

Portland General Electric Company

Trojan ISFSI 71760 Columbia River Hwy Rainier, Oregon 97048

November 28, 2011

VPN-006-2011

Trojan ISFSI Docket No. 72-017 License No. SNM-2509

ATTN: Document Control Desk Director, Division of Spent Fuel Storage and Transportation Office of Nuclear Material Safety and Safeguards U. S. Nuclear Regulatory Commission Washington, DC 20555-0001

> Revision to PGE-8010, "Trojan Nuclear Quality Assurance Program," to Revise Quality Assurance Record Storage Commitments

Pursuant to 10 CFR 72.140(b) and (c) and 10 CFR 71.101(b) and (c), this letter submits for Nuclear Regulatory Commission (NRC) approval proposed Revision 29 to PGE-8010, "Portland General Electric (PGE) Nuclear Quality Assurance [QA] Program For Trojan Independent Spent Fuel Storage Installation (10 CFR 72) Operations And Radioactive Material Packaging And Transportation (10 CFR 71) Activities" (Trojan Nuclear QA Program).

In addition, this letter also requests the NRC to issue a revision to PGE QA Program Approval for Radioactive Material Packages No. 0327, Docket No. 71-0327, to reflect NRC approval of the proposed Revision 29 to the Trojan Nuclear QA Program enclosed with this letter. The current PGE QA Program Approval for Radioactive Material Packages No. 0327 is Revision 15, which expires March 31, 2015. As required by 10 CFR 170.31 Section 10.B.2, the \$3,900.00 Application Fee, for QA Program Users associated with this 10 CFR 71 QA Program change, accompanies this letter in the form of an "Authorization for Payment By Credit Card" form contained in Enclosure IV.

The primary reason for the changes incorporated into the proposed Revision 29 to the Trojan Nuclear QA Program is to revise the requirements related to QA Record storage. This revision reflects a change in the media on which the majority of QA records will be stored (i.e., from optical disks to electronic media disks).

A detailed description of and reason and justification for each change incorporated into proposed Revision 29 of the Trojan Nuclear QA Program is provided as Enclosure I to this letter. Enclosure II to this letter provides a redline version of the four (4) changed pages for the proposed Revision 29 to the Trojan Nuclear QA Program, PGE-8010, with strikethroughs,

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insertions, and sidebars annotated. Enclosure III to this letter provides a copy of the entire QA Program containing a clean version of the proposed Revision 29 with sidebars annotated.

These proposed changes to the Trojan Nuclear QA Program, section 17.0, "Quality Assurance Records" will continue to satisfy the requirements of 10 CFR 72.174 and 10 CFR 71.135 for managing Trojan ISFSI QA records. They do not change the types of QA records being stored and the stored QA records will continue to be identifiable, retained, and retrievable. The two new redundant electronic media storage systems are each located in a secure, controlled access room that will continue to provide protection of stored records from fire, theft, flood and deterioration.

Upon receipt of the NRC approvals requested in this letter, PGE will issue the approved Trojan Nuclear QA Program, Revision 29, concurrently with necessary revisions to Trojan ISFSI procedures.

If there are any questions regarding this letter, please contact Mr. Jay P. Fischer of my staff at (503) 556-7030.

Sincerely,

ighten Mon

Stephen M. Quennoz Vice President Nuclear & Power Supply/Generation

Enclosures (4)

c: Regional Administrator, NRC Region IV, DNMS Christopher M. Staab, NRC, NMSS/DSFST Thomas M. Stoops, ODOE

ENCLOSURE I TO VPN-006-2011

Proposed Revision 29 to PGE-8010 – Description of and Reason and Justification for Changes

The table below provides the Nuclear Regulatory Commission (NRC) with a description of each change incorporated into proposed Revision 29 to PGE-8010, "Portland General Electric (PGE) Nuclear Quality Assurance [QA] Program For Trojan Independent Spent Fuel Storage Installation (10 CFR 72) Operations And Radioactive Material Packaging And Transportation (10 CFR 71) Activities" (Trojan Nuclear QA Program), which is provided as Enclosures II and III to PGE Letter No. VPN-006-2011 concurrently with this Enclosure I. Also included in the table is the reason for each change and justification supporting the conclusion that, following implementation of the change, the Trojan Nuclear QA Program will continue to satisfy the requirements and applicable criteria of 10 CFR 72, Subpart G, and 10 CFR 71, Subpart H.

As mentioned in PGE Letter No. VPN-006-2011 forwarding this enclosure, the primary reason for the changes incorporated into the proposed Revision 29 of the Trojan Nuclear QA Program is to revise the requirements related to QA Record storage. This revision reflects a change in the media on which the majority of QA records will be stored (i.e., from optical disks to electronic media disks).

PGE-8010 Section	Description of and Reason and Justification for Change		
FRONT MATTER			
Title Page	An administrative change is made to this page to reflect the proposed Revision 29.		
Page ii Approval Page	An administrative change is made to this blank signature page to reflect the proposed Revision 29. This page will be signed subsequent to NRC approval of the change.		
Page iv List of Effective Pages	The List of Effective Pages is updated to reflect the proposed Revision 29 changes to the Title page and pages ii, iv, and 17-1.		

PGE-8010 Section	Description of and Reason and Justification for Change		
	CHAPTER 17.0		
Page 17-1 17.0, Quality Assurance Records, Section 17.2	Wording is added to Section 17.2, "Quality Assurance Records Control Program," last paragraph to reflect the proposed storage of the majority of Trojan QA Records on electronic media disks versus on optical disks. The changes also clarify that selected QA Records on other media will continue to be filed and maintained in a Permanent Records Storage Facility.		
Section 17.2	It is noted that the current Trojan ISFSI Nuclear QA Program Revision 28 covering 10 CFR 72, subpart G and 10 CFR 71, subpart H activities was previously approved by NRC in 2005 (reference PGE submittal letter dated January 21, 2005 [ADAMS No. ML050250303] and NRC approval letter dated May 23, 2005 [ADAMS No. ML050680345]).		
	Prior to termination of the Trojan Nuclear Plant License (NPF-1, Docket 50-344) on May 23, 2005, the Trojan QA Program was shared by both the Trojan Nuclear Plant and the Trojan ISFSI. Since 1996, as the majority of Trojan Nuclear Plant and ISFSI hardcopy QA records were completed, they were electronically scanned and the QA record images were saved onto two redundant optical disks, which have been stored in two separate locations. As required by the current Trojan Nuclear QA Program, Revision 28, section 17.2, statement: "Quality assurance records are ultimately filed and maintained at a Permanent Records Storage Facility," one of these optical disk ultimate storage locations has been in a Permanent Records Storage Facility. It is noted that the Glossary of the Trojan Nuclear QA Program contains the definition for a Permanent Records Storage Facility as: "A Permanent Records Storage Facility is an environmentally controlled room or vault with controlled access which provides protection of quality assurance records from fire, theft, flood and deterioration."		
	Record storage technology has been evolving and PGE's optical disk vendor, Hewlett Packard, has informed PGE that as of June 2011, they would no longer sell or provide replacement parts for the optical disk jukebox equipment that is used to view the record images on optical disks. PGE has selected and purchased EMC Centera Content Addressed Storage (CAS) equipment for storage of selected PGE corporate business records. This Centera CAS equipment is composed of two fault-tolerant, redundant, electronic media storage systems, which are housed at two separate PGE facility locations (approximately 2 miles apart). The two EMC Centera CAS systems are each located in a secure, controlled access room that will continue to provide protection of storage from fire theft flood and datarioration. PCE has completed transferring their selected corporate		

PGE-8010 Section	Description of and Reason and Justification for Change	
	a test program to verify that a sample of Trojan ISFSI records currently stored on optical disks can be accurately transferred onto the two redundant Centera CAS systems and are retrievable from each system.	
	Based on the above, PGE is proposing to make the following change in the way Trojan ISFSI QA records are stored. PGE will continue to electronically scan Trojan ISFSI hardcopy QA records and the record images will then be saved onto the two Centera CAS fault-tolerant, redundant, electronic media storage systems, which are housed at two separate PGE facility locations (approximately 2 miles apart). The basic change is that the electronic record images will be stored on two redundant electronic media storage systems instead of the two redundant optical disks. The Trojan ISFSI QA record images currently stored on optical disks will be copied in a controlled manner onto the redundant Centera CAS systems and verified to ensure that the images are accurately transferred to and retrievable from both Centera storage systems.	
	Subsequent to this proposed change (no longer using optical disks), there will be no QA record images stored on a removable optical disk that could be placed into a Permanent Records Storage Facility, therefore, a proposed change to section 17.0 of the Trojan QA Program is needed. As detailed in the redline version enclosed as Enclosure II, the following changes are being made to the last paragraph of section 17.2:	
	Quality assurance records are ultimately filed and maintained at a Permanent Records Storage Facility. Prior to final transmittal of quality assurance records to permanent storage, the originating organization will be responsible for maintaining quality assurance record controls. <u>The majority of ISFSI quality assurance</u> <u>records are ultimately scanned and stored as electronic images on two redundant, electronic media storage</u> <u>systems housed at two separate locations</u> . <u>Quality assurance records in electronic format (e.g., .pdf format)</u> <u>may be directly filed and stored on the electronic media storage systems</u> . <u>Selected quality assurance records</u> <u>on other media (e.g., paper hardcopies, microfilm, DVDs) are ultimately filed and maintained in a Permanent Records Storage Facility</u> .	
	 The first sentence is moved to the last sentence and reworded to clarify that only selected records stored on other media will be placed in a Permanent Records Storage Facility. The second sentence is not changed. Two new sentences are added to reflect that ISFSI quality assurance records, in electronic format, will be stored on the two redundant, electronic media storage systems housed at two separate locations. 	

PGE-8010 Section	Description of and Reason and Justification for Change	
	These proposed changes to the Trojan Nuclear QA Program, section 17.0, "Quality Assurance Records" will continue to satisfy the requirements of 10 CFR 72.174 and 10 CFR 71.135 for managing Trojan ISFSI QA records. They do not change the types of QA records being stored and the stored QA records will continue to be identifiable, retained, and retrievable. The two EMC Centera CAS systems are each located in a secure, controlled access room that will continue to provide protection of stored records from fire, theft, flood and deterioration.	

ENCLOSURE II TO VPN-006-2011

PROPOSED REVISION 29 TO PGE-8010, "PORTLAND GENERAL ELECTRIC (PGE) NUCLEAR QUALITY ASSURANCE PROGRAM FOR TROJAN INDEPENDENT SPENT FUEL STORAGE INSTALLATION (10 CFR 72) OPERATIONS AND RADIOACTIVE MATERIAL PACKAGING AND TRANSPORTATION (10 CFR 71) ACTIVITIES"

(Redline Version of four changed pages with Strikethroughs and Insertions Annotated)

PGE-8010

PORTLAND GENERAL ELECTRIC (PGE) NUCLEAR QUALITY ASSURANCE PROGRAM FOR

TROJAN INDEPENDENT SPENT FUEL STORAGE INSTALLATION (10 CFR 72) OPERATIONS AND RADIOACTIVE MATERIAL PACKAGING AND TRANSPORTATION (10 CFR 71) ACTIVITIES

Revision 298

Portland General Electric Company 121 SW Salmon Street Portland, Oregon 97204

PGE-8010

PGE NUCLEAR QUALITY ASSURANCE PROGRAM FOR TROJAN INDEPENDENT SPENT FUEL STORAGE INSTALLATION (10 CFR 72) OPERATIONS AND RADIOACTIVE MATERIAL PACKAGING AND TRANSPORTATION (10 CFR 71) ACTIVITIES

Approval:

ISRC Member Responsible for Managing Nuclear Oversight Resources Date

Approval:____

Corporate Executive Responsible for Trojan

Date

Portland General Electric Company 121 SW Salmon Street Portland, Oregon 97204

PGE

NUCLEAR QUALITY ASSURANCE PROGRAM

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17.0 QUALITY ASSURANCE RECORDS

17.1 PURPOSE

In accordance with 10 CFR 72.174 and 10 CFR 71.135, this chapter describes measures for the identification, retention, and retrievability of records associated with the ISFSI (10 CFR 72) and/or radioactive material transportation packages (10 CFR 71) which furnish documentary evidence of the quality of items or activities affecting quality.

17.2 QUALITY ASSURANCE RECORDS CONTROL PROGRAM

In addition to the records required by the definition of Quality Assurance Records in the Glossary of this QA Program, ISFSI records required by 10 CFR 72.30, 72.48, 72.72, 72.80, 72.154, and 72.174 shall be maintained. ISFSI records pertaining to the design, fabrication, erection, testing, maintenance, and use of SSCs important to safety shall be maintained by or under the control of PGE for the applicable durations specified in 10 CFR 72.

In addition to the records required by the definition of Quality Assurance Records in the Glossary of this QA Program, the records must include the instructions, procedures, and drawings required by 10 CFR 71.111. These records shall be retained for three years beyond the date when PGE last engages in 10 CFR 71 radioactive materials packaging and transportation. If any portion of the written procedures or instructions is superseded, PGE shall retain the superseded material for three years after it is superseded.

Records should be identifiable to specific systems, structures, and components, when applicable. Documents which are designated as quality assurance records shall be legible, accurate, and completed as appropriate for the work accomplished. Records are indexed, including as a minimum retention times and location of the records within the record system, to provide for retrieval without undue delay.

Quality assurance records are ultimately filed and maintained at a Permanent Records Storage Facility. Prior to final transmittal of quality assurance records to permanent storage, the originating organization will be responsible for maintaining quality assurance record controls. The majority of ISFSI quality assurance records are ultimately scanned and stored as electronic images on two redundant, electronic media storage systems housed at two separate locations. Quality assurance records in electronic format (e.g., .pdf format) may be directly filed and stored on the electronic media storage systems. Selected quality assurance records on other media (e.g., paper hardcopies, microfilm, DVDs) are ultimately filed and maintained in a Permanent Records Storage Facility.

ENCLOSURE III TO VPN-006-2011

PROPOSED REVISION 29 TO PGE-8010, "PORTLAND GENERAL ELECTRIC (PGE) NUCLEAR QUALITY ASSURANCE PROGRAM FOR TROJAN INDEPENDENT SPENT FUEL STORAGE INSTALLATION (10 CFR 72) OPERATIONS AND RADIOACTIVE MATERIAL PACKAGING AND TRANSPORTATION (10 CFR 71) ACTIVITIES"

(Copy of entire QA Program Containing Clean Version of the Proposed Revision 29 with Sidebars Annotated)

PGE-8010

PORTLAND GENERAL ELECTRIC (PGE) NUCLEAR QUALITY ASSURANCE PROGRAM

FOR

TROJAN INDEPENDENT SPENT FUEL STORAGE INSTALLATION (10 CFR 72) OPERATIONS AND RADIOACTIVE MATERIAL PACKAGING AND TRANSPORTATION (10 CFR 71) ACTIVITIES

Revision 29

Portland General Electric Company 121 SW Salmon Street Portland, Oregon 97204

PGE-8010

PGE NUCLEAR QUALITY ASSURANCE PROGRAM FOR TROJAN INDEPENDENT SPENT FUEL STORAGE INSTALLATION (10 CFR 72) OPERATIONS AND RADIOACTIVE MATERIAL PACKAGING AND TRANSPORTATION (10 CFR 71) ACTIVITIES

Approval:

ISRC Member Responsible for Managing Nuclear Oversight Resources

Date

Approval:

Corporate Executive Responsible for Trojan

Date

Portland General Electric Company 121 SW Salmon Street Portland, Oregon 97204

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PORTLAND GENERAL ELECTRIC COMPANY NUCLEAR QUALITY ASSURANCE PROGRAM

POLICY STATEMENT

Portland General Electric Company implements a Quality Assurance (QA) Program which directs quality-related activities at the Trojan Independent Spent Fuel Storage Installation (ISFSI).

This QA Program complies with and applies to Important-to-Safety activities conducted under Title 10, Code of Federal Regulations, Part 72, Subpart G, "Quality Assurance for Independent Storage of Spent Nuclear Fuel, High-Level Radioactive Waste, and Reactor-Related Greater Than Class C Waste." These activities include managerial and administrative controls used to ensure safe operation of the ISFSI. This QA Program also complies with and applies to Important-to-Safety activities conducted under 10 CFR 71, Subpart H, "Quality Assurance for Packaging and Transportation of Radioactive Material."

The approval of this document commits the Portland General Electric Company to the requirements of the QA Program described herein and its successful implementation. Portland General Electric Company personnel who perform quality-related and/or Important-to-Safety functions are responsible for complying with the requirements of this QA Program.

Changes to the QA Program must be approved by the Nuclear Regulatory Commission, the ISFSI Safety Review Committee member assigned the management oversight function for Nuclear Oversight resources, and the Corporate Executive Responsible for Trojan prior to implementation.

Corporate Executive Responsible for Trojan

(Date)

1.0 ORGANIZATION

1.1 INTRODUCTION

Portland General Electric Company (PGE or Company), as a licensee under the purview of 10 CFR 72 and 10 CFR 71, is responsible for the establishment and execution of this Nuclear Quality Assurance Program (hereafter referred to as the QA Program) for activities conducted in support of the Trojan Independent Spent Fuel Storage Installation (ISFSI) that affect the functions of structures, systems, and components (SSCs) that are important to safety. These activities include managerial and administrative controls used to ensure safe operation of the ISFSI, as well as the performance of functions associated with assuring that the QA Program is effectively implemented. Pursuant to 10 CFR 72.142 and 10 CFR 71.103, the purpose of this chapter is to delineate the authorities, responsibilities, and interfaces of persons and organizations performing activities in support of spent fuel storage and/or radioactive material transport at the Trojan ISFSI that affect the functions of SSCs that are important to safety.

1.2 ASSIGNMENT OF FUNCTIONAL RESPONSIBILITIES

Figure 1.0-1 illustrates the functional authorities, responsibilities, and interfaces of persons and organizations performing activities that are governed by and/or required to effectively implement the QA Program. The functional responsibilities indicated in Figure 1.0-1 are further described below.

1.2.1 CORPORATE EXECUTIVE RESPONSIBLE FOR TROJAN

The Corporate Executive Responsible for Trojan has overall authority and responsibility for nuclear safety at the facility, and is responsible for promulgating PGE's QA policies; maintaining a continuing involvement in QA matters; maintaining management controls for effectively implementing applicable QA Program elements; and resolution of disputes between organizational elements that may arise related to quality-related activities.

The ISFSI Manager and the ISFSI Safety Review Committee (ISRC) report to the Corporate Executive Responsible for Trojan. ISFSI Staff personnel and/or contractors, agents, and/or consultants providing Nuclear Oversight services, including establishing and/or implementing the QA Program, also report directly to the Corporate Executive Responsible for Trojan when conducting (1) audits of ISRC activities; and/or (2) the biennial audit of past QA audits of ISFSI Department (including support personnel) activities that have been performed pursuant to Chapter 18 of this QA Program.

1.2.2 ISRC

The ISRC performs review and audit functions as required by the ISFSI Safety Analysis Report, and advises the Corporate Executive Responsible for Trojan on matters relating to the safe storage of spent nuclear fuel. As the ISRC reports directly to the Corporate Executive Responsible for Trojan, ISRC review and audit functions are independent of the ISFSI line organization responsibilities.

With the exception of audits of ISRC activities and/or the biennial audit of past QA audits of ISFSI Department activities, which as indicated in Section 1.2.1 are the responsibility of the Corporate Executive Responsible for Trojan, the ISRC is responsible for ensuring the conduct of QA audits of ISFSI Department activities pursuant to Chapter 18 of this QA Program. The ISRC also ensures that the adequacy of QA Program implementation is assessed biennially.

1.2.3 NUCLEAR OVERSIGHT

Nuclear Oversight services are provided as needed by qualified contractors, agents, and/or consultants. These resources report directly to a designated ISRC Member as detailed below.

1.2.3.1 ISRC Member Responsible for Managing Nuclear Oversight Resources

One ISRC Member reports directly to and is designated by the Corporate Executive Responsible for Trojan as the position having the authority and responsibility for maintaining and implementing the QA Program. This individual directs Nuclear Oversight resources in the overall implementation of the QA Program, including oversight and evaluation of work that is assigned to Nuclear Oversight resources to verify the adequate implementation of the QA Program. The ISRC Member responsible for managing Nuclear Oversight resources, together with the Corporate Executive Responsible for Trojan, is responsible for approving revisions to the QA Program.

Nuclear Oversight resources report directly to this ISRC Member, unless the Nuclear Oversight resources are conducting audit(s) of ISRC activities or are conducting the biennial audit of Nuclear Oversight internal QA audit activities that have been performed pursuant to Chapter 18 of this QA Program. In these instances, the auditing resources report directly to the Corporate Executive Responsible for Trojan. This organizational structure ensures that persons assigned responsibility for assuring effective implementation of any portion of the QA Program (e.g., review and audit functions) have direct access to levels of management, and the required authority and organizational freedom, as necessary to perform required functions.

The ISRC Member responsible for managing Nuclear Oversight resources must be knowledgeable of the QA Program; 10 CFR 72, Subpart G; and 10 CFR 71, Subpart H, and maintain up-to-date knowledge of applicable regulatory guides, codes, and standards related to Trojan ISFSI QA. Qualifications of this individual must include eight years of experience in the field of QA or equivalent number of years of nuclear plant and/or fuel storage facility experience in a supervisory position or a combination of the two. Graduation from a four-year accredited engineering or science college or university may be substituted for four years of this experience. At least one year of this experience shall be nuclear power plant and/or fuel storage facility experience in the implementation of an approved QA Program.

1.2.3.2 Nuclear Oversight Resources

Nuclear Oversight resources include contractors, agents,¹ and/or consultants who are independent of the ISFSI line organization. The primary role of Nuclear Oversight resources is to conduct audits of ISFSI Department activities in accordance with Chapter 18 of this QA Program. These resources may also augment the ISFSI Staff in performance of other QA/QC activities, including the performance of audits of ISRC activities or the biennial audit of past QA audits of ISFSI Department activities that have been performed pursuant to Chapter 18 of this QA Program; source and receipt inspections, surveys, or audits of contractors and suppliers of quality-related items; QC inspections; and/or procurement document/record reviews.

Nuclear Oversight resources are under the management direction of the ISRC Member responsible for managing Nuclear Oversight resources, unless the Nuclear Oversight resources are conducting audit(s) of ISRC activities or are conducting the biennial audit of past QA audits of ISFSI Department activities that have been performed pursuant to Chapter 18 of this QA Program. In these instances, the auditing resources report directly to the Corporate Executive Responsible for Trojan. These auditing resources must be individuals other than those that performed the ISRC activity or conducted the internal audit(s) being audited.

With this organizational structure, Nuclear Oversight auditing resources are ensured to be independent of the Trojan ISFSI Department representatives performing quality-related activities. As such, Nuclear Oversight resources have the authority and independence to identify quality problems; initiate, recommend, or provide solutions to quality problems through designated channels; and verify implementation of solutions to quality problems. To control deviations from QA Program requirements, contractors, agents, and/or consultants providing Nuclear Oversight services have the authority and responsibility to initiate stop work orders, as necessary, for any condition adverse to quality that has occurred or is developing.

¹ Agents may include PGE employees outside the Trojan ISFSI organization.

1.2.4 ISFSI DEPARTMENT

1.2.4.1 ISFSI Manager

The ISFSI Manager is responsible for the day-to-day implementation of the QA Program. The ISFSI Manager reports directly to the Corporate Executive Responsible for Trojan.

1.2.4.2 ISFSI Staff

The ISFSI Staff reports to the ISFSI Manager. Responsibilities, qualifications, and training required for ISFSI staff personnel performing quality-related activities are detailed in the Trojan ISFSI SAR and associated implementing procedures. ISFSI Staff personnel shall not be used to perform (Chapter 18) audits of ISFSI Department activities. Appropriately trained and qualified ISFSI Staff personnel (which may include corporate and/or contracted support personnel) may perform audits of ISRC activities or the biennial audit of past QA audits of ISFSI Department activities that have been performed by Nuclear Oversight resources pursuant to Chapter 18 of this QA Program. In the performance of these audits, the ISFSI Staff audit personnel report directly to the Corporate Executive Responsible for Trojan, and must be individuals other than those that performed the ISRC activity or conducted the internal audit(s) being audited. Appropriately trained ISFSI Staff personnel knowledgeable of QA/QC practices and concepts may also perform quality-related receipt inspections; source inspections, surveys, or audits of contractors and suppliers of quality-related items; QC inspections; and/or quality-related procurement document/record and procedure reviews. Individuals performing procurement document/record and/or procedure review activities must be someone other than those that originated the document/record or procedure revision being reviewed. Individuals performing inspection activities must be someone other than those that perform or supervise the performance of the work/activity being inspected.

1.2.5 CORPORATE EXECUTIVES RESPONSIBLE FOR SUPPORT ORGANIZATIONS

Corporate executives with responsibility for nuclear support activities shall assure that their assigned managers implement the QA Program, as applicable.

1.2.5.1 Managers of Nuclear Support Organizations

Managers of nuclear support organizations that perform quality-related activities, such as records control services, are responsible for ensuring that procedures that implement the applicable portions of the QA Program are established, implemented, and maintained.



Trojan ISFSI and QA Program Implementation Functional Organization

Figure 1.0-1

2.0 QUALITY ASSURANCE PROGRAM

2.1 PURPOSE

Pursuant to 10 CFR 72.144 and 10 CFR 71.105, this chapter describes the QA Program for the ISFSI as specified in 10 CFR 72, Subpart G, and for radioactive material packaging and transportation activities as specified in 10 CFR 71, Subpart H. This chapter also defines the applicability of the QA Program including training necessary to assure its proper implementation and effectiveness.

2.2 QUALITY ASSURANCE PROGRAM

2.2.1 GENERAL

The QA Program assures that the QA requirements for the ISFSI as specified in 10 CFR 72 and for radioactive material packaging and transportation activities as specified in 10 CFR 71 are satisfied. With regard to the ISFSI QA Program requirements of 10 CFR 72, the requirements of the QA Program apply to the design, fabrication, construction, testing, operation, modification, and decommissioning of the SSCs of the ISFSI that are important to safety, and to the managerial and administrative controls used to ensure safe operation of the ISFSI. Specific important-to-safety ISFSI SSCs and a detailed listing of quality-related activities are designated in and maintained in accordance with controlled procedure(s). These SSCs and activities governed by this QA Program, collectively referred to as "quality-related" items, are further described as follows:

- ISFSI SSCs classified as important to safety;
- Security Plan Implementing Procedures;
- Radiation Protection Program;
- Packaging radioactive material for transport pursuant to 10 CFR 71;
- Calibration of ISFSI monitoring instruments as specified in the ISFSI SAR; and
- Managerial and administrative controls to ensure safe operation of the ISFSI.

With regard to the QA Program requirements of 10 CFR 71, the requirements of the QA Program apply to the procurement, maintenance, repair, and use of important-to-safety radioactive material packagings for transport as specified in 10 CFR 71. All other 10 CFR 71 activities (i.e., design, fabrication, assembly, testing, and modification of important-to-safety radioactive material packagings) are not performed by PGE, but rather are satisfied by obtaining certifications from packaging suppliers that these activities are conducted in accordance with an NRC-approved QA Program.

The QA Program provides requirements for obtaining objective evidence that all SSCs classifed as important to safety are in conformance with the design specifications, test specifications, and criteria established for the ISFSI and its components. Controls are established over activities affecting the quality of materials and components as necessary to ensure conformance to the approved design of the ISFSI (pursuant to 10 CFR 72 requirements), and of each individual package used for the transport of radioactive material (pursuant to 10 CFR 71 requirements). QA requirements and procedures are based on the following considerations concerning the complexity and proposed use of ISFSI SSCs, and of the radioactive material transportation package and its components.

- (1) The impact of malfunction or failure of the item on safety;
- (2) The design and fabrication complexity or uniqueness of the item;
- (3) The need for special controls over and QA oversight of processes and equipment;
- (4) The degree to which functional compliance can be demonstrated by inspection or test; and
- (5) The quality history and degree of standardization of the item.

2.2.2 QUALITY-RELATED PROCEDURES

Procedures cover quality-related aspects of administration and control implemented by PGE, including the implementation of QA Program elements applicable to the ISFSI and to the use of packaging for radioactive material transportation pursuant to 10 CFR 71. The procedures document the policies and instructions necessary to fulfill the intent of the QA Program. They also include standard forms, lists, and checkoffs used in documenting the audits, inspections, certifications, and reviews.

Where appropriate, the procedures assure that activities affecting quality are performed under suitably controlled conditions. Controlled conditions include the use of appropriate equipment, suitable environmental conditions for performing the activity, and adequate cleanliness, handling, and storage to assure that required prerequisites for the given activity have been satisfied.

2.2.3 TRAINING

As detailed further in the Trojan ISFSI SAR, the training program provides for indoctrination and training of personnel performing quality-related activities as necessary to assure that suitable proficiency is achieved and maintained.

3.0 DESIGN CONTROL

3.1 PURPOSE

Pursuant to 10 CFR 72.146, this chapter describes controls to assure that ISFSI design requirements affecting quality-related items are correctly translated into ISFSI design documents. This chapter does not apply to packaging radioactive material for transport, since PGE is not authorized to and does not design 10 CFR 71 radioactive material transportation packages.

3.2 <u>GENERAL</u>

PGE does not perform design work affecting Trojan ISFSI SSCs classified as important to safety. Rather, all quality-related design work, including engineering calculations, design change control, and independent design verification, is performed by a qualified contracted design/engineering company under its own approved QA Program and procured in accordance with approved procedures and Chapters 4 and 7 of this QA Program.

Pursuant to Trojan ISFSI Technical Specification 5.1.1, design changes shall be approved by the ISFSI Manager prior to implementation. Procedural measures are established to assure that proposed design changes received from contracted suppliers are evaluated to determine if a change to the ISFSI license is required, and that appropriate personnel are notified of design modifications that may affect the performance of their duties.

4.0 PROCUREMENT DOCUMENT CONTROL

4.1 PURPOSE

Pursuant to 10 CFR 72.148 and 10 CFR 71.109, this chapter describes the preparation, review, approval, and control of procurement documents pertaining to ISFSI (10 CFR 72) and/or radioactive material packaging and transportation (10 CFR 71) quality-related items and services to assure the inclusion of applicable quality assurance requirements.

4.2 PROCUREMENT DOCUMENT CONTROL PROGRAM

Applicable procurement requirements for quality-related items and services are specified or referenced in procurement documents. Measures are established to assure that, to the extent necessary, contractors or subcontractors provide a QA Program consistent with the applicable provisions of 10 CFR 72, Subpart G. In addition, measures are established to assure that the applicable requirements of 10 CFR 71 are included or referenced in documents for procurement of radioactive material packaging and/or associated services, and that packages and procedures for use of these packages have been authorized by the NRC and documented in the NRC Certificate of Compliance.

Procurement requisitions and supplements thereto are reviewed for adequacy by personnel other than those that originated the requisition and/or supplements, and who are knowledgeable of QA practices and concepts.

Procurement documents are reviewed and approved by the ISFSI manager or his designee.

Approved procurement documents are submitted to the purchasing manager or designee for procurement.

5.0 INSTRUCTIONS, PROCEDURES, AND DRAWINGS

5.1 PURPOSE

Pursuant to 10 CFR 72.150 and 10 CFR 71.111, this chapter describes measures which will assure that activities affecting quality-related items and services associated with the ISFSI (10 CFR 72) and/or radioactive material packaging and transportation (10 CFR 71) are delineated, controlled, implemented, and accomplished through utilization of approved and documented instructions, procedures, or drawings.

5.2 INSTRUCTIONS, PROCEDURES, AND DRAWINGS

Activities affecting quality shall be accomplished in accordance with approved and documented instructions, procedures, or drawings. Instructions and procedures that describe activities affecting quality include the necessary limits and tolerances on material, equipment, processes, and specifications for activities associated with quality-related items and services. Instructions and procedures also prescribe special controls, processes, test equipment, tools and skills to attain the required quality, and requirements for documentation and/or verification of quality by inspection and test. Also included are appropriate qualitative and quantitative acceptance criteria for determining that important activities have been satisfactorily accomplished.

6.0 DOCUMENT CONTROL

6.1 <u>PURPOSE</u>

Pursuant to 10 CFR 72.152 and 10 CFR 71.113, this chapter describes methods for review, approval, distribution, and control of documents and changes thereto which affect quality-related items associated with the ISFSI (10 CFR 72) and/or radioactive material packaging and transportation (10 CFR 71).

6.2 DOCUMENT CONTROL PROGRAM

Written procedures are available which provide for the preparation, review, and approval of documents requiring control.

These procedures identify the appropriate qualified individuals or groups responsible for determining that appropriate quantitative and qualitative criteria are included in documents describing quality-related activities and for verifying that these criteria have been satisfactorily met. Procedures also require that documents are approved for implementation by appropriate levels of management and changes to the documents are reviewed and approved by the same organizations as the original unless another responsible organization is designated by the governing procedure. Approved changes are included in controlled documents prior to implementation of the change.

Procedures shall ensure that documents are distributed in a timely manner to appropriate locations and are available for use by personnel performing prescribed activities.

Master lists or equivalent document control systems are established to identify the current revision of controlled documents. These lists are available for use by cognizant personnel to preclude the use of superseded documents.

Quality-related procedures, including contractor procedures to be used onsite for quality-related work, are reviewed by personnel other than those that prepared the procedure or procedure revision, and who are knowledgeable of QA practices and concepts.

Temporary changes to quality-related documents may be made and implemented if a procedural method has been established to control the review and approval of the temporary changes.

7.0 CONTROL OF PURCHASED MATERIAL, EQUIPMENT, AND SERVICES

7.1 <u>PURPOSE</u>

Pursuant to 10 CFR 72.154 and 10 CFR 71.115, this chapter describes the measures for selection and evaluation of procurement sources for quality-related items and services associated with the ISFSI (10 CFR 72) and/or radioactive material packaging and transportation (10 CFR 71) and for verification activities to assure that specified requirements are met.

7.2 QUALITY ASSURANCE PROGRAM EVALUATION

PGE purchase orders/contracts for quality-related items or services are placed with contractors, suppliers, and service organizations who have been evaluated by designated Nuclear Oversight resource personnel for the applicable quality system level. Procedures govern the selection of procurement sources.

The effectiveness of the control of quality by contractors and suppliers shall be assessed at intervals consistent with the importance, complexity, and quantity of the product or service.

Quality-related items and services procured from a contractor, supplier, or service organization for which a quality assurance program is required but has not been reviewed or accepted may be utilized by PGE when appropriate additional controls such as source inspection, special receipt instructions, and/or testing are imposed. These additional controls shall be documented and approved by the ISFSI Manager.

7.2.1 SOURCE INSPECTION, SURVEY, AND AUDIT OF CONTRACTORS AND SUPPLIERS OF QUALITY-RELATED ITEMS

The designated Nuclear Oversight resource personnel or ISFSI staff personnel with appropriate qualifications are responsible for assuring source inspections, surveys, or audits of suppliers are performed as necessary.

7.3 <u>RECEIPT INSPECTION</u>

Receipt inspection of quality-related items is performed to assure that the requirements of the procurement documents have been met.

Accepted items are appropriately marked, removed from the inspection area, and located in a controlled storage area until use.

Documentary evidence that items conform to the procurement document requirements shall be available at the ISFSI site prior to installation or use.

8.0 IDENTIFICATION AND CONTROL OF MATERIAL, PARTS, AND COMPONENTS

8.1 PURPOSE

Pursuant to 10 CFR 72.156 and 10 CFR 71.117, this chapter describes measures for the identification and control of quality-related items associated with the ISFSI (10 CFR 72) and/or radioactive material transportation packages (10 CFR 71) to assure they can be traced to associated documents and to prevent the use of incorrect or defective material, parts, and components.

8.2 GENERAL

Quality-related items and subassemblies are identified (on the item or on records traceable to the item) in such a manner as to allow traceability to the appropriate quality documentation. The location and method of identification are selected to prevent affecting the function or quality of the item.

When an item is subdivided, required identification markings will be transferred to each part or reflected in the records.

When several parts are joined in fabrication, a list of parts and corresponding identification documents will accompany the assembly, as necessary. This documentation will include, as applicable, heat, lot, serial or part numbers, material certifications, weld or braze qualifications, test reports, NDE records, fabrication travelers, and other documentation to provide the bases for determining the acceptability of the assembly and its component parts.

Proper identification of materials, parts, and components is verified and documented at receipt inspection or prior to release for fabrication, assembly, shipping, or installation.

9.0 CONTROL OF SPECIAL PROCESSES

9.1 PURPOSE

Pursuant to 10 CFR 72.158, this chapter describes the methods for the control of special processes relative to quality-related items associated with the ISFSI (10 CFR 72). This chapter does not apply to radioactive material transportation packages, since PGE is not authorized to and does not fabricate 10 CFR 71 radioactive material transportation packages.

9.2 SPECIAL PROCESS CONTROL PROGRAM

PGE does not perform special processes involving Trojan ISFSI SSCs classified as important to safety. Rather, all quality-related special processes are performed by a qualified contracted company under its own approved QA Program and procured in accordance with approved procedures and Chapters 4 and 7 of this QA Program.

10.0 INSPECTION

10.1 PURPOSE

Pursuant to 10 CFR 72.160 and 10 CFR 71.121, this chapter establishes and describes the methods for the inspection of quality-related items and activities associated with the ISFSI (10 CFR 72) and/or radioactive material packaging and transportation (10 CFR 71) to assure their acceptability.

10.2 <u>GENERAL</u>

Inspections are performed in accordance with written, approved inspection plans and/or inspection procedures, to verify that quality-related items and processes conform to documented instructions, procedures, and drawings for accomplishing the activity.

Inspection programs are implemented through procedures which provide for preparation, review, and approval of inspection plans and procedures and provide for establishing mandatory hold points for witness by inspection. Inspection plans are approved by the ISFSI Manager or designee.

Inspections shall be performed by Nuclear Oversight resources or by qualified ISFSI Staff individuals other than those who performed or directly supervised the activity being inspected.

If direct inspection of items is impossible or disadvantageous, indirect control by monitoring processing methods, equipment, and personnel shall be provided. Both inspection and process monitoring shall be provided when control is inadequate without both.

11.0 TEST CONTROL

11.1 PURPOSE

Pursuant to 10 CFR 72.162, this chapter describes the controls for testing required to demonstrate satisfactory performance of quality-related items associated with the ISFSI (10 CFR 72). This chapter does not apply to radioactive material transportation packages, since PGE is not authorized to and does not perform testing of 10 CFR 71 radioactive material transportation packages.

Tests within the scope of this chapter include but are not limited to tests required by modifications and/or maintenance of SSCs classified as important to safety. These tests are performed to verify that an item will perform satisfactorily in service.

11.2 TEST CONTROL PROGRAM

11.2.1 GENERAL

The work package for maintenance or modifications to quality-related items identifies those tests necessary to demonstrate satisfactory performance of the affected equipment.

Measures are established to assure that test procedures incorporate the applicable requirements of 10 CFR 72 and the acceptance limits contained in the ISFSI license. Each test procedure is prepared and reviewed in accordance with applicable design documents, codes, and specifications.

The procedures shall include provisions for assuring that all prerequisites for the given test have been met, that adequate test instrumentation is available and used, and that the test is performed under suitable environmental conditions.

11.2.2 TEST DOCUMENTATION

Test results are documented, evaluated, and their acceptability determined by qualified personnel.

12.0 <u>CONTROL OF MEASURING AND TEST EQUIPMENT AND INSTALLED</u> <u>INSTRUMENTATION</u>

12.1 PURPOSE

Pursuant to 10 CFR 72.164 and 10 CFR 71.125, this chapter describes the provisions for the control of portable measuring and testing equipment and installed instrumentation utilized in the inspection, testing (10 CFR 72 only), and monitoring of quality-related items associated with the ISFSI (10 CFR 72) and/or radioactive material transportation packages (10 CFR 71).

12.2 <u>MEASURING AND TEST EQUIPMENT AND INSTALLED INSTRUMENTATION</u> <u>CONTROL PROGRAM</u>

12.2.1 GENERAL

PGE does not perform calibration of Trojan ISFSI installed instrumentation and/or portable measuring and test equipment. Rather, all quality-related calibration is performed by qualified contracted calibration facility(ies) under its/their own approved QA Program and procured in accordance with approved procedures and Chapters 4 and 7 of this QA Program. Instruments are calibrated at intervals consistent with the instrument manufacturer's guaranteed repeatability and the user's experience.

The control of portable measuring and test equipment and installed instrumentation is implemented by specific procedures or instructions that describe calibration control and recall frequency requirements. Instruments, tools, gages, and fixtures used in quantitative measurement are uniquely identified, indicate calibration status, appear on a controlled list, and are included in the calibration program.

12.2.2 DEFECTIVE OR OUT-OF-CALIBRATION MEASURING AND TEST EQUIPMENT AND INSTALLED INSTRUMENTATION

When portable measuring or test equipment or installed instrumentation is found to be out of calibration or when its repair or replacement is required, an investigation is conducted and documented to determine the validity of previous inspection or test results and to determine the acceptability of those items previously inspected or tested.

13.0 HANDLING, STORAGE, AND SHIPPING

13.1 PURPOSE

Pursuant to 10 CFR 72.166 and 10 CFR 71.127, this chapter describes measures for the control of the handling, storage, shipping, cleaning, and preservation of quality-related items associated with the ISFSI (10 CFR 72) and/or radioactive material transportation packages (10 CFR 71) to preclude damage, loss, or deterioration.

13.2 HANDLING, STORAGE, SHIPPING, CLEANING, AND PRESERVATION PROGRAM

13.2.1 GENERAL

On receipt of quality-related items, compliance with special requirements for protective environments is verified and documented by qualified personnel responsible for quality-related receipt inspection.

Items are stored in a manner to protect against damage, degradation, or misuse.

Quality-related items are handled, stored, preserved, or protected in accordance with codes and standards as specified in implementing procedures.

13.2.2 HANDLING OF QUALITY-RELATED ITEMS

Procedures or instructions will be used to ensure that handling equipment, cranes, and rigging are examined and tested prior to performing critical lifts of quality-related items.

13.2.3 HANDLING, STORAGE, AND 10 CFR 71 TRANSPORTATION OF RADIOACTIVE MATERIALS

Personnel with specific radiation protection training and qualification are responsible for establishing administrative controls and requirements for handling, storing, and 10 CFR 71 packaging/transportation of radioactive materials. These requirements are established in implementing procedures.

14.0 INSPECTION, TEST, AND OPERATING STATUS

14.1 <u>PURPOSE</u>

Pursuant to 10 CFR 72.168 and 10 CFR 71.129, this chapter provides measures for the identification of the inspection, test, and operating status of quality-related items associated with the ISFSI (10 CFR 72) and/or radioactive material transportation packages (10 CFR 71) to preclude bypassing of requirements and inadvertent operation.

14.2 INSPECTION, TEST, AND OPERATING STATUS PROGRAM

14.2.1 INSPECTION AND TEST STATUS

Procedures are established to indicate the status of inspections and tests performed on qualityrelated items.

ISFSI or other designated personnel are responsible for maintaining sufficient knowledge of tests or inspections in progress to control ISFSI and/or radioactive material transportation package activities.

14.2.2 OPERATING STATUS

The operating status of SSCs classified as important to safety that are found to have nonconformances is identified using tags, if appropriate, under the direction of ISFSI or other designated personnel to prevent inadvertent operation. Prior to the removal from service of SSCs classified as important to safety, ISFSI Manager permission to change status is given and documented in accordance with procedures to assure that the removal will not have an adverse effect on safe ISFSI operations.

15.0 NONCONFORMING MATERIAL, PARTS, OR COMPONENTS

15.1 <u>PURPOSE</u>

Pursuant to 10 CFR 72.170 and 10 CFR 71.131, this chapter describes measures for documentation, control, and disposition of nonconforming quality-related items associated with the ISFSI (10 CFR 72) and/or radioactive material transportation packages (10 CFR 71) to prevent their inadvertent use or installation.

15.2 NONCONFORMING MATERIAL CONTROL PROGRAM

15.2.1 GENERAL

Items that deviate from approved specifications, codes, drawings, or other applicable documents are considered as nonconforming.

Procedures govern the use of nonconformance reports for identification, control, disposition of nonconforming items, and notification of affected organizations.

Unless such controls are not feasible, nonconforming items are identified with appropriate tags and segregated to indicate their unacceptable status until the nonconformance is properly dispositioned. If this is not feasible, other methods are established to identify and control the nonconforming items.

15.2.2 WORK PACKAGE

A work package may be used in lieu of a nonconformance report in accordance with implementing procedures when nonconforming items are identified which can be restored to the original design requirements under a "rework" disposition.

15.2.3 NONCONFORMANCE REPORT

Management reviews and approves nonconformance report dispositions.

"Use as is" or "modify" dispositions require the review and approval of designated engineering support personnel.

Tags associated with a nonconformance report are removed only by authorized personnel.

16.0 CORRECTIVE ACTION

16.1 <u>PURPOSE</u>

Pursuant to 10 CFR 72.172 and 10 CFR 71.133, this chapter describes the corrective action measures to assure that conditions adverse to quality associated with the ISFSI (10 CFR 72) and/or radioactive material packaging and transportation (10 CFR 71) are identified, evaluated, and corrected.

16.2 CORRECTIVE ACTION PROGRAM

Procedures govern the use of nonconformance reports to assure that conditions adverse to quality are identified and corrected in a timely manner.

Any individual has the authority and responsibility to report a condition adverse to quality to their manager or supervisor who will assure that it is or has been documented on a nonconformance report.

Nonconformance reports documenting significant conditions adverse to quality require determination of cause and corrective actions taken to preclude repetition.

Copies of nonconformance reports which identify significant conditions adverse to quality are distributed to appropriate levels of management for information and review.

17.0 QUALITY ASSURANCE RECORDS

17.1 PURPOSE

In accordance with 10 CFR 72.174 and 10 CFR 71.135, this chapter describes measures for the identification, retention, and retrievability of records associated with the ISFSI (10 CFR 72) and/or radioactive material transportation packages (10 CFR 71) which furnish documentary evidence of the quality of items or activities affecting quality.

17.2 QUALITY ASSURANCE RECORDS CONTROL PROGRAM

In addition to the records required by the definition of Quality Assurance Records in the Glossary of this QA Program, ISFSI records required by 10 CFR 72.30, 72.48, 72.72, 72.80, 72.154, and 72.174 shall be maintained. ISFSI records pertaining to the design, fabrication, erection, testing, maintenance, and use of SSCs important to safety shall be maintained by or under the control of PGE for the applicable durations specified in 10 CFR 72.

In addition to the records required by the definition of Quality Assurance Records in the Glossary of this QA Program, the records must include the instructions, procedures, and drawings required by 10 CFR 71.111. These records shall be retained for three years beyond the date when PGE last engages in 10 CFR 71 radioactive materials packaging and transportation. If any portion of the written procedures or instructions is superseded, PGE shall retain the superseded material for three years after it is superseded.

Records should be identifiable to specific systems, structures, and components, when applicable. Documents which are designated as quality assurance records shall be legible, accurate, and completed as appropriate for the work accomplished. Records are indexed, including as a minimum retention times and location of the records within the record system, to provide for retrieval without undue delay.

Prior to final transmittal of quality assurance records to permanent storage, the originating organization will be responsible for maintaining quality assurance record controls. The majority of ISFSI quality assurance records are ultimately scanned and stored as electronic images on two redundant, electronic media storage systems housed at two separate locations. Quality assurance records in electronic format (e.g., .pdf format) may be directly filed and stored on the electronic media storage systems. Selected quality assurance records on other media (e.g., paper hardcopies, microfilm, DVDs) are ultimately filed and maintained in a Permanent Records Storage Facility.

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18.0 AUDITS

18.1 PURPOSE

In accordance with 10 CFR 72.176 and 10 CFR 71.137, this chapter describes the audit program utilized to verify the implementation, adequacy, and effectiveness of the QA Program for the ISFSI (10 CFR 72) and/or radioactive material transportation packages (10 CFR 71).

18.2 AUDIT PROGRAM

18.2.1 GENERAL

Audit schedules are established to meet applicable regulatory requirements and are based on the safety importance of the activities to be audited.

Audits shall be performed in accordance with written procedures using a check list or an annotated procedure which details the areas to be evaluated.

Audit results shall be documented. These results shall be reviewed by management having responsibility in the area audited.

Followup action, including reaudit of deficient areas, shall be taken where indicated.

18.2.2 AUDIT PERSONNEL

Auditors are appropriately trained and qualified to assure competence for performing the required audits. Nuclear Oversight resources have overall responsibility for performing planned and periodic audits of ISFSI Department activities. To ensure organizational independence, ISFSI Staff personnel shall not perform audits of ISFSI Department activities. External audits may be performed by either designated Nuclear Oversight resources or by properly qualified ISFSI Staff personnel.

Similarly, Nuclear Oversight resources or appropriately trained and qualified ISFSI Staff personnel may perform audits of ISRC activities or the biennial audit of audits of the ISFSI Department performed by Nuclear Oversight resources pursuant to this chapter. To ensure organizational independence in the performance of these audits, the audit team members report directly to the Corporate Executive Responsible for Trojan, and must be individuals other than those that performed the ISRC activity or conducted the internal audit(s) being audited.

GLOSSARY

<u>Audit</u>: An activity which determines through investigation, review, and objective evidence, the adequacy of, and adherence to, established procedures, instructions, specifications, codes, standards, or other applicable contractual and licensing requirements, and the effectiveness of implementation.

<u>Calibration</u>: The process by which measuring or test equipment is checked against standards of equal or higher accuracy and adjusted as necessary to assure its compliance with designated specifications.

<u>Conditions Adverse to Quality</u>: Departures from specified quality-related requirements, such as failures, malfunctions, deficiencies, deviations, defective material or equipment, and nonconformances.

<u>Corrective Action</u>: Action taken to correct conditions adverse to quality and to preclude repetition of significant conditions adverse to quality.

<u>Design Documents</u>: Specifications, drawings, calculations, and analyses associated with design changes and modifications that define technical requirements.

<u>Documents Requiring Control</u>: Documents requiring control contain written or pictorial information describing, defining, specifying, reporting, or certifying activities, requirements, procedures, or results. As a minimum, these include design specifications; procurement documents; drawings; QA Program; procedures; ISFSI Safety Analysis Report; manufacturing, inspection, maintenance, modification, design change and testing instructions; nonconformance reports; as-built packages; and other documentation affecting quality-related items.

<u>Examination</u>: An element of inspection consisting of investigation of materials, components, supplies, and services to determine conformance to those specified requirements which can be determined by such investigation. Examination is usually nondestructive and includes simple physical manipulation, gauging, and measurement.

<u>Identification</u>: A means by which material, equipment, or parts can be traced to their associated quality documentation through the use of heat number, lot number, serial number, part number, purchase order number, or other appropriate means.

<u>Inspection</u>: An element 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.

<u>Measuring and Test Equipment</u>: Devices or systems used to calibrate, measure, gauge, test, or inspect in order to control or acquire data to verify conformance to specified requirements. Measuring and Test Equipment does not include permanently installed instrumentation nor does it include test equipment used for preliminary checks where data obtained will not be used to determine acceptability or verify conformance to established criteria.

<u>Modification</u>: A planned change in facility design or operation accomplished in accordance with the requirements and limitations of applicable codes, standards, procedures, specifications, licenses, and predetermined safety restrictions.

<u>Modify (termed "repair" in ANSI N45.2.10</u>): The disposition applied to nonconforming items which are restored to a condition such that the capability of an item to function reliably and safely is unimpaired, even though that item still may not conform to the original requirement.

<u>Nonconformance</u>: A deficiency in characteristic, documentation, or procedure which renders the quality of an item or activity unacceptable or indeterminate.

<u>Permanent Records Storage Facility</u>: A Permanent Records Storage Facility is an environmentally controlled room or vault with controlled access which provides protection of quality assurance records from fire, theft, flood, and deterioration.

<u>Procedure</u>: A document that specifies or describes how an activity is to be performed. It may include methods to be employed, equipment or materials to be used, and sequence of operation.

<u>Procurement Documents</u>: Those purchase requisitions, release letters, letters of intent, bid specifications, contracts, purchase orders, specifications, or other documents which provide contractual basis for procurement actions. They identify and define the requirements which items or services must meet in order to be acceptable to the purchaser.

<u>Purchased Services</u>: Purchased services are services procured by PGE to support quality-related items. Examples include design analysis, evaluations, reviews, audits, calibration, and data reduction.

<u>Quality Assurance (QA)</u>: All those planned and systematic actions necessary to provide adequate confidence that an item or facility will perform satisfactorily in service.

<u>Quality Assurance Records</u>: Those records which provide documentary evidence of the quality of items and/or activities affecting quality. A document is considered a QA record when the document is complete, valid, legible, and adequately identifiable to the item or activity involved. Documents shall be considered valid records only if stamped, initialed, signed, or otherwise authenticated and dated by authorized personnel. A record is completed when the final review signature or other authentication is placed on the document or on a documentation package containing multiple documents. QA records include the following: design records, records of use, and the results of reviews, inspections, tests, audits, monitoring of work performance, and materials analyses. The records must include closely related data such as qualifications of personnel, procedures, and equipment. Inspection and test records must, at a minimum, identify the inspector or data recorder, the type of observation, the results, the acceptability, and the action taken in connection with any noted deficiencies. The records must include the procedures that establish the records retention program.

<u>Quality Requirements</u>: Quality requirements include, but are not limited to, such items as test, inspection, and acceptance criteria and any special instructions and prerequisites for such activities as designing, identification, fabrication, cleaning, erecting, packaging, handling, shipping, and extended storage.

<u>Radiation Protection</u>: Radiological controls applied to radiation areas, radiation services, or radiation-producing machines consistent with the requirements of 10 CFR 19, 10 CFR 20, and 10 CFR 72.

<u>Reject</u>: The disposition applied to nonconforming items which are unsuitable for their intended purpose but which may be feasible to return to the supplier as salvage for replacement or credit, or feasible to scrap.

<u>Rework</u>: The disposition applied to nonconforming items which are made to conform to a prior specified requirement by completion, remachining, reassembly, or other corrective means.

Significant Condition Adverse to Quality: A departure from specified requirements is considered to be a significant condition adverse to quality if the condition appears to be an event which (1) requires reporting in 24 hours or less in accordance with the ISFSI License, 10 CFR 20, or 10 CFR 72.75; (2) requires reporting in accordance with 10 CFR 21; or (3) involves a significant breakdown in the QA Program implementation.

<u>Stop Work</u>: The authority that permits immediate stoppage of quality-related activities such as design, procurement, fabrication, inspection, testing, or removal.

<u>Testing</u>: The determination or verification of the capability of an item to meet specified requirements by subjecting the item to a set of physical, chemical, environmental, or operating conditions.

<u>Use As Is</u>: A disposition applied to nonconforming items which do not meet all specified requirements but do safely and reliably meet their intended purpose.

ENCLOSURE IV TO VPN-006-2011

PROPOSED REVISION 29 TO PGE-8010, "PORTLAND GENERAL ELECTRIC (PGE) NUCLEAR QUALITY ASSURANCE PROGRAM FOR TROJAN INDEPENDENT SPENT FUEL STORAGE INSTALLATION (10 CFR 72) OPERATIONS AND RADIOACTIVE MATERIAL PACKAGING AND TRANSPORTATION (10 CFR 71) ACTIVITIES"

(Authorization for Payment by Credit Card form to pay \$3,900.00 Application Fee required by 10 CFR 170.31, Section 10.B.2.)