overall Quality Assurance Program
- Interpreting corporate quality assurance policy and for assuring its implementation. This includes assuring that the program continues to satisfy the requirements of 10CFR50, Appendix B.
- Establishing and implementing an independent assessment program that encompasses all organizations and functions related to the safe operation of Ginna~~, including the qualified suppliers of safety related materials and services~~.
- Assuring that all planned and systematic actions necessary to provide adequate confidence that Ginna Station will operate safely and reliably are established and followed.
- Providing management with objective information concerning quality, independent of the individual or group directly responsible for performing the specific activity.

The Director, Q&PA has the authority and organizational freedom to assure all necessary quality activities are performed. The Director, Q&PA and staff are responsible for assuring that station activities affecting quality are prescribed and carried out in accordance with approved drawings, specifications, and procedures. Quality Control is also responsible for ensuring the performance of verification inspection and assuring that inspection requirements are included in approved procedures and work packages.

~~Director, Supply Chain Management~~

~~The Director, Supply Chain Management is responsible to the Vice President, Ginna for overall purchasing and warehouse functions for Ginna LLC. This includes coordinating the efforts of supply chain personnel involved in procurement activities, receipt inspection activities, inventory control, storage of materials and equipment, and control and storage of portable material handling equipment.~~

~~Director, Ginna IT~~

~~The Director, Ginna IT is responsible to the Vice President, Ginna for computer support.~~

~~Director, Nuclear Safety and Licensing~~

~~The Director, Nuclear Safety and Licensing is responsible to the Vice President, Ginna for implementing the licensing and compliance program.~~

Manager, Nuclear Training

The Manager, Nuclear Training ~~is responsible~~reports to the Vice President, Ginna and functionally to a corporate management position (offsite), and is responsible for maintaining and implementing a National Academy for Nuclear Training accredited training program. In addition, the Manager, Nuclear Training is responsible for ~~Nuclear Emergency Preparedness~~administration of the corrective action, self-assessment and industry operating experience programs.

REVIEW AND AUDIT ORGANIZATIONS

Three separate organizational units are established for the purpose of review and audit of plant operations and safety-related matters. They are:

- Plant Operations Review Committee (PORC), the on-site operations review group responsible for reviewing those activities that affect nuclear safety.
- Quality and Performance Assessment, the group responsible for the audit of safety related activities associated with plant operations.
- Nuclear Safety Review Board (NSRB), the independent audit and review group responsible for the periodic review of the activities of the Plant Operations Review Committee, for directing internal audits and evaluating their results, and for the management evaluation of the status and adequacy of the Quality Assurance Program.

PORC

Review activities of the PORC provide, as part of the normal duties of plant supervisory personnel, timely and continuing monitoring of operating activities to assist the Plant General Manager, Ginna Station in keeping abreast of general plant conditions and to verify that the day-to-day operating activities are conducted safely and in accordance with applicable administrative controls. PORC also reviews facility operations to detect potential safety hazards. These continuing monitoring activities are considered to be an integral part of the routine supervisory function and are important to the safety of plant operation.

The PORC performs reviews, periodically and as situations demand, to evaluate plant operations and to plan future activities. The important elements of the reviews are documented.

The PORC scope of review, organization, quorum, and records meet the requirements of ANSI/ANS-3.2-1988, Section 4.3. PORC is comprised of personnel who collectively have the experience and competence in the following areas:

- Nuclear Operations

- Mechanical Maintenance
- Electrical Maintenance
- Plant Engineering
- Reactor Engineering
- Radiation Safety
- Chemistry
- Quality Assurance/Quality Control

The PORC chairman meets the qualifications of ANSI Standard N18.1-1971, Section 4.2.2, and holds, or has held, a Senior Reactor Operating License or SRO certification. PORC members meet the qualifications of section 4.3.1 or 4.4 as applicable. The PORC is comprised of a minimum of five (5) and maximum of nine (9) regular members, as designated by the Plant General Manager, Ginna Station. Alternates are designated in writing by the chairman. The number of attending alternates will not exceed a minority of the number representing a quorum. The PORC meets at least once per calendar month and as convened by the PORC Chairman.

The PORC reviews proposed changes to the facility, changes to procedures, tests and experiments for which a 10CFR50.59 evaluation has been performed.

The PORC recommends in writing to the Plant General Manager, Ginna Station approval of items submitted for review, documents whether any change requires regulatory review in accordance with 10CFR50.59, and provides immediate notification to the Vice President, Ginna and the Chairman, NSRB of disagreement between the PORC and the Plant General Manager, Ginna Station.

NSRB

The NSRB scope of review meets the requirements of ANSI Standard N18.7-1976, Section 4.3.4. The NSRB composition, meeting frequency, quorum, and record requirements meet ANSI Standard N18.7-1976, Section 4.3.2. Qualifications of members are commensurate with their functional responsibilities as defined in ANSI/ANS-3.1-1987, Section 4.7, with the exception that the functional areas of nuclear power plant operations and nuclear engineering have over eight (8) years experience in their field with over four (4) years responsible engineering management. The Chairman and Vice-Chairman of the NSRB are appointed by the CNO. ~~Senior Vice President and Chief Nuclear Officer, CGG.~~ The members of the NSRB are appointed by the Chairman of the NSRB.

DELEGATION OF WORK

Quality affecting activities may be delegated to corporate organizations external to Ginna LLC, contractor organizations, and equipment vendors. Delegated activities are subject to Quality Assurance Program requirements through conformance with the external organization's QA Program as approved by Ginna LLC, through conformance with Ginna LLC's Quality Assurance Program, or an approved combination of the two. Ginna LLC retains overall responsibility for the Quality Assurance Program and management oversight of delegated activities. The scope of delegated activities and applicable Quality Assurance Program requirements

are defined in procedures and procurement documents.

17.1.3 Responsibility

All employees of Ginna LLC involved in the operation of Ginna Station and associated support activities have full personal and corporate responsibility to assure that the plant is operated, maintained, tested, inspected, and modified in a safe and reliable manner. This responsibility includes assuring that an effective Quality Assurance Program is implemented.

The operation of Ginna Station is governed by the Nuclear Policy Manual, a portion of which governs the Quality Assurance Program. It contains the requirements and assignment of responsibilities for implementation of the program. The manual is prepared, reviewed, and maintained by Ginna Station and approved by the Vice President, Ginna.

The Nuclear Safety Review Board is directed by the Senior Vice President and Chief Nuclear Officer, CGG to review the status and adequacy of the Quality Assurance Program at least once every two years to assure that it is meaningful and effectively complies with corporate policy and 10CFR50, Appendix B. This review consists of an audit, or a review equivalent to an audit, performed by company personnel or outside organizations.

The Quality Assurance Program is implemented through procedures prepared and maintained by the responsible organization and approved for use by their designated manager. Quality affecting activities are performed in accordance with these procedures, utilizing sufficiently trained personnel and necessary resources to accomplish the work.

17.1.4 Authority

Persons or organizations who are delegated responsibility for planning, establishing, or implementing any part of the Ginna LLC Quality Assurance Program also have the authority to carry out those responsibilities.

Nuclear Operations and nuclear support organization personnel are empowered to take stop work action on their own activities if they determine that continuing the activity would preclude identifying and correcting a condition adverse to quality or lead to an unsafe condition. Designated independent inspection and audit personnel have the authority to stop work within Nuclear Operations, nuclear support organizations, and at supplier locations. The Plant General Manager, Ginna Station has stop work authority for all activities performed in operating the station.

17.1.5 Personnel Training and Qualification

Ginna LLC is committed to maintaining National Academy for Nuclear Training accredited training programs that produce qualified, competent personnel to operate and maintain Ginna Station. Nuclear Training is assigned the responsibility for supporting Nuclear Operations line management with the

development, monitoring, and evaluation of an adequate staff of experienced, trained, and qualified personnel to ensure the safe and efficient operation, modification, and maintenance of the plant.

Supervisory personnel are indoctrinated in quality assurance policies, instructions, and procedures to assure they understand that these must be implemented and enforced. Personnel responsible for performing activities affecting quality are trained and indoctrinated in the requirements, purpose, scope, and implementation of applicable quality related program instructions and procedures. Refresher sessions are held periodically. Training of personnel is the responsibility of each department performing an activity affecting quality.

The Vice President, Ginna is responsible for the formal training, qualification, licensing, and re-qualification of operators, as necessary. As appropriate, personnel granted unescorted access to Ginna Station are trained in radiation protection, plant safety, and security.

Training and qualification records are maintained for each employee when required. Documentation of formal training includes objectives, content of the program, attendees, and date of attendance.

17.1.6 Corrective Action

Ginna LLC has established a corrective action process whereby all personnel are responsible for assuring that conditions adverse to quality are promptly identified, reported, controlled, and corrected. The process is focused on correcting the problem and its root cause rather than assigning blame or fault. Adverse trends in performance are identified, monitored, and reported to management. Corrective action and nonconformance control processes are discussed in Section 17.2.13.

17.1.7 Regulatory Commitments

The Quality Assurance Program is designed to meet the requirements of 10CFR50, Appendix B, "Quality Assurance Criteria for Nuclear Power Plants." A listing of Regulatory Guides, requirements, and standards with the conformance status of each is contained in Table 17.1.7-1.

A grace period of 90 days is applied to several activities specifically defined on Table 17.1.7-1. The grace period will not allow the "clock" for a particular activity to be reset forward. For example, if an annual activity is due on June 15th of a particular year, but is not performed until August 13th, the next due date for that activity will be June 15th of the following year. However, the clock for an activity is reset backwards by performing the activity early.

TABLE 17.1.1-1

R.E. Ginna Nuclear Power Plant, LLC

Corporate Statement of Quality Assurance Policy

The R.E. Ginna Nuclear Power Plant, LLC continues to be an advocate of quality performance in our daily activities. The Quality Assurance Program described in the Nuclear Policy Manual has been developed to assure that activities, as defined within the program scope, are being performed correctly and in conformance with applicable requirements. This program is designed to assure the safe operation of Ginna Station and to meet the requirements of Title 10, Code of Federal Regulations, Part 50 (10CFR50), Appendix B, "Quality Assurance Criteria for Nuclear Power Plants."

The Quality Assurance Program applies to all activities affecting the safety related functions of those Seismic Category I or Class 1E structures, systems, and components that prevent or mitigate the consequences of or monitor the course of postulated accidents, events, or phenomena that could cause undue risk to the health and safety of the public. These activities include operating, maintaining, modifying, refueling, testing, and inspecting. In addition, this program applies to 10CFR50 concerns associated with:

a. maintaining the high degree of integrity of primary and secondary barriers of systems or structures containing radioactive materials

b. providing fire detection, suppression, and consequence mitigation items utilized both to protect the safety related structures, systems, and components and to assure safe operation in the event of postulated fire

c. providing assurance that instrumentation and controls which monitor accidents, or provide a secondary role in accident monitoring, function correctly and accurately.

This program also applies to the shipping of licensed radioactive material under 10CFR71, except for design and fabrication of shipping casks.

The Director, Quality and Performance Assessment is responsible for coordinating the formulation of the Quality Assurance Program and for assuring the program's implementation. Nuclear Operations personnel are responsible for implementing the Quality Assurance Program in accordance with the requirements of the Nuclear Policy Manual.

John M. Heffley
Senior Vice President and Chief Nuclear Officer,
Constellation Generation Group, LLC

Date 12/14/04

TABLE 17.1.1-2

Supplementary Glossary

Terms with special meanings used in this document that are not defined in ANSI N45.2.10, "Quality Assurance Terms and Definitions," are defined below.

Adopted - Ginna LLC has endorsed, wholly or in part, an industry code, standard, or NRC Regulatory Guide for which no formal commitment has been made.

Alternative - Relates to existing and proposed industry code, standard, or NRC Regulatory Guide for which Ginna LLC provides other means to assure quality.

Approval - The formal act of endorsing or adding positive authorization, or both, to an action or document. Approval may be given only by an authorized individual.

As-built drawings - Drawings such as flow prints, electrical elementary diagrams, instrumentation and control schematics, and piping layout drawings that reflect the actual current plant field configuration.

Audit - A documented activity to determine, through investigation, the adequacy of and adherence to established procedures, instructions, specifications, codes and standards, or other applicable contractual and licensing requirements and the effectiveness of implementation.

Audit (internal) - Audit of those portions of Ginna LLC's Quality Assurance Program retained under its direct control and within its organizational structure.

Certification - The action, by an authorized person, of determining, verifying, and attesting, in writing, to the qualifications of personnel or material.

Commitment - A documented explicit statement, made either by Ginna LLC or through

uncontested imposition by the NRC or other regulatory agencies, that requires actions to be performed.

Conforms - Ginna LLC has committed fully to the requirements without exception.

Deviation - A departure of a characteristic from specified requirements.

Handling - An act of physically moving items by hand or by mechanical means, but not including transport on a conveyance, such as motor vehicles, ships, railroad cars, or aircraft.

Heavy load - Any load, carried in a given area after a plant becomes operational, that weighs more than the combined weight of a single spent fuel assembly and its associated handling tool ($\geq$1500#).

Inservice Inspection - A planned, periodic evaluation of the continued structural integrity of installed plant systems and components by nondestructive methods, conducted in accordance with the rules of Section XI of the ASME Boiler & Pressure Vessel Code.

Inspector - An individual who has been qualified to perform quality verification inspections.

Measuring and test equipment - Devices or systems used to calibrate, measure, gage, test, inspect, or control in order to control data or to acquire data to verify conformance to specified requirements. Measuring and test equipment does not include permanently installed plant instrumentation or test equipment used for preliminary checks where data obtained will not be used to determine acceptability or be the basis for design or engineering evaluation.

Nonconformance disposition	-	Designated resolution to a nonconforming item by cognizant personnel (e.g., rework, repair, use-as-is or reject).
Performance-based	-	An approach that focuses on the end results that directly contribute to safe and reliable plant operation. Meeting a predetermined set of goals, limits, or performance criteria based upon the design basis safety function and the past performance of structures, systems, components, and organizations, allowing the licensee flexibility to determine how the results will be achieved and adjust quality practices, as necessary.
Procedure	-	A document that specifies or describes how an activity is to be performed. It may include methods to be employed, a description of equipment or materials to be used, and sequence of operations.
Procurement document	-	Purchase requisitions, purchase orders, drawings, contracts, specifications, documents referenced by purchase orders, bills of material, or other instructions used to define requirements for purchase.
QA surveillance	-	A technique which uses observation or monitoring to provide confidence that ongoing processes and activities are adequately and effectively performed.
Qualified procedure	-	A procedure which incorporates all applicable codes and standards, manufacturer's parameters, and engineering specifications and has been proven adequate for its intended purpose. Section IX of the ASME Code defines procedure qualifications for welding activities.
Quality affecting activities	-	Activities for which the Quality Assurance Program applies.

Safety related structures, systems, and components - Equipment that is relied upon to remain functional during and following design basis events to ensure (1) the integrity of the reactor coolant boundary, (2) the capability to shutdown the reactor and maintain it in a safe shutdown condition, and (3) the capability to prevent or mitigate the consequences of accidents that could result in potential offsite exposures comparable to the 10CFR100 guidelines.

Safety significant structures, systems, and components - Subset of equipment not required to perform a safety related function but which are subject to additional controls established by Ginna LLC.

Supplier surveillance - A review, observation, or inspection for the purpose of verifying that an action has been accomplished as specified at the location of material procurement or manufacture.

Traceability - A characteristic given to material, a document, a group of documents, or material and its related documents which permits the retrieval or reassociation of the items, if necessary, at a later time. The term is also used to denote a document which records a chronological history of all processes or operations which have been performed on an item.

Verification inspection - A phase of quality control which by means of examination, observation, or measurement determines the conformance of materials, supplies, components, parts, appurtenances, systems, processes, or structures to predetermined quality requirements.

TABLE 17.1.7-1

Conformance of Ginna Station Program to Quality Assurance Standards, Requirements, and Guides

Standard, Requirement, or Guide	Conformance Status	Remarks
Regulatory Guide 1.8 Rev.(1)-Personnel Selection and Training	Conforms	RG 1.8 Rev.(1) incorporates ANSI N18.1.
Regulatory Guide 1.26 Rev.(3)-Quality Group Classifications & Standards for Water, Steam, and Radioactive-Waste Containing Components of Nuclear Power Plants	Alternative	A classification process is established to identify SSCs that are safety related (SR), safety significant (SS), or Non-Nuclear Safety (NS). Criteria are based on information contained in the Updated Final Safety Analysis Report (UFSAR), licensing commitments, guidelines contained in NRC regulatory guides, and functional guidance derived from ANSI/ANS 51.1-1983.
Regulatory Guide 1.28 Rev.(2)-Quality Assurance Program Requirements (Design and Construction)	Conforms	RG 1.28 Rev.(2) incorporates ANSI N45.2-1977.
Regulatory Guide 1.29 Rev.(3)-Seismic Design Classification	Alternative	Seismic design requirements for existing structures, systems, and components performing functions listed in positions C.1 and C.3 of the Regulatory Guide are specified in the UFSAR. New structures, systems, and components, and configuration changes meet the seismic design requirements of this regulatory guide or the UFSAR. The pertinent quality assurance requirements of 10CFR50, Appendix B are applied as required by positions C.1 and C.4 of this Regulatory Guide, irrespective of an item's seismic design. Portions of existing structures, systems, and components with failure consequences described in position C.2 of this guide are designed and constructed to seismic requirements specified in the UFSAR. New structures, systems, and components, and configuration changes meet the design and construction seismic requirements of the UFSAR or this Regulatory Guide. A quality assurance program similar to 10CFR50, Appendix B is applied to the SSE failure prevention function of these items. These items are not considered basic components pursuant to 10CFR21.
Regulatory Guide 1.30 Rev.(0)-Quality Assurance Requirements for the Installation, Inspection, and Testing of Instrumentation and Electric Equipment	Conforms	RG 1.30 Rev.(0) ANSI N.45.2.4-1972.

TABLE 17.1.7-1 (cont'd)

Standard, Requirement, or Guide	Conformance Status	Remarks	
Regulatory Guide 1.33 Rev.(0)-Quality Assurance Program Requirements (Operations)	Alternative	Original Criteria	Substituted Criteria
		Regulatory Guide 1.33 Rev.(0) except for Appendix A.	Regulatory Guide 1.33 Rev.(2) Regulatory Position 1 (including its Appendix A)
		ANSI N18.7-1972 except for Sections:	
		• 4.2.2	ANSI/ANS-3.1-1987 Section 4.7
		• 4.2.3,4.2.4, & 4.2.5	ANSI N18.7-1976/ANS-3.2 Section 4.3.2
		• 4.3	ANSI N18.7-1976/ANS-3.2 Section 4.3.4 as invoked and modified by Regulatory Guide 1.33 Rev.(2) Regulatory Position 3.
		• 4.4	Ginna conforms to ANSI N18.7-1972 Section 4.4 with the exception that a 90 day grace period may be applied to the 24 month frequency for performance of internal audits.
		• 4.5	The on-site review organization scope of review, organization, quorum and records meet the requirements of ANSI/ANS-3.2-1988, Section 4.3. The qualification requirements for PORC members and PORC meeting frequency is described in QAPSO Section 17.1.2, PORC.
		Ginna also conforms to regulatory staff comments and supplementary guidance in "Guidelines on Quality Assurance Requirements During the Operations Phase of Nuclear Power Plants," Revision 0, October 1973 (Orange Book-Revision 0).	

TABLE 17.1.7-1 (cont'd)

Standard, Requirement, or Guide	Conformance Status	Remarks
Regulatory Guide 1.36 Rev.(0)-Nonmetallic Thermal Insulation for Austenitic Stainless Steel	Adopted	This Regulatory Guide is adopted for the testing of insulating materials installed on or near safety related stainless steel piping. Insulating materials are not considered basic components pursuant to 10CFR21 and thus the supplier is not required to have a quality assurance program to cover the testing, lot control, and contamination control provisions of this Regulatory Guide. A quality assurance program similar to 10CFR50, Appendix B is applied to insulating materials on or near Ginna Station safety related stainless steel piping and components.
Regulatory Guide 1.37 Rev.(0)-Quality Assurance Requirements for Cleaning of Fluid Systems and Associated Components of Water-Cooled Nuclear Power Plants	Conforms	RG 1.37 Rev.(0) incorporates ANSI N45.2.1-1973. For new construction activities, the cleanliness requirements of ANSI N45.2.1-1973 as modified by RG 1.37 are followed. Consistent with Position C.2 of RG 1.37, the cleanliness requirements of this standard are used when applicable to maintenance on operating systems. The cleanliness requirements applied to operational systems are established in station procedures.
Regulatory Guide 1.38 Rev.(2)-Quality Assurance Requirements for Packaging, Shipping, Receiving, Storage, and Handling of Items for Water-Cooled Nuclear Power Plants	Conforms	RG 1.38 Rev.(2) incorporates ANSI N45.2.2-1972.
Regulatory Guide 1.39 Rev.(2)-Housekeeping Requirements for Water-Cooled Nuclear Power Plants	Conforms	RG 1.39 Rev.(2) incorporates ANSI N45.2.3-1973.
Regulatory Guide 1.54 Rev.(0)-Quality Assurance Requirements for Protective Coatings Applied to Water-Cooled Nuclear Power Plants	Alternative	For new coatings and configuration changes to existing coatings, which have the potential to adversely affect a safety related function, the quality assurance requirements of 10CFR50, Appendix B, in conjunction with engineering specifications, are used instead of the detailed requirements included in this Regulatory Guide and its referenced standard, ANSI N101.4-1972.

TABLE 17.1.7-1 (cont'd)

Standard, Requirement, or Guide	Conformance Status	Remarks
Regulatory Guide 1.58 Rev.(1)-Qualification of Nuclear Power Plant Inspection, Examination, and Testing Personnel	Alternative	RG 1.58 Rev.(1) incorporates ANSI N45.2.6-1978. Ginna conforms to Reg. Guide 1.58 Rev.(1) and ANSI N45.2.6-1978 with the following exceptions: • A 90 day grace period may be applied to the performance of annual evaluations of inspection, examination and testing personnel qualifications defined in Section 2.3 of ANSI N45.2.6-1978. • A 90 day grace period may be applied to the annual verification of special physical characteristics defined in Section 2.5 of ANSI N45.2.6-1978. • RG&E's ISI Plan endorses ASME Code Section XI. The version of the ASME code endorsed is updated periodically. ASME Code Section XI references standards for the qualification and certification of nondestructive testing personnel. Section XI of the ASME Code contains specific requirements for nondestructive examination and also references the use of other supplementary standards for the qualification and certification of personnel performing nondestructive examinations. The applicable versions of the standards referenced in Section XI of the ASME code, as permitted for use by 10 CFR Part 50.55a, may be used for the qualification and certification of personnel performing nondestructive examinations required by Section III and Section XI of the ASME Code in lieu of the standard identified in Reg. Guide 1.58, Rev. 1, (SNT-TC-1A-1975) provided that other applicable rules contained in Section XI of the ASME Code are met.
Regulatory Guide 1.64 Rev.(1)-Quality Assurance Requirements for Design of Nuclear Power Plants	Conforms	RG 1.64 Rev.(1) incorporates ANSI N45.2.11-1974.
Regulatory Guide 1.74 Rev.(0)-Quality Assurance Terms and Definitions	Conforms	RG 1.74 Rev.(0) incorporates ANSI N45.2.10-1973. Some definitions used by Ginna are worded differently than those in this standard; however, the general meanings are the same.
Regulatory Guide 1.88 Rev.(2)-Collection, Storage, and Maintenance of Nuclear Power Plant Quality Assurance Records	Alternative	RG 1.88 Rev.(2) incorporates ANSI N45.2.9-1974. Ginna conforms to ANSI N45.2.9-1974 as supplemented by the following alternatives to the requirements in Section 5.6 (Facility). • Records may be stored in a 2 hour rated facility meeting the requirements described in QAPSO Section 17.2.15. • Records may be stored temporarily in 1 hour fire rated cabinets provided that the requirements of QAPSO Section 17.2.15 are met.

TABLE 17.1.7-1 (cont'd)

Standard, Requirement, or Guide	Conformance Status	Remarks
Regulatory Guide 1.94 Rev. (1)-Quality Assurance Installation, Inspections, and Testing of Structural Concrete and Structural Steel During the Construction Phase of Nuclear Power Plants	Not applicable	RG 1.94 Rev.(1) incorporates ANSI N45.2.5-1974. Regulatory Guide applies to plants in the construction phase and was issued after Ginna was built.
Regulatory Guide 1.116 Rev.(0-R)-Quality Assurance Requirements for Installation, Inspections, and Testing of Mechanical Equipment and Systems	Conforms	RG 1.116 Rev.(0-R) incorporates ANSI N45.2.8-1975.
Regulatory Guide 1.123 Rev.(1)-Quality Assurance Requirements for Control of Procurement of Items and Services for Nuclear Power Plants	Conforms	RG 1.123 Rev.(1) incorporates ANSI N45.2.13-1976.
Regulatory Guide 1.143 Rev.(1)-Design Guidance for Radioactive Waste Management Systems, Structures, and Components Installed in Light-Water-Cooled Nuclear Power Plants	Alternative	See the UFSAR for design and quality assurance provisions applied to existing radioactive waste management systems, structures, and components. New systems, structures, and components and configuration changes to existing items meet the design and quality assurance provisions described in the UFSAR or those specified by this Regulatory Guide.

TABLE 17.1.7-1 (cont'd)

Standard, Requirement, or Guide	Conformance Status	Remarks
Regulatory Guide 1.144 Rev.(1)-Auditing of Quality Assurance Programs for Nuclear Power Plants	Alternative	RG 1.144 Rev.(1) incorporates ANSI N45.2.12-1977. Ginna conforms to RG 1.144 Rev.(1) and ANSI N45.2.12-1977 with the following exceptions: • A grace period of 90 days may be applied to the performance of triennial supplier audits and annual supplier evaluations described in Section C.3.b.(2). • In lieu of the 30 day requirement of Section 4.5.1 of ANSI N45.2.12-1977 the following is used: Corrective action response due dates and priority shall be based on safety significance. For audit findings that are determined to be significant conditions adverse to quality, the audited organization's response shall be provided within 30 days. In the event that the corrective action for an audit finding cannot be completed by the response due date, the audited organization's response shall include a scheduled date for corrective action. • In lieu of the requirements of Section 4.5.1 of ANSI N45.2.12-1977, the following is used in cases where the audited organization is a supplier: Ginna LLC shall evaluate the acceptability of actions taken to address findings from audits of suppliers. In cases where corrective actions are not taken or are not satisfactory, and the product or service of the supplier is still desired, compensatory actions shall be taken to ensure the quality of the products or services. These actions may include: commercially dedicating the product or service, restrictions placed on supplier activities, surveillance of supplier activities, or inspection/testing of supplier products and services. In cases where the vendor does not comply with 10CFR21, the vendor shall be removed from the Approved Vendors List. The following additional controls shall be applied when this alternative is used: - Supplier program deficiencies that require compensatory actions by Ginna LLC will be documented in the station's corrective action process. - Compensatory actions to be taken shall be established within 30 days of discovery by Ginna LLC of the condition that requires the actions. - Records of compensatory actions taken shall be retained as records in accordance with ANSI N45.2.9.

TABLE 17.1.7-1 (cont'd)

Standard, Requirement, or Guide	Conformance Status	Remarks
Regulatory Guide 1.146 Rev.(0)-Qualification of QA Program Audit Personnel for Nuclear Power Plants	Alternative	RG 1.146 Rev.(0) incorporates ANSI N45.2.23-1978. Ginna conforms to RG 1.146 Rev.(0) and ANSI N45.2.23-1978 with the following exceptions: • A grace period of 90 days may be applied to the performance of annual lead auditor recertifications described in Sections 3.2 and 5.3 of ANSI N45.2.23-1978. • With regard to Section 2.3.1.3 of ANSI N45.2.23-1978, holders of NRC issued Reactor Operator/Senior Reactor Operator Licenses comply with the requirements of this section and may be awarded two credits. • In lieu of the requirements of 2.3.4 of ANSI N45.2.23-1978 the following is used: Prospective lead auditors shall demonstrate their ability to effectively implement the audit process and effectively lead an audit team. Ginna LLC will describe this demonstration process in written procedures and shall evaluate and document the results of the demonstration. Regardless of the methods used for the demonstration, the prospective lead auditor shall have participated in at least one nuclear quality assurance audit within the year preceding the individual's effective date of qualification. Upon successful demonstration of the ability to effectively implement the audit process and effectively lead audits, and having met the other provisions of Section 2.3 of ANSI N45.2.23-1978, the individual may be certified as being qualified to lead audits.
Regulatory Guide 1.152 Rev.(0)-Criteria for Programmable Digital Computer System Software in Safety-Related Systems of Nuclear Power Plants	Alternative	Ginna conforms to Generic Letter 95-02, and its endorsement of NUMARC/EPRI Report TR-102348 "Guidelines on Licensing Digital Upgrades".
Regulatory Guide 4.15 Rev.(1)-Quality Assurance for Radiological Monitoring Program (Normal Operations)-Effluent Streams and the Environment	Adopted	Ginna conforms to the intent of this Regulatory Guide as addressed in the Process Control Program and applicable to Ginna effluent and environmental radioactivity measurements.
Regulatory Guide 7.10 Rev.(1)-Establishing Quality Assurance Programs for Packaging Used in the Transport of Radioactive Material	Adopted	Ginna conforms to the intent of this Regulatory Guide as addressed in the Process Control Program.
10CFR21	Conforms	
10CFR50, Appendix A-General Design Criteria	Alternative	These criteria were in draft form or not written at the time Ginna was designed and built. For existing systems, see UFSAR for criteria applied. New systems, structures, and components, and configuration changes to existing items meet the criteria as described in the UFSAR or 10CFR50, Appendix A.

TABLE 17.1.7-1 (cont'd)

Standard, Requirement, or Guide	Conformance Status	Remarks
10CFR50, Appendix B-Quality Assurance Criteria for Nuclear Power Plants	Conforms	
10CFR50.55a-Licensing of Production and Utilization Facilities (ASME Boiler and Pressure Vessel Code, Section XI-Rules for Inservice Inspection of Nuclear Reactor Coolant Systems)	Conforms	10CFR50.55 specifies ASME Section XI code dates. The Ginna program conforms to 10CFR50.55a with the specific editions and addenda of Section XI specified in the Inservice Inspection Plan.
10CFR50.55(e)-Conditions of Construction Permits	Not applicable	Regulatory Guide applies to plants in the construction phase.
10CFR55-Operators Licenses	Conforms	
Regulatory Positions 2 and 4 of Branch Technical Position CMEB 9.5-1	Alternative	Fire protection controls are in accordance with APCSB 9.5-1, regulatory position IV b.6 and IV b.7.
Generic Letter 89-02, and its endorsement of EPRI NP5652 "Guideline for the Utilization of Commercial Grade Items in Safety-Related Applications (NCIG-07)".	Conforms	
ANSI/ANS 3.1-1987, Selection, Qualification and Training of Personnel for Nuclear Power Plants, section 4.7.	Conforms	Qualification requirements apply to NSRB members only as addressed by this standard.

17.2 PERFORMANCE/VERIFICATION

17.2.1 Methodology

All personnel performing activities affecting quality involved in the operation and support of Ginna Station are directly responsible for quality. Employees are empowered to make decisions in their areas of responsibility and are held accountable for the quality of their own work. Verification of work is performed by each organization to assure that quality objectives are achieved and established performance standards are met.

Nuclear Operations and supporting organizations involved in Ginna quality related activities accomplish and verify their work using instructions and procedures. For quality affecting activities within their area of responsibility, each organization develops, reviews, approves, and implements such documents. The activities covered include operation, maintenance, repair, inservice inspection, refueling, procurement, modification, special processes, inspection and testing, document control and records management, training of personnel, and audit and surveillance. In addition, Ginna LLC suppliers and contractors are required to have appropriate instructions and procedures as specified in procurement documents.

Persons preparing, reviewing, and approving instructions and procedures are responsible for assuring that they include appropriate quantitative or qualitative acceptance criteria for determining that important activities have been satisfactorily accomplished. In addition, they assure that these documents are kept current.

17.2.2 Design Control

Plant configuration changes, including temporary changes, are implemented utilizing design control measures at least commensurate with those applied to the original design.

Nuclear Engineering Services is the design authority for Ginna Station. Other organizations are authorized to perform design activities as designated in the Nuclear Policy Manual and supported by approved procedures and instructions.

Design control measures are defined and implemented by trained and qualified personnel through approved procedures and instructions. These procedures and instructions assure that:

- Design inputs are appropriately specified on a timely basis and correctly translated into design documents
- Design interfaces are identified and controlled
- The design is suitable for its intended application
- Design adequacy is verified by personnel other than those who performed the design
- Design changes, including field changes, are governed by

control measures
- Deviations and nonconformances are controlled
- Design records are identified, controlled, and retrievable

Design inputs (such as design bases, performance requirements, regulatory requirements, codes, and standards) and changes to design inputs are identified, documented, reviewed and approved, and controlled.

Design documents, including drawings and specifications, are prepared and technically reviewed by qualified personnel. The technical reviewer ensures that the design document is in accordance with the design concept, incorporates appropriate design inputs, and conforms to approved procedures and instructions. Design change packages are approved by appropriate management or supervision prior to release for implementation.

Design interfaces, both internal and external, are formally identified, and design activities are coordinated among the participating organizations to ensure that design inputs and outputs are properly developed, reviewed, approved, and distributed. Multi-discipline changes are reviewed to ensure integration of design outputs.

Design changes are reviewed to determine whether the change results in a change to plant Technical Specifications or requires regulatory review in accordance with 10CFR50.59.

Design data bases, documents, and procedures are revised to reflect changes installed in the plant. Design records are identified, indexed, and controlled to allow for retrievability of design basis information and to provide evidence of appropriate design controls.

17.2.3 Design Verification

Design verification is the process of reviewing, confirming, or substantiating the design to assure:

- the acceptability of the design inputs
- adherence to the design process
- that the design inputs are reflected in the design outputs
- that design changes are implemented under controls commensurate with those applied to the initial design

Procedures define acceptable verification methods and controls, design parameters subject to verification, acceptance criteria, and verification documentation and records requirements.

A design change is verified prior to release of the change to perform its design function. A design may be released for prefabrication or installation prior to completion of the design verification only if controls are established. The scope of work that can be completed must be defined and controls implemented to ensure that design verification is completed prior to use of the

change.

Verification methods include:

- performance of design reviews
- use of alternate calculations
- performance of qualification tests

If used, qualification tests shall verify the adequacy of the specific design or design feature under the most adverse design conditions, unless those conditions cannot be generated without initiating a plant transient. In those cases, simulated or extrapolated conditions are used.

Design verification is performed by technically qualified individuals other than those who developed the design. Design verification by the designer's immediate supervisor is allowable if other qualified individuals are not readily available. The designer's supervisor documents independence from the design development when required to perform a verification.

The design organization determines the extent of verification required, based upon safety significance, the degree of standardization, and the state-of-the-art of the change.

17.2.4 Procurement Control

Purchased material, equipment, and services are controlled using five major means:

- planning
- procurement document requirements
- supplier selection
- control of supplier performance
- acceptance of items and services

All procurement is conducted in accordance with procurement documents and governing procedures. In unusual circumstances, (e.g. replacement parts are needed to preclude the development of some unsafe or undesirable condition), an item, which is relatively simple and standard in design and manufacture, may be purchased under a commercial (non-safety related) purchase order and subsequently upgraded to safety-related using the commercial grade dedication process.

All reviews, inspections, surveillances, and audits are conducted by personnel who are competent to determine whether a supplier is capable of providing acceptable quality products.

Planning

Procurement planning by procuring organizations consists of determining the supplier of choice, methods to be used for acceptance of the item or service, and requirements for control of supplier performance. Source inspection (surveillance),

certificate of conformance, receipt inspection, and pre- or post-installation testing are methods which are considered for item acceptance. The extent of the acceptance methods and associated verification activities will vary depending upon the relative importance and complexity of the purchased item or service and the supplier's past performance.

Procurement Document Requirements

Procurement document control for the procurement of materials, parts, components, and services is initiated by department staff personnel. Procurement procedures require that organizations preparing procurement documents consider and include, as appropriate:

- scope of work
- technical requirements
- Quality Assurance Program requirements
- right of access
- documentation requirements
- reporting requirements (nonconformance and 10CFR Part 21)

Changes or revisions to procurement documents are subject to the same review and approval requirements as the original documents.

Originating department review of procurement documents includes verification of applicable regulatory, code, and design requirements and suitability for intended service. In addition, a verification of proper inclusion of the quality standards, quality assurance program requirements, method of procurement, and the applicable acceptance criteria is performed. For spare or replacement parts, procurement documents are reviewed to determine similarity to, compatibility with, and acceptance criteria commensurate with the original design. Personnel performing these reviews shall be trained and qualified in accordance with the training programs discussed in Section 17.1.5.

Supplier Selection

Selection of a supplier is based on the evaluation of their capability to provide the items or services in accordance with procurement document requirements. The evaluation, which is accomplished during procurement planning, determines the necessity for the supplier selection to be made from the approved vendors list. For items and services procured from suppliers required to have a quality assurance program, supplier selection is made from the approved vendors list or from those who are in the process of being added to the list. Addition of a supplier to the approved vendors list is based on satisfactory evaluation of the supplier's quality assurance program. The evaluation guidelines for source selection considers the complexity of the item, method(s) of acceptance, and, for a replacement item, whether the source is to be restricted to the original supplier.

Items or services which meet industry standards and are typically utilized in applications other than nuclear may be purchased from suppliers not listed on the approved vendors list, provided that item acceptance through receipt inspection can be based on acceptance of standard commercial quality. This is supplemented, as necessary, with source surveillance, pre- or post-installation tests, receipt tests, commercial supplier surveys, supplier test reports, or commercial supplier certificates. For commercial grade items and services, an evaluation of intended use is completed to determine critical characteristics which must be verified prior to acceptance for use.

Control of Supplier Performance

Control of supplier performance shall include:

- Monitoring supplier activities through audits and surveillances
- Evaluation by requesting submittal of supplier documents for review
- Identifying under what conditions suppliers are to report nonconformances

Acceptance of Items and Services

The verification methods for the acceptance of items and services are specified during procurement planning and purchase order preparation. Receipt inspection is a verification method common for the acceptance of items.

17.2.5 Procurement Verification

The supplier's overall quality assurance organization and program is evaluated in accordance with applicable parts of 10CFR50, Appendix B; codes and standards; and Ginna LLC requirements. Suppliers on the approved vendors list are reviewed annually for performance and program changes, and audited on a triennial basis.

The degree of supplier surveillance (including review, inspection, or audit) required during design, fabrication, inspection, testing, and shipping shall be determined and documented. The objectives of supplier surveillance are to provide a sampling review of the supplier's quality assurance program implementation and to verify product conformance with respect to the purchase order requirements. The extent of supplier surveillance will be consistent with the safety significance, complexity, quantity, and frequency of procurement of the item or service. As necessary, this may require verification of the activities of suppliers below the first tier.

The verification responsibilities for evaluation and surveillance of supplier activities are assigned to Quality and Performance Assessment.

Department supervision is responsible for receipt and control of items pending their acceptance.

Receipt inspection is performed for items and associated services

for maintenance, repair, modification, and refueling. Inspections are performed to verify acceptability. To be acceptable, the items and services must conform to procurement documents, have satisfied required inspection and test requirements, and have documentary evidence of conformance available at the plant prior to acceptance for use. Personnel performing receipt inspection and test activities are trained and qualified.

17.2.6 Identification and Control of Items

The identification and control of materials, parts, and components (including consumable materials and items with limited shelf life) is accomplished in accordance with written requirements and applies in any stage of fabrication, storage, or installation. Identification and control requirements are established either by an existing procedure or by requirement documents prepared during the planning stages of a project. The identification and control requirements cover:

- Traceability to associated documents (such as drawings, specifications, purchase orders, manufacturing test data and inspection documents, and physical and chemical mill test reports)
- Specification of the degree of identification to preclude a degradation of the item's functional capability or quality
- Proper identification of materials, parts, and components prior to release for manufacturing, shipping, construction, and installation

Nuclear Engineering Services is responsible for assuring that drawings and specifications contain appropriate requirements for the identification and control of materials, parts, or components. Suppliers are required to assure that all required documentation for an item is properly identified and related to the item.

17.2.7 Handling, Storage, and Shipping

Nuclear Operations and support organizations are responsible for developing and implementing procedures for the handling, storage, shipping, preservation, and cleaning of quality related material and equipment. These procedures provide guidelines to protect items from damage, loss, and deterioration. Also, items are marked or labeled during packaging, shipping, handling, and storage to identify and maintain the items' integrity and to indicate need for special controls.

Under normal circumstances, manufacturer's specific written instructions and recommendations and purchase specification requirements are invoked for cleanliness, preservation, special handling, and environmental requirements for storage. In the absence of, or in addition to, specific manufacturer requirements, management may invoke requirements in accordance with department procedures. Examples of such requirements include desiccants, shelf life, endcaps, and special packaging

requirements.

Procurement documents and engineering specifications define requirements for the handling, shipping, storage, cleaning, and preservation of new fuel and fuel assemblies, materials, and equipment. When necessary to maintain acceptable quality, special protective measures (such as containers, shock absorbers, etc.) are specified and provided.

Procedures are established for the routine maintenance and inspection of lifting and handling equipment and for the handling of heavy loads and safe load paths.

17.2.8 Test Control

The Ginna Station test program includes the surveillance test program required by Technical Specifications, inservice pump and valve testing, and testing following modification and maintenance.

The test program requires the identification, control, and documentation of all tests and the preparation of written procedures required for satisfactory accomplishment of the testing. Written procedures and checklists for the testing program include: instructions and prerequisites to perform the test, use of proper test equipment, inspection hold points, and acceptance criteria.

Testing is utilized as follows:

- To determine continued operability of installed structures, systems, and components consistent with the surveillance requirements of Technical Specifications and the inservice pump and valve program
- To demonstrate the ability and to support the qualification of safety related equipment to function in harsh environmental conditions
- To demonstrate the acceptability of replacement and purchased items
- To support troubleshooting and investigation of degraded conditions
- To demonstrate the acceptability of items involved in maintenance, repair, and modifications

Contractors who perform testing are required to do so in accordance with Ginna LLC procurement document requirements.

All test results are required to be documented, reviewed, and approved by those responsible for performing the test. Unacceptable test results and test anomalies are evaluated in accordance with established procedures to determine the cause of the problem and the need for retest or for increasing test frequency.

The design organization is responsible for assuring that required tests for modifications are included in design documents.

17.2.9 Measuring and Test Equipment Control

Programs are established which assure that test instruments, tools, gauges, shop and reference standards, and other measuring and testing devices used in activities affecting quality are properly controlled and calibrated. Elements of control include calibration procedures, establishment of calibration frequencies, and maintenance requirements for measuring and test equipment.

Calibration procedures include step-by-step calibration methods and requirements for instrument accuracy. Calibration frequency is based on required accuracy, degree of usage, stability characteristics, manufacturer's recommendations, experience, and other conditions affecting measurement capability.

The program for control of measuring and test equipment includes:

- Assuring timely calibration of equipment.
- Providing unique identification of the next calibration date on the equipment calibration tags or stickers and traceability to calibration test data.
- Providing traceability of shop standards to nationally recognized standards and periodic revalidation of shop standards. Where national standards do not exist, procedures contain instructions to document the basis for calibration. Except where standards with the same accuracy as the instruments being calibrated are shown to be adequate for the requirements, calibration standards are to have a greater accuracy than the standards being calibrated.
- Assuring that calibrating equipment is calibrated against standards that have an accuracy of at least four times the required accuracy of the equipment being calibrated or, if not possible, have an accuracy that ensures the equipment being calibrated will be within the required tolerance.
- Providing for records to be maintained which indicate the complete status of all items under the calibration system including the maintenance, calibration results, abnormalities, and last and future calibration dates.
- Controlling the purchase requirements of new equipment to be entered into the calibration and control system including requirements for accuracy, stability, and repeatability under normal use conditions.

In the event a measuring instrument (i.e., shop or field standard) is found out of calibration, an investigation is conducted to determine the validity of previous measurements.

Responsibilities and requirements for the selection and use of calibrated measuring and test equipment are described in the Nuclear Policy Manual and related procedures.

Installed plant instrumentation is subject to calibration and control requirements of Technical Specifications and is not subject to calibration and control requirements for measuring and test equipment. The Nuclear Policy Manual amplifies responsibilities and requirements for installed plant instruments.

17.2.10 Inspection, Test, and Operating Status

Equipment or systems not ready for normal service are clearly identified by use of tags, control logs, and other suitable means to indicate the status of the items being isolated in order to prevent their inadvertent use.

Ginna Station is responsible for indicating the status of operating equipment or systems to be removed from service for maintenance, repair, or modification in accordance with the approved Electric System Operating Rules.

System status is indicated through the use of hold tags, block tags, and corresponding control logs. Equipment or system inspection and test status are indicated by use of test tags, labels, or status sheets.

Written procedures control the use of hold tags, test tags, and labels. Personnel who have station holding authority, as designated by the Plant General Manager, Ginna Station, are responsible for directing the status change of equipment and systems in accordance with the approved station holding procedures.

Job control documents are used to indicate status of the work, inspections or tests, and corresponding acceptance or rejection criteria. These job control documents preclude the inadvertent bypassing of inspections and tests. They are maintained at a designated control location to indicate the status and the completion of required inspections and tests.

Measures are established to monitor the completion status of inservice inspection.

17.2.11 Special Process Control

Written procedures are established to control special processes, such as welding, brazing, heat treating, and nondestructive examination to assure compliance with applicable codes, standards, and design specifications. Qualification of personnel and special process procedures comply with the requirements of applicable codes and standards. When special process qualification requirements are not included in existing codes and standards, they are described in procedures which give details of the special process, personnel qualification requirements, equipment necessary, and special process qualification requirements.

The Nuclear Policy Manual describes the criteria that define which processes are special. These criteria include processes which are highly dependent on the skill of the worker or the control of the process or both, and in which the desired quality cannot be readily determined by inspection or test.

Procuring organizations are responsible for requiring suppliers, in procurement documents, to control special processes in accordance with the above requirements. Special process procedures submitted by suppliers and contractors are reviewed

for adequacy by Ginna LLC.

Nuclear Operations organizations are responsible for assuring that personnel performing special processes under their cognizance are qualified and are using qualified procedures. Qualification of personnel and procedures is documented.

17.2.12 Inspection

Procedures prepared for the control of activities include inspection requirements and hold points as required by drawings, instructions, requirement documents, specifications, codes, standards, or regulatory requirements. For clarification, and to distinguish from preventive maintenance inspections, the following controls are associated with the quality assurance function inspections and referred to as verification inspections.

Verification inspection planning is used to determine the optimum method for performing hold point or final inspections. Planning considerations include: hold point execution by witness or inspection, the need for calibrated measuring tools and equipment, use of sample plans for multiple quantities, and the need for other verification options (e.g., non-destructive examination).

Hold points are used as necessary to ensure that inspections are accomplished at the correct points in the sequence of work activities.

Verification inspection procedures include:

- identification of quality characteristics to be inspected
- a description of the method of inspection to be used
- acceptance and rejection criteria
- requirements for recording the inspection results
- the need to provide evidence of inspection activity completion

Verification inspections are performed by inspection personnel who are appropriately qualified and independent. They are performed in accordance with approved procedures, instructions, or plans to support preplanned hold points, final acceptance verification, or receipt acceptance activities. Inspection results are required to be documented. When items are reworked, the rework is reinspected to the original or equivalent requirements.

Outside contractors are required by procurement documents to have and to follow similar procedures and to use independent inspectors.

17.2.13 Corrective Action

Conditions adverse to quality are those conditions which reduce confidence that a structure, system, or component at Ginna Station will perform satisfactorily in service.

Significant conditions adverse to quality are those conditions which, if uncorrected, could affect the health and safety of the public, seriously affect the ability to operate the plant in a safe manner, represent a serious breakdown in activity controls, or will require a major effort to restore capability to perform specified functions.

Conditions adverse to quality are promptly identified, reported to supervision, corrected, and evaluated to determine if a significant condition adverse to quality exists.

When a significant condition adverse to quality is identified, an evaluation of the effect of continuing the activity is performed. If continuing the activity would obscure or preclude identification and correction of the deficiency, or if continuing the activity would increase the extent of the deficiency or lead to an unsafe condition, stop work action is taken.

Designated independent inspection and audit personnel have authority to stop work on all activities at or in support of Ginna Station, with the exception of operating deficiencies. For operating deficiencies, designated independent inspection and audit personnel may recommend stop work action to station management.

For significant conditions adverse to quality, Ginna LLC management reviews initiated reports to determine causes, develops corrective action plans to resolve the condition, and takes action to preclude recurrence.

Procedures are established for the control, evaluation, and disposition of deficient material, parts, and components to prevent their inadvertent test, installation, or use. Items which do not conform to the drawing or specification requirements are identified, controlled, and reported.

Nonconformances identified at a supplier's facility and reported to Ginna LLC, for which the supplier has recommended a disposition of use-as-is or repair, are normally reviewed and the disposition approved by the procuring organization.

Items are repaired and reworked in accordance with approved procedures and drawings. The repair or rework must be verified as acceptable by an inspection of the affected item or process which is at least equal to the original inspection method.

Items which are accepted "use-as-is" are fully documented with the drawing or specification requirement and technical justification for acceptance, and are screened under the requirements of 10CFR50.59.

Nonconformance status information is compiled and analyzed for adverse trends and provided to management.

17.2.14 Document Control

Document control requirements contained in the Nuclear Policy Manual control the issuance of procedures, instructions, drawings, and specifications. These document control requirements are delineated in approved procedures which define the responsibilities for the control of each type of controlled document.

Each organization responsible for an activity is also responsible for providing the necessary review and approval of instructions, procedures, or drawings. Such review is to assure that documents are adequate, include appropriate qualitative and quantitative requirements, and include quality assurance requirements.

Changes to procedures specified in the Administrative Controls Section of the Technical Specifications receive a technical review in accordance with ANSI/ANS 3.2-1988, Section 4.2. The change also receives an applicability review, and if necessary, a screening to determine if a 10CFR50.59 evaluation is required. Reviewers shall not have been involved with formulating the change, shall be designated by the PORC Chairman or Plant General Manager, Ginna Station, and shall have qualifications equivalent to those of regular PORC members and meet ANSI Standard N18.1-1971, Section 4.3.1 or 4.4 as applicable. Changes that have been determined to require a 10CFR50.59 evaluation are referred to and subsequently reviewed by PORC. The change is subsequently approved by the Plant General Manager, Ginna Station or designee. All procedure changes have a minimum of two individuals involved.

Temporary changes to procedures, in addition to the review and approval process described above, are also approved by the Shift Supervisor. Requirements for the pre-approval review of Ginna Station procedures and the temporary change process are consistent with the guidelines of ANSI N18.7-1972, Sections 5.4 and 5.5.

The Nuclear Policy Manual requires that documents be controlled as appropriate, considering the type of document, safety significance, and intended use.

Types of documents which are controlled include Technical Specifications, UFSAR, Nuclear Directives, procedures, drawings, and specifications.

Suppliers of materials, equipment, and services having an approved quality assurance program are required in procurement documents to provide for control of documents.

The Nuclear Policy Manual requires that each organization provide in its procedures for measures to:

- Assure that documents are available when required
- Properly review and approve documents such as procedures and instructions
- Provide the same reviews and approvals for changes to documents as was required of the original document
- Require that organizations which review and approve documents have access to pertinent information and adequate knowledge of the original document intent
- Assure that approved changes are promptly transmitted for incorporation into documents
- Assure that obsolete or superseded documents are eliminated from the system and not used

17.2.15 Records

The Nuclear Policy Manual defines responsibility and establishes the basic requirements for quality assurance record retention and maintenance. Organizations performing quality affecting activities are responsible for forwarding the records they initiate to Records Management. Each organization generating records is responsible for preparation, review, approval, and implementation of specific quality assurance record procedures for their area of responsibility.

Records to be controlled are delineated in ANSI N45.2.9-1974. Sufficient records of items and activities are generated and maintained to document completed work. Items and activities requiring records include:

- design
- engineering
- procurement
- manufacturing
- construction
- inspection and test (e.g., manufacturer's proof and receipt)
- installation
- operations
- maintenance
- modification
- audits

Requirements and responsibilities for preparation, inspection, identification, indexing, review, storage, retrieval, maintenance, safekeeping, retention, and disposition of quality assurance records are in accordance with applicable records procedures, codes, standards, and procurement documents.

Non-duplicated records shall be stored in facilities which meet one of the following requirements:

The first option is a NFPA Class A, four hour minimum rated facility. In addition, this facility shall consider the nine features described in ANSI N45.2.9-1974 Section 5.6 in its construction.

The second option is a two hour rated facility designed to meet the requirements of NFPA 232 "Standard for the Protection of Records." These requirements may be met by any one of the following three ways: (1) a 2 hour vault meeting NFPA 232; (2) 2 hour rated file containers meeting NFPA 232 (Class B); or (3) a 2 hour rated fire resistant file room meeting NFPA 232. A fire resistant file room must meet the following additional provisions:

a. Early warning fire detection and automatic fire suppression should be provided, with electronic supervision at a constantly attended central station.
b. Records should be stored in fully enclosed metal cabinets. Records should not be permitted on open steel shelving. No storage of records should be permitted on the floor of the facility. Adequate access and aisle ways should be maintained at all times throughout the facility.
c. Work not directly associated with records storage or retrieval should be prohibited within the records storage facility. Examples of such prohibited activities include but are not limited to: records reproduction, film developing, and fabrication of microfiche cards.
d. Smoking and eating/drinking should be prohibited throughout the records storage facility.
e. Ventilation, temperature, and humidity control equipment should be protected inside with standard fire-door dampers where they penetrate fire barriers bounding the storage facility.

The third option is used when temporary storage of records (such as for processing, review, or use) is required. In this case, records shall be stored in a 1 hour fire rated container. The container shall bear a UL label (or equivalent) certifying 1 hour fire protection or be certified by a person competent in the technical field of fire protection. Additionally, sprinkler protection shall be provided in the area in which the containers are stored. The maximum allowable time limit for temporary storage is described in procedures.

The requirements and responsibilities for record accessibility and transmittal are described in the Nuclear Policy Manual. Removal of records from storage is documented and accountability is maintained by the responsible record control organization.

17.3 ASSESSMENT

17.3.1 Methodology

A comprehensive program of planned and periodic self and independent assessments is established to keep management apprised of the overall performance of Ginna Station.

Managers and supervisors assess the activities and results within their organizations' areas of responsibility to assure that they meet quality requirements and performance standards. Through observation and routine monitoring, they detect adverse operational events, declining performance trends, and precursors of potential problems. They take action to correct these problems as well as those identified by external sources.

Independent assessment of the effectiveness of quality program implementation and overall Ginna Station performance is the primary role of the QA organization. Independent assessments are conducted through internal audits and QA surveillances on behalf of the NSRB; the Vice President, Ginna; and as requested by line management. This is accomplished by monitoring performance, reporting findings to line management in a timely manner, and verifying satisfactory resolution of problems. Operational assessment is the evaluation of anomalous performance and potential problem precursors from external sources.

The NSRB conducts independent assessment through periodic review of plant activities and by directing biennial audits and evaluating their results. The responsibilities of the NSRB are discussed in sections 17.1.2 and 17.1.3.

Independent assessment activities are performed in accordance with instructions and procedures by organizations independent of the areas being assessed. Organizations performing independent assessment are technically and performance oriented, with their primary focus on the quality of the end product and secondary focus on processes.

17.3.2 Assessment

Self-assessment

Self-assessment is established in the Nuclear Policy Manual as the responsibility of all organizations with involvement in the operation and support of Ginna Station. Individuals and work groups are accountable for achieving acceptable quality by adhering to procedures and verifying that their work meets quality requirements and performance standards.

Independent Assessment

A program of planned and periodic independent assessments is established and implemented to confirm that activities affecting quality comply with the Quality Assurance Program and that the program has been implemented effectively. Assessments provide comprehensive independent evaluation of activities, results, and procedures.

The independent assessment program includes internal audits, external audits, and QA surveillances. These assessments are both performance-based and compliance-based, with the focus on activities and functions which often cut across organizational lines. Strengths and weaknesses of an organization's performance are determined in these assessments, allowing QA to identify areas of weaknesses for more frequent scrutiny. In areas of strength, assessment efforts can be reduced, freeing resources for examination of activities that could benefit most from independent assessment.

Internal audits of selected aspects of quality affecting activities are performed at a frequency commensurate with safety significance and management concerns. The audits are regularly scheduled on a formal, preplanned audit schedule in a manner which assures that audits of safety related activities are completed once every twenty-four (24) months. The audit schedule is dynamic, reviewed and revised periodically to assure appropriate coverage of current and planned activities.

Table 17.3.2-1 is a list of audits. Supplementing this list are audits of the Nuclear Emergency Response Plan to satisfy the requirements of 10CFR50.54 (t), and Station Security Plan to satisfy the requirements of 10CFR50.54 (p)(3), 73.56 (g)(1) and (g)(2) and 10CFR73.55 (g)(4). Audits may also be used to meet the periodic review requirements of the code for the Radiological Protection program. Audit frequency and further discussion of these audits are described in their respective plans. Required audits may be accomplished using one of the following methods:

- Audit activities only,
- A combination of audit and QA surveillance activities, or
- A series of QA surveillance activities.

When the results of QA surveillance activities are used, the audit team leader must:

- Review the results of the QA Surveillance(s) for applicability,
- Integrate those results into the audit scope, and
- Include those results in the audit report.

QA surveillances, by their nature, require less planning and are more responsive to management requests. They are also better suited to event driven activities, such as drills, corrective maintenance, and surveillance tests.

Additional audits and QA surveillances are conducted as necessitated by situations or evaluations including:

- special conditions which preclude deferral
- management concerns resulting from previous assessment results and corrective action
- information from external sources (e.g., generic experience of the nuclear industry, ASME, peer organizations, and regulatory bodies)

Each audit requires the development of an audit plan to provide

information about the audit, such as characteristics and activities to be assessed, acceptance criteria, names of those who will perform the audit, scheduling arrangements, and the method of reporting findings and recommendations. Audit planning and performance utilize performance-based techniques that facilitate achievement of assessment objectives.

Audit and QA surveillance assessments are performed in accordance with written procedures or checklists by personnel who do not have direct responsibility in the areas being assessed. Independent assessments may be conducted by Quality and Performance Assessment engineers or other qualified personnel, such as technical specialists from other company departments, outside consultants, and individuals from other utilities.

Assessment results are documented and reported to the assessor's management, the supervisor and group head having responsibility in the area assessed, and, for internal audits, to the Nuclear Safety Review Board. Within a specified time period, the person having supervisory responsibility in the area assessed is required to review the results, take necessary action to correct the deficiencies identified by the report, and document and report the corrective action.

External audits of major contractors, subcontractors, and suppliers are conducted during the early stages of design and procurement to evaluate their quality assurance program for compliance with all procurement document requirements. Audits are conducted, as necessary, to assure that major contractors, subcontractors, and suppliers are auditing their suppliers' quality assurance programs in accordance with procurement documents. During the project or procurement process, additional audits are performed, as required, to assure all quality assurance program requirements are properly implemented in accordance with procurement documents.

Nuclear Assessment performs regular analyses of assessment results to evaluate quality and performance trends. Results of these analyses, including strengths and weaknesses, are provided to management for their regular review. Management concerns due to assessment results may necessitate a follow-up assessment, either by audit or by QA surveillance. The Nuclear Policy Manual provides guidelines for conducting unscheduled audits including the need for reaudits.

~~Operational Assessment~~Operating Experience

The operating experience ~~Operational Review~~ section receives and evaluates information from INPO and other utilities and vendors. The operating experience ~~Operational Review S~~section also receives and evaluates NRC Information Notices. They ensure that relevant and timely recommended actions are provided to management that will eliminate precursors of similar problems at Ginna. This is accomplished through:

- coordinating feedback programs to measure and improve the internalization of lessons learned from ~~O~~operating ~~E~~experience
- reviewing INPO SOERs and SERs
- reviewing vendor 10CFR Part 21 report of defects
- reviewing NRC Information Notices

Table 17.3.2-1

Audit List

Audit Topic Areas (24 months)

a. The conformance of facility operation to provisions contained within the Technical Specifications and applicable license conditions.

b. Performance, training, and qualifications of the operating and technical staff.

c. The results of actions taken to correct deficiencies occurring in facility equipment, structures, systems, or methods of operation that affect nuclear safety.

d. The performance of activities required by the Quality Assurance Program to meet the criteria of 10CFR50, Appendix B.

e. Facility Fire Protection Program and implementing procedures.

f. Inspection and audit of the fire protection and loss prevention program performed by non-licensee personnel. The personnel may be representatives of a fire insurance brokerage firm, or other qualified individuals.

g. The radiological environmental monitoring program and the results thereof.

h. The Offsite Dose Calculation Manual and implementing procedures.

i. The Process Control Program and implementing procedures.

Enclosure 1

R.E. GINNA NUCLEAR POWER PLANT, LLC

R.E. GINNA NUCLEAR POWER PLANT

Quality Assurance Program for Station Operation

Revision 33

DOCKET NO. 50-244

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QUALITY ASSURANCE PROGRAM FOR STATION OPERATION

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QUALITY ASSURANCE PROGRAM FOR STATION OPERATION

17.1 MANAGEMENT

17.1.1 Methodology

The R.E. Ginna Nuclear Power Plant, LLC ("Ginna LLC") quality assurance policy is established by the Senior Vice President and Chief Nuclear Officer of Constellation Generation Group, LLC. This policy is set forth in the R.E. Ginna Nuclear Power Plant, LLC Corporate Statement of Quality Assurance Policy, shown in Table 17.1.1-1, and is binding on all organizations and individuals performing Ginna Station quality affecting activities. The policy is implemented under the overall direction of the Vice President, Ginna.

The Quality Assurance Program has been developed by Ginna LLC to assure safe and reliable operation of the R. E. Ginna Nuclear Power Plant. The program covers all existing Seismic Category I and Class 1E structures, systems, and components (SSCs) including their foundations and supports. It applies to all activities affecting the safety-related functions of these structures, systems, and components that prevent or mitigate the consequences of postulated accidents that could cause undue risk to the health and safety of the public.

These activities include designing, operating, maintaining, repairing, fabricating, handling, shipping, storing, procuring, refueling, modifying, cleaning, erecting, installing, testing, inspecting, and inservice inspection. Quality affecting activities are controlled to an extent consistent with their safety significance. In addition, the Quality Assurance Program applies to the activities associated with the packaging of licensed radioactive materials to be shipped in accordance with 10CFR Part 71, excluding design and fabrication of shipping casks.

A classification process is established to identify SSCs that are safety related (SR), safety significant (SS), or Non-Nuclear Safety (NS). Criteria are based on information contained in the Updated Final Safety Analysis Report (UFSAR), licensing commitments, guidelines contained in NRC regulatory guides, and functional guidance derived from ANSI/ANS 51.1-1983. For changes to Ginna Station, safety classification and corresponding QA program applicability are determined using approved procedures.

The Nuclear Policy Manual provides a method of applying a graded QA Program to systems, components, items, and services which are not classified as safety related (SR), but are considered necessary for reliable plant operation.

Special terms used in this document which are not found in ANSI N45.2.10 "Quality Assurance Terms and Definitions" are defined in Table 17.1.1-2, Supplementary Glossary.

17.1.2 Organization

The organizational structure responsible for implementation of the Quality Assurance Program is under the leadership of the President, Constellation Generation Group, LLC (CGG). Specific details for the quality assurance functions described are identified in procedures. The authority to accomplish the quality assurance functions described is delegated to the incumbent's staff as necessary to fulfill the identified responsibility.

Corporate Organization

The following positions have the described corporate functional responsibilities:

President, CGG

The President, CGG is responsible for establishing the overall corporate policy and implementation of the Quality Assurance Program (QAP). The President provides executive direction and guidance for the corporation as well as promulgates corporate policy through Constellation Generation's senior management staff. Overall responsibility for the implementation of the QAP is delegated to the Senior Vice President and Chief Nuclear Officer, CGG.

Senior Vice President and Chief Nuclear Officer (CNO), CGG

The Senior Vice President and Chief Nuclear Officer, CGG has responsibility for establishing the Quality Assurance Program and issuing the governing policy statement. The CNO oversees all organizations involved in the operation and support of Ginna Station, including the Quality Assurance Program, and establishes the Nuclear Safety Review Board (NSRB) to review and audit plant operations. The Chairman of the NSRB is responsible to the CNO on all activities of the NSRB.

Operations Support, CGG

An executive management position for operations support reports to the CNO and provides direction to the nuclear security, emergency preparedness, training, and fleet procedures departments. Responsibilities for nuclear security include facility physical security, nuclear access programs, and fitness for duty programs. Emergency preparedness responsibilities include development and maintenance of the company radiological emergency plans and coordination with off-site radiological emergency response groups for the nuclear facilities. Training ensures qualified personnel operate and support the nuclear facilities and administers the fleet corrective action, self-assessment, and industry operating experience programs. The fleet procedures department ensures that fleet procedures are prepared in accordance with applicable regulatory requirements, industry quality standards, and this QAP. Additionally, corporate oversight and support is provided in the areas of operations, maintenance, refueling services, radiation protection, chemistry, and work management. Some of these

responsibilities may be assigned to the Vice President, Ginna at the discretion of the CNO.

Technical Services, CGG

An executive management position for technical services reports to the CNO and provides direction to corporate engineering, licensing, nuclear fuel services, and probabilistic risk assessment (PRA) departments. Additionally, corporate oversight and support is provided for site engineering. This position is responsible for the engineering functions supporting design and construction activities and long-term nuclear operations, providing for regulatory compliance and licensing support through NRC communications, and activities related to safety and management of nuclear fuel. Some of these responsibilities may be assigned to the Vice President, Ginna at the discretion of the CNO.

Quality and Performance Assessment (Q&PA), CGG

A senior management position reporting to the CNO is responsible for the verification of effective Company and Supplier quality assurance program development, documentation, and implementation. This position is independent of cost and scheduling concerns associated with construction, operations, maintenance, modification, and decommissioning activities for performing quality assurance program verification. Where implementation of any or all of these functions is delegated to Suppliers, procedures require the establishment of interface documents including defining lines of communication and authorities as appropriate for the delegated functions. However, this senior management position retains responsibility for the scope and effective implementation of the quality assurance program for those functions. This management position has the necessary authority and responsibility for verifying quality achievement; identifying quality problems, recommending solutions and verifying implementation of the solutions; and escalating quality problems to higher management levels. This position has the authority to suspend unsatisfactory work and control further processing or installation of non-conforming materials. The authority to stop work delegated to Q&PA personnel is delineated in procedures.

Q&PA is responsible for the evaluation of Suppliers' quality programs through a system of external audits, evaluations, and reviews of Supplier performance in accordance with quality assurance requirements. A list of approved Suppliers is maintained. Q&PA is responsible for assuring Company compliance with this QAP through administration of a comprehensive and systematic internal audit program. Q&PA is also responsible for the Employee Concerns Program, and developing and maintaining an appropriate quality verification inspection program where not provided for in the facility construction or operating organization functions.

Project Management, CGG

A senior management position reporting to the CNO is responsible for the implementation of large projects for the nuclear facilities. Implementation includes development of the detailed scope, estimate, schedule, cost, design procurement, construction, testing, and closeout of each project. Project management also oversees siting and construction activities. Focus is on defined projects separate from ongoing routine engineering projects. Some of these responsibilities may be assigned to the Vice President, Ginna at the discretion of the CNO.

Supply Chain, CGG

Supply Chain is responsible for material management, purchasing, procurement engineering, and receipt inspection. This position has the authority to control further processing or installation of nonconforming materials. This authority is delegated to inspection personnel as delineated in procedures.

Information Technology, CGG

Information Technology is responsible for network infrastructure maintenance and upgrade, network and application security, network operations; automation strategy, application development and support, automation training; development and maintenance of the software control program; and oversight, maintenance, and repair of the Emergency Offsite Facility Computer System.

Site Organization

The following positions have the described site functional responsibilities:

Vice President, Ginna

The Vice President, Ginna is responsible to the CNO and has corporate responsibility for operation of Ginna Station in accordance with applicable regulatory requirements. In addition, the Vice President, Ginna has overall responsibility and authority for directing the Quality Assurance Program and is responsible for the approval of the Nuclear Policy Manual. The Vice President, Ginna is responsible for those items delineated in the Administrative Controls section of the Technical Specifications, for establishing the policies and requirements necessary to assure safe and reliable operation of Ginna Station, and for oversight of Ginna Station and those support activities associated with site engineering and training.

Plant General Manager, Ginna Station

The Plant General Manager, Ginna Station is responsible to the Vice President, Ginna for the overall on-site safe operation of Ginna Station. The Plant General Manager, Ginna Station is responsible for:

- the performance of all Ginna Station quality affecting

activities in accordance with the requirements of the Quality Assurance Program
- providing qualified personnel to perform quality affecting activities in accordance with approved drawings, specifications, and procedures
- implementation of those items delineated in the Administrative Controls Section of Technical Specifications
- timely referral of appropriate matters to management and the NSRB
- assuring that significant conditions adverse to quality are identified and corrected

The Plant General Manager, Ginna Station assigns responsibility to Managers, Directors, and designated staff members for the control of all activities involving operation, maintenance, repair, refueling, implementation of modifications, radiation protection, chemistry, and fire protection. Responsibility is delegated for the implementation of Quality Assurance Program requirements at the plant for testing, operation and test status control, and calibration and control of measuring and test equipment.

Manager, Nuclear Engineering Services

The Manager, Nuclear Engineering Services reports to the Vice President, Ginna and functionally to a Corporate Vice President (offsite), and is responsible for day-to-day engineering support activities including design engineering, engineering programs, equipment reliability, and system engineering.

Director, Quality and Performance Assessment (Q&PA)

The Director, Q&PA reports to the corporate management position (offsite) responsible for Q&PA and functionally to the Vice President, Ginna and is responsible for site Q&PA activities The Director, Q&PA and staff are responsible to the NSRB for:

- Establishing the overall Quality Assurance Program
- Interpreting corporate quality assurance policy and for assuring its implementation. This includes assuring that the program continues to satisfy the requirements of 10CFR50, Appendix B.
- Establishing and implementing an independent assessment program that encompasses all organizations and functions related to the safe operation of Ginna.
- Assuring that all planned and systematic actions necessary to provide adequate confidence that Ginna Station will operate safely and reliably are established and followed.
- Providing management with objective information concerning quality, independent of the individual or group directly responsible for performing the specific activity.

The Director, Q&PA has the authority and organizational freedom to assure all necessary quality activities are performed. The Director, Q&PA and staff are responsible for assuring that station activities affecting quality are prescribed and carried out in accordance with approved drawings, specifications, and procedures. Quality Control is also responsible for ensuring the

performance of verification inspection and assuring that inspection requirements are included in approved procedures and work packages.

Manager, Nuclear Training

The Manager, Nuclear Training reports to the Vice President, Ginna and functionally to a corporate management position (offsite), and is responsible for maintaining and implementing a National Academy for Nuclear Training accredited training program. In addition, the Manager, Nuclear Training is responsible for administration of the corrective action, self-assessment and industry operating experience programs.

REVIEW AND AUDIT ORGANIZATIONS

Three separate organizational units are established for the purpose of review and audit of plant operations and safety-related matters. They are:

- Plant Operations Review Committee (PORC), the on-site operations review group responsible for reviewing those activities that affect nuclear safety.
- Quality and Performance Assessment, the group responsible for the audit of safety related activities associated with plant operations.
- Nuclear Safety Review Board (NSRB), the independent audit and review group responsible for the periodic review of the activities of the Plant Operations Review Committee, for directing internal audits and evaluating their results, and for the management evaluation of the status and adequacy of the Quality Assurance Program.

PORC

Review activities of the PORC provide, as part of the normal duties of plant supervisory personnel, timely and continuing monitoring of operating activities to assist the Plant General Manager, Ginna Station in keeping abreast of general plant conditions and to verify that the day-to-day operating activities are conducted safely and in accordance with applicable administrative controls. PORC also reviews facility operations to detect potential safety hazards. These continuing monitoring activities are considered to be an integral part of the routine supervisory function and are important to the safety of plant operation.

The PORC performs reviews, periodically and as situations demand, to evaluate plant operations and to plan future activities. The important elements of the reviews are documented.

The PORC scope of review, organization, quorum, and records meet the requirements of ANSI/ANS-3.2-1988, Section 4.3. PORC is comprised of personnel who collectively have the experience and competence in the following areas:

- Nuclear Operations
- Mechanical Maintenance

- Electrical Maintenance
- Plant Engineering
- Reactor Engineering
- Radiation Safety
- Chemistry
- Quality Assurance/Quality Control

The PORC chairman meets the qualifications of ANSI Standard N18.1-1971, Section 4.2.2, and holds, or has held, a Senior Reactor Operating License or SRO certification. PORC members meet the qualifications of section 4.3.1 or 4.4 as applicable. The PORC is comprised of a minimum of five (5) and maximum of nine (9) regular members, as designated by the Plant General Manager, Ginna Station. Alternates are designated in writing by the chairman. The number of attending alternates will not exceed a minority of the number representing a quorum. The PORC meets at least once per calendar month and as convened by the PORC Chairman.

The PORC reviews proposed changes to the facility, changes to procedures, tests and experiments for which a 10CFR50.59 evaluation has been performed.

The PORC recommends in writing to the Plant General Manager, Ginna Station approval of items submitted for review, documents whether any change requires regulatory review in accordance with 10CFR50.59, and provides immediate notification to the Vice President, Ginna and the Chairman, NSRB of disagreement between the PORC and the Plant General Manager, Ginna Station.

NSRB

The NSRB scope of review meets the requirements of ANSI Standard N18.7-1976, Section 4.3.4. The NSRB composition, meeting frequency, quorum, and record requirements meet ANSI Standard N18.7-1976, Section 4.3.2. Qualifications of members are commensurate with their functional responsibilities as defined in ANSI/ANS-3.1-1987, Section 4.7, with the exception that the functional areas of nuclear power plant operations and nuclear engineering have over eight (8) years experience in their field with over four (4) years responsible engineering management. The Chairman and Vice-Chairman of the NSRB are appointed by the CNO. The members of the NSRB are appointed by the Chairman of the NSRB.

DELEGATION OF WORK

Quality affecting activities may be delegated to corporate organizations external to Ginna LLC, contractor organizations, and equipment vendors. Delegated activities are subject to Quality Assurance Program requirements through conformance with the external organization's QA Program as approved by Ginna LLC, through conformance with Ginna LLC's Quality Assurance Program, or an approved combination of the two. Ginna LLC retains overall responsibility for the Quality Assurance Program and management oversight of delegated activities. The scope of delegated activities and applicable Quality Assurance Program requirements are defined in procedures and procurement documents.

17.1.3 Responsibility

All employees of Ginna LLC involved in the operation of Ginna Station and associated support activities have full personal and corporate responsibility to assure that the plant is operated, maintained, tested, inspected, and modified in a safe and reliable manner. This responsibility includes assuring that an effective Quality Assurance Program is implemented.

The operation of Ginna Station is governed by the Nuclear Policy Manual, a portion of which governs the Quality Assurance Program. It contains the requirements and assignment of responsibilities for implementation of the program. The manual is prepared, reviewed, and maintained by Ginna Station and approved by the Vice President, Ginna.

The Nuclear Safety Review Board is directed by the Senior Vice President and Chief Nuclear Officer, CGG to review the status and adequacy of the Quality Assurance Program at least once every two years to assure that it is meaningful and effectively complies with corporate policy and 10CFR50, Appendix B. This review consists of an audit, or a review equivalent to an audit, performed by company personnel or outside organizations.

The Quality Assurance Program is implemented through procedures prepared and maintained by the responsible organization and approved for use by their designated manager. Quality affecting activities are performed in accordance with these procedures, utilizing sufficiently trained personnel and necessary resources to accomplish the work.

17.1.4 Authority

Persons or organizations who are delegated responsibility for planning, establishing, or implementing any part of the Ginna LLC Quality Assurance Program also have the authority to carry out those responsibilities.

Nuclear Operations and nuclear support organization personnel are empowered to take stop work action on their own activities if they determine that continuing the activity would preclude identifying and correcting a condition adverse to quality or lead to an unsafe condition. Designated independent inspection and audit personnel have the authority to stop work within Nuclear Operations, nuclear support organizations, and at supplier locations. The Plant General Manager, Ginna Station has stop work authority for all activities performed in operating the station.

17.1.5 Personnel Training and Qualification

Ginna LLC is committed to maintaining National Academy for Nuclear Training accredited training programs that produce qualified, competent personnel to operate and maintain Ginna Station. Nuclear Training is assigned the responsibility for supporting Nuclear Operations line management with the development, monitoring, and evaluation of an adequate staff of

experienced, trained, and qualified personnel to ensure the safe and efficient operation, modification, and maintenance of the plant.

Supervisory personnel are indoctrinated in quality assurance policies, instructions, and procedures to assure they understand that these must be implemented and enforced. Personnel responsible for performing activities affecting quality are trained and indoctrinated in the requirements, purpose, scope, and implementation of applicable quality related program instructions and procedures. Refresher sessions are held periodically. Training of personnel is the responsibility of each department performing an activity affecting quality.

The Vice President, Ginna is responsible for the formal training, qualification, licensing, and re-qualification of operators, as necessary. As appropriate, personnel granted unescorted access to Ginna Station are trained in radiation protection, plant safety, and security.

Training and qualification records are maintained for each employee when required. Documentation of formal training includes objectives, content of the program, attendees, and date of attendance.

17.1.6 Corrective Action

Ginna LLC has established a corrective action process whereby all personnel are responsible for assuring that conditions adverse to quality are promptly identified, reported, controlled, and corrected. The process is focused on correcting the problem and its root cause rather than assigning blame or fault. Adverse trends in performance are identified, monitored, and reported to management. Corrective action and nonconformance control processes are discussed in Section 17.2.13.

17.1.7 Regulatory Commitments

The Quality Assurance Program is designed to meet the requirements of 10CFR50, Appendix B, "Quality Assurance Criteria for Nuclear Power Plants." A listing of Regulatory Guides, requirements, and standards with the conformance status of each is contained in Table 17.1.7-1.

A grace period of 90 days is applied to several activities specifically defined on Table 17.1.7-1. The grace period will not allow the "clock" for a particular activity to be reset forward. For example, if an annual activity is due on June 15th of a particular year, but is not performed until August 13th, the next due date for that activity will be June 15th of the following year. However, the clock for an activity is reset backwards by performing the activity early.

TABLE 17.1.1-1

R.E. Ginna Nuclear Power Plant, LLC

Corporate Statement of Quality Assurance Policy

The R.E. Ginna Nuclear Power Plant, LLC continues to be an advocate of quality performance in our daily activities. The Quality Assurance Program described in the Nuclear Policy Manual has been developed to assure that activities, as defined within the program scope, are being performed correctly and in conformance with applicable requirements. This program is designed to assure the safe operation of Ginna Station and to meet the requirements of Title 10, Code of Federal Regulations, Part 50 (10CFR50), Appendix B, "Quality Assurance Criteria for Nuclear Power Plants."

The Quality Assurance Program applies to all activities affecting the safety related functions of those Seismic Category I or Class 1E structures, systems, and components that prevent or mitigate the consequences of or monitor the course of postulated accidents, events, or phenomena that could cause undue risk to the health and safety of the public. These activities include operating, maintaining, modifying, refueling, testing, and inspecting. In addition, this program applies to 10CFR50 concerns associated with:

a. maintaining the high degree of integrity of primary and secondary barriers of systems or structures containing radioactive materials

b. providing fire detection, suppression, and consequence mitigation items utilized both to protect the safety related structures, systems, and components and to assure safe operation in the event of postulated fire

c. providing assurance that instrumentation and controls which monitor accidents, or provide a secondary role in accident monitoring, function correctly and accurately.

This program also applies to the shipping of licensed radioactive material under 10CFR71, except for design and fabrication of shipping casks.

The Director, Quality and Performance Assessment is responsible for coordinating the formulation of the Quality Assurance Program and for assuring the program's implementation. Nuclear Operations personnel are responsible for implementing the Quality Assurance Program in accordance with the requirements of the Nuclear Policy Manual.

John M. Heffley
Senior Vice President and Chief Nuclear Officer,
Constellation Generation Group, LLC

Date 12/14/04

TABLE 17.1.1-2

Supplementary Glossary

Terms with special meanings used in this document that are not defined in ANSI N45.2.10, "Quality Assurance Terms and Definitions," are defined below.

Adopted	-	Ginna LLC has endorsed, wholly or in part, an industry code, standard, or NRC Regulatory Guide for which no formal commitment has been made.
Alternative	-	Relates to existing and proposed industry code, standard, or NRC Regulatory Guide for which Ginna LLC provides other means to assure quality.
Approval	-	The formal act of endorsing or adding positive authorization, or both, to an action or document. Approval may be given only by an authorized individual.
As-built drawings	-	Drawings such as flow prints, electrical elementary diagrams, instrumentation and control schematics, and piping layout drawings that reflect the actual current plant field configuration.
Audit	-	A documented activity to determine, through investigation, the adequacy of and adherence to established procedures, instructions, specifications, codes and standards, or other applicable contractual and licensing requirements and the effectiveness of implementation.
Audit (internal)	-	Audit of those portions of Ginna LLC's Quality Assurance Program retained under its direct control and within its organizational structure.
Certification	-	The action, by an authorized person, of determining, verifying, and attesting, in writing, to the qualifications of personnel or material.
Commitment	-	A documented explicit statement, made either by Ginna LLC or through

		uncontested imposition by the NRC or other regulatory agencies, that requires actions to be performed.
Conforms	-	Ginna LLC has committed fully to the requirements without exception.
Deviation	-	A departure of a characteristic from specified requirements.
Handling	-	An act of physically moving items by hand or by mechanical means, but not including transport on a conveyance, such as motor vehicles, ships, railroad cars, or aircraft.
Heavy load	-	Any load, carried in a given area after a plant becomes operational, that weighs more than the combined weight of a single spent fuel assembly and its associated handling tool ($\geq$1500#).
Inservice Inspection	-	A planned, periodic evaluation of the continued structural integrity of installed plant systems and components by nondestructive methods, conducted in accordance with the rules of Section XI of the ASME Boiler & Pressure Vessel Code.
Inspector	-	An individual who has been qualified to perform quality verification inspections.
Measuring and test equipment	-	Devices or systems used to calibrate, measure, gage, test, inspect, or control in order to control data or to acquire data to verify conformance to specified requirements. Measuring and test equipment does not include permanently installed plant instrumentation or test equipment used for preliminary checks where data obtained will not be used to determine acceptability or be the basis for design or engineering evaluation.

Nonconformance disposition	-	Designated resolution to a nonconforming item by cognizant personnel (e.g., rework, repair, use-as-is or reject).
Performance-based	-	An approach that focuses on the end results that directly contribute to safe and reliable plant operation. Meeting a predetermined set of goals, limits, or performance criteria based upon the design basis safety function and the past performance of structures, systems, components, and organizations, allowing the licensee flexibility to determine how the results will be achieved and adjust quality practices, as necessary.
Procedure	-	A document that specifies or describes how an activity is to be performed. It may include methods to be employed, a description of equipment or materials to be used, and sequence of operations.
Procurement document	-	Purchase requisitions, purchase orders, drawings, contracts, specifications, documents referenced by purchase orders, bills of material, or other instructions used to define requirements for purchase.
QA surveillance	-	A technique which uses observation or monitoring to provide confidence that ongoing processes and activities are adequately and effectively performed.
Qualified procedure	-	A procedure which incorporates all applicable codes and standards, manufacturer's parameters, and engineering specifications and has been proven adequate for its intended purpose. Section IX of the ASME Code defines procedure qualifications for welding activities.
Quality affecting activities	-	Activities for which the Quality Assurance Program applies.

Safety related structures, systems, and components - Equipment that is relied upon to remain functional during and following design basis events to ensure (1) the integrity of the reactor coolant boundary, (2) the capability to shutdown the reactor and maintain it in a safe shutdown condition, and (3) the capability to prevent or mitigate the consequences of accidents that could result in potential offsite exposures comparable to the 10CFR100 guidelines.

Safety significant structures, systems, and components - Subset of equipment not required to perform a safety related function but which are subject to additional controls established by Ginna LLC.

Supplier surveillance - A review, observation, or inspection for the purpose of verifying that an action has been accomplished as specified at the location of material procurement or manufacture.

Traceability - A characteristic given to material, a document, a group of documents, or material and its related documents which permits the retrieval or reassociation of the items, if necessary, at a later time. The term is also used to denote a document which records a chronological history of all processes or operations which have been performed on an item.

Verification inspection - A phase of quality control which by means of examination, observation, or measurement determines the conformance of materials, supplies, components, parts, appurtenances, systems, processes, or structures to predetermined quality requirements.

TABLE 17.1.7-1

Conformance of Ginna Station Program to Quality Assurance Standards, Requirements, and Guides

Standard, Requirement, or Guide	Conformance Status	Remarks
Regulatory Guide 1.8 Rev.(1)-Personnel Selection and Training	Conforms	RG 1.8 Rev.(1) incorporates ANSI N18.1.
Regulatory Guide 1.26 Rev.(3)-Quality Group Classifications & Standards for Water, Steam, and Radioactive-Waste Containing Components of Nuclear Power Plants	Alternative	A classification process is established to identify SSCs that are safety related (SR), safety significant (SS), or Non-Nuclear Safety (NS). Criteria are based on information contained in the Updated Final Safety Analysis Report (UFSAR), licensing commitments, guidelines contained in NRC regulatory guides, and functional guidance derived from ANSI/ANS 51.1-1983.
Regulatory Guide 1.28 Rev.(2)-Quality Assurance Program Requirements (Design and Construction)	Conforms	RG 1.28 Rev.(2) incorporates ANSI N45.2-1977.
Regulatory Guide 1.29 Rev.(3)-Seismic Design Classification	Alternative	Seismic design requirements for existing structures, systems, and components performing functions listed in positions C.1 and C.3 of the Regulatory Guide are specified in the UFSAR. New structures, systems, and components, and configuration changes meet the seismic design requirements of this regulatory guide or the UFSAR. The pertinent quality assurance requirements of 10CFR50, Appendix B are applied as required by positions C.1 and C.4 of this Regulatory Guide, irrespective of an item's seismic design. Portions of existing structures, systems, and components with failure consequences described in position C.2 of this guide are designed and constructed to seismic requirements specified in the UFSAR. New structures, systems, and components, and configuration changes meet the design and construction seismic requirements of the UFSAR or this Regulatory Guide. A quality assurance program similar to 10CFR50, Appendix B is applied to the SSE failure prevention function of these items. These items are not considered basic components pursuant to 10CFR21.
Regulatory Guide 1.30 Rev.(0)-Quality Assurance Requirements for the Installation, Inspection, and Testing of Instrumentation and Electric Equipment	Conforms	RG 1.30 Rev.(0) ANSI N.45.2.4-1972.

TABLE 17.1.7-1 (cont'd)

Standard, Requirement, or Guide	Conformance Status	Remarks	
Regulatory Guide 1.33 Rev.(0)-Quality Assurance Program Requirements (Operations)	Alternative	Original Criteria	Substituted Criteria
		Regulatory Guide 1.33 Rev.(0) except for Appendix A.	Regulatory Guide 1.33 Rev.(2) Regulatory Position 1 (including its Appendix A)
		ANSI N18.7-1972 except for Sections:	
		• 4.2.2	ANSI/ANS-3.1-1987 Section 4.7
		• 4.2.3,4.2.4, & 4.2.5	ANSI N18.7-1976/ANS-3.2 Section 4.3.2
		• 4.3	ANSI N18.7-1976/ANS-3.2 Section 4.3.4 as invoked and modified by Regulatory Guide 1.33 Rev.(2) Regulatory Position 3.
		• 4.4	Ginna conforms to ANSI N18.7-1972 Section 4.4 with the exception that a 90 day grace period may be applied to the 24 month frequency for performance of internal audits.
		• 4.5	The on-site review organization scope of review, organization, quorum and records meet the requirements of ANSI/ANS-3.2-1988, Section 4.3. The qualification requirements for PORC members and PORC meeting frequency is described in QAPSO Section 17.1.2, PORC.
		Ginna also conforms to regulatory staff comments and supplementary guidance in "Guidelines on Quality Assurance Requirements During the Operations Phase of Nuclear Power Plants," Revision 0, October 1973 (Orange Book-Revision 0).	

TABLE 17.1.7-1 (cont'd)

Standard, Requirement, or Guide	Conformance Status	Remarks
Regulatory Guide 1.36 Rev.(0)-Nonmetallic Thermal Insulation for Austenitic Stainless Steel	Adopted	This Regulatory Guide is adopted for the testing of insulating materials installed on or near safety related stainless steel piping. Insulating materials are not considered basic components pursuant to 10CFR21 and thus the supplier is not required to have a quality assurance program to cover the testing, lot control, and contamination control provisions of this Regulatory Guide. A quality assurance program similar to 10CFR50, Appendix B is applied to insulating materials on or near Ginna Station safety related stainless steel piping and components.
Regulatory Guide 1.37 Rev.(0)-Quality Assurance Requirements for Cleaning of Fluid Systems and Associated Components of Water-Cooled Nuclear Power Plants	Conforms	RG 1.37 Rev.(0) incorporates ANSI N45.2.1-1973. For new construction activities, the cleanliness requirements of ANSI N45.2.1-1973 as modified by RG 1.37 are followed. Consistent with Position C.2 of RG 1.37, the cleanliness requirements of this standard are used when applicable to maintenance on operating systems. The cleanliness requirements applied to operational systems are established in station procedures.
Regulatory Guide 1.38 Rev.(2)-Quality Assurance Requirements for Packaging, Shipping, Receiving, Storage, and Handling of Items for Water-Cooled Nuclear Power Plants	Conforms	RG 1.38 Rev.(2) incorporates ANSI N45.2.2-1972.
Regulatory Guide 1.39 Rev.(2)-Housekeeping Requirements for Water-Cooled Nuclear Power Plants	Conforms	RG 1.39 Rev.(2) incorporates ANSI N45.2.3-1973.
Regulatory Guide 1.54 Rev.(0)-Quality Assurance Requirements for Protective Coatings Applied to Water-Cooled Nuclear Power Plants	Alternative	For new coatings and configuration changes to existing coatings, which have the potential to adversely affect a safety related function, the quality assurance requirements of 10CFR50, Appendix B, in conjunction with engineering specifications, are used instead of the detailed requirements included in this Regulatory Guide and its referenced standard, ANSI N101.4-1972.

TABLE 17.1.7-1 (cont'd)

Standard, Requirement, or Guide	Conformance Status	Remarks
Regulatory Guide 1.58 Rev.(1)-Qualification of Nuclear Power Plant Inspection, Examination, and Testing Personnel	Alternative	RG 1.58 Rev.(1) incorporates ANSI N45.2.6-1978. Ginna conforms to Reg. Guide 1.58 Rev.(1) and ANSI N45.2.6-1978 with the following exceptions: • A 90 day grace period may be applied to the performance of annual evaluations of inspection, examination and testing personnel qualifications defined in Section 2.3 of ANSI N45.2.6-1978. • A 90 day grace period may be applied to the annual verification of special physical characteristics defined in Section 2.5 of ANSI N45.2.6-1978. • RG&E's ISI Plan endorses ASME Code Section XI. The version of the ASME code endorsed is updated periodically. ASME Code Section XI references standards for the qualification and certification of nondestructive testing personnel. Section XI of the ASME Code contains specific requirements for nondestructive examination and also references the use of other supplementary standards for the qualification and certification of personnel performing nondestructive examinations. The applicable versions of the standards referenced in Section XI of the ASME code, as permitted for use by 10 CFR Part 50.55a, may be used for the qualification and certification of personnel performing nondestructive examinations required by Section III and Section XI of the ASME Code in lieu of the standard identified in Reg. Guide 1.58, Rev. 1, (SNT-TC-1A-1975) provided that other applicable rules contained in Section XI of the ASME Code are met.
Regulatory Guide 1.64 Rev.(1)-Quality Assurance Requirements for Design of Nuclear Power Plants	Conforms	RG 1.64 Rev.(1) incorporates ANSI N45.2.11-1974.
Regulatory Guide 1.74 Rev.(0)-Quality Assurance Terms and Definitions	Conforms	RG 1.74 Rev.(0) incorporates ANSI N45.2.10-1973. Some definitions used by Ginna are worded differently than those in this standard; however, the general meanings are the same.
Regulatory Guide 1.88 Rev.(2)-Collection, Storage, and Maintenance of Nuclear Power Plant Quality Assurance Records	Alternative	RG 1.88 Rev.(2) incorporates ANSI N45.2.9-1974. Ginna conforms to ANSI N45.2.9-1974 as supplemented by the following alternatives to the requirements in Section 5.6 (Facility). • Records may be stored in a 2 hour rated facility meeting the requirements described in QAPSO Section 17.2.15. • Records may be stored temporarily in 1 hour fire rated cabinets provided that the requirements of QAPSO Section 17.2.15 are met.

TABLE 17.1.7-1 (cont'd)

Standard, Requirement, or Guide	Conformance Status	Remarks
Regulatory Guide 1.94 Rev. (1)-Quality Assurance Installation, Inspections, and Testing of Structural Concrete and Structural Steel During the Construction Phase of Nuclear Power Plants	Not applicable	RG 1.94 Rev.(1) incorporates ANSI N45.2.5-1974. Regulatory Guide applies to plants in the construction phase and was issued after Ginna was built.
Regulatory Guide 1.116 Rev.(0-R)-Quality Assurance Requirements for Installation, Inspections, and Testing of Mechanical Equipment and Systems	Conforms	RG 1.116 Rev.(0-R) incorporates ANSI N45.2.8-1975.
Regulatory Guide 1.123 Rev.(1)-Quality Assurance Requirements for Control of Procurement of Items and Services for Nuclear Power Plants	Conforms	RG 1.123 Rev.(1) incorporates ANSI N45.2.13-1976.
Regulatory Guide 1.143 Rev.(1)-Design Guidance for Radioactive Waste Management Systems, Structures, and Components Installed in Light-Water-Cooled Nuclear Power Plants	Alternative	See the UFSAR for design and quality assurance provisions applied to existing radioactive waste management systems, structures, and components. New systems, structures, and components and configuration changes to existing items meet the design and quality assurance provisions described in the UFSAR or those specified by this Regulatory Guide.

TABLE 17.1.7-1 (cont'd)

Standard, Requirement, or Guide	Conformance Status	Remarks
Regulatory Guide 1.144 Rev.(1)-Auditing of Quality Assurance Programs for Nuclear Power Plants	Alternative	RG 1.144 Rev.(1) incorporates ANSI N45.2.12-1977. Ginna conforms to RG 1.144 Rev.(1) and ANSI N45.2.12-1977 with the following exceptions: • A grace period of 90 days may be applied to the performance of triennial supplier audits and annual supplier evaluations described in Section C.3.b.(2). • In lieu of the 30 day requirement of Section 4.5.1 of ANSI N45.2.12-1977 the following is used: Corrective action response due dates and priority shall be based on safety significance. For audit findings that are determined to be significant conditions adverse to quality, the audited organization's response shall be provided within 30 days. In the event that the corrective action for an audit finding cannot be completed by the response due date, the audited organization's response shall include a scheduled date for corrective action. • In lieu of the requirements of Section 4.5.1 of ANSI N45.2.12-1977, the following is used in cases where the audited organization is a supplier: Ginna LLC shall evaluate the acceptability of actions taken to address findings from audits of suppliers. In cases where corrective actions are not taken or are not satisfactory, and the product or service of the supplier is still desired, compensatory actions shall be taken to ensure the quality of the products or services. These actions may include: commercially dedicating the product or service, restrictions placed on supplier activities, surveillance of supplier activities, or inspection/testing of supplier products and services. In cases where the vendor does not comply with 10CFR21, the vendor shall be removed from the Approved Vendors List. The following additional controls shall be applied when this alternative is used: - Supplier program deficiencies that require compensatory actions by Ginna LLC will be documented in the station's corrective action process. - Compensatory actions to be taken shall be established within 30 days of discovery by Ginna LLC of the condition that requires the actions. - Records of compensatory actions taken shall be retained as records in accordance with ANSI N45.2.9.

TABLE 17.1.7-1 (cont'd)

Standard, Requirement, or Guide	Conformance Status	Remarks
Regulatory Guide 1.146 Rev.(0)-Qualification of QA Program Audit Personnel for Nuclear Power Plants	Alternative	RG 1.146 Rev.(0) incorporates ANSI N45.2.23-1978. Ginna conforms to RG 1.146 Rev.(0) and ANSI N45.2.23-1978 with the following exceptions: • A grace period of 90 days may be applied to the performance of annual lead auditor recertifications described in Sections 3.2 and 5.3 of ANSI N45.2.23-1978. • With regard to Section 2.3.1.3 of ANSI N45.2.23-1978, holders of NRC issued Reactor Operator/Senior Reactor Operator Licenses comply with the requirements of this section and may be awarded two credits. • In lieu of the requirements of 2.3.4 of ANSI N45.2.23-1978 the following is used: Prospective lead auditors shall demonstrate their ability to effectively implement the audit process and effectively lead an audit team. Ginna LLC will describe this demonstration process in written procedures and shall evaluate and document the results of the demonstration. Regardless of the methods used for the demonstration, the prospective lead auditor shall have participated in at least one nuclear quality assurance audit within the year preceding the individual's effective date of qualification. Upon successful demonstration of the ability to effectively implement the audit process and effectively lead audits, and having met the other provisions of Section 2.3 of ANSI N45.2.23-1978, the individual may be certified as being qualified to lead audits.
Regulatory Guide 1.152 Rev.(0)-Criteria for Programmable Digital Computer System Software in Safety-Related Systems of Nuclear Power Plants	Alternative	Ginna conforms to Generic Letter 95-02, and its endorsement of NUMARC/EPRI Report TR-102348 "Guidelines on Licensing Digital Upgrades".
Regulatory Guide 4.15 Rev.(1)-Quality Assurance for Radiological Monitoring Program (Normal Operations)-Effluent Streams and the Environment	Adopted	Ginna conforms to the intent of this Regulatory Guide as addressed in the Process Control Program and applicable to Ginna effluent and environmental radioactivity measurements.
Regulatory Guide 7.10 Rev.(1)-Establishing Quality Assurance Programs for Packaging Used in the Transport of Radioactive Material	Adopted	Ginna conforms to the intent of this Regulatory Guide as addressed in the Process Control Program.
10CFR21	Conforms	
10CFR50, Appendix A-General Design Criteria	Alternative	These criteria were in draft form or not written at the time Ginna was designed and built. For existing systems, see UFSAR for criteria applied. New systems, structures, and components, and configuration changes to existing items meet the criteria as described in the UFSAR or 10CFR50, Appendix A.

TABLE 17.1.7-1 (cont'd)

Standard, Requirement, or Guide	Conformance Status	Remarks
10CFR50, Appendix B-Quality Assurance Criteria for Nuclear Power Plants	Conforms	
10CFR50.55a-Licensing of Production and Utilization Facilities (ASME Boiler and Pressure Vessel Code, Section XI-Rules for Inservice Inspection of Nuclear Reactor Coolant Systems)	Conforms	10CFR50.55 specifies ASME Section XI code dates. The Ginna program conforms to 10CFR50.55a with the specific editions and addenda of Section XI specified in the Inservice Inspection Plan.
10CFR50.55(e)-Conditions of Construction Permits	Not applicable	Regulatory Guide applies to plants in the construction phase.
10CFR55-Operators Licenses	Conforms	
Regulatory Positions 2 and 4 of Branch Technical Position CMEB 9.5-1	Alternative	Fire protection controls are in accordance with APCSB 9.5-1, regulatory position IV b.6 and IV b.7.
Generic Letter 89-02, and its endorsement of EPRI NP5652 "Guideline for the Utilization of Commercial Grade Items in Safety-Related Applications (NCIG-07)".	Conforms	
ANSI/ANS 3.1-1987, Selection, Qualification and Training of Personnel for Nuclear Power Plants, Section 4.7.	Conforms	Qualification requirements apply to NSRB members only as addressed by this standard.

17.2 PERFORMANCE/VERIFICATION

17.2.1 Methodology

All personnel performing activities affecting quality involved in the operation and support of Ginna Station are directly responsible for quality. Employees are empowered to make decisions in their areas of responsibility and are held accountable for the quality of their own work. Verification of work is performed by each organization to assure that quality objectives are achieved and established performance standards are met.

Nuclear Operations and supporting organizations involved in Ginna quality related activities accomplish and verify their work using instructions and procedures. For quality affecting activities within their area of responsibility, each organization develops, reviews, approves, and implements such documents. The activities covered include operation, maintenance, repair, inservice inspection, refueling, procurement, modification, special processes, inspection and testing, document control and records management, training of personnel, and audit and surveillance. In addition, Ginna LLC suppliers and contractors are required to have appropriate instructions and procedures as specified in procurement documents.

Persons preparing, reviewing, and approving instructions and procedures are responsible for assuring that they include appropriate quantitative or qualitative acceptance criteria for determining that important activities have been satisfactorily accomplished. In addition, they assure that these documents are kept current.

17.2.2 Design Control

Plant configuration changes, including temporary changes, are implemented utilizing design control measures at least commensurate with those applied to the original design.

Nuclear Engineering Services is the design authority for Ginna Station. Other organizations are authorized to perform design activities as designated in the Nuclear Policy Manual and supported by approved procedures and instructions.

Design control measures are defined and implemented by trained and qualified personnel through approved procedures and instructions. These procedures and instructions assure that:

- Design inputs are appropriately specified on a timely basis and correctly translated into design documents
- Design interfaces are identified and controlled
- The design is suitable for its intended application
- Design adequacy is verified by personnel other than those who performed the design
- Design changes, including field changes, are governed by

control measures
- Deviations and nonconformances are controlled
- Design records are identified, controlled, and retrievable

Design inputs (such as design bases, performance requirements, regulatory requirements, codes, and standards) and changes to design inputs are identified, documented, reviewed and approved, and controlled.

Design documents, including drawings and specifications, are prepared and technically reviewed by qualified personnel. The technical reviewer ensures that the design document is in accordance with the design concept, incorporates appropriate design inputs, and conforms to approved procedures and instructions. Design change packages are approved by appropriate management or supervision prior to release for implementation.

Design interfaces, both internal and external, are formally identified, and design activities are coordinated among the participating organizations to ensure that design inputs and outputs are properly developed, reviewed, approved, and distributed. Multi-discipline changes are reviewed to ensure integration of design outputs.

Design changes are reviewed to determine whether the change results in a change to plant Technical Specifications or requires regulatory review in accordance with 10CFR50.59.

Design data bases, documents, and procedures are revised to reflect changes installed in the plant. Design records are identified, indexed, and controlled to allow for retrievability of design basis information and to provide evidence of appropriate design controls.

17.2.3 Design Verification

Design verification is the process of reviewing, confirming, or substantiating the design to assure:

- the acceptability of the design inputs
- adherence to the design process
- that the design inputs are reflected in the design outputs
- that design changes are implemented under controls commensurate with those applied to the initial design

Procedures define acceptable verification methods and controls, design parameters subject to verification, acceptance criteria, and verification documentation and records requirements.

A design change is verified prior to release of the change to perform its design function. A design may be released for prefabrication or installation prior to completion of the design verification only if controls are established. The scope of work that can be completed must be defined and controls implemented to ensure that design verification is completed prior to use of the

change.

Verification methods include:

- performance of design reviews
- use of alternate calculations
- performance of qualification tests

If used, qualification tests shall verify the adequacy of the specific design or design feature under the most adverse design conditions, unless those conditions cannot be generated without initiating a plant transient. In those cases, simulated or extrapolated conditions are used.

Design verification is performed by technically qualified individuals other than those who developed the design. Design verification by the designer's immediate supervisor is allowable if other qualified individuals are not readily available. The designer's supervisor documents independence from the design development when required to perform a verification.

The design organization determines the extent of verification required, based upon safety significance, the degree of standardization, and the state-of-the-art of the change.

17.2.4 Procurement Control

Purchased material, equipment, and services are controlled using five major means:

- planning
- procurement document requirements
- supplier selection
- control of supplier performance
- acceptance of items and services

All procurement is conducted in accordance with procurement documents and governing procedures. In unusual circumstances, (e.g. replacement parts are needed to preclude the development of some unsafe or undesirable condition), an item, which is relatively simple and standard in design and manufacture, may be purchased under a commercial (non-safety related) purchase order and subsequently upgraded to safety-related using the commercial grade dedication process.

All reviews, inspections, surveillances, and audits are conducted by personnel who are competent to determine whether a supplier is capable of providing acceptable quality products.

Planning

Procurement planning by procuring organizations consists of determining the supplier of choice, methods to be used for acceptance of the item or service, and requirements for control of supplier performance. Source inspection (surveillance),

certificate of conformance, receipt inspection, and pre- or post-installation testing are methods which are considered for item acceptance. The extent of the acceptance methods and associated verification activities will vary depending upon the relative importance and complexity of the purchased item or service and the supplier's past performance.

Procurement Document Requirements

Procurement document control for the procurement of materials, parts, components, and services is initiated by department staff personnel. Procurement procedures require that organizations preparing procurement documents consider and include, as appropriate:

- scope of work
- technical requirements
- Quality Assurance Program requirements
- right of access
- documentation requirements
- reporting requirements (nonconformance and 10CFR Part 21)

Changes or revisions to procurement documents are subject to the same review and approval requirements as the original documents.

Originating department review of procurement documents includes verification of applicable regulatory, code, and design requirements and suitability for intended service. In addition, a verification of proper inclusion of the quality standards, quality assurance program requirements, method of procurement, and the applicable acceptance criteria is performed. For spare or replacement parts, procurement documents are reviewed to determine similarity to, compatibility with, and acceptance criteria commensurate with the original design. Personnel performing these reviews shall be trained and qualified in accordance with the training programs discussed in Section 17.1.5.

Supplier Selection

Selection of a supplier is based on the evaluation of their capability to provide the items or services in accordance with procurement document requirements. The evaluation, which is accomplished during procurement planning, determines the necessity for the supplier selection to be made from the approved vendors list. For items and services procured from suppliers required to have a quality assurance program, supplier selection is made from the approved vendors list or from those who are in the process of being added to the list. Addition of a supplier to the approved vendors list is based on satisfactory evaluation of the supplier's quality assurance program. The evaluation guidelines for source selection considers the complexity of the item, method(s) of acceptance, and, for a replacement item, whether the source is to be restricted to the original supplier.

Items or services which meet industry standards and are typically utilized in applications other than nuclear may be purchased from suppliers not listed on the approved vendors list, provided that item acceptance through receipt inspection can be based on acceptance of standard commercial quality. This is supplemented, as necessary, with source surveillance, pre- or post-installation tests, receipt tests, commercial supplier surveys, supplier test reports, or commercial supplier certificates. For commercial grade items and services, an evaluation of intended use is completed to determine critical characteristics which must be verified prior to acceptance for use.

Control of Supplier Performance

Control of supplier performance shall include:

- Monitoring supplier activities through audits and surveillances
- Evaluation by requesting submittal of supplier documents for review
- Identifying under what conditions suppliers are to report nonconformances

Acceptance of Items and Services

The verification methods for the acceptance of items and services are specified during procurement planning and purchase order preparation. Receipt inspection is a verification method common for the acceptance of items.

17.2.5 Procurement Verification

The supplier's overall quality assurance organization and program is evaluated in accordance with applicable parts of 10CFR50, Appendix B; codes and standards; and Ginna LLC requirements. Suppliers on the approved vendors list are reviewed annually for performance and program changes, and audited on a triennial basis.

The degree of supplier surveillance (including review, inspection, or audit) required during design, fabrication, inspection, testing, and shipping shall be determined and documented. The objectives of supplier surveillance are to provide a sampling review of the supplier's quality assurance program implementation and to verify product conformance with respect to the purchase order requirements. The extent of supplier surveillance will be consistent with the safety significance, complexity, quantity, and frequency of procurement of the item or service. As necessary, this may require verification of the activities of suppliers below the first tier.

The verification responsibilities for evaluation and surveillance of supplier activities are assigned to Quality and Performance Assessment.

Department supervision is responsible for receipt and control of items pending their acceptance.

Receipt inspection is performed for items and associated services

for maintenance, repair, modification, and refueling. Inspections are performed to verify acceptability. To be acceptable, the items and services must conform to procurement documents, have satisfied required inspection and test requirements, and have documentary evidence of conformance available at the plant prior to acceptance for use. Personnel performing receipt inspection and test activities are trained and qualified.

17.2.6 Identification and Control of Items

The identification and control of materials, parts, and components (including consumable materials and items with limited shelf life) is accomplished in accordance with written requirements and applies in any stage of fabrication, storage, or installation. Identification and control requirements are established either by an existing procedure or by requirement documents prepared during the planning stages of a project. The identification and control requirements cover:

- Traceability to associated documents (such as drawings, specifications, purchase orders, manufacturing test data and inspection documents, and physical and chemical mill test reports)
- Specification of the degree of identification to preclude a degradation of the item's functional capability or quality
- Proper identification of materials, parts, and components prior to release for manufacturing, shipping, construction, and installation

Nuclear Engineering Services is responsible for assuring that drawings and specifications contain appropriate requirements for the identification and control of materials, parts, or components. Suppliers are required to assure that all required documentation for an item is properly identified and related to the item.

17.2.7 Handling, Storage, and Shipping

Nuclear Operations and support organizations are responsible for developing and implementing procedures for the handling, storage, shipping, preservation, and cleaning of quality related material and equipment. These procedures provide guidelines to protect items from damage, loss, and deterioration. Also, items are marked or labeled during packaging, shipping, handling, and storage to identify and maintain the items' integrity and to indicate need for special controls.

Under normal circumstances, manufacturer's specific written instructions and recommendations and purchase specification requirements are invoked for cleanliness, preservation, special handling, and environmental requirements for storage. In the absence of, or in addition to, specific manufacturer requirements, management may invoke requirements in accordance with department procedures. Examples of such requirements include desiccants, shelf life, endcaps, and special packaging

requirements.

Procurement documents and engineering specifications define requirements for the handling, shipping, storage, cleaning, and preservation of new fuel and fuel assemblies, materials, and equipment. When necessary to maintain acceptable quality, special protective measures (such as containers, shock absorbers, etc.) are specified and provided.

Procedures are established for the routine maintenance and inspection of lifting and handling equipment and for the handling of heavy loads and safe load paths.

17.2.8 Test Control

The Ginna Station test program includes the surveillance test program required by Technical Specifications, inservice pump and valve testing, and testing following modification and maintenance.

The test program requires the identification, control, and documentation of all tests and the preparation of written procedures required for satisfactory accomplishment of the testing. Written procedures and checklists for the testing program include: instructions and prerequisites to perform the test, use of proper test equipment, inspection hold points, and acceptance criteria.

Testing is utilized as follows:

- To determine continued operability of installed structures, systems, and components consistent with the surveillance requirements of Technical Specifications and the inservice pump and valve program
- To demonstrate the ability and to support the qualification of safety related equipment to function in harsh environmental conditions
- To demonstrate the acceptability of replacement and purchased items
- To support troubleshooting and investigation of degraded conditions
- To demonstrate the acceptability of items involved in maintenance, repair, and modifications

Contractors who perform testing are required to do so in accordance with Ginna LLC procurement document requirements.

All test results are required to be documented, reviewed, and approved by those responsible for performing the test. Unacceptable test results and test anomalies are evaluated in accordance with established procedures to determine the cause of the problem and the need for retest or for increasing test frequency.

The design organization is responsible for assuring that required tests for modifications are included in design documents.

17.2.9 Measuring and Test Equipment Control

Programs are established which assure that test instruments, tools, gauges, shop and reference standards, and other measuring and testing devices used in activities affecting quality are properly controlled and calibrated. Elements of control include calibration procedures, establishment of calibration frequencies, and maintenance requirements for measuring and test equipment.

Calibration procedures include step-by-step calibration methods and requirements for instrument accuracy. Calibration frequency is based on required accuracy, degree of usage, stability characteristics, manufacturer's recommendations, experience, and other conditions affecting measurement capability.

The program for control of measuring and test equipment includes:

- Assuring timely calibration of equipment.
- Providing unique identification of the next calibration date on the equipment calibration tags or stickers and traceability to calibration test data.
- Providing traceability of shop standards to nationally recognized standards and periodic revalidation of shop standards. Where national standards do not exist, procedures contain instructions to document the basis for calibration. Except where standards with the same accuracy as the instruments being calibrated are shown to be adequate for the requirements, calibration standards are to have a greater accuracy than the standards being calibrated.
- Assuring that calibrating equipment is calibrated against standards that have an accuracy of at least four times the required accuracy of the equipment being calibrated or, if not possible, have an accuracy that ensures the equipment being calibrated will be within the required tolerance.
- Providing for records to be maintained which indicate the complete status of all items under the calibration system including the maintenance, calibration results, abnormalities, and last and future calibration dates.
- Controlling the purchase requirements of new equipment to be entered into the calibration and control system including requirements for accuracy, stability, and repeatability under normal use conditions.

In the event a measuring instrument (i.e., shop or field standard) is found out of calibration, an investigation is conducted to determine the validity of previous measurements.

Responsibilities and requirements for the selection and use of calibrated measuring and test equipment are described in the Nuclear Policy Manual and related procedures.

Installed plant instrumentation is subject to calibration and control requirements of Technical Specifications and is not subject to calibration and control requirements for measuring and test equipment. The Nuclear Policy Manual amplifies responsibilities and requirements for installed plant instruments.

17.2.10 Inspection, Test, and Operating Status

Equipment or systems not ready for normal service are clearly identified by use of tags, control logs, and other suitable means to indicate the status of the items being isolated in order to prevent their inadvertent use.

Ginna Station is responsible for indicating the status of operating equipment or systems to be removed from service for maintenance, repair, or modification in accordance with the approved Electric System Operating Rules.

System status is indicated through the use of hold tags, block tags, and corresponding control logs. Equipment or system inspection and test status are indicated by use of test tags, labels, or status sheets.

Written procedures control the use of hold tags, test tags, and labels. Personnel who have station holding authority, as designated by the Plant General Manager, Ginna Station, are responsible for directing the status change of equipment and systems in accordance with the approved station holding procedures.

Job control documents are used to indicate status of the work, inspections or tests, and corresponding acceptance or rejection criteria. These job control documents preclude the inadvertent bypassing of inspections and tests. They are maintained at a designated control location to indicate the status and the completion of required inspections and tests.

Measures are established to monitor the completion status of inservice inspection.

17.2.11 Special Process Control

Written procedures are established to control special processes, such as welding, brazing, heat treating, and nondestructive examination to assure compliance with applicable codes, standards, and design specifications. Qualification of personnel and special process procedures comply with the requirements of applicable codes and standards. When special process qualification requirements are not included in existing codes and standards, they are described in procedures which give details of the special process, personnel qualification requirements, equipment necessary, and special process qualification requirements.

The Nuclear Policy Manual describes the criteria that define which processes are special. These criteria include processes which are highly dependent on the skill of the worker or the control of the process or both, and in which the desired quality cannot be readily determined by inspection or test.

Procuring organizations are responsible for requiring suppliers, in procurement documents, to control special processes in accordance with the above requirements. Special process procedures submitted by suppliers and contractors are reviewed

for adequacy by Ginna LLC.

Nuclear Operations organizations are responsible for assuring that personnel performing special processes under their cognizance are qualified and are using qualified procedures. Qualification of personnel and procedures is documented.

17.2.12 Inspection

Procedures prepared for the control of activities include inspection requirements and hold points as required by drawings, instructions, requirement documents, specifications, codes, standards, or regulatory requirements. For clarification, and to distinguish from preventive maintenance inspections, the following controls are associated with the quality assurance function inspections and referred to as verification inspections.

Verification inspection planning is used to determine the optimum method for performing hold point or final inspections. Planning considerations include: hold point execution by witness or inspection, the need for calibrated measuring tools and equipment, use of sample plans for multiple quantities, and the need for other verification options (e.g., non-destructive examination).

Hold points are used as necessary to ensure that inspections are accomplished at the correct points in the sequence of work activities.

Verification inspection procedures include:

- identification of quality characteristics to be inspected
- a description of the method of inspection to be used
- acceptance and rejection criteria
- requirements for recording the inspection results
- the need to provide evidence of inspection activity completion

Verification inspections are performed by inspection personnel who are appropriately qualified and independent. They are performed in accordance with approved procedures, instructions, or plans to support preplanned hold points, final acceptance verification, or receipt acceptance activities. Inspection results are required to be documented. When items are reworked, the rework is reinspected to the original or equivalent requirements.

Outside contractors are required by procurement documents to have and to follow similar procedures and to use independent inspectors.

17.2.13 Corrective Action

Conditions adverse to quality are those conditions which reduce confidence that a structure, system, or component at Ginna Station will perform satisfactorily in service.

Significant conditions adverse to quality are those conditions which, if uncorrected, could affect the health and safety of the public, seriously affect the ability to operate the plant in a safe manner, represent a serious breakdown in activity controls, or will require a major effort to restore capability to perform specified functions.

Conditions adverse to quality are promptly identified, reported to supervision, corrected, and evaluated to determine if a significant condition adverse to quality exists.

When a significant condition adverse to quality is identified, an evaluation of the effect of continuing the activity is performed. If continuing the activity would obscure or preclude identification and correction of the deficiency, or if continuing the activity would increase the extent of the deficiency or lead to an unsafe condition, stop work action is taken.

Designated independent inspection and audit personnel have authority to stop work on all activities at or in support of Ginna Station, with the exception of operating deficiencies. For operating deficiencies, designated independent inspection and audit personnel may recommend stop work action to station management.

For significant conditions adverse to quality, Ginna LLC management reviews initiated reports to determine causes, develops corrective action plans to resolve the condition, and takes action to preclude recurrence.

Procedures are established for the control, evaluation, and disposition of deficient material, parts, and components to prevent their inadvertent test, installation, or use. Items which do not conform to the drawing or specification requirements are identified, controlled, and reported.

Nonconformances identified at a supplier's facility and reported to Ginna LLC, for which the supplier has recommended a disposition of use-as-is or repair, are normally reviewed and the disposition approved by the procuring organization.

Items are repaired and reworked in accordance with approved procedures and drawings. The repair or rework must be verified as acceptable by an inspection of the affected item or process which is at least equal to the original inspection method.

Items which are accepted "use-as-is" are fully documented with the drawing or specification requirement and technical justification for acceptance, and are screened under the requirements of 10CFR50.59.

Nonconformance status information is compiled and analyzed for adverse trends and provided to management.

17.2.14 Document Control

Document control requirements contained in the Nuclear Policy Manual control the issuance of procedures, instructions, drawings, and specifications. These document control requirements are delineated in approved procedures which define the responsibilities for the control of each type of controlled document.

Each organization responsible for an activity is also responsible for providing the necessary review and approval of instructions, procedures, or drawings. Such review is to assure that documents are adequate, include appropriate qualitative and quantitative requirements, and include quality assurance requirements.

Changes to procedures specified in the Administrative Controls Section of the Technical Specifications receive a technical review in accordance with ANSI/ANS 3.2-1988, Section 4.2. The change also receives an applicability review, and if necessary, a screening to determine if a 10CFR50.59 evaluation is required. Reviewers shall not have been involved with formulating the change, shall be designated by the PORC Chairman or Plant General Manager, Ginna Station, and shall have qualifications equivalent to those of regular PORC members and meet ANSI Standard N18.1-1971, Section 4.3.1 or 4.4 as applicable. Changes that have been determined to require a 10CFR50.59 evaluation are referred to and subsequently reviewed by PORC. The change is subsequently approved by the Plant General Manager, Ginna Station or designee. All procedure changes have a minimum of two individuals involved.

Temporary changes to procedures, in addition to the review and approval process described above, are also approved by the Shift Supervisor. Requirements for the pre-approval review of Ginna Station procedures and the temporary change process are consistent with the guidelines of ANSI N18.7-1972, Sections 5.4 and 5.5.

The Nuclear Policy Manual requires that documents be controlled as appropriate, considering the type of document, safety significance, and intended use.

Types of documents which are controlled include Technical Specifications, UFSAR, Nuclear Directives, procedures, drawings, and specifications.

Suppliers of materials, equipment, and services having an approved quality assurance program are required in procurement documents to provide for control of documents.

The Nuclear Policy Manual requires that each organization provide in its procedures for measures to:

- Assure that documents are available when required
- Properly review and approve documents such as procedures and instructions
- Provide the same reviews and approvals for changes to documents as was required of the original document
- Require that organizations which review and approve documents have access to pertinent information and adequate knowledge of the original document intent
- Assure that approved changes are promptly transmitted for incorporation into documents
- Assure that obsolete or superseded documents are eliminated from the system and not used

17.2.15 Records

The Nuclear Policy Manual defines responsibility and establishes the basic requirements for quality assurance record retention and maintenance. Organizations performing quality affecting activities are responsible for forwarding the records they initiate to Records Management. Each organization generating records is responsible for preparation, review, approval, and implementation of specific quality assurance record procedures for their area of responsibility.

Records to be controlled are delineated in ANSI N45.2.9-1974. Sufficient records of items and activities are generated and maintained to document completed work. Items and activities requiring records include:

- design
- engineering
- procurement
- manufacturing
- construction
- inspection and test (e.g., manufacturer's proof and receipt)
- installation
- operations
- maintenance
- modification
- audits

Requirements and responsibilities for preparation, inspection, identification, indexing, review, storage, retrieval, maintenance, safekeeping, retention, and disposition of quality assurance records are in accordance with applicable records procedures, codes, standards, and procurement documents.

Non-duplicated records shall be stored in facilities which meet one of the following requirements:

The first option is a NFPA Class A, four hour minimum rated facility. In addition, this facility shall consider the nine features described in ANSI N45.2.9-1974 Section 5.6 in its construction.

The second option is a two hour rated facility designed to meet the requirements of NFPA 232 "Standard for the Protection of Records." These requirements may be met by any one of the following three ways: (1) a 2 hour vault meeting NFPA 232; (2) 2 hour rated file containers meeting NFPA 232 (Class B); or (3) a 2 hour rated fire resistant file room meeting NFPA 232. A fire resistant file room must meet the following additional provisions:

a. Early warning fire detection and automatic fire suppression should be provided, with electronic supervision at a constantly attended central station.
b. Records should be stored in fully enclosed metal cabinets. Records should not be permitted on open steel shelving. No storage of records should be permitted on the floor of the facility. Adequate access and aisle ways should be maintained at all times throughout the facility.
c. Work not directly associated with records storage or retrieval should be prohibited within the records storage facility. Examples of such prohibited activities include but are not limited to: records reproduction, film developing, and fabrication of microfiche cards.
d. Smoking and eating/drinking should be prohibited throughout the records storage facility.
e. Ventilation, temperature, and humidity control equipment should be protected inside with standard fire-door dampers where they penetrate fire barriers bounding the storage facility.

The third option is used when temporary storage of records (such as for processing, review, or use) is required. In this case, records shall be stored in a 1 hour fire rated container. The container shall bear a UL label (or equivalent) certifying 1 hour fire protection or be certified by a person competent in the technical field of fire protection. Additionally, sprinkler protection shall be provided in the area in which the containers are stored. The maximum allowable time limit for temporary storage is described in procedures.

The requirements and responsibilities for record accessibility and transmittal are described in the Nuclear Policy Manual. Removal of records from storage is documented and accountability is maintained by the responsible record control organization.

17.3 ASSESSMENT

17.3.1 Methodology

A comprehensive program of planned and periodic self and independent assessments is established to keep management apprised of the overall performance of Ginna Station.

Managers and supervisors assess the activities and results within their organizations' areas of responsibility to assure that they meet quality requirements and performance standards. Through observation and routine monitoring, they detect adverse operational events, declining performance trends, and precursors of potential problems. They take action to correct these problems as well as those identified by external sources.

Independent assessment of the effectiveness of quality program implementation and overall Ginna Station performance is the primary role of the QA organization. Independent assessments are conducted through internal audits and QA surveillances on behalf of the NSRB; the Vice President, Ginna; and as requested by line management. This is accomplished by monitoring performance, reporting findings to line management in a timely manner, and verifying satisfactory resolution of problems. Operational assessment is the evaluation of anomalous performance and potential problem precursors from external sources.

The NSRB conducts independent assessment through periodic review of plant activities and by directing biennial audits and evaluating their results. The responsibilities of the NSRB are discussed in sections 17.1.2 and 17.1.3.

Independent assessment activities are performed in accordance with instructions and procedures by organizations independent of the areas being assessed. Organizations performing independent assessment are technically and performance oriented, with their primary focus on the quality of the end product and secondary focus on processes.

17.3.2 Assessment

Self-assessment

Self-assessment is established in the Nuclear Policy Manual as the responsibility of all organizations with involvement in the operation and support of Ginna Station. Individuals and work groups are accountable for achieving acceptable quality by adhering to procedures and verifying that their work meets quality requirements and performance standards.

Independent Assessment

A program of planned and periodic independent assessments is established and implemented to confirm that activities affecting quality comply with the Quality Assurance Program and that the program has been implemented effectively. Assessments provide comprehensive independent evaluation of activities, results, and procedures.

The independent assessment program includes internal audits, external audits, and QA surveillances. These assessments are both performance-based and compliance-based, with the focus on activities and functions which often cut across organizational lines. Strengths and weaknesses of an organization's performance are determined in these assessments, allowing QA to identify areas of weaknesses for more frequent scrutiny. In areas of strength, assessment efforts can be reduced, freeing resources for examination of activities that could benefit most from independent assessment.

Internal audits of selected aspects of quality affecting activities are performed at a frequency commensurate with safety significance and management concerns. The audits are regularly scheduled on a formal, preplanned audit schedule in a manner which assures that audits of safety related activities are completed once every twenty-four (24) months. The audit schedule is dynamic, reviewed and revised periodically to assure appropriate coverage of current and planned activities.

Table 17.3.2-1 is a list of audits. Supplementing this list are audits of the Nuclear Emergency Response Plan to satisfy the requirements of 10CFR50.54 (t), and Station Security Plan to satisfy the requirements of 10CFR50.54 (p)(3), 73.56 (g)(1) and (g)(2) and 10CFR73.55 (g)(4). Audits may also be used to meet the periodic review requirements of the code for the Radiological Protection program. Audit frequency and further discussion of these audits are described in their respective plans. Required audits may be accomplished using one of the following methods:

- Audit activities only,
- A combination of audit and QA surveillance activities, or
- A series of QA surveillance activities.

When the results of QA surveillance activities are used, the audit team leader must:

- Review the results of the QA Surveillance(s) for applicability,
- Integrate those results into the audit scope, and
- Include those results in the audit report.

QA surveillances, by their nature, require less planning and are more responsive to management requests. They are also better suited to event driven activities, such as drills, corrective maintenance, and surveillance tests.

Additional audits and QA surveillances are conducted as necessitated by situations or evaluations including:

- special conditions which preclude deferral
- management concerns resulting from previous assessment results and corrective action
- information from external sources (e.g., generic experience of the nuclear industry, ASME, peer organizations, and regulatory bodies)

Each audit requires the development of an audit plan to provide

information about the audit, such as characteristics and activities to be assessed, acceptance criteria, names of those who will perform the audit, scheduling arrangements, and the method of reporting findings and recommendations. Audit planning and performance utilize performance-based techniques that facilitate achievement of assessment objectives.

Audit and QA surveillance assessments are performed in accordance with written procedures or checklists by personnel who do not have direct responsibility in the areas being assessed. Independent assessments may be conducted by Quality and Performance Assessment engineers or other qualified personnel, such as technical specialists from other company departments, outside consultants, and individuals from other utilities.

Assessment results are documented and reported to the assessor's management, the supervisor and group head having responsibility in the area assessed, and, for internal audits, to the Nuclear Safety Review Board. Within a specified time period, the person having supervisory responsibility in the area assessed is required to review the results, take necessary action to correct the deficiencies identified by the report, and document and report the corrective action.

External audits of major contractors, subcontractors, and suppliers are conducted during the early stages of design and procurement to evaluate their quality assurance program for compliance with all procurement document requirements. Audits are conducted, as necessary, to assure that major contractors, subcontractors, and suppliers are auditing their suppliers' quality assurance programs in accordance with procurement documents. During the project or procurement process, additional audits are performed, as required, to assure all quality assurance program requirements are properly implemented in accordance with procurement documents.

Nuclear Assessment performs regular analyses of assessment results to evaluate quality and performance trends. Results of these analyses, including strengths and weaknesses, are provided to management for their regular review. Management concerns due to assessment results may necessitate a follow-up assessment, either by audit or by QA surveillance. The Nuclear Policy Manual provides guidelines for conducting unscheduled audits including the need for reaudits.

Operating Experience

The operating experience section receives and evaluates information from INPO and other utilities and vendors. The operating experience section also receives and evaluates NRC Information Notices. They ensure that relevant and timely recommended actions are provided to management that will eliminate precursors of similar problems at Ginna. This is accomplished through:

- coordinating feedback programs to measure and improve the internalization of lessons learned from operating experience
- reviewing INPO SOERs and SERs
- reviewing vendor 10CFR Part 21 report of defects
- reviewing NRC Information Notices

Table 17.3.2-1

Audit List

Audit Topic Areas (24 months)

a. The conformance of facility operation to provisions contained within the Technical Specifications and applicable license conditions.

b. Performance, training, and qualifications of the operating and technical staff.

c. The results of actions taken to correct deficiencies occurring in facility equipment, structures, systems, or methods of operation that affect nuclear safety.

d. The performance of activities required by the Quality Assurance Program to meet the criteria of 10CFR50, Appendix B.

e. Facility Fire Protection Program and implementing procedures.

f. Inspection and audit of the fire protection and loss prevention program performed by non-licensee personnel. The personnel may be representatives of a fire insurance brokerage firm, or other qualified individuals.

g. The radiological environmental monitoring program and the results thereof.

h. The Offsite Dose Calculation Manual and implementing procedures.

i. The Process Control Program and implementing procedures.