

February 28, 2006

10 CFR 50.54(a)(4)

U.S. Nuclear Regulatory Commission
Document Control Desk
Washington, DC 20555-0001**DOCKETS 50-155 AND 72-043 - LICENSE DPR-6 - BIG ROCK POINT PLANT
CHANGE TO THE QUALITY PROGRAM DESCRIPTION – NO REDUCTION IN COMMITMENT**

This letter provides Revision 22 to the Consumers Energy "Quality Program Description for Nuclear Power Plants Part 1 – Big Rock Point." (CPC-2A) – renamed "Quality Program Description for Big Rock Point" (QPD). The revisions to the program are not reductions in commitment. Included in this submittal are:

- A copy of the Responsibility and Authority Letter (Attachment 1),
- A copy of CPC-2A and Appendices (Revision 22), with revisions marked in the text (Attachment 2),
- Justification for Changes to CPC-2A (Revision 22), Quality Program Description (Attachment 3), and
- A copy of the complete quality program, as revised (Attachment 4).

In Attachment 2, strike-throughs indicate deleted text, underlines indicate new text, and vertical lines in the right-hand margins indicate the locations of all revisions.

These changes do not reduce previous commitments, the quality program, as revised, continues to meet 10 CFR Part 50 Appendix B requirements. Attachment 3 provides the bases for concluding that the revised Quality Program continues to satisfy 10 CFR 50, Appendix B.

The changes in Revision 22 were made to revise the title of the quality program description to reflect the description applies only to Big Rock Point. In addition, several editorial and administrative revisions were incorporated in the revision. The title change is an editorial revision to the Defueled Technical Specifications.

Revision 22 to the quality program continues to allow Big Rock Point to delegate execution of certain quality assurance functions to contractors, agents, or consultants. However, wording was revised to clarify these entities may perform the functions under the requirements of the Quality Program Description for Big Rock Point or other NRC approved quality program. A minor revision associated with the use of qualified contractors, agents or consultants resulted in the deletion of the organizational title and requirements for the responsibilities for the Environmental and Laboratory Services Department.

Responsibilities of the Radiation Protection Manager were added in the first section. The purpose of the addition is twofold. First, the requirements consolidate qualifications and exceptions as currently stated in the BRP Defueled Technical Specifications. Second, this position will be maintained during the operation of the Independent Spent Fuel Storage Installation (ISFSI) Facility.

If you have any questions related to this submittal, please contact Linda Castiglione at 231-547-8365.



Kurt M. Haas
Site General Manager

cc: Administrator, Region III, USNRC
NRC NMSS Project Manager

Attachments

Attachment 1
Big Rock Point Plant
Dockets 50-155 and 72-043

February 28, 2006

**Copy of the Responsibility and Authority Letter (with revisions
marked in the text)**

2 Pages

QUALITY PROGRAM DESCRIPTION FOR BIG ROCK POINT NUCLEAR POWER PLANTS

~~PART 1~~ BIG ROCK POINT NUCLEAR PLANT

SUBJECT: STATEMENT OF RESPONSIBILITY AND AUTHORITY REGARDING THE ~~CONSUMERS ENERGY QUALITY PROGRAM FOR THE BIG ROCK POINT NUCLEAR PLANT SITE~~

As President and Chief ~~Executive Operating~~ Officer, ~~Electric~~ of Consumers Energy, I have the ultimate management authority for the ~~Consumers Energy Quality Program Description for Big Rock Point quality program Nuclear Site Nuclear Power Plants, Part 1, Big Rock Point Nuclear Plant. The Quality quality Program-program Description (QPD) for Big Rock Point~~ complies with the quality assurance requirements contained in Appendix B of 10 CFR 50, "Quality Assurance Criteria for Nuclear Power Plants and Fuel Reprocessing Plants," ~~The quality program~~ responds to the additional guidance contained in ANSI N18.7, and ~~to the ANSI N45.2 Series-series of s~~Standards and corresponding Regulatory Guides within the context of applicability imposed by ANSI N18.7. In addition to activities governed by 10 CFR 50 Appendix B, this ~~Quality quality Program-program~~ applies to activities governed by 10 CFR 71 Subpart H "Quality Assurance for Packaging and Transportation of Radioactive Waste", and 10 CFR 72 Subpart G "Quality Assurance for Independent Storage of Spent Nuclear Fuel and High-Level Radioactive Waste".

Because the Big Rock Point reactor ~~will no longer be operated~~ has been shipped offsite for disposal, and prior to implementation of this revised QPD, ~~fuel and high-level radioactive waste will be~~ stored only at the Independent Spent Fuel Storage Installation (ISFSI), application of ~~Quality quality Program-program~~ requirements to the in-plant structures, systems and components formerly associated with ~~either of these operating~~ functions will no longer be required. Quality Program requirements will be applied to structures, systems and components at the ~~Independent Spent Fuel Storage Installation (ISFSI)~~ that are required for safe storage of spent nuclear fuel and high-level radioactive waste. ~~Quality Program-program~~ requirements will also be applied to selected activities and programs as long as they are required for decommissioning or operation of the ISFSI; ~~for example, packaging and transportation of radioactive materials, and activities required to achieve compliance with 10 CFR 20.~~

I have delegated responsibility for establishing, maintaining and implementing the Quality Program Description to the Senior Vice President, Nuclear, Fossil and Hydro Operations. This Quality Program Description describes the Consumers Energy and Big Rock Point organizations responsible for implementation.

The ~~Quality quality Program-program~~ Description contains mandatory requirements which must be implemented and enforced by all responsible organizations and individuals.

/s/ John Russell 11/11/03
John G. Russell Date
President and Chief ~~Executive Operating~~ Officer, ~~Electric~~ Consumers Energy

QUALITY PROGRAM DESCRIPTION FOR BIG ROCK POINT NUCLEAR POWER
PLANTS

~~PART 1 - BIG ROCK POINT NUCLEAR PLANT~~

APPROVED BY:

/s/ Robert A. Fenech
Senior Vice President, Nuclear, Fossil, and
Hydro Operations, Consumers Energy
Robert A. Fenech

1/11/2003
Date

Attachment 2
Big Rock Point Plant
Dockets 50-155 and 72-043

February 28, 2006

**Copy of CPC-2A and Appendices, Revision 22 (with revisions
marked in the text)**

90 Pages

CONTENTS

Section	Title	Page
	Statement of Responsibility and Authority	1
	Approval Page	2
	Contents	3
1.0	ORGANIZATION.....	54
2.0	QUALITY PROGRAM.....	11
3.0	DESIGN CONTROL	16
4.0	PROCUREMENT DOCUMENT CONTROL.....	20
5.0	INSTRUCTIONS, PROCEDURES AND DRAWINGS	22
6.0	DOCUMENT CONTROL.....	25
7.0	CONTROL OF PURCHASED MATERIAL, EQUIPMENT AND SERVICES..	27
8.0	IDENTIFICATION AND CONTROL OF ITEMS	30
9.0	CONTROL OF SPECIAL PROCESSES	31
10.0	INSPECTION.....	32
11.0	TEST CONTROL.....	35
12.0	CONTROL OF MEASURING AND TEST EQUIPMENT	37
13.0	HANDLING, STORAGE AND SHIPPING	39
14.0	INSPECTION, TEST AND OPERATING STATUS.....	40
15.0	NONCONFORMING MATERIALS, PARTS OR COMPONENTS.....	41
16.0	CORRECTIVE ACTION.....	43
17.0	QUALITY RECORDS	44
18.0	AUDITS	46

QUALITY PROGRAM DESCRIPTION FOR BIG ROCK POINT NUCLEAR POWER PLANTS

~~PART 1—BIG ROCK POINT NUCLEAR PLANT~~

APPENDIX A, PART 1, REGULATORY GUIDE AND ANSI STANDARD COMMITMENTS 48

APPENDIX A, PART 2, BIG ROCK POINT EXCEPTIONS TO OPERATING PHASE: STANDARDS AND REGULATORY GUIDES 50

APPENDIX B, SAFETY REVIEW..... 7776

APPENDIX C, INDEPENDENT SAFETY REVIEW COMMITTEE 7978

APPENDIX D, AUDIT FREQUENCIES 8281

APPENDIX E, RECORD RETENTION..... 8483

FIGURE

- 1 Consumers Energy Organization Chart for Big Rock Point Quality Program... 10

QUALITY PROGRAM DESCRIPTION FOR BIG ROCK POINT NUCLEAR POWER PLANTS

PART 1 - BIG ROCK POINT NUCLEAR PLANT

1.0 ORGANIZATION

1.1 REQUIREMENTS

Consumers Energy is responsible for establishing and implementing the Quality quality Program program, as described herein, for the Big Rock Point Nuclear Plant (BRP) and its Independent Spent Fuel Storage Installation (ISFSI). Consumers Energy may delegate the authority for development and maintenance of the Quality quality Program program Description (QPDQUALITY PROGRAM) and execution of certain quality assurance functions to others who are independent and qualified, such as contractors, agents or consultants. Quality assurance functions performed by such delegates may be completed under the requirements of either this Qquality Pprogram Description or the delegates' comparable, NRC approved, Qquality Pprogram Description. Although authority for development and execution of some parts of the program may be delegated to others, Consumers Energy retains overall responsibility.

This section of the QPD quality program identifies the responsibilities of Consumers Energy and other organizations for activities: 1) affecting radiological safety during decommissioning; 2) related to packaging and transportation of radioactive materials; and 3) affecting safe operation of the ISFSI. It addresses responsibilities for attaining quality objectives; for establishing and maintaining the QPD quality program; and for assessing the performance of activities affecting quality.

Quality assessment functions, such as audits, surveillances and supplier evaluations are performed by personnel who report to the Quality Assurance Lead or by members of other organizations selected by the Quality Assurance Lead. Audit frequency is outlined in Appendix D of this quality program. The reporting level of the Quality Assurance Organization Lead affords sufficient authority and organizational freedom, including sufficient independence from the cost and schedule impacts of Quality quality Assurance Organization actions, to enable people in that organization the Quality Assurance Lead to identify quality problems; to initiate, recommend, or provide solutions; and to verify implementation of solutions.

The following exceptions/interpretations in Appendix A, Part 2, are relevant to implementation of the requirements of this section of the QPD quality program:

<u>Paragraph</u>	<u>Exceptions/Interpretations</u>
1.2.1	2a
1.2.2	2g 2, 2b, 2c, 2t, 18a, 19, 20
1.2.3	2, 2b, 2e

QUALITY PROGRAM DESCRIPTION FOR BIG ROCK POINT NUCLEAR POWER PLANTS

PART 1—BIG ROCK POINT NUCLEAR PLANT

1.2 IMPLEMENTATION

1.2.1 Source of Authority

The President and Chief ~~Executive-Operating Officer, Electric-Consumers Energy~~ (see Figure 1, Company Organization Chart) of ~~Consumers Energy~~ is responsible for safe decommissioning of Big Rock Point and safe operation of the ISFSI. Authority and responsibility for establishing and implementing the Quality-quality Program-program are delegated to the Senior Vice President - Nuclear, Fossil, and Hydro Operations (NFHO). This delegation is formalized in a STATEMENT OF RESPONSIBILITY AND AUTHORITY signed by the President and Chief ~~Executive-Operating Officer, ElectricConsumers Energy~~. Other quality-related functions are provided by other organizations as described herein.

1.2.2 Responsibility for Attaining Quality Objectives at Big Rock Point

a. Senior Vice President, Nuclear, Fossil and Hydro Operations (NFHO)

The Senior Vice President, NFHO is responsible to the President and Chief ~~Executive-Operating Officer, Electric-Consumers Energy~~, for decommissioning BRP and operation of the ISFSI. Managers who report to the Senior Vice President, NFHO have responsibilities as indicated for directing the performance of activities that affect safe ~~plant-decommissioning and ISFSI operation~~, and/or functions of structures, systems and components of the ISFSI that are important to safety in accordance with Quality-quality Program-program requirements. The Independent Safety Review Committee (ISRC) reports to the Senior Vice President, NFHO. ISRC function, composition, responsibility, and authority are described in Appendix C of this quality program.

b. Big Rock Point Site General Manager

The BRP Site General Manager (see Figure 1) is responsible to the Senior Vice President NFHO for decommissioning BRP and operation and maintenance of the ISFSI in a manner that achieves compliance with licenses, applicable regulations and the Quality Program-program. The Site General Manager delegates to appropriate staff personnel in his organization responsibility for carrying out applicable controls required by the Quality Program-program. Quality Program-program activities performed on the authority of the Site General Manager include:

- (1) Preparation, review, and approval of methods to identify ISFSI structures, systems and components, and ISFSI/plant-site activities to which this QPD quality program apply, as described in Section 2.0, QUALITY PROGRAM.
- (2) Establishing, implementing and documenting the appropriate training of decommissioning and ISFSI/site personnel, including Quality-quality Program-program indoctrination and training.

QUALITY PROGRAM DESCRIPTION FOR BIG ROCK POINT NUCLEAR POWER PLANTS

PART 1 - BIG ROCK POINT NUCLEAR PLANT

- (3) Accomplishing ~~plantsite/ISFSI~~ licensing activities including maintaining licensing documents up-to-date, interfacing with the NRC, accomplishing and/or tracking licensing commitments and coordinating internal action on NRC bulletins, generic letters, etc., implementing the special nuclear material control program, and performing reviews specified in Appendix B, SAFETY REVIEW.

The Site General Manager shall provide written notification within 24 hours to the Senior Vice President, NFHO, the Quality Assurance Lead, and ISRC of any disagreement between the recommendation of a Safety Reviewer and the decision of the Site General Manager; however the Site General Manager has authority for resolution of such disagreements.

- (4) Functioning as the ISFSI design and configuration control authority for compliance of ISFSI modifications and design changes to existing ISFSI design criteria.
- (5) Performing the engineering, construction, inspection and testing associated with ISFSI modification projects.
- (6) Procurement, including preparation, reviews and approval of purchase requests for spare parts, replacement items, consumables, materials, items and services, and submittal of purchase requests to the purchasing organization. Planning and execution of vendor source surveillance or inspection, receiving inspection, and review of supplier quality-related documentation.
- (7) Preparation, review, approval and control of required procedures and instructions.
- (8) Developing, maintaining and implementing security, fire protection and emergency plans.
- (9) Providing for handling, storage, protection, and preservation of identification of purchased materials and items awaiting disposition after removal from service.
- (10) Qualification of appropriate ~~decommissioningsite/ISFSI~~ personnel, including certification of inspection personnel.
- (11) Performing necessary surveillance testing.
- (12) Inspection of ISFSI maintenance and testing, fuel transfer operations, activities associated with packaging and transportation of radioactive material, and activities required to achieve compliance with 10 CFR 20.

QUALITY PROGRAM DESCRIPTION FOR BIG ROCK POINT NUCLEAR POWER PLANTS

~~PART 1—BIG ROCK POINT NUCLEAR PLANT~~

- (13) Control, calibration, and use of Measuring and Test Equipment (M&TE) and installed instrumentation.
- (14) Maintaining equipment status control.
- (15) Stopping unsatisfactory work to control further processing, delivery or installation of nonconforming materials or items.
- (16) Assuring that nonconforming items are identified, segregated and dispositioned.
- (17) Implementing the Corrective Action process.
- (18) Preparation, protection and retention of quality records.
- (19) ~~Packaging and transportation of radioactive materials.~~
- ~~(20) Maintenance of the Quality Program Description for Big Rock Point~~

c. Responsibilities of the Quality Assurance Organization Lead

_____ (1) ~~The Quality Assurance Lead, (see Figure 1) is directly responsible to the Senior Vice President, NFHO, for:~~

- (21) ~~Assessment of the effectiveness of the Nuclear Big Rock Point Quality quality Program program by performing Audits as specified in Appendix D of this quality program.~~
- (32) Supplier surveys and evaluation including review/approval of supplier QA programs, and maintenance of the Qualified Suppliers List.
- (43) Preparation, review, approval and implementation of departmental procedures governing nuclear assessment activities.
- (54) Assuring that assessments are done by personnel not directly responsible for the work being performed.
- (65) Assessment of on-site and off-site programs and activities including follow-up on corrective action for audit findings.
- (76) Review of performance trends associated with decommissioning and ISFSI site activities including corrective actions.
- (87) Analysis of new and/or changed regulatory direction, codes and standards to determine their effect on the Quality Program program.

QUALITY PROGRAM DESCRIPTION FOR BIG ROCK POINT NUCLEAR POWER PLANTS

~~PART 1—BIG ROCK POINT NUCLEAR PLANT~~

~~(9) Maintenance of the Quality Program Description for Big Rock Point Nuclear Power Plants Part 1—Big Rock Point Nuclear Plant.~~

(408) Reporting audit findings relative to follow-up on corrective actions and the effectiveness of the Quality quality Program-program to Consumers Energy Managementmanagement.

——(11) In fulfilling the above responsibilities, the Quality Assurance Lead may use a combination of Consumers Energy employees and others who are qualified and independent, including contractors, agents or consultants. The Quality Assurance Lead is provided with "Stop Work" authority whereby he can suspend any quality related activity or process that may, in his opinion, adversely affect public safety, the safe decommissioning of BRP, or safe fuel storage operations. When a Stop Work Order that would result in suspension of in-process activities related to spent fuel transfer operations or storage operations is given, the persons responsible for the operation in question shall ensure stored fuel is in a safe condition before stopping work.

——(12) The Quality Assurance Lead has no other duties or responsibilities that would prevent his attention to Quality-quality Program-program matters, is sufficiently free from schedule and cost pressures to give appropriate weight to quality considerations in his decisions and recommendations, and has direct access to high enough levels of Managementmanagement to obtain resolution of quality problems.

d. Responsibilities of the Radiation Protection Manager Environmental and Laboratory Services Department

——The Radiation Protection Manager is responsible for Manager, Environmental and Laboratory (E&LS) is responsible for: radiation protection, control of radioactive materials (except special nuclear materials), and the ALARA program. His duties include:

- (1) Administration of radioactive waste, storage, packaging, shipping, and disposal activities.
- (2) Issuing a Stop Work Order upon identifying the potential for excessive or unplanned radiation exposure or loss of contamination control.
- (3) Assisting and providing recommendations to maintain radiation parameters in accordance with licenses, permits and industry standards.
- (4) Accounting for radioactive materials on-site other than special nuclear material.
- (5) Packaging and transportation of radioactive materials.

QUALITY PROGRAM DESCRIPTION FOR BIG ROCK POINT NUCLEAR POWER PLANTS

PART 1—BIG ROCK POINT NUCLEAR PLANT

(6) Ensuring radiation protection programs and reports are prepared and controlled in accordance with the requirements of this quality program and Appendix F, RADIATION PROTECTION PROGRAM AND REPORTS.

If qualified, the Site General Manager may perform the function of the Radiation Protection Manager.

~~(1) Maintaining the Company's Echelon II calibration facility for calibrating reference and secondary standards and general usage portable and laboratory measuring and test equipment.~~

~~(2) Controlling the calibration recall system for Portable and Laboratory (PL) Measuring and Test Equipment (M&TE) owned by E&LS, and other departments, as requested.~~

~~(3) Maintaining a Master PL-M&TE List for E&LS PL-M&TE and for other departments, as requested.~~

~~(4) Providing a PL-M&TE Inventory List for the ISFSI.~~

~~(5) Preparing, reviewing, approving and obtaining additional reviews and approvals if required, of purchase requests for services, equipment and consumables, and submitting such requests to purchasing for procurement action.~~

~~(6) Conducting performance tests on materials, equipment and systems when requested.~~

~~(7) Performing nondestructive examination, and controlling/maintaining Non-Destructive Examination (NDE) equipment.~~

~~(8) Providing qualified NDE procedures and equipment and NDE personnel.~~

~~(9) Providing chemical and metallurgical analytical services.~~

(10)(7) Providing necessary corrective action processing and status reporting for assigned corrective action documents.

The individual responsible for radiation protection functions shall meet the minimum requirements of Regulatory Guide 1.8, September 1975. As applied to this specification, "equivalent," as used in Regulatory Guide 1.8 for the bachelor's degree requirement, may be met with four years of any one or combination of the following: (a) formal training in science engineering or (b) operational or technical experience and training in nuclear power.

QUALITY PROGRAM DESCRIPTION FOR BIG ROCK POINT NUCLEAR POWER PLANTS

PART 1—BIG ROCK POINT NUCLEAR PLANT

- e. Responsibility for Attaining Quality Objectives Outside Nuclear, Fossil, and Hydro Operations

Certain functions that constitute part of the ~~Nuclear Quality~~ quality Program program may be performed by Consumers Energy organizational units outside the Nuclear, Fossil and Hydro Operations Department. However, when off-site organizations perform quality activities in support of Big Rock Point, they do so under the provisions of this Quality Program Description for Big Rock Point, and the activities or services performed are subject to acceptance by the Site General Manager or designate.

Independent Safety Review Committee responsibilities, composition and function are described in Appendix C of this quality program.

QUALITY PROGRAM DESCRIPTION FOR BIG ROCK POINT NUCLEAR POWER PLANTS

PART 1 – BIG ROCK POINT NUCLEAR PLANT

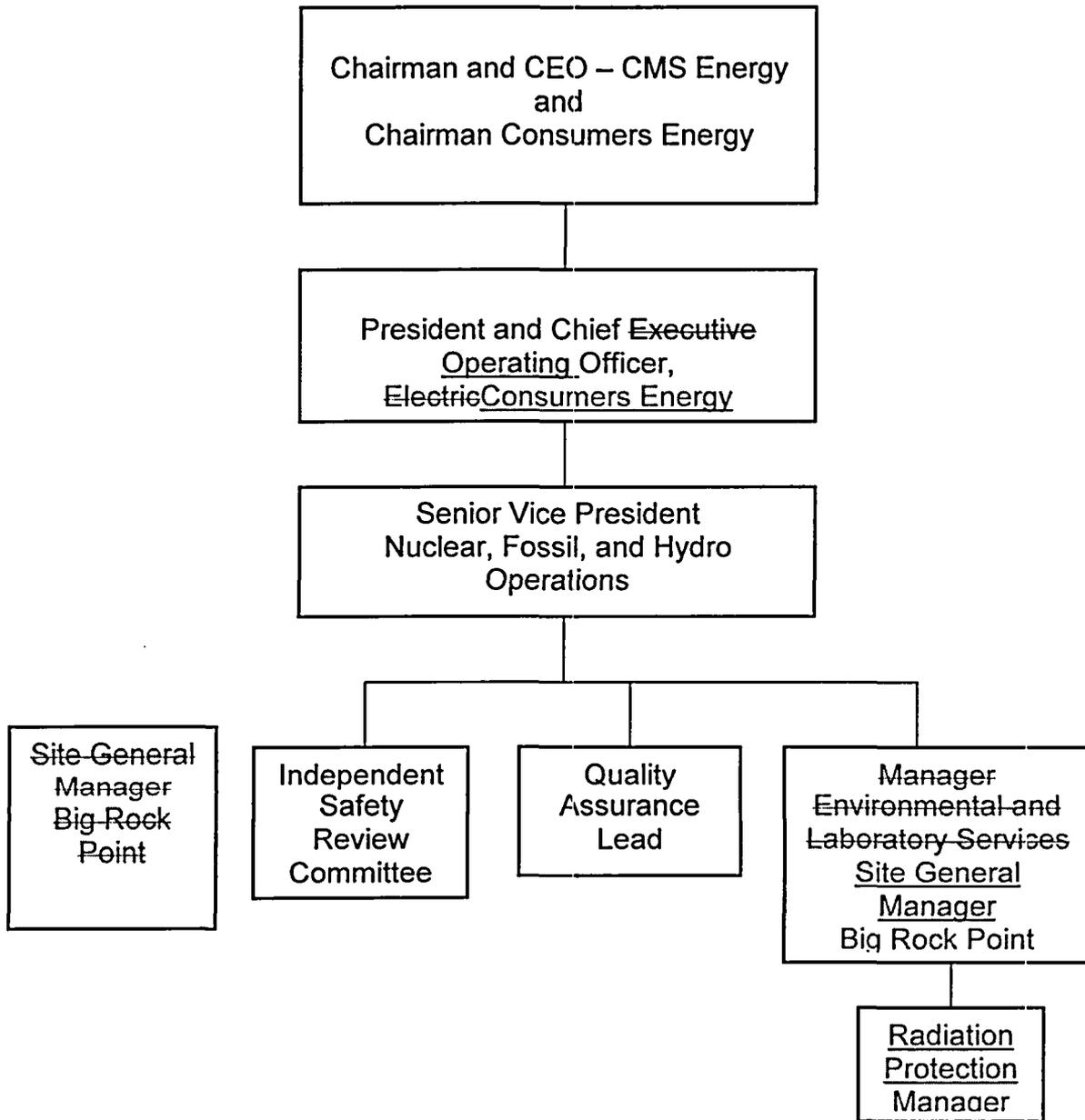


Figure 1 – Consumers Energy Organization for Big Rock Point Quality Program

QUALITY PROGRAM DESCRIPTION FOR BIG ROCK POINT NUCLEAR POWER PLANTS

PART 1—BIG ROCK POINT NUCLEAR PLANT

2.0 QUALITY PROGRAM

2.1 REQUIREMENTS

Policies that define and establish the ~~Consumers Energy Quality-quality Program~~ program for Big Rock Point Nuclear Power Plants (Part 1) — Big Rock Point Nuclear Plant are stated in the individual sections of this document. The program is implemented through procedures and instructions responsive to provisions of the QPDquality program and will be carried out for the life of BRP and its associated ISFSI. ~~Plant's~~ Plant's ISFSI life is defined as the period covered by a valid license under 10 CFR 50 and/or 10 CFR 72.

Quality controls apply to activities affecting the quality of structures, systems and components, to an extent based on the importance of those structures, systems, or components to safety. Such activities are performed under suitably controlled conditions, including the use of appropriate equipment, maintenance of proper environmental conditions, assignment of qualified personnel and assurance that all applicable prerequisites have been met.

Quality ~~Program-program~~ status, scope, adequacy and compliance with 10 CFR 50, Appendix B, 10 CFR 71 Subpart H, and 10CFR 72 Subpart G are regularly reviewed by Consumers Energy Management through reports, meetings and review of audit results.

The following exceptions/interpretations in Appendix A, Part 2, are relevant to implementation of the requirements of this section of the QPDquality program:

<u>Paragraph</u>	<u>Exceptions/Interpretations</u>
2.2.3	21a, 21.b
2.2.5	19a
2.2.6	1, 19a, 21a, 21b
2.2.9	2j, 4a, 5a, 5b, 6a, 7b, 10a, 11a, 12a, 12b, 12c, 12d, 13a, 17e
2.2.10	2e, 2f

2.2 IMPLEMENTATION

2.2.1 The President and Chief ~~Executive-Operating~~ Officer, ElectricConsumers Energy, has stated in a formal STATEMENT OF RESPONSIBILITY AND AUTHORITY, signed by him, that it is corporate policy to comply with the provisions of applicable legislation and regulations pertaining to quality assurance as defined by 10 CFR 50, Appendix B, 10 CFR 71 Subpart H, and 10 CFR 72, Subpart G, as they apply to plant decommissioning and operation of the ISFSI. The statement makes this QPDquality program and the associated implementing procedures and instructions mandatory and requires compliance by all responsible organizations and individuals. It identifies the Management-management positions in the Company vested with responsibility and authority for implementing the Quality-quality Program-program and assuring its effectiveness.

QUALITY PROGRAM DESCRIPTION FOR BIG ROCK POINT NUCLEAR POWER PLANTS

~~PART 1—BIG ROCK POINT NUCLEAR PLANT~~

2.2.2 The ~~Quality-quality Program-program~~ at ~~Consumers Energy~~ Big Rock Point consists of controls exercised by organizations responsible for attaining quality objectives and by organizations responsible for quality assessment functions (see Section 1.0, ORGANIZATION).

2.2.3 The effective dates and applicability of this ~~QPD~~ quality program are as follows:

a. Effective Dates

- (1) For Big Rock Point, the ~~QPD~~ quality program became effective on April 1, 1982, with full implementation on January 1, 1983.
- (2) By letter dated February 1, 2002, the Nuclear Regulatory Commission notified Consumers Energy Company that NRC had approved the Big Rock Point Plant ~~Quality-quality Assurance-assurance Program-program~~ for ~~Radioactive-radioactive Material-material Packagespackages~~. The NRC indicated that the QA Program approval contained in their February 1, 2002 letter satisfied the approval requirements of 10 CFR 71.101(c).
- (3) In accordance with 10 CFR 72.4, the NRC Spent Fuel Project Office was notified by letter dated February 17, 2000 of Consumers Energy's intent to apply this ~~Quality-quality~~ program to the ISFSI and spent fuel storage cask activities as required by 10 CFR Part 72.140.
- (4) The ~~Quality-quality Program-program~~ described in this Quality Program Description for Big Rock Point is intended to apply for the life of BRP U.S. Nuclear Regulatory Commission license and its associated ISFSI.

b. Applicability

QUALITY PROGRAM DESCRIPTION FOR BIG ROCK POINT NUCLEAR POWER PLANTS

PART 1—BIG ROCK POINT NUCLEAR PLANT

~~Because the Big Rock Point reactor will no longer be operated, and prior to implementation of this revised QPD, fuel and high-level radioactive waste will be stored only at the ISFSI, application of Quality Program requirements to the in-plant structures, systems and components formerly associated with either of these functions will no longer be required. Quality Program requirements will be applied to structures, systems and components at the ISFSI that are defined in the Quality List as being required for safe storage of spent nuclear fuel and high-level radioactive waste. Quality Program requirements will also be applied to selected activities and programs defined in the Quality List as being required for decommissioning or operation of the ISFSI; for example, packaging and transportation of radioactive materials, and activities required to achieve compliance with 10 CFR 20.~~

This QPD quality program applies to those structures, systems and components (SSCs), and programs or activities that are Important to Safety, as described in 10CFR72, and assure one or more of the following functions:

- (1). To maintain the conditions required to store spent fuel, high-level radioactive waste, or reactor-related waste safely;
- (2). To prevent damage to the spent fuel, high-level radioactive waste, reactor-related waste container during handling and storage; or
- (3). To provide reasonable assurance that spent fuel, high-level radioactive waste, or reactor-related waste can be received, handled, packaged, stored and retrieved without undue risk to the health and safety of the public.

Big Rock Point Volume 35A-11, Quality List, identifies ISFSI structures, systems, and components to which quality program elements are applicable. Applicable elements of the quality program are applied to the emergency, security, and fire protection and radiation protection plans and programs for site activities and ISFSI operation.

Big Rock Point Volume 35A-11, Quality List, also applies to activities performed at BRP pursuant to 10CFR71, Subpart H, Quality Assurance for Packaging and Transportation of Radioactive Waste.

- 2.2.4 ~~This QPD, organized to present the Consumers Energy. The Quality Program Description for Big Rock Point for Nuclear Power Plants (Part 1) in the order of organized around the 18 criteria of 10 CFR 50, Appendix B, states Consumers Energy Big Rock Point requirements for each of the criteria and describes how the controls pertinent to each are carried out. Any changes made to this QPD quality program that do not reduce the commitments previously accepted by the NRC must be submitted to the NRC as specified by 10 CFR 50.71.e. Any changes made to this QPD quality program that do reduce the commitments previously accepted by the NRC must be submitted to the NRC and receive NRC approval prior to implementation in accordance with the requirements of 10 CFR 50.54(a)(4).~~

QUALITY PROGRAM DESCRIPTION FOR BIG ROCK POINT NUCLEAR POWER PLANTS

~~PART 1—BIG ROCK POINT NUCLEAR PLANT~~

Appendix A, Part 1, to this QPDquality program lists the ANSI Standards and Regulatory Guides to which Consumers Energy commits. Appendix A, Part 2, also describes necessary exceptions and clarifications to the requirements of those documents.

The program described in this QPDquality program will not be changed in any way that would prevent it from meeting the criteria of 10 CFR 50, Appendix B.

2.2.5 Documents used for implementing the provisions of the QPDquality program include the following:

- a. Administrative procedures specify the standard methods of accomplishing quality program activities. Because the Quality-quality Program-program is an integral part of these activities, the methods for implementing Quality-quality Program program controls are integrated into these documents.
- b. When Contractors-contractors perform work under their own quality assurance programs, these programs are reviewed for compliance with the requirements of 10 CFR 50, Appendix B, 10 CFR 71 Subpart H and 10 CFR 72 Subpart G, as applicable; and the contract, and are approved by Consumers Energy prior to the start of work.
- c. ~~Applicable elements of the Quality Program are applied to the emergency, security, and fire protection plans and radiation protection procedures for decommissioning and ISFSI operation. These plans describe quality controls applicable to associated equipment and activities.~~

2.2.6 Provisions of the Quality-quality Program-program for Nuclear Power Plants (Part 1)Big Rock Point apply to activities affecting the quality of structures, systems, components and related consumables that are within the scope of the program. Consumers EnergyBig Rock Point uses the following criteria in the selection of structures, systems, components, and activities to which the Quality-quality Program-program is applied. Application of the Quality-quality Program-program assures that such structures, systems, components, and activities are monitored and controlled in a manner sufficient to provide reasonable assurance that they are capable of fulfilling their intended functions.

- a. The Qquality Program-program shall be applied to structures, systems, components, and activities selected based on evaluations that use quality classification criteria of the FuelSolutions™ Storage System Final Safety Analysis Report and FuelSolutions™ W74 Canister Final Safety Analysis Report (SARs) (documents WSNF-220 and WSNF-223) to determine those items and activities whose function is important to safe operation of the ISFSI. These items and activities are commonly referred to as "Important to Safety:(ITS)."

QUALITY PROGRAM DESCRIPTION FOR BIG ROCK POINT NUCLEAR POWER PLANTS

PART 1 - BIG ROCK POINT NUCLEAR PLANT

- b. The ~~Quality Program~~ program shall be applied to radiation protection requirements that are required to meet the ~~Technical Specifications and applicable regulations~~.
- c. The ~~Quality~~ quality Program ~~program~~ shall be applied to activities related to packaging and transportation of radioactive material.

Application of these criteria in performing an evaluation of an activity or an item's function results in its classification and identification as being either subject or not subject to the ~~Quality~~ quality Program ~~program~~. Identification ~~may be~~ via a ~~the~~ "Quality-List", ~~electronic database, or other controlled means.~~ Identification is maintained current as conditions change. This information is available for inquiry by individuals involved in site activities. The extent to which controls specified in the Quality Program are applied is determined for each item considering its relative importance to the above criteria. Such determinations are based on information in such documents as the ~~Defueled Technical Specifications, Dry Fuel Storage Technical Specifications,~~ the Updated Final Hazards Summary Report (UFHSR), and the Storage System and Canister SARs.

2.2.7 Activities affecting quality of items within the scope of this ~~Program~~ program are accomplished under controlled conditions. Preparations for such activities include confirmation that prerequisites have been met, such as:

- a. Assigned personnel are qualified.
- b. Work has been planned to the proper revisions of applicable engineering and/or technical specifications License Conditions or Cask Storage System Certificate of Compliance.
- c. Specified equipment and/or tools, if any, are on hand to be used.
- d. Materials and items are in an acceptable status.
- e. Systems, components, or structures on which work is to be performed are in the proper condition for the task.
- f. Authorized current instructions/procedures for the work are available for use.
- g. Items and facilities that could be damaged by the work have been protected, as required.
- h. Provisions have been made for special controls, processes, tests and verification methods.

2.2.8 Development, control, and use of computer programs affecting design and operation of the ISFSI and activities important to quality are subject to quality program design control.

QUALITY PROGRAM DESCRIPTION FOR BIG ROCK POINT NUCLEAR POWER PLANTS

PART 1 BIG ROCK POINT NUCLEAR PLANT

- 2.2.9 Responsibility and authority for planning and implementing indoctrination and training are designated in Section 1.0, ORGANIZATION.
- a. The training and indoctrination program provides for ongoing training and periodic familiarization with this QPDquality program.
 - b. Personnel who perform inspection and examination functions are qualified in accordance with requirements of Regulatory Guide 1.58, SNT TC-1A, or the ASME Code, or Section 10.2.3 of this QPDquality program, as applicable.
 - c. Personnel who lead audits are qualified in accordance with Regulatory Guide 1.146. Others are either qualified to ANSI N45.2.23 or have detailed expertise in the area being audited.
 - d. Personnel assigned duties such as special cleaning processes, welding, etc., are qualified in accordance with applicable codes, standards and regulatory guides.
 - e. The training/qualification program for personnel leading audits includes provisions for retraining, re-evaluation and recertification to ensure that proficiency is maintained.
 - f. Training and qualification records including documentation of objectives, content of program, attendees and dates of attendance are maintained at least as long as the personnel involved are performing activities to which the training/qualification is relevant.
 - g. Personnel responsible for performing activities that affect quality are instructed as to the requirements identified in applicable quality related manuals, instructions and procedures.
- 2.2.10 Status and adequacy of the Quality quality Program-program are regularly assessed by the Quality Assurance LeadConsumers Energy Management. The following activities constitute formal elements of that assessment:
- a. Audit reports, including follow-up on corrective action accomplishment and effectiveness, are distributed to appropriate levels of Managementmanagement (see Section 18.0, AUDITS).
 - b. The Independent Safety Review Committee assesses nuclear safety performance as described in Appendix C. Conclusions and recommendations are reported to the Senior Vice President, NFHO.
 - c. Corrective actions in response to recommendations are tracked in the corrective action tracking system (see Section 16.0, CORRECTIVE ACTION).

QUALITY PROGRAM DESCRIPTION FOR BIG ROCK POINT NUCLEAR POWER PLANTS

PART 1—BIG ROCK POINT NUCLEAR PLANT

3.0 DESIGN CONTROL

3.1 REQUIREMENTS

Modifications to structures, systems and components to which this ~~Program-program~~ applies according to Section 2.0, QUALITY PROGRAM, are accomplished in accordance with approved designs. Activities to develop such designs are controlled. Depending on the type of modification, these activities include design and field engineering; the performance of physics, seismic, stress, thermal, hydraulic, and radiation analyses; ~~UFHSR and Storage-storage System-system and Canister-canister~~ SAR accident analyses; the development and control of associated computer programs; studies of material compatibility; accessibility for inspection and maintenance; and determination of quality standards. The controls apply to preparation and review of design documents, including the correct translation of applicable regulatory requirements and design bases into design, procurement and procedural documents.

The following exceptions/interpretations in Appendix A, Part 2, are relevant to implementation of the requirements of this section of the ~~QPDquality program~~:

<u>Paragraph</u>	<u>Exceptions/Interpretations</u>
3.1	9a, 13b
3.2.9	15a
3.2.10	13d

3.2 IMPLEMENTATION

3.2.1 Authority and responsibility for modification activities are described in Section 1.0, ORGANIZATION. This authority and responsibility includes the preparation, review, approval and verification of the following design documents: a) Equipment descriptions in the ~~Storage-storage System-system and Canister-canister~~ SARs; b) Design input and criteria; c) Drawings and specifications; and d) Engineering analyses and associated computer programs.

3.2.2 Errors and deficiencies in approved design documents or in design methods (such as computer codes) that could adversely affect structures, systems and components are documented. Action is taken to assure that the errors and deficiencies are corrected. Section 16.0 of this quality program describes Corrective Action requirements, responsibilities, and controls.

3.2.3 Materials, parts and processes that are essential to functions that are important to safety are selected and specified, based on the requirements of applicable codes and standards or on known, successful use under similar conditions. This includes standard commercial materials, parts and processes. Alternatively, materials, parts and processes may be qualified for use through qualification testing (see Item 3.2.8). The adequacy of the selected materials, parts and processes is assured through the required design verifications or approvals.

- 3.2.4 Exceptions and waivers to or deviations from the engineering (quality) standards (i.e., the required dimensions, material properties, features and other characteristics specified for modifications) are required by procedure and by contract, when applicable, to be documented and controlled (see, also, Section 15 concerning the approval of "repair" or "use as is" dispositions of nonconformances).
- 3.2.5 When modifications involve design interfaces between internal or external design organizations or across technical disciplines, these interfaces are controlled. Procedures are used for the review, approval, release, distribution and revision of documents involving design interfaces to ensure that structures, systems and components are compatible geometrically, functionally and with processes and environment. *Lines of communication are established for controlling the flow of needed design information across design interfaces, including changes to the information as work progresses. Decisions and problem resolutions involving design interfaces are made by the Consumers Energy organization having responsibility for engineering direction of the design effort.*
- 3.2.6 Checks are performed and documented to verify the dimensional accuracy and completeness of design drawings and specifications (i.e., the products of a design process).
- 3.2.7 Modification design document packages are reviewed to assure that the documents that they contain have been prepared, verified, reviewed and approved in accordance with Company procedures and that they contain the necessary quality requirements. These requirements include the inspection and test requirements, quantitative and/or qualitative acceptance criteria and the requirements for documenting inspection and test results.
- 3.2.8 The extent of and methods for design verification are documented. The extent of design verification performed is a function of the importance of the item to safety, design complexity, degree of standardization, the state-of-the-art and similarity with previously proven designs. Methods for design verification include evaluation of the applicability of standardized or previously proven designs, alternate calculations, qualification testing and design reviews. These methods may be used singly or in combination, depending on the needs for the design under consideration.

When design verification is done by evaluating standardized or previously proven designs, the applicability of such designs is confirmed. Any differences from the proven design are documented and evaluated for the intended application.

PART 1—BIG ROCK POINT NUCLEAR PLANT

Qualification testing of prototypes, components or features is used when the ability of an item to perform an essential function that is important to safety cannot otherwise be adequately substantiated. This testing is performed before ~~plant-site~~ equipment installation where possible, but always before reliance upon the item to perform a function that is important to safety. Qualification testing is performed under conditions that simulate the most adverse design conditions, considering all relevant operating modes. Test requirements, procedures and results are documented. Results are evaluated to assure that test requirements have been satisfied. Modifications shown to be necessary through testing are made, and any necessary retesting or other verification is performed. Scaling laws are established and verified, when applicable. Test configurations are clearly documented.

Design reviews are performed by multi-organizational or interdisciplinary groups or by single individuals. Criteria are established to determine when a formal group review is required and when review by an individual is sufficient.

Unless otherwise stated, the verification of design addresses all information conveyed by the design document. When the verification is limited to certain areas or features, the scope or extent and any limitations on the verification are documented.

3.2.9 Persons representing applicable technical disciplines are assigned to perform design verifications. These persons are qualified by appropriate education or experience but are not directly responsible for the design. The designer's immediate supervisor may perform the verification, provided that:

- a. ~~He~~The supervisor is the only technically qualified individual available, and
- b. ~~He~~The supervisor has not specified a singular design approach, ruled out certain design considerations or established the design inputs for the particular design aspect being verified, and
- c. ~~His~~The supervisor's review is either:
 - (1) Approved in advance by the supervisor's management, with documentation of the approval included in the design package, or
 - (2) Controlled by a procedure that provides specific limitations regarding the types of design work that may or may not be verified by a designer's supervisor, and shall provide for clear documentation that the supervisor performed the design verification.

Independent audits by the Quality Assurance ~~Organization~~Lead cover the frequency, effectiveness, and technical adequacy of the use of supervisors as design verifiers to guard against abuse.

~~PART 1—BIG ROCK POINT NUCLEAR PLANT~~

- 3.2.10 When designs must be released for use before they have been fully completed or before they have been verified, the incomplete or unverified parts of the design and the hold point to which work may proceed are identified. This hold point occurs before the work becomes irreversible or before the item is relied on to perform a function that is important to safety. Justification for such early release is documented.
- 3.2.11 Computer codes used in design are appropriately documented, verified, certified for use and controlled. Their use is specified.
- 3.2.12 Changes to design output documents, including field changes, are controlled in a manner commensurate with that used for the original design. Such changes are evaluated for impact. Those that affect fit, form, or function are reviewed and approved by the same, or equivalent, organizations that approved the original design. Information on approved changes is transmitted to all affected organizations.

QUALITY PROGRAM DESCRIPTION FOR BIG ROCK POINT NUCLEAR POWER PLANTS

PART 1 - BIG ROCK POINT NUCLEAR PLANT

4.0 PROCUREMENT DOCUMENT CONTROL

4.1 REQUIREMENTS

Procurement documents for structures, systems, components and services to which this Program applies according to Section 2.0, QUALITY PROGRAM, define the characteristics of item(s) to be procured, identify requirements of applicable regulatory and industry codes and standards and specify supplier quality assurance program requirements to the extent necessary to assure adequate quality.

The following exceptions/interpretations in Appendix A, Part 2, are relevant to implementation of the requirements of this section of the QPDquality program:

<u>Paragraph</u>	<u>Exceptions/Interpretations</u>
4.2.1	17c, 17d
4.2.3	2l, 17a, 17b
4.2.5	17d

4.2 IMPLEMENTATION

4.2.1 Responsibilities and authorities for procurement planning and for preparation, review and approval of procurement documents are described in Section 1.0, ORGANIZATION.

Procurement request packages are reviewed and approved prior to submittal to the ~~Purchasing and Materials Department~~. Review includes verification that the necessary quality requirements are specified.

Bids are evaluated by an individual or organization having appropriate knowledge related to the item or service being procured.

4.2.2 Supplier selection is described in Section 7.0, CONTROL OF PURCHASED MATERIALS, EQUIPMENT, AND SERVICES.

4.2.3 The content of a procurement document varies according to the item or service being purchased and its function. Provisions of this QPDquality program are considered for application to suppliers. As applicable, procurement documents include:

- a. Scope of work to be performed.
- b. Technical requirements, with applicable drawings, specifications, codes and standards identified by title, document number, revision, and date. Required procedures, such as special process instructions, will be identified.
- c. Regulatory, administrative and reporting requirements.

QUALITY PROGRAM DESCRIPTION FOR BIG ROCK POINT NUCLEAR POWER PLANTS

PART 1—BIG ROCK POINT NUCLEAR PLANT

- d. Quality requirements appropriate to the complexity and scope of the work, including necessary tests and inspections.
 - e. A requirement for a documented Quality-quality Programprogram, subject to Big Rock Point Consumers Energy-review and written concurrence prior to the start of work.
 - f. A requirement for the supplier to invoke applicable quality requirements on sub-tier suppliers.
 - g. Provisions for access to supplier and sub-tier supplier facilities and records for inspections, surveillances and audits.
 - h. Identification of documentation to be provided by the supplier, identification of documents to be compatible with the records system, the schedule of submittals and identification of documents requiring Consumers EnergyBig Rock Point approval.
- 4.2.4 Trained, qualified personnel perform and document reviews of procurement request packages to assure that:
- a. Quality requirements (see 4.2.3 of this Section) are correctly stated, inspectable, and controllable.
 - b. Adequate acceptance and rejection criteria are included.
 - c. The procurement documents have been prepared, reviewed, and approved per Quality Program requirements.
- 4.2.5 Changes to the technical or quality requirements in procurement documents are controlled in a manner commensurate with that used for the original requirements. Those changes that could affect fit, form, function or assurance of quality are reviewed and approved by the same, or equivalent, organizations that approved the original procurement request packages.

QUALITY PROGRAM DESCRIPTION FOR BIG ROCK POINT NUCLEAR POWER PLANTS

PART 1—BIG ROCK POINT NUCLEAR PLANT

5.0 INSTRUCTIONS, PROCEDURES AND DRAWINGS

5.1 REQUIREMENTS

Activities affecting the quality of structures, systems and components to which this Program applies according to Section 2.0, QUALITY PROGRAM, are accomplished using instructions, procedures and drawings appropriate to the circumstances that include acceptance criteria for determining if an activity has been satisfactorily completed.

The following exceptions/interpretations in Appendix A, Part 2, are relevant to implementation of the requirements of this section of the QPD quality program:

<u>Paragraph</u>	<u>Exceptions/Interpretations</u>
5.1	<u>2v, 2w, 9a, 13b</u>
5.2, item 5	2r, 2s, 8a
5.2, item 4 <u>12</u>	6b

5.2 IMPLEMENTATION

The authority and responsibility for performing activities affecting the quality of structures, systems and components are described in Section 1.0, ORGANIZATION. Management personnel assigned these responsibilities assure that the instructions, procedures, and drawings necessary to accomplish the activity are prepared and implemented.

Instructions, procedures and drawings incorporate (1) a description of the activity to be accomplished and (2) appropriate quantitative acceptance criteria, such as tolerances and operating limits, and/or qualitative acceptance criteria, such as workmanship standards, sufficient to determine that the activity has been satisfactorily accomplished.

Temporary procedures may be issued to provide management instructions that have short-term applicability. Temporary procedures include a designation of the time period during which they may be used.

The procedures used by ~~Consumers Energy~~ Big Rock Point to control its activities include the following:

1. Administrative Procedures implementing the requirements of this quality program.
2. Procedures as needed to describe operation of ISFSI equipment.
3. Process monitoring procedures that provide for monitoring system performance and which, as appropriate, identify limits for significant process parameters.

QUALITY PROGRAM DESCRIPTION FOR BIG ROCK POINT NUCLEAR POWER PLANTS

~~PART 1 BIG ROCK POINT NUCLEAR PLANT~~

4. Spent fuel management procedures that provide for activities such as:
 - a. Fuel accountability,
 - b. Preparation of fuel for transportation,
 - c. Nuclear safety measures, or
 - d. Fuel transfer operations.
5. Maintenance procedures that provide for:
 - a. Preparation for maintenance,
 - b. Performance of maintenance,
 - c. Post-maintenance and operability checks and tests, and
 - d. Use of supporting maintenance documents
6. Radiation ~~control~~ Protection Program procedures that provide for:
 - a. Implementation of the radiation control program including the acquisition of radiation data,
 - b. Identification of equipment for performing radiation surveys, or
 - c. Measurement, evaluation and assessment of radiation hazards.
7. Calibration and test procedures that provide for:
 - a. Periodic calibration and testing of instrumentation and control systems, or
 - b. Calibration of portable measuring and test equipment used in activities affecting safety.
8. Chemical-radiochemical control procedures that provide for activities including:
 - a. Control of deleterious agents,
 - b. Control, treatment and management of radioactive wastes, and
 - c. The control of radioactive calibration sources.

QUALITY PROGRAM DESCRIPTION FOR BIG ROCK POINT NUCLEAR POWER PLANTS

PART 1 – BIG ROCK POINT NUCLEAR PLANT

9. Independent Spent Fuel Storage Installation (ISFSI) Emergency Plan and Implementing Procedures.

The ISFSI Emergency Plan meets the requirements of 10 CFR 50.47 and 10 CFR Part 50 Appendix E, as modified by U.S. Nuclear Regulatory Commission (NRC) approved exemptions of September 30, 1998 and Safety Evaluation Report of October 13, 2005.

10. ISFSI Security Plan and Implementing Procedure.

11. Fire Protection Plan.

40.12 Inspection, test and examination procedures that identify:

- a. Objectives,
- b. Acceptance criteria,
- c. Prerequisite and special conditions,
- d. Limiting conditions,
- e. Test or inspection instructions,
- f. Any required special equipment or calibration,
- g. Hold and Witness points, as appropriate.

44.13. Modification procedures that provide for:

- a. Administrative control and technical support during ISFSI modifications,
- b. The basis for a consistent method of performing recurring engineering, construction and quality activities,
- c. Control of the interfaces between ~~Consumers Energy~~ Big Rock Point and its suppliers, and
- d. Control of onsite-quality-related modification activities that assure the Quality Program-program is implemented and its effectiveness is assessed and reported.

~~12. Decommissioning procedures when needed to provide for controlled dismantlement of BRP and restoration of the plant site.~~

QUALITY PROGRAM DESCRIPTION FOR BIG ROCK POINT NUCLEAR POWER PLANTS

~~PART 1—BIG ROCK POINT NUCLEAR PLANT~~

6.0 DOCUMENT CONTROL

6.1 REQUIREMENTS

Documents controlling activities within the scope defined in Section 2.0, QUALITY PROGRAM, are issued and changed according to established procedures. Documents such as instructions, procedures and drawings, including changes thereto, are reviewed for adequacy, approved for release prior to implementation by authorized personnel and are distributed and used at the location where a prescribed activity is performed.

Changes to controlled documents are reviewed and approved by the same organizations that performed the original review and approval or by other qualified, responsible organizations specifically designated in accordance with the procedures governing these documents.

The following exceptions/interpretations in Appendix A, Part 2, are relevant to implementation of the requirements of this section of the QPD quality program:

<u>Paragraph</u>	<u>Exceptions/Interpretations</u>
6.1	2h
6.2.3	2h, 2s, 12b

6.2 IMPLEMENTATION

6.2.1 The authority and responsibility for the control of documents are described in Section 1.0, ORGANIZATION.

6.2.2 Controls are established for approval, issue and change of documents in the following categories:

- a. Design documents (i.e., calculations, drawings, specifications, analyses) including documents related to computer codes
- b. As-built drawings (record drawings) and related documents
- c. Procurement documents
- d. Instructions and procedures for activities such as fabrication, construction, modification, installation, inspection, test, ISFSI maintenance and operation, and decommissioning which implement the Quality-quality Program program.
- e. Big Rock Point Updated Final Hazards Summary Report (UFHSR).

QUALITY PROGRAM DESCRIPTION FOR BIG ROCK POINT NUCLEAR POWER PLANTS

~~PART 1—BIG ROCK POINT NUCLEAR PLANT~~

- f. BNFL-BNG FuelSolutions™ Storage System and W74 Canister SARs, WSNF-220 and WSNF-223, and the associated Dry Fuel Storage Exceptions Document and Dry Fuel Storage Technical Specifications.
- g. Reports of nonconformances
- h. Big Rock Point U.S. Nuclear Regulatory Commission License Conditions or Cask Storage System Certificate of Compliance. Defueled Technical Specifications
- i. ~~Dry Fuel Storage Technical Specifications~~

6.2.3 The review, approval, issue and change of the above documents are controlled by:

- a. Establishment of criteria to ensure that adequate technical and quality requirements are incorporated.
- b. Identification of the organizations responsible for review, approval, issue and revision.
- c. Review of changes to documents by the organizations designated in accordance with the procedure governing the review and approval of specific types of documents, including quality aspects.

6.2.4 Controlled documents are issued and distributed so that:

- a. The documents are available at the work location prior to commencing work.
- b. Obsolete or superseded documents are removed from work areas and replaced by applicable revisions in a timely manner.

6.2.5 Master lists or equivalent controls are used to identify the current revision of instructions, procedures, specifications, drawings and procurement documents. When master lists are used they are updated and distributed to designated personnel who are responsible for maintaining current copies of the lists.

6.2.6 Accurate as-built drawings (record drawings) and related documentation are prepared in a timely manner.

QUALITY PROGRAM DESCRIPTION FOR BIG ROCK POINT NUCLEAR POWER PLANTS

~~PART 1 – BIG ROCK POINT NUCLEAR PLANT~~

7.0 CONTROL OF PURCHASED MATERIAL, EQUIPMENT AND SERVICES

7.1 REQUIREMENTS

Activities that implement approved procurement requests for material, equipment and services used in systems, structures, and components to which this ~~Program~~ program applies according to Section 2.0, QUALITY PROGRAM, are controlled to assure conformance with procurement document requirements. Controls include a system of ~~supplier evaluation and selection, source inspection, examination and acceptance of items and documents upon delivery, and periodic assessment of supplier performance.~~ Objective evidence of quality that demonstrates conformance with specified procurement document requirements is available prior to reliance on equipment, material or services.

The following exceptions/interpretations in Appendix A, Part 2, are relevant to implementation of the requirements of this section of the ~~QPD~~ quality program:

<u>Paragraph</u>	<u>Exceptions/Interpretations</u>
7.1	2i
7.2.2	16d
7.2.3	7b, 17e
7.2.5	2m, 7e, 17f
7.2.6	2m, 9b, 13c, 13d, 17f

7.2 IMPLEMENTATION

7.2.1 Authority and responsibility for implementing the controls outlined herein are described in Section 1.0, ORGANIZATION.

7.2.2 ~~Consumers Energy~~ Big Rock Point qualifies suppliers by performing a documented evaluation of their capability to provide items or services specified by procurement documents. To remain qualified, suppliers involved in active procurements are evaluated continuously and are audited triennially. If an audit is acquired from an external source, the audit is evaluated prior to its use.

Supplier evaluation and triennial audits are not necessary when the items or services supplied are all of the following:

- a. Relatively simple and standard in design, manufacture and test, and
- b. Adaptable to standard or automated inspections or tests of the end product to verify quality characteristics after delivery, and
- c. Such that receiving inspection does not require operations that could adversely affect the integrity, function or cleanness of the item.

QUALITY PROGRAM DESCRIPTION FOR BIG ROCK POINT NUCLEAR POWER PLANTS

~~PART 1—BIG ROCK POINT NUCLEAR PLANT~~

In the above cases, source and/or receipt inspection provides the necessary assurance of an acceptable item or service.

- 7.2.3 Supplier activities that affect quality are verified in accordance with written procedures. These procedures provide the method of verifying (such as audit, surveillance or inspection) and documenting that the characteristics or processes meet the requirements of the procurement document. For commercial "off-the-shelf" items where the requirements for a specific quality assurance program appropriate for nuclear applications cannot be imposed in a practical manner, source verification is used to provide adequate assurance of acceptability unless the quality of the item can be adequately verified upon receipt.
- 7.2.4 Spare and replacement parts are procured in such a manner that their performance and quality are at least equivalent to those of the parts that will be replaced.
- a. Specifications and codes referenced in procurement documents for spare or replacement items are at least equivalent to those for the original items or to properly reviewed and approved revisions.
 - b. Parts intended as spares or replacements for "off-the-shelf" items, or other items for which quality requirements were not originally specified, are evaluated for performance at least equivalent to the original.
 - c. Where quality requirements for the original items cannot be determined, requirements and controls are established by evaluation performed by qualified individuals. The evaluation assures there is no adverse effect on interfaces, interchangeability, safety, fit, form, function, or compliance with applicable regulatory or code requirements. Evaluation results are documented.
 - d. Any additional or modified design criteria, imposed after previous procurement of the item(s), are identified and incorporated.
- 7.2.5 Receipt inspections are performed to verify that items are undamaged and properly identified, that they conform to procurement requirements not previously verified by source surveillance or inspection and that required supplier furnished documentation is available. Items inspected are identified as to their acceptance status prior to their storage or release for installation.

QUALITY PROGRAM DESCRIPTION FOR BIG ROCK POINT NUCLEAR POWER
PLANTS

~~PART 1—BIG ROCK POINT NUCLEAR PLANT~~

7.2.6 Suppliers are required to furnish the following records:

- a. Applicable drawings and related engineering documentation that identify the purchased item and the specific procurement requirements (i.e., codes, standards, and specifications) met by the item.
- b. Documentation identifying any procurement requirements that have not been met.
- c. A description of those nonconformances from the procurement requirements dispositioned "accept as is" or "repair."
- d. Quality records as specified in the procurement requirements.

The acceptability of these documents is evaluated during source and/or receipt inspection.

7.2.7 Supplier's certificates of conformance are periodically evaluated by audits, independent inspections, or tests to assure that they are valid. The results of these evaluations are documented.

QUALITY PROGRAM DESCRIPTION FOR BIG ROCK POINT NUCLEAR POWER PLANTS

~~PART 1 - BIG ROCK POINT NUCLEAR PLANT~~

8.0 IDENTIFICATION AND CONTROL OF ITEMS

8.1 REQUIREMENTS

Materials, parts and components (items) used in structures, systems, and components to which this ~~Program~~ program applies according to Section 2.0, QUALITY PROGRAM, are identified and controlled to prevent their inadvertent use. Identification of items is maintained either on the items, their storage areas or containers, or on records traceable to the items.

The following exceptions/interpretations in Appendix A, Part 2, are relevant to implementation of the requirements of this section of the ~~QPD~~ quality program:

<u>Paragraph</u>	<u>Exceptions/Interpretations</u>
8.2.2	7d, 7g
8.2.3	7a

8.2 IMPLEMENTATION

8.2.1 Controls are established that provide for the identification and control of materials (including consumables), parts and components (including partially fabricated assemblies). Authority and responsibility for the identification and control of items are described in Section 1.0, ORGANIZATION.

8.2.2 Items are identified by physically marking the item, its storage area or its container or by maintaining records traceable to the item. The method of identification is such that the quality of the item is not degraded.

8.2.3 Items are traceable to applicable drawings, specifications, or other pertinent documents to ensure that only correct and acceptable items are used. Verification of traceability is performed and documented prior to release for fabrication, assembly, or installation.

QUALITY PROGRAM DESCRIPTION FOR BIG ROCK POINT NUCLEAR POWER PLANTS

PART 1—BIG ROCK POINT NUCLEAR PLANT

9.0 CONTROL OF SPECIAL PROCESSES

9.1 REQUIREMENTS

Special processes affecting structures, systems, and components to which this ~~Program~~ program applies according to Section 2.0, QUALITY PROGRAM, are controlled and are accomplished by qualified personnel using qualified procedures and equipment in accordance with applicable codes, standards, specifications, criteria, and other special requirements.

The following exceptions/interpretations in Appendix A, Part 2, are relevant to implementation of the requirements of this section of the QPD quality program:

<u>Paragraph</u>	<u>Exceptions/Interpretations</u>
9.2.1	6e-13e

9.2 IMPLEMENTATION

9.2.1 Processes subject to special process controls are those for which full verification or characterization by direct inspection is impossible or impractical. Such processes include welding, heat treating, chemical cleaning, application of protective coatings, concrete placement, and nondestructive examination.

9.2.2 Authority and responsibility for implementation of special processes and for qualification of procedures, personnel, and equipment used to perform special processes are described in Section 1.0, ORGANIZATION.

9.2.3 Special process procedures are prepared by personnel with expertise in the discipline involved. The procedures are reviewed for technical adequacy by other personnel with the necessary technical competence, and are qualified by testing, as necessary.

9.2.4 Special process personnel qualification is determined by individuals authorized to administer the pertinent examinations. Certification is based on examination results. Personnel qualification is kept current by performance of the special process and/or re-examination at time intervals specified by applicable codes, specifications, and standards. Unsatisfactory performance or, where applicable, failure to perform within the designated time intervals requires recertification.

9.2.5 For special processes that require qualified equipment, such equipment is qualified in accordance with applicable codes, standards and specifications.

9.2.6 Qualification records are maintained in accordance with QPD quality program Section 17.

9.2.7 The Quality Assurance ~~Organization~~ Lead assesses special process activities, including qualification activities to assure they are satisfactorily performed.

QUALITY PROGRAM DESCRIPTION FOR BIG ROCK POINT NUCLEAR POWER PLANTS

PART 1 — BIG ROCK POINT NUCLEAR PLANT

10.0 INSPECTION

10.1 REQUIREMENTS

Activities affecting the quality of structures, systems, and components to which this ~~Program~~ program applies according to Section 2.0, QUALITY PROGRAM, are inspected to verify their conformance with requirements. Inspections are accomplished by independent verification or process monitoring as necessary. Verification points are used as necessary to ensure that inspections are accomplished at the correct points in the sequence of work activities.

The following exceptions/interpretations in Appendix A, Part 2, are relevant to implementation of the requirements of this section of the ~~QPD~~ quality program:

<u>Paragraph</u>	<u>Exceptions/Interpretations</u>
10.2.2	2p, 2q
10.2.3	2j, 6a
10.2.7	2j, 6a
10.2.10	2j

10.2 IMPLEMENTATION

10.2.1 Authority and responsibility for inspections are described in Section 1.0, ORGANIZATION.

10.2.2 Inspections are applied to procurement, maintenance, modification, testing, -fuel transfer operations, and ~~decommissioning~~ other site activities to verify that Quality-List items and activities conform to specified requirements. Work authorizing documents (i.e.; procedures, instructions, maintenance work orders) are reviewed in accordance with established criteria to do the following as necessary:

- a. Determine the need for inspection(s).
- b. Identify the inspection organization or personnel.
- c. Identify independent verification points.
- d. Determine how and when the inspections are to be performed.
- e. Specify measuring and test equipment of the necessary accuracy for performing inspection.
- f. Provide for documentation of inspection results to provide adequate objective evidence of acceptability.

QUALITY PROGRAM DESCRIPTION FOR BIG ROCK POINT NUCLEAR POWER PLANTS

~~PART 1—BIG ROCK POINT NUCLEAR PLANT~~

Independent verification is performed at each operation where it is necessary to verify conformance with requirements.

Process monitoring is used in whole or in part where direct inspection alone is impractical or inadequate.

- 10.2.3 Training and qualification programs for personnel who perform inspections, including nondestructive examination, are established, implemented, and documented in accordance with Section 2.0, QUALITY PROGRAM, and onsite or offsite procedures. These programs meet the requirements of applicable codes and standards. The Site General Manager (SGM) is responsible for review and concurrence with training and qualification programs that are under his direct responsibility.

~~Training and qualification programs for Environmental and Laboratory Services (E&LS) personnel who perform inspections, including nondestructive examination, are documented in E&LS procedures.~~

Qualifications and certifications of inspection and NDE personnel are maintained by the entity performing in the inspection in accordance with the recordkeeping requirements in the approved quality plan for that entity.

- 10.2.4 Inspection requirements are specified in procedures, instructions, drawings or checklists and are either provided or concurred with by the organization that performs the inspection planning. The procedures, instructions, drawings or checklists provide for the following as appropriate:
- a. Identification of applicable revisions of required procedures, instructions, drawings and specifications.
 - b. Identification of characteristics and activities to be inspected.
 - c. Inspection methods (independent verification or process monitoring).
 - d. Specification of measuring and test equipment having the necessary accuracy.
 - e. Identification of personnel responsible for performing the inspection.
 - f. Acceptance criteria.
 - g. Recording of the inspection results and the identification of the inspector.
- 10.2.5 Independent verification points are designated when confirmation is needed that critical characteristics are acceptable before the work can be allowed to proceed further. Independent verifications are performed and work is released for further processing or use by assigned verification personnel. Independent verification points may be waived only by the organization that performs the inspection planning.

QUALITY PROGRAM DESCRIPTION FOR BIG ROCK POINT NUCLEAR POWER PLANTS

~~PART 1—BIG ROCK POINT NUCLEAR PLANT~~

- 10.2.6 Independent verifications are performed and documented in accordance with the written instructions provided. The results are evaluated by designated personnel in order to ensure that the results substantiate the acceptability of the item or work. Evaluation and review results are documented.

Independent verification should be designated when the activity/task being verified is necessary to ensure critical characteristics are in conformance with requirements and/or the verification is the result of codes, standards, regulations, or commitments.

- 10.2.7 Independent verification may be performed by individuals in the same organization as that which performed the work provided:

- a. Qualifications of the independent verifier are equal to or better than the minimum qualifications for persons who can be authorized to perform the task; and
- b. The work is within the skills of ~~Consumers Energy~~Big Rock Point personnel and/or is addressed by ~~Consumers Energy~~Big Rock Point procedures.
- c. If work involves breaching a pressure retaining item, the quality of the work can be demonstrated through a functional test.

When a, b, and c are not met, inspections will be carried out by individuals certified in accordance with ANSI N45.2.6.

The verification is performed by individuals other than the person(s) performing or directly supervising the work.

- 10.2.8 For independent verification, when acceptance criteria are not met, corrected areas are to be re-verified. Results of independent verification are documented and retained for the purposes of performance trending and analysis.

- 10.2.9 The independent verifier has the authority to stop work if inspection criteria are not met. Resolution of disagreements between the verifier and worker is resolved by site management.

- 10.2.10 Contractors may be used as independent verifiers in accordance with Section 10.2.7 provided:

- a. The work is performed using procedures.
- b. Individuals are trained and qualified in accordance with Section 10.2.3.

Otherwise, contractors must be certified to ANSI N45.2.6 to perform inspections.

QUALITY PROGRAM DESCRIPTION FOR BIG ROCK POINT NUCLEAR POWER PLANTS

~~PART 1 - BIG ROCK POINT NUCLEAR PLANT~~

11.0 TEST CONTROL

11.1 REQUIREMENTS

Testing is performed in accordance with established programs to demonstrate that structures, systems, and components to which this ~~Program~~ program applies according to Section 2.0, QUALITY PROGRAM, will perform satisfactorily in service. The testing is performed in accordance with written procedures that incorporate specified requirements and acceptance criteria. The test program includes qualification (as applicable), acceptance, surveillance, and maintenance tests. Test parameters, including any prerequisites, instrumentation requirements and environmental conditions are specified and met. Test results are documented and evaluated.

The following exceptions/interpretations in Appendix A, Part 2, are relevant to implementation of the requirements of this section of the ~~QPD~~ quality program:

<u>Paragraph</u>	<u>Exceptions/Interpretations</u>
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11.2.2	2k, 17g
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11.2 IMPLEMENTATION

11.2.1 Authority and responsibility for testing are described in Section 1.0, ORGANIZATION.

11.2.2 Tests are performed in accordance with programs, procedures, and criteria that designate when tests are required and how they are to be performed. Such testing includes the following:

- a. Qualification tests, as applicable, to verify design adequacy in accordance with Section 3.0, DESIGN CONTROL.
- b. Acceptance tests of equipment and components to assure their proper operation prior to delivery or to pre-operational tests.
- c. Surveillance tests to assure continuing proper and safe operation of systems and equipment.
- d. Maintenance tests after preventive or corrective maintenance.

11.2.3 Test procedures and instructions include provisions for the following, as applicable:

- a. The requirements and acceptance limits contained in applicable design and procurement documents.

QUALITY PROGRAM DESCRIPTION FOR BIG ROCK POINT NUCLEAR POWER
PLANTS

~~PART 1—BIG ROCK POINT NUCLEAR PLANT~~

- b. Test prerequisites such as calibrated instrumentation, adequate test equipment, and instrumentation including accuracy requirements, completeness of the item to be tested, suitable and controlled environmental conditions, and provisions for data collection and storage.
- c. Instructions for performing the test.
- d. Mandatory inspection hold points for witness by the appropriate authority.
- e. Acceptance and rejection criteria.
- f. Methods of documenting or recording test data and results.
- g. Assuring that test prerequisites have been met.
- h. Verification of completion of modification activities.

Test procedures and instructions are reviewed for technical content and quality aspects, by the site engineering organization, or an offsite technical support organization, as applicable.

When acceptance criteria are not met, corrected areas are to be retested.

QUALITY PROGRAM DESCRIPTION FOR BIG ROCK POINT NUCLEAR POWER PLANTS

~~PART 1 - BIG ROCK POINT NUCLEAR PLANT~~

12.0 CONTROL OF MEASURING AND TEST EQUIPMENT

12.1 REQUIREMENTS

Measuring and testing equipment used in activities affecting the quality of structures systems, and components to which this ~~Program~~ program applies according to Section 2.0, QUALITY PROGRAM, are properly identified, controlled, calibrated, and adjusted at specified intervals to maintain accuracy within necessary limits.

The following exceptions/interpretations in Appendix A, Part 2, are relevant to implementation of the requirements of this section of the ~~QPD~~ quality program:

<u>Paragraph</u>	<u>Exceptions/Interpretations</u>
12.2.3	2o, 9c
12.2.4	2o, 9c
12.2.5	10c
12.2.8	10b

12.2 IMPLEMENTATION

12.2.1 Authority and responsibility for the control of measuring and test equipment are described in Section 1.0, ORGANIZATION.

12.2.2 Procedures are established for measuring and test equipment utilized in the measurement, inspection and monitoring of structures, systems and components. These procedures describe calibration technique and frequency and maintenance and control of the equipment.

12.2.3 Measuring and test equipment is uniquely identified and is traceable to its calibration source.

12.2.4 ~~Consumers Energy~~ Big Rock Point uses a system of labels to be attached to measuring and test equipment to display the next calibration due date. Where labels cannot be attached, a control system is used that identifies to potential users any equipment beyond the calibration due date.

12.2.5 Measuring and test equipment (M&TE) and installed instrumentation are calibrated at specified intervals based on the required accuracy, purpose, degree of usage, stability characteristics, and other conditions affecting the measurement.

Calibration of M&TE is against standards that have an accuracy of at least four times the required accuracy of the equipment being calibrated or, when this is not possible, have an accuracy that assures the equipment being calibrated will be within required tolerance and the basis of acceptance is documented and authorized by responsible management.

QUALITY PROGRAM DESCRIPTION FOR BIG ROCK POINT NUCLEAR POWER
PLANTS

~~PART 1 BIG ROCK POINT NUCLEAR PLANT~~

Calibration standards used for installed instrumentation shall normally have greater accuracy than the instrumentation being calibrated. Standards with the same accuracy may be used when shown to be adequate for specific calibration requirements. The basis for this acceptance is documented and is approved by responsible management.

- 12.2.6 Calibrating standards have greater accuracy than standards being calibrated. Calibrating standards with the same accuracy may be used if it can be shown to be adequate for the requirements and the basis of acceptance is documented and authorized by responsible management.
- 12.2.7 Reference and transfer standards are traceable to nationally recognized standards; where national standards do not exist, provisions are established to document the basis for calibration.
- 12.2.8 When measuring and testing equipment used for inspection and test is found to be outside of required accuracy limits at the time of calibration, evaluations are conducted to determine the validity of the results obtained since the most recent calibration. The results of evaluations are documented. Retests or reinspections are performed on suspect items.

QUALITY PROGRAM DESCRIPTION FOR BIG ROCK POINT NUCLEAR POWER PLANTS

~~PART 1—BIG ROCK POINT NUCLEAR PLANT~~

13.0 HANDLING, STORAGE AND SHIPPING

13.1 REQUIREMENTS

Activities with the potential for causing contamination or deterioration that could adversely affect the ability of an item (to which this ~~Program~~program applies according to Section 2.0, QUALITY PROGRAM) to perform its intended safety functions, and activities necessary to prevent undetected or uncorrectable damage are identified and controlled. These activities include cleaning, packaging, preserving, handling, shipping, and storing. Controls are effected through the use of appropriate procedures and instructions implemented by suitably trained personnel.

The following exceptions/interpretations in Appendix A, Part 2, are relevant to implementation of the requirements of this section of the ~~QPD~~quality program:

<u>Paragraph</u>	<u>Exceptions/Interpretations</u>
13.2.2	7a, 7d, 7f, 7g, 7h

13.2 IMPLEMENTATION

13.2.1 Authority and responsibility for material cleaning, handling, storing, packaging, preserving, and shipping activities are described in Section 1.0, ORGANIZATION.

13.2.2 Procedures are used to control the cleaning, handling, storing, packaging, preserving, and shipping of materials, components and systems in accordance with design and procurement requirements. These procedures include, but are not limited to, the following functions:

- a. Cleaning, to assure that required cleanliness levels are achieved and maintained.
- b. Packaging and preservation, to provide adequate protection against damage or deterioration. When necessary, these procedures provide for special environments such as inert gas atmospheres, specific moisture content levels, and temperature levels.
- c. Handling, to preclude damage or safety hazards.
- d. Storing, to minimize the possibility of loss, damage to or deterioration of items in storage, including consumables such as chemicals, reagents, and lubricants. Storage procedures also provide methods to assure that specified shelf lives are not exceeded.

QUALITY PROGRAM DESCRIPTION FOR BIG ROCK POINT NUCLEAR POWER PLANTS

PART 1 - BIG ROCK POINT NUCLEAR PLANT

14.0 INSPECTION, TEST AND OPERATING STATUS

14.1 REQUIREMENTS

Operating status of structures, systems, and components to which this Program ~~program~~ applies according to Section 2.0, QUALITY PROGRAM, is indicated by ~~tagging of valves and switches, or by other specified means,~~ in such a manner as to prevent inadvertent operation. The status of inspections and tests performed on individual items is clearly indicated by markings and/or logging under strict procedural controls to prevent inadvertent bypassing of such inspections and tests.

The following exceptions/interpretations in Appendix A, Part 2, are relevant to implementation of the requirements of this section of the ~~QPD~~quality program:

<u>Paragraph</u>	<u>Exceptions/Interpretations</u>
14.1	2r
14.2.5	2i

14.2 IMPLEMENTATION

14.2.1 Authority and responsibility for identifying inspection, test and operating status are described in Section 1.0, ORGANIZATION.

14.2.2 For modification activities, including item fabrication, installation and test, procurement documents, service contracts, and procedures specify the degree of control required for the indication of inspection and test status of structures, systems, and components.

14.2.3 Application and removal of inspection and welding stamps and of such status indicators as tags, markings, labels, etc., are controlled by procedures.

14.2.4 The sequence of inspections, tests and other operations important to safety are controlled by procedures. Changes in the approved sequence are subject to the same review and approval as the original, or as specified in administrative procedures if the original organization no longer exists.

14.2.5 The status of nonconforming, inoperable or malfunctioning structures, systems, and components is clearly identified and documented to prevent inadvertent use.

QUALITY PROGRAM DESCRIPTION FOR BIG ROCK POINT NUCLEAR POWER PLANTS

PART 1—BIG ROCK POINT NUCLEAR PLANT

15.0 NONCONFORMING MATERIALS, PARTS OR COMPONENTS

15.1 REQUIREMENTS

Materials, parts, or components for structures, systems and components to which this ~~Program~~program applies according to Section 2.0, QUALITY PROGRAM, that do not conform to requirements are controlled in order to prevent their inadvertent use. Nonconforming items are identified, documented, segregated when practical, and dispositioned. Affected organizations are notified of nonconformances

The following exceptions/interpretations in Appendix A, Part 2, are relevant to implementation of the requirements of this section of the ~~QPD~~quality program:

<u>Paragraph</u>	<u>Exceptions/Interpretations</u>
15.1	2i

15.2 IMPLEMENTATION

15.2.1 Items, services, or activities that are deficient in characteristic, documentation, or procedure that render the quality unacceptable or indeterminate, are identified as nonconforming and any further use is controlled. Nonconformances are documented and dispositioned, and notification is made to affected organizations. Personnel authorized to disposition, conditionally release, and close out nonconformances are designated. The authority and responsibility for the implementation of activities related to the processing and control of nonconforming materials, parts, or components are described in Section 1.0, ORGANIZATION.

- a. Nonconforming items are identified by marking, tagging, or segregating or by documented administrative controls. Documentation describes the nonconformance, the disposition of the nonconformance and the inspection requirements. It also includes signature approval of the disposition.
- b. The original inspection planning authority reviews the disposition of nonconformances, and documents concurrence with the acceptance, conditional release or repair of a nonconforming item.
- c. Items that have been repaired or reworked are inspected and tested in accordance with the original inspection and test requirements or alternatives that have been documented as acceptable and concurred with by the original inspection planning authority.
- d. Items that have the disposition "repair" or "use as is" require documentation justifying acceptability. Any changes made are recorded to denote the as-built condition.

QUALITY PROGRAM DESCRIPTION FOR BIG ROCK POINT NUCLEAR POWER
PLANTS

~~PART 1 - BIG ROCK POINT NUCLEAR PLANT~~

- 15.2.2 Dispositions of conditionally released items are closed out before the items are relied upon to perform functions that are important to safety.
- 15.2.3 Prior to the initiation of preoperational testing on an item, all nonconformances are corrected or dispositioned and evaluated for impact upon the item or the testing program.
- 15.2.4 Nonconformance reports are analyzed to identify quality trends. Trend reports, which highlight significant results, are issued periodically to upper management for review and assessment.

QUALITY PROGRAM DESCRIPTION FOR BIG ROCK POINT NUCLEAR POWER PLANTS

~~PART 1—BIG ROCK POINT NUCLEAR PLANT~~

16.0 CORRECTIVE ACTION

16.1 REQUIREMENTS

Conditions adverse to quality of structures, systems, components, or activities to which this ~~Program~~ program applies according to Section 2.0, QUALITY PROGRAM, such as failures, malfunctions, deficiencies, deviations, defective material, and equipment and nonconformances, are identified promptly and corrected as soon as practical.

For significant conditions adverse to quality, the cause of the condition is determined and corrective action is taken to preclude repetition. In these cases, the condition, cause and corrective action taken is documented and reported to appropriate levels of management for review and assessment.

16.2 IMPLEMENTATION

16.2.1 The responsibility and authority for the control of corrective action are described in Section 1.0, ORGANIZATION.

16.2.2 Controls are established to assure that conditions adverse to quality are identified and documented and that appropriate remedial action is taken.

16.2.3 For significant conditions adverse to quality, necessary corrective action is promptly determined and recorded. Corrective action includes determining the cause and extent of the condition, and taking appropriate action to preclude similar problems in the future. The controls also assure that corrective action is implemented in a timely manner.

QUALITY PROGRAM DESCRIPTION FOR BIG ROCK POINT NUCLEAR POWER PLANTS

~~PART 1—BIG ROCK POINT NUCLEAR PLANT~~

17.0 QUALITY RECORDS

17.1 REQUIREMENTS

Records that furnish evidence of activities affecting the quality of structures, systems and components to which this ~~Program~~program applies according to Section 2.0, QUALITY PROGRAM, are maintained. They are accurate, complete and legible and are protected against damage, deterioration or loss. They are identifiable and retrievable.

The following exceptions/interpretations in Appendix A, Part 2, are relevant to implementation of the requirements of this section of the QPDquality program:

<u>Paragraph</u>	<u>Exceptions/Interpretations</u>
17.1	14b
17.2.5	14c
17.2.8	14a, 14c

17.2 IMPLEMENTATION

17.2.1 Authority and responsibility for the identification and control of Quality~~quality~~ records are described in Section 1.0, ORGANIZATION.

17.2.2 Documents that furnish evidence of activities affecting quality are generated and controlled in accordance with the procedures that govern those activities. Upon completion, these documents are considered records. These records include:

- a. Results of reviews, inspections, surveillances, tests, audits, and material analyses
- b. Qualification of personnel, procedures, and equipment
- c. Operating and decommissioning logs
- d. Maintenance and modification procedures and related inspection results
- e. Reportable occurrences
- f. Records required by Appendix E of this QPDquality program
- g. Nonconformance reports
- h. Corrective action reports
- i. Other documentation such as drawings, specifications, procurement documents, calibration procedures, and reports

QUALITY PROGRAM DESCRIPTION FOR BIG ROCK POINT NUCLEAR POWER
PLANTS

~~PART 1 - BIG ROCK POINT NUCLEAR PLANT~~

- 17.2.3 Inspection and test records contain the following where applicable:
- a. A description of the type of observation
 - b. The date and results of the inspection or test
 - c. Information related to conditions adverse to quality
 - d. Inspector or data recorder identification
 - e. Evidence as to the acceptability of the results
 - f. Action taken to resolve any discrepancies noted
- 17.2.4 When a document becomes a record, it is designated as permanent or nonpermanent and then transmitted to file. Nonpermanent records have specified retention times. Permanent records are maintained for the life of the item. Appendix E identifies retention periods for certain specific records.
- 17.2.5 Temporary storage of completed documents during processing to become records is in rated fire-resistant file cabinets.
- 17.2.6 Only authorized personnel may issue corrections or supplements to records.
- 17.2.7 Traceability between the record and the item or activity to which it applies is provided.
- 17.2.8 Records are stored in remote, dual facilities to prevent damage, deterioration, or loss due to natural or unnatural causes. Records that can only be stored as originals, such as radiographs and some strip charts are retained in a four-hour fire-rated facility.

QUALITY PROGRAM DESCRIPTION FOR BIG ROCK POINT NUCLEAR POWER PLANTS

~~PART 1 - BIG ROCK POINT NUCLEAR PLANT~~

18.0 AUDITS

18.1 REQUIREMENTS

A comprehensive system of audits is carried out to provide independent assessment of performance and effectiveness of the Quality-quality Program-program to achieve nuclear safety, including those elements of the program implemented by suppliers and contractors. Audits are performed in accordance with written procedures or checklists by qualified personnel not having direct responsibility in the areas audited. Audit results are documented and are reviewed by management. Follow-up action is taken where indicated.

The following exceptions/interpretations in Appendix A, Part 2, are relevant to implementation of the requirements of this section of the QPDquality program:

<u>Paragraph</u>	<u>Exceptions/Interpretations</u>
18.2.2	3a, 3b, 3c, 16a, 16b
18.2.3	16c
18.2.9	2e

18.2 IMPLEMENTATION

- 18.2.1 Responsibility and authority for the audit program are described in Section 1.0, ORGANIZATION.
- 18.2.2 *Internal audits are performed in accordance with established schedules that reflect the status and importance to safety of the activities being performed. Audits are conducted in accordance with frequencies stated in Appendix D, Audit Frequencies.*
- 18.2.3 Audits of suppliers and contractors are scheduled based on the status and safety importance of the activities being performed as well as performance of the suppliers and contractors and are initiated early enough to assure effective quality during design, procurement, manufacturing, construction, installation, inspection, and testing.
- 18.2.4 *Principal contractors are required to audit their suppliers based on performance and on a schedule based on the status and safety importance of the activities being performed. Such audits shall be initiated early enough to assure an effective Quality-quality Program-program on the part of their suppliers.*
- 18.2.5 Regularly scheduled audits are supplemented by special audits when significant changes are made in the Qquality Program-program, when it is suspected that quality is in jeopardy or when an independent assessment of program effectiveness is considered necessary.

QUALITY PROGRAM DESCRIPTION FOR BIG ROCK POINT NUCLEAR POWER
PLANTS

~~PART 1 - BIG ROCK POINT NUCLEAR PLANT~~

- 18.2.6 Audits include an objective evaluation of quality-related practices, procedures, instructions, activities and items, and review of documents and records to confirm that the ~~Quality~~ quality Program-program is effective and properly implemented.
- 18.2.7 Audit procedures and the scope, plans, checklists, and results of individual audits are documented.
- 18.2.8 Personnel selected for auditing assignments have experience or are given training commensurate with the needs of the audit and have no direct responsibilities in the areas audited.
- 18.2.9 Audit data are analyzed by the Quality Assurance ~~Organization~~ Lead. The resulting audit reports identify any quality deficiencies and assess the effectiveness of the Quality Program in the area audited. The reports are distributed to the responsible management of both the audited and auditing organizations.
- 18.2.10 Management of the audited organization identifies and takes appropriate corrective action to correct observed deficiencies and to prevent recurrence of any significant conditions adverse to quality. Follow-up for internal audits is performed by the Quality Assurance ~~Organization~~ Lead to ensure that appropriate corrective action is taken and is effective. Such follow-up includes re-audits when necessary. For vendor audits, such follow-up shall be performed by the organization performing the audit.

QUALITY PROGRAM DESCRIPTION FOR BIG ROCK POINT NUCLEAR POWER PLANTS

~~PART 1 - BIG ROCK POINT NUCLEAR PLANT~~

APPENDIX A, PART 1
REGULATORY GUIDE AND ANSI STANDARD COMMITMENTS

The ~~Consumers Energy~~ Big Rock Point Quality Program complies with the regulatory position of the Regulatory Guides referenced in this appendix as modified by the exceptions stated in Part 2.

1. Appendix B to 10 CFR, Part 50, Quality Assurance Criteria for Nuclear Power Plants and Fuel Reprocessing Plants
2. 10 CFR 72, Subpart F – General Design Criteria
3. Regulatory Guide 1.8 - (9/80 Draft) - Personnel Qualification and Training - Endorses ANSI/ANS 3.1 - (12/79 Draft) (application limited as described in Exceptions 4a and 5a of Appendix A, Part 2)
4. Regulatory Guide 30 (Safety Guide 30) - (8/11/72) - Quality Assurance Requirements for the Installation, Inspection, and Testing of Instrumentation and Electrical Equipment - Endorses ANSI N45.2.4
5. Regulatory Guide 1.33 - (2/78, Rev 2) - Quality Assurance Program Requirements (Operation) - Endorses ANSI N18.7 - 1976
6. Regulatory Guide 1.37 - (3/16/73) - Quality Assurance Requirements for Cleaning of Fluid Systems and Associated Components of Water-Cooled Nuclear Power Plants - Endorses ANSI N45.2.1 - 1973
7. Regulatory Guide 1.38 - (5/77, Rev 2) - Quality Assurance Requirements for Packaging, Shipping, Receiving, Storage, and Handling of Items for water-Cooled Nuclear Power Plants - Endorses ANSI N45.2.2 - 1972
8. Regulatory Guide 1.39 - (9/77, Rev 2) - Housekeeping Requirements for Water-Cooled Nuclear Power Plants - Endorses ANSI N45.2.3 - 1973
9. Regulatory Guide 1.58 - (9/80, Rev I) - Qualification of Nuclear Power Plant Inspection, Examination, and Testing Personnel - Endorses N45.2.6 1978
10. Regulatory Guide 1.64 - (6/76, Rev 2) - Quality Assurance Requirements for the Design of Nuclear Power Plants – Endorses N45.2.11 - 1974
11. Regulatory Guide 1.74 - (2/74) - Quality Assurance Requirements Terms and Definitions - Endorses ANSI N45.2.10 - 1973

QUALITY PROGRAM DESCRIPTION FOR BIG ROCK POINT NUCLEAR POWER PLANTS

~~PART 1 - BIG ROCK POINT NUCLEAR PLANT~~

12. Regulatory Guide 1.88 - (10/76, Rev 2) - Collection, Storage, and Maintenance of Nuclear Power Plant Quality Assurance Records – Endorses N45.2.9 - 1974
13. Regulatory Guide 1.94 - (4/76, Rev 1) - Quality Assurance Requirements for Installation, Inspection, and Testing of Structural Concrete and Structural Steel During the Construction Phase of Nuclear Power Plants - Endorses ANSI N45.2.5 - 1974
14. Regulatory Guide 1.116 - (5/77) - Quality Assurance Requirements for Installation, Inspection, and Testing of Mechanical Equipment and Systems - Endorses ANSI N45.2.8 - 1975
15. Regulatory Guide 1.123 - (7/77, Rev 1) - Quality Assurance Requirements for Control of Procurement of Items and Services for Nuclear Power Plants - Endorses N45.2.13 - 1976
16. Regulatory Guide 1.144 - (9/80, Rev 1) - Auditing of Quality Assurance Programs for Nuclear Power Plants - Endorses N45.2.12 - 1977
17. Regulatory Guide 1.146 - (8/80) - Qualification of Quality Assurance Program Audit Personnel for Nuclear Power Plants - Endorses N45.2.23 -1978
18. ANSI/ANS 3.1-1987, Selection, Qualification, and Training of Personnel for Nuclear Power Plants (application limited as described in Appendix C of this document)
19. ANSI N18.1-1971, American National Standard for Selection and Training of Nuclear Power Plant Personnel.

QUALITY PROGRAM DESCRIPTION FOR BIG ROCK POINT NUCLEAR POWER PLANTS

PART 1 - BIG ROCK POINT NUCLEAR PLANT

APPENDIX A, PART 2
CONSUMERS ENERGY BIG ROCK POINT EXCEPTIONS TO OPERATING PHASE
STANDARDS
AND REGULATORY GUIDES

1. General

Requirement

Certain Regulatory Guides invoke or imply Regulatory Guides and standards in addition to the standard each primarily endorses.

Certain ANSI Standards invoke or imply additional standards.

Exception/Interpretation

The ~~Consumers Energy~~ Big Rock Point commitment refers to the Regulatory Guides and ANSI Standards specifically identified in Appendix A, Part 1. Additional Regulatory Guides, ANSI Standards, and similar documents implied or referenced in those specifically identified are not part of this commitment.

Imposition of these Regulatory Guides on ~~Consumers Energy~~ Big Rock Point suppliers and sub-tier suppliers will be on a case-by-case basis depending upon the item or service to be procured.

2. N18.7 General

Exception/Interpretation

As permitted by 4.3.3 of ANSI N18.7, Consumers Energy has established an organizational unit, the *Independent Safety Review Committee*, (ISRC) to perform independent review activities.

The standard numeric and qualification requirements may not be met by the ISRC. Procedures will be established to specify how the ISRC will acquire necessary expertise to carry out its review responsibilities in accordance with Appendix C, *Independent Safety Review Committee*.

2a. N18.7, Section 3.4.2

Requirement

"The Plant Manager shall have overall responsibility for the execution of the administrative controls and quality assurance program at the plant to assure safety."

Exception/Interpretation

QUALITY PROGRAM DESCRIPTION FOR BIG ROCK POINT NUCLEAR POWER PLANTS

PART 1 - BIG ROCK POINT NUCLEAR PLANT

Since Consumers Energy has more than one organization providing services to Big Rock Point/ISFSI, overall responsibility cannot be centralized in a single on-site position. Instead, responsibilities are as designated within the QPD quality program.

2b. N18.7, Section 4.3.1

Requirement

"Personnel assigned responsibility for independent reviews shall be specified in both number and technical disciplines and shall collectively have the experience and competence required to review problems in the following areas:..."

Exception/Interpretation

The ISRC will not have members specified by number or by technical disciplines and its members may not have the experience and competence required to review problems in all areas listed in this section; however, the ISRC will function as described in Appendix C, Independent Safety Review Committee, and will acquire the services of personnel having such experience and competence as necessary.

2c. N18.7, Section 4.3.4

Requirement

"The following subjects shall be reviewed by the independent review body:"

Exception/Interpretation

Subjects requiring review will be as specified in Appendix C, Independent Safety Review Committee.

2d. N18.7, Section 4.3.4(3)

Requirement

Changes in the Technical Specifications or license amendments relating to nuclear safety are to be reviewed by the independent review body prior to implementation, except in those cases where the change is identical to a previously reviewed proposed change.

Exception/Interpretation

The ISRC will not review Technical Specification License Conditions or Cask Storage System Certificate of Compliance. Changes after NRC approval prior to implementation. The basis for this position is that all Technical Specification License Conditions or Cask Storage System Certificate of Compliance changes are reviewed prior to submittal to the NRC.

QUALITY PROGRAM DESCRIPTION FOR BIG ROCK POINT NUCLEAR POWER PLANTS

PART 1 - BIG ROCK POINT NUCLEAR PLANT

2e. N18.7, Section 4.5

Requirement

Written reports of audits specified in ANSI N18.7 shall be reviewed by the independent review body and by appropriate members of Management including those having responsibility in the area audited.

Exception/Interpretation

The ISRC shall review or arrange for reviews of those audits over which it has cognizance, in accordance with Appendix C, Independent Safety Review Committee.

~~Some audits required during decommissioning and ISFSI operation are in areas other than those requiring independent review in accordance with ANSI N18.7, Section 4.3.4.~~

2f. N18.7, Section 4.5

Requirement

Periodic review of the audit program shall be performed by the independent review body or by a management representative at least semiannually to assure that audits are being accomplished in accordance with requirements of technical specifications and of this standard.

Exception/Interpretation

Audits of nuclear facility activities are performed under the cognizance of the ISRC as described in Appendix C, Independent Safety Review Committee.

2g. N18.7, Section 5.2.1

Requirement

"The responsibilities and authorities of the plant operating personnel shall be delineated."

Exception/Interpretation

~~On-site personnel not directly associated with operating activities, as defined in ANSI N18.7, Section 2.2, are not considered to be operating personnel. The exception taken to this section of ANSI N18.7 has been deleted.~~

2h. N18.7, Section 5.2.2

Requirement

"Temporary changes, which clearly do not change the intent of the approved procedure, shall as a minimum be approved by two members of the plant staff knowledgeable in the areas affected by the procedures. At least one of these individuals shall be the supervisor in charge of the shift and hold a senior operators license on the unit affected."

QUALITY PROGRAM DESCRIPTION FOR BIG ROCK POINT NUCLEAR POWER PLANTS

~~PART 1—BIG ROCK POINT NUCLEAR PLANT~~

Exception/Interpretation

~~Consumers Energy~~Big Rock Point considers that this requirement applies only to procedures identified in ~~Plant Technical Specifications~~ this quality program and to Security Plan and Emergency Plan implementing procedures. Temporary changes to these procedures may be made provided:

- a. The intent of the original procedure is not altered;
- b. The change is approved by an individual designated by the Site General Manager; and
- c. The change is documented, reviewed by a safety reviewer as described in Appendix B within 30 days of initial approval, and approved by the Site General Manager.

2i. N18.7, Section 5.2.6

Requirement

"In cases where required documentary evidence is not available, the associated equipment or materials must be considered nonconforming in accordance with Section 5.2.14. Until suitable documentary evidence is available to show the equipment or material is in conformance, affected systems shall be considered to be inoperable and reliance shall not be placed on such systems to fulfill their intended safety functions."

Exception/Interpretation

~~Consumers Energy~~Big Rock Point initiates appropriate corrective action when it is discovered that documentary evidence does not exist for a test or inspection which is required to verify equipment acceptability. This action includes a technical evaluation of the equipment's operability status.

QUALITY PROGRAM DESCRIPTION FOR BIG ROCK POINT NUCLEAR POWER PLANTS

~~PART 1 - BIG ROCK POINT NUCLEAR PLANT~~

2j. N18.7, Section 5.2.7

Requirement

The following standards contain useful guidance concerning design and construction-related activities associated with modifications and shall be applied to those activities that are comparable in nature and extent to related activities occurring during initial plant design and construction: American National Standard Installation, Inspection and Testing of Instrumentation and Electric Equipment During the Construction of Nuclear Power Generation Station, N45.2.4-1972 (IEEE 336-1972) [6]; American National Standard Supplementary Quality Assurance Requirements for Installation, Inspection and Testing of Structural Concrete and Structural Steel During the Construction Phase of Nuclear Power Plants, N45.2.5-1974 [7]; American National Standard Qualifications of Inspection, Examination and Testing Personnel for the Construction Phase of Nuclear Power Plants N45.2.6-1973 [5]; American National Standard Supplementary Quality Assurance Requirements for Installation, Inspection and Testing of Mechanical Equipment and Systems for Construction Phase of Nuclear Power Plants, N45.2.8-1975 [8]; American National Standard Quality Assurance Requirements for the Design of Nuclear Power Plants, N45.2.11 1974 [9]; and American National Standard Quality Assurance for Protective Coating Applied to Nuclear Facilities N101.4-1972 [10]. Considerable care is required in assessing which operational phase activities are comparable in nature and extent to activities normally associated with design and construction.

Exception/Clarification

Work that is within the skills of Consumers Energy personnel and is covered by Consumers Energy Big Rock Point procedures may be inspected by independent verifiers qualified in accordance with Sections 10.2.3, 10.2.7 and 10.2.10 of this QPD quality program, rather than ANSI N45.2.6.

2k. N18.7, Section 5.2.8

Requirement

"A surveillance testing and inspection program...shall include the establishment of a master surveillance schedule reflecting the status of all planned in-plant surveillance tests and inspections."

Exception/Interpretation

Separate master schedules may exist for different programs such as storage cask inspection, Defueled Technical Specification surveillance requirements, and Dry Fuel Storage Technical Specification surveillance requirements.

2l. N18.7, Section 5.2.13.1

Requirement

"To the extent necessary, procurement documents shall require suppliers to provide a quality assurance program consistent with the pertinent requirements of ANSI N45.2 - 1971."

QUALITY PROGRAM DESCRIPTION FOR BIG ROCK POINT NUCLEAR POWER PLANTS

PART 1 BIG ROCK POINT NUCLEAR PLANT

Exception/Interpretation

To the extent necessary, procurement documents require that the supplier have a documented quality assurance program consistent with the pertinent requirements of ANSI N45.2 or other nationally recognized codes and standards.

2m. N18.7, Section 5.2.13.2

Requirement

ANSI N18.7 and N45.2.13 specify that where required by code, regulation, or contract, documentary evidence that items conform to procurement requirements shall be available at the nuclear power plant site prior to installation or use of such items.

Exception/Interpretation

The required documentary evidence is available at the site prior to use, but not necessarily prior to installation. This allows installation to proceed while any missing documents are being obtained, but precludes dependence on the item for safety purposes.

2n. N18.7, Section 5.2.15

Requirement

Plant procedures shall be reviewed by an individual knowledgeable in the area affected by the procedure no less frequently than every two years to determine if changes are necessary or desirable.

Exception/Interpretation

The exception taken to this section of ANSI N18.7 has been deleted.

2o. N18.7, Section 5.2.16

Requirement

Records shall be made and equipment suitably marked to indicate calibration status.

Exception/Interpretation

See Item 9c.

2p. N18.7, Section 5.2.17

Requirement

For modifications and non-routine maintenance, inspections shall be conducted in a manner similar (frequency, type, and personnel performing such inspections) to that associated with construction phase activities (see also Section 5.2.7)

Exception/Interpretation

QUALITY PROGRAM DESCRIPTION FOR BIG ROCK POINT NUCLEAR POWER
PLANTS

~~PART 1—BIG ROCK POINT NUCLEAR PLANT~~

Maintenance and modification activities that are within the skills of Consumers Energy maintenance personnel and are carried out using ~~Consumers Energy~~Big Rock Point procedures may be inspected by independent verifiers qualified in accordance with Sections 10.2.3, 10.2.7, and 10.2.10 of this program description.

QUALITY PROGRAM DESCRIPTION FOR BIG ROCK POINT NUCLEAR POWER
PLANTS

PART 1—BIG ROCK POINT NUCLEAR PLANT

2q. N18.7, Section 5.2.17

Requirement

If mandatory inspection hold points are required, the specific hold points shall be indicated in appropriate documents. Information concerning inspection shall be obtained from the related design drawings, specifications, and/or other controlled documents.

Exception/Interpretation

~~Consumers Energy~~Big Rock Point uses the terminology "independent verification point" as equivalent to a hold point.

2r. N18.7, Section 5.3.5(3)

Requirement

Instructions shall be included, or referenced (in maintenance procedures), for returning the equipment to its normal operating status.

Exception/Interpretation

At ~~Consumers Energy~~Big Rock Point, equipment is returned to its normal operating status, i.e., declared operable, by qualified personnel. Verification of equipment operability will be by line-up verification or appropriate functional testing, and will be documented.

2s. N18.7, Section 5.3.5(4)

Requirement

This section requires that where sections of documents such as vendor manuals, operating and maintenance instructions, or drawings are incorporated directly or by reference into a maintenance procedure, they shall receive the same level of review and approval as operating procedures.

Exception/Interpretation

Such documents are reviewed by appropriately qualified personnel prior to use to ensure that, when used as instructions, they provide proper and adequate information to ensure the required quality of work. Maintenance procedures which reference these documents receive the same level of review and approval as operating procedures.

QUALITY PROGRAM DESCRIPTION FOR BIG ROCK POINT NUCLEAR POWER PLANTS

PART 1—BIG ROCK POINT NUCLEAR PLANT

2t. N18.7, Section 3.4.2

Requirement

This section requires that the onsite operating organization include individuals knowledgeable in nuclear power plant operation, nuclear power plant mechanical, electrical and electronic systems, nuclear engineering, chemistry and radiochemistry, radiation protection, and quality assurance.

Exception/Interpretation

When needed to support ISFSI operations, Consumers Energy Company will retain or contract persons knowledgeable in ISFSI operations, ISFSI structural, and electronic systems, nuclear engineering, radiation protection, and quality assurance. For ISFSI operations, chemistry and radiochemistry controls do not apply after loaded casks have been placed on the ISFSI pad. There are no mechanical or electrical systems directly associated with dry fuel storage casks.

2u. N18.7, Section 5.1

Requirement

If source documents are not compiled in one master document, a summary document shall be compiled to identify the sources, to index the source documents to the requirements of ANSI N18.7 and to provide a consolidated base for description of the program.

Exception/Interpretation

Appendix A of this QPD quality program is the compilation of source documents that apply to the total program for providing administrative controls and quality assurance during decommissioning and ISFSI operation.

2v. N18.7, Section 5.2.1

Requirement

5.2.1(1), (2) and (3) require identification of authority and responsibilities related to reactor shutdown, reactor trip or unexplained operation, and reactor restart.

Exception/Interpretation

Because these reactor events are no longer possible at the Big Rock Point-site, the authority and responsibilities associated with these events will not be addressed in site procedures.

QUALITY PROGRAM DESCRIPTION FOR BIG ROCK POINT NUCLEAR POWER PLANTS

PART 1—BIG ROCK POINT NUCLEAR PLANT

2w. N18.7, Section 5.3.4

Requirement

This section (5.3.4.1 through 5.3.4.10) requires procedures for the integrated operation of a plant.

Exception/interpretation

Some of the procedures, for example, those required by ANSI N18.7 sections 5.3.4.1, 5.3.4.2 and 5.3.4.3, apply only to reactor operation and will not be developed for ISFSI operations. The procedures required by ANSI N18.7 sections 5.4.3.4 through 5.3.4.10 will be developed and will address conditions applicable to ISFSI operation.

~~2x. N18.7, Section 4.3.1~~

~~Requirement~~

~~"Personnel assigned responsibility for independent reviews shall...collectively have the experience and competence required to review problems in the following areas:"~~

- ~~(1) Nuclear power plant operations~~
- ~~(2) Nuclear engineering~~
- ~~(3) Chemistry and radiochemistry~~
- ~~(4) Metallurgy~~
- ~~(5) Nondestructive testing~~
- ~~(6) Instrumentation and control~~
- ~~(7) Radiological safety~~
- ~~(8) Mechanical and electrical engineering~~
- ~~(9) Administrative controls and quality assurance practices~~
- ~~(10) Other appropriate fields associated with the unique characteristics of the nuclear power plant involved.~~

~~Exception/interpretation~~

~~Personnel assigned responsibility for independent reviews shall collectively have the competence to identify problems in the areas specified. When competence to perform a thorough review of a problem area is identified, such competence will be made available to the independent review group.~~

- ~~(1) Nuclear power plant operations no longer apply; in lieu of this item, competence to review ISFSI operations will be required.~~
- ~~(2) In lieu of specifying "Nuclear Engineering", "Engineering" will be the required competency to have represented in ISRC membership. It is reasonable to expect that the person representing the engineering competency will be able to identify when competency in nuclear engineering is needed. One individual may satisfy both the nuclear and metallurgical competency requirement.~~

QUALITY PROGRAM DESCRIPTION FOR BIG ROCK POINT NUCLEAR POWER PLANTS

~~PART 1—BIG ROCK POINT NUCLEAR PLANT~~

- ~~(3) There are no specifications for chemistry control or sampling in either the Dry-Fuel Storage Technical Specifications or the Storage System or Canister SARs, nor are there any chemically induced hazards identified in either SAR. As a result, there is no need to specify review competence in this discipline.~~
- ~~(4) In lieu of specifying "Metallurgy", "Engineering" will be the required competency to have represented in the ISRC membership. It is reasonable to expect that the person representing the engineering competency will be able to identify when competency in metallurgy is needed. One individual may satisfy both the nuclear and metallurgical competency requirement.~~
- ~~(5) Nondestructive testing is not performed on casks, canisters or baskets after they have been placed on the ISFSI pad. Therefore, there is no need to specify review competence in this discipline.~~
- ~~(6) Instrumentation for the cask storage system consists of temperature monitoring, which has been classified as "Not Important to Safety" in the SAR. The instrumentation is sufficiently simple in design as to not warrant review expertise. There are no control systems associated with the fuel storage casks. Therefore, there is no need to specify review competence in this discipline.~~
- ~~(7) No exception taken.~~
- ~~(8) There are no mechanical or electrical systems associated with the fuel storage casks, therefore, competency in either of these disciplines will not be required.~~
- ~~(9) No exception taken.~~
- ~~(10)(1) Competence to review items related to the uniqueness of the Big Rock Point ISFSI will be specified when the need for such competence is identified.~~

3a. RG 1.33, Section C4a

Requirement

The results of actions taken to correct deficiencies that affect nuclear safety and occur in facility equipment, structures, systems, or method of operation are to be audited at least once per six months.

Exception/Interpretation

Performance trends are reviewed by the ISRC. In addition, the corrective action system is audited in accordance with Appendix D, Audit Frequencies.

3b. RG 1.33, Section C4b

Requirement

The conformance of facility operations to provisions contained within the Technical Specifications and applicable license conditions-at least once per 12 months.

QUALITY PROGRAM DESCRIPTION FOR BIG ROCK POINT NUCLEAR POWER PLANTS

PART 1 - BIG ROCK POINT NUCLEAR PLANT

Exception/Interpretation

- a. Consistent with NRC Safety Evaluation, Amendment 106, for Millstone Nuclear Power Station Unit 1 (ADAMS Accession Number ML993330283), and NRC Transmittal QA1 99 221 dated November 18, 1999 (ADAMS Accession Number ML993310022) and NRC Administrative Letter 95-06 dated December 12, 1995, ~~Consumers Energy~~Big Rock Point interprets the commitment to audit ~~Technical Specification~~License conditions and Cask Storage System Certificate of Compliance conditions contained in 18.2.2 of the ~~QPD~~quality program, and in Appendix D, Audit Frequencies, as follows:

~~Consumers Energy~~Big Rock Point maintains a matrix that identifies all applicable Technical Specification line items to be audited. Prior to each audit, the matrix is reviewed and updated as required to conform to approved ~~Technical Specification~~Operating License Conditions or Cask Storage System Certificate of Compliance changes. During each 24-month period, a selected sample of line items is audited.

The items to be audited during each 24-month period are selected from the following sections of the ~~Defueled Technical Specifications~~Operating License Conditions or Cask Storage System Certificate of Compliance -and Dry Fuel Storage Technical Specifications:

- ~~Defueled Technical Specifications:~~Operating License Conditions
- ~~Cask Storage System Certificate of Compliance~~Limiting Conditions for Operation and Surveillance Requirements
- Administrative Controls
- Dry Fuel Storage Technical Specifications

(1) Functional and Operating Limits

(2) Limiting Conditions for Operation and Surveillance Requirements

(3) Administrative Controls

- b. The previously approved quality plan required that Technical Specification audits be scheduled so that all line items are covered within a maximum period of five years. This interval was noted to be consistent with guidance presented in NRC letters dated March 29, 1983 (RLSpessard to JMTaylor) and January 30, 1984 (JGPartlow to RLSpessard), and was accepted by the NRC in an NRC letter dated August 2, 1989 (Goeffrey C. Wright to David P. Hoffman).

QUALITY PROGRAM DESCRIPTION FOR BIG ROCK POINT NUCLEAR POWER PLANTS

~~PART 1—BIG ROCK POINT NUCLEAR PLANT~~

Audits are scheduled so that all line items are covered within a maximum period of 5 years. The audit period for any of the above elements may be reduced depending on ~~Technical Specification compliance history.~~

3c. RG 1.33, Section C4c

Requirement

The performance, training, and qualifications of the facility staff (should be audited) - at least once per 12 months.

Exception/Interpretation

Consistent with NRC Safety Evaluation, Amendment 106, for Millstone Nuclear Power Station Unit 1 (ADAMS Accession Number ML993330283), and NRC Transmittal QA1-99-221 dated November 18, 1999 (ADAMS Accession Number ML993310022) and NRC Administrative Letter 95-06 dated December 12, 1995, ~~Consumers Energy~~ Big Rock Point interprets the commitment to audit performance, training, and qualifications of the facility staff contained in 18.2.2 of this QPD ~~quality program~~ quality program, and in Appendix D, Audit Frequencies, as once per 24 months.

4a. ANS 3.1, General

Exception/Interpretation

The commitment to ANS 3.1 (12/79, draft) is limited to the requirements that apply to the training and qualification of persons performing independent quality assurance functions, except for Lead Auditors. Lead auditors are trained and qualified to Regulatory Guide 1.146 (8/80)/ANSI 45.2.23-1978. Other personnel are trained and qualified as designated in the ~~Defueled Technical Specifications and the Dry-Fuel Storage Technical Specifications~~ Section 1.0 of the Quality Program Description for Big Rock Point.

5a. RG 1.8, C.3.1, General

Exception/Interpretation

The commitment to Regulatory Guide 1.8 (9/80, draft) is limited to the requirements that apply to the training and qualification of persons performing independent quality assurance functions, except for Lead Auditors. Lead Auditors are trained and qualified to Regulatory Guide 1.146 (8/80)/ANSI N45.2.23-1978. Other personnel are trained and qualified as designated in the ~~Defueled Technical Specifications and the Dry-Fuel Storage Technical Specifications~~ Section 1.0 of the Quality Program Description for Big Rock Point.

5b. RG 1.8, C1.2.2

Requirement

QUALITY PROGRAM DESCRIPTION FOR BIG ROCK POINT NUCLEAR POWER PLANTS

~~PART 1—BIG ROCK POINT NUCLEAR PLANT~~

"When an individual is hired to temporarily function as a plant employee, such as for contracted services, evidence of previous education, experience, and training should be provided and reviewed by the appropriate professional-technical group leaders. The appropriate group leaders should then determine the content for that individual's training, including plant-specific training. As a minimum, each individual should receive General Employee Training."

Exception/Interpretation

~~Consumers Energy~~Big Rock Point understands that this requirement applies both to ~~Consumers Energy~~site employees, ~~Consumers Energy~~employees from another site, and to contract personnel who are temporarily assigned to BRP either as replacements for regular employees or to augment the staff. ~~Consumers Energy~~Employees so assigned possess the required qualifications as a prerequisite to the assignment and the review is waived. The qualifications of contract personnel are reviewed and arrangements made for any necessary training. Temporarily assigned personnel requiring unescorted access receive the site general orientation as embodied in General Employee Training.

6a. N45.2.1, Section 2.4

Requirement

Those personnel who perform inspection, examination, or testing activities required by this standard shall be qualified in accordance with ANSI N45.2.6 Qualifications of Inspection, Examination and Testing Personnel for the Construction Phase of Nuclear Power Plants.

Exception/Interpretation

~~Consumers Energy~~Big Rock Point certifies its inspectors in accordance with Paragraphs 10.2.3, 10.2.7 and 10.2.10 of this ~~QPD~~quality program unless the work is comparable in nature and extent to original construction (see Item 2j).

6b. N45.2.1, Section 3.1

Requirement

N45.2.1 establishes criteria for classifying items into "cleanness levels," and requires that items be so classified.

Exception/Interpretation

Instead of using the cleanness level classification system of N45.2.1, the required cleanness for specific items and activities is addressed on a case-by-case basis.

QUALITY PROGRAM DESCRIPTION FOR BIG ROCK POINT NUCLEAR POWER PLANTS

~~PART 1—BIG ROCK POINT NUCLEAR PLANT~~

Cleanness is maintained, consistent with the work being performed, so as to prevent the introduction of foreign material. As a minimum, cleanness inspections are performed prior to system closure. Such inspections are documented.

~~6c. N45.2.1, Section 5~~

Requirement

~~"Fitted and tack welded joints (which will not be immediately sealed by welding) shall be wrapped with polyethylene or other non-halogenated plastic film until the welds can be completed."~~

Exception/Interpretation

~~Consumers Energy sometimes uses other non-halogenated material, compatible with the parent material, since plastic film is subject to damage and does not always provide adequate protection.~~

7a. N45.2.2, General

Requirement

N45.2.2 establishes requirements and criteria for classifying items subject to this program into protection levels.

Exception/Interpretation

Instead of classifying items subject to this program into protection levels, controls over the packaging, shipping, handling, and storage of such items are established on a case-by-case basis with due regard for the item's complexity, use, and sensitivity to damage. Prior to installation or use, the items are inspected and serviced as necessary to assure that no damage or deterioration exists which could affect their function.

7b. N45.2.2, Section 2.4

Requirement

"...Offsite inspection, examination or testing shall be audited and monitored by personnel who are qualified in accordance with N45.2.6."

Exception/Interpretation

QUALITY PROGRAM DESCRIPTION FOR BIG ROCK POINT NUCLEAR POWER PLANTS

~~PART 1 - BIG ROCK POINT NUCLEAR PLANT~~

Offsite inspection, examination, or testing activities are audited or inspected by persons qualified and certified in accordance with ANSI N45.2.23-1978, as endorsed by Regulatory Guide 1.146, or by personnel meeting the requirements of paragraphs 10.2.3, 10.2.7 or 10.2.10. Monitoring activities not involving audit or inspection may be conducted by persons trained and qualified to effectively carry out such tasks, but not necessarily certified to either ANSI N45.2.23, N45.2.6 or Paragraph 10.2.7.

7c. This exception/interpretation no longer applies and has been deleted.

7d. N45.2.2, Section 3.9 and Appendix A 3.9

Requirement

"The item and the outside of containers shall be marked."

(Further criteria for marking and tagging are given in the appendix.)

Exception/Interpretation

These requirements were originally written for items packaged and shipped to construction projects. Full compliance is not always necessary in the case of items shipped to operating plants and may, in some cases, increase the probability of damage to the item. The requirements are implemented to the extent necessary to assure traceability and integrity of the item.

7e. N45.2.2, Section 5.2.2

Requirement

"The inspections shall be performed in an area equivalent to the level of storage."

Exception/Interpretation

Receiving inspection area environmental controls may be less stringent than storage environmental requirements for an item. However, such inspections are performed in a manner and in an environment that do not endanger the required quality of the item.

7f. N45.2.2, Section 6.2.4

Requirement

"The use or storage of food, drinks, and salt tablet dispensers in any storage area shall not be permitted."

Exception/Interpretation

QUALITY PROGRAM DESCRIPTION FOR BIG ROCK POINT NUCLEAR POWER PLANTS

PART 1 - BIG ROCK POINT NUCLEAR PLANT

Packaged food for emergency or extended overtime use may be stored in material stock rooms. The packaging assures that materials are not contaminated. Food will not be "used" in these areas.

7g. N45.2.2, Section 6.3.4

Requirement

"All items and their containers shall be plainly marked so that they are easily identified without excessive handling or unnecessary opening of crates and boxes."

Exception/Interpretation

See N45.2.2, Section 3.9 (Exception 7d).

7h. N45.2.2, Section 6.4.1

Requirement

"Inspections and examinations shall be performed and documented on a periodic basis to assure that the integrity of the item and its container...is being maintained."

Exception/Interpretation

The requirement implies that all inspections and examinations of items in storage are to be performed on the same schedule. Instead, the inspections and examinations are performed and documented in accordance with material storage procedures that identify the characteristics to be inspected and include the required frequencies. These procedures are based on technical considerations that recognize that inspections and frequencies needed vary from item to item.

8a. N45.2.3, Section 2.1

Requirement

Cleanliness requirements for housekeeping activities shall be established on the basis of five zone designations.

Exception/Interpretation

QUALITY PROGRAM DESCRIPTION FOR BIG ROCK POINT NUCLEAR POWER PLANTS

PART 1—BIG ROCK POINT NUCLEAR PLANT

Instead of the five-level zone designation system referenced in ANSI N45.2.3, ~~Consumers Energy~~Big Rock Point bases its controls over housekeeping activities on a consideration of what is necessary and appropriate for the activity involved. The controls are effected through procedures or instructions which, in the case of maintenance or modifications work, are developed on a case-by-case basis. Factors considered in developing the procedures and instructions include cleanliness control, personnel safety, fire prevention and protection, radiation control, and security. The procedures and instructions make use of standard janitorial and work practices to the extent possible. However, in preparing these procedures, consideration is also given to the recommendations of Section 2.1 of ANSI N45.2.3.

9a. N45.2.4, Section 2.2

Requirement

Section 2.2 establishes prerequisites that must be met before the installation, inspection, and testing of instrumentation and electrical equipment may proceed. These prerequisites include personnel qualification, control of design, conforming and protected materials, and availability of specified documents.

Exception/Interpretation

During the decommissioning phase, this requirement is considered to be applicable to modifications and initial start-up of electrical equipment. For routine or periodic inspection and testing, the prerequisite conditions will be achieved as necessary.

9b. N45.2.4, Section 2.2(5)

Requirement

Section 2.2(5) of ANSI N45.2.4 lists documents that are to be available at the construction site.

Exception/Clarification

All of the documents listed are not necessarily required at the plant-site for installation and testing. ~~Consumers Energy~~Big Rock Point assures that they are available to the site as necessary.

9c. N45.2.4, Section 6.2.1

Requirement

"Items requiring calibration shall be tagged or labeled on completion, indicating date of calibration and identity of person that performed the calibration."

Exception/Interpretation

QUALITY PROGRAM DESCRIPTION FOR BIG ROCK POINT NUCLEAR POWER PLANTS

~~PART 1 – BIG ROCK POINT NUCLEAR PLANT~~

If the physical size or location of installed instrumentation prevents calibration labels or tags from being affixed to the instrument, each instrument is uniquely identified and is traceable to its calibration record.

A scheduled calibration program assures that each instrument's calibration is current.

10a. N45.2.5, Section 2.4

Requirement

"Persons charged with engineering managerial responsibility of the inspection and testing organization at the site in either a resident or non-resident capacity shall be certified for Level III capability."

Exception/Interpretation

This standard (N45.2.5) was written for the construction phase of nuclear power plants; as such, it presumes significant activity in the areas of concrete and structural steel that do not generally occur at an Independent Spent Fuel Storage Installation or decommissioning site. At ~~Consumers Energy~~Big Rock Point, persons having engineering managerial responsibility for inspections and tests¹ may be certified to Level III, or may meet other qualification criteria established for the position, including, but not limited to, nuclear power and management experience. For major modifications involving significant concrete or structural steel work, the services of a properly qualified Level III individual will be obtained in at least an advisory capacity.

10b. N45.2.5, Section 2.5.2

Requirement

"When discrepancies, malfunctions, or inaccuracies in inspection and testing equipment are found during calibration, all items inspected with that equipment since the last previous calibration shall be considered unacceptable until an evaluation has been made by the responsible authority and appropriate action taken."

Exception/Interpretation

~~Consumers Energy~~Big Rock Point uses the requirements of N18.7, Section 5.2.16, rather than N45.2.5, Section 2.5.2. The N18.7 requirements are more applicable to ISFSI operation and a plant-site undergoing decommissioning.

10c. N45.2.5, Section 5.4

¹ Within the scope of N45.2.5.

QUALITY PROGRAM DESCRIPTION FOR BIG ROCK POINT NUCLEAR POWER PLANTS

PART 1 - BIG ROCK POINT NUCLEAR PLANT

Requirement

"Hand torque wrenches used for inspection shall be controlled and must be calibrated at least weekly and more often if deemed necessary. Impact torque wrenches used for inspection must be calibrated at least twice daily."

Exception/Interpretation

Torque wrenches are controlled as measuring and test equipment in accordance with ANSI N18.7, Section 5.2.16. Calibration intervals are based on use and calibration history rather than N45.2.5.

11a. N45.2.6, Section 1.2

Requirement

"The requirements of this standard apply to personnel who perform inspections, examinations, and tests during fabrication prior to and during receipt of items at the construction site, during construction, during preoperational and start-up testing, and during operational phases of nuclear power plants."

Exception/Interpretation

See Exception/Interpretation 2j for those inspectors who must be certified to ANSI N45.2.6. Others are qualified to Paragraphs 10.2.3, 10.2.7 and 10.2.10 of this QPD quality program.

Qualification of ~~plant~~-personnel who are involved with testing associated with ~~plant~~-ISFSI operation is provided in specific ~~plant specifications~~ procedures. In addition, personnel participating in inspection or testing who take data or make observations, where special training is not required to perform this function, need not be qualified in accordance with ANSI N45.2.6 but need only be trained to the extent necessary to perform the assigned function.

12a. RG 1.58, Section C.1

Requirement

"However, for qualification of personnel (1) who approve preoperational, start-up and operational test procedures and test results and (2) who direct or supervise the conduct of individual preoperational, start-up and operational tests, the guidelines contained in Regulatory Guide 1.8, Personnel Selection and Training, should be followed in lieu of the Guidelines of ANSI N45.2.6 - 1978."

Exception/Interpretation

~~Consumers Energy~~ Big Rock Point endorses this position, as also stated in 11a, above, except that offsite support organizations involved in testing may apply ANSI N45.2.6. Some of these departments have already developed their qualification programs based on ANSI N45.2.6, and provide services throughout decommissioning of ~~BRP~~ Big Rock Point and operation of the ISFSI.

QUALITY PROGRAM DESCRIPTION FOR BIG ROCK POINT NUCLEAR POWER PLANTS

PART 1 - BIG ROCK POINT NUCLEAR PLANT

12b. RG 1.58, Section C.5

Requirement

"In addition, the individual should be capable of reviewing and approving inspection, examination and testing procedures and of evaluating the adequacy of such procedures to accomplish the inspection, examination and test objectives."

Exception/Interpretation

While a Level III individual should be capable of reviewing and approving inspection, examination and testing procedures and of evaluating the adequacy of such procedures to accomplish the inspection, examination and test objectives, this is not construed by ~~Consumers Energy~~ Big Rock Point as requiring personnel who review, approve or evaluate such procedures to be certified as Level III personnel.

12.c. RG 1.58, Section C.6

Requirement

"Since only one set of recommendations is provided for the education and experience of personnel, a commitment to comply with the regulatory position of this guide in lieu of providing an alternative to the recommendations of the standard means that the specified education and experience recommendations of the standard will be followed."

Exception/Interpretation

The content of the ~~Consumers Energy~~ Big Rock Point qualification and certification program is based upon the recommendations of ANSI N45.2.6, and satisfactory completion of capability testing is required prior to certification. Therefore, it is our position that a candidate should not be required to be a high school graduate or have earned the GED equivalent.

12.d. RG 1.58, Section C.10

Requirement

"Use of the measures outlined in these actions to establish that an individual has the required qualifications in lieu of required education and experience should result in documented evidence (i.e., procedure and record of written test) demonstrating that the individual indeed does have comparable or equivalent competence to that which would be gained from having the required education and experience."

Exception/Interpretation

We will maintain documented objective evidence that demonstrates that an individual does have "comparable" or "equivalent" competence to that which would be gained from having the required education and experience. However, this may take the form of documentation other than "procedures and records of written test" such as documentation of oral tests and on-the-job performance demonstrations.

13a. N45.2.8, Section 2.7

QUALITY PROGRAM DESCRIPTION FOR BIG ROCK POINT NUCLEAR POWER PLANTS

PART 1 — BIG ROCK POINT NUCLEAR PLANT

Requirement

Section 2.7 requires that personnel performing inspection and test activities be qualified according to ANSI N45.2.6.

Exception/Interpretation

See Exception/Interpretation 2j, 11a, and 12a. Test personnel who are part of the plant site staff need not be certified to N45.2.6, provided they meet applicable qualification criteria of the Technical Specifications procedures.

13b. N45.2.8, Section 2.9

Requirement

Section 2.9 establishes prerequisites that must be met before the installation, inspection and testing of mechanical equipment may proceed. These prerequisites include personnel and procedure qualification, control of design, material selection and fabrication, and availability of specified documents.

Exception/Interpretation

During the decommissioning phase, this requirement is considered to be applicable to modifications of mechanical equipment. For routine or periodic inspection and testing, the prerequisites will be achieved as necessary.

13c. N45.2.8, Section 2.9e

Requirement

Section 2.9e of N45.2.8 lists documents relating to the specific stage of installation activity which are to be available at the construction site.

Exception/Interpretation

All of the documents listed are not necessarily required at the plant site for installation and testing. Consumers Energy Big Rock Point assures that they are available to the site as necessary.

13d. N45.2.8, Section 2.9e

Requirement

Evidence that engineering or design changes are documented and approved shall be available at the construction site prior to installation.

Exception/Interpretation

QUALITY PROGRAM DESCRIPTION FOR BIG ROCK POINT NUCLEAR POWER PLANTS

PART 1—BIG ROCK POINT NUCLEAR PLANT

Equipment may be installed before final approval of engineering or design changes. However, the system is not declared operable until such changes are documented and approved.

13e. N45.2.8, Section 4.5.1

Requirement

"Installed systems and components shall be cleaned, flushed, and conditioned according to requirements..." (requirements are given for chemical conditioning, flushing and process controls).

Exception/Interpretation

Systems and components are cleaned, flushed and conditioned as determined on a case-by-case basis. Measures are taken to help preclude the need for cleaning, flushing, and conditioning through good practices during maintenance or modification activities.

14a. N45.2.9, Section 5.4, Item 2

Requirement

Records shall not be stored loosely. They shall be firmly attached in binders or placed in folders or envelopes for storage on shelving in containers. Steel cabinets are preferred.

Exception/Interpretation

Records are suitably stored in steel file cabinets or on shelving in containers. Methods other than binders, folders or envelopes (for example, dividers or electronic media) may be used to organize the records for storage.

14b. N45.2.9, Section 6.2

Requirement

"A list shall be maintained designating those personnel who shall have access to the files."

Exception/Interpretation

Rules are established governing access to and control of files as provided for in ANSI N45.2.9, Section 5.3, Item 5. These rules do not always include a requirement for a list of personnel who are authorized access. It should be noted that duplicate files and/or microforms exist for general use and backup.

QUALITY PROGRAM DESCRIPTION FOR BIG ROCK POINT NUCLEAR POWER PLANTS

PART 1—BIG ROCK POINT NUCLEAR PLANT

14c. RG 1.88, C2

Requirement

"Two methods of protection of quality assurance records from the hazards of fire are described in Subdivision 5.6 of ANSI N45.2.9-1974. NFPA No 232-1975...also contains provisions for records protection equipment and records handling techniques that provide protection from the hazards of fire. This standard, within its scope of coverage, is considered by the NRC staff to provide an acceptable alternative to the fire protection provisions listed in Subdivision 5.6...When NFPA 232-1975 is used, quality assurance records should be classified as NFPA Class 1 records...."

Exception/Interpretation

~~Consumers Energy~~Big Rock Point adheres to ANSI N45.2.9-1974, Subdivision 5.6 for the facility for permanent storage of non-duplicated records. Temporary storage of documents after completion and during processing as records is in file cabinets selected in accordance with provisions of NFPA 232-1975 for Class 1 records (usually NFPA Class C, 1 hour or UL-Class 350).

15a. RG 1.64, C2

Requirement

"Regardless of their title, individuals performing design verification should not (1) have immediate supervisory responsibility for the individual performing the design...."

Exception/Interpretation

~~Consumers Energy~~Big Rock Point follows the requirements of ANSI N45.2.11-1974, Section 6.1, and the guidance of Section 3E4(a) of the Standard Review Plan, with the exception that use of supervisors as design verifiers may be controlled by a procedure instead of individually approved in advance in each case (see Section 3.2.9, herein). This approach is necessary to allow small organizational units (having limited numbers of technically qualified staff, or having the only technically qualified staff available in the Company) the flexibility needed to most effectively accomplish their assigned tasks.

16a. RG 1.144, Section C3_a(1)

Requirement

This section requires that for operational phase activities, RG 1.33 "Quality Assurance Program Requirements (Operations)" are to be followed. One of the RG 1.33 requirements is that the results of actions taken to correct deficiencies that affect nuclear safety and occur in facility equipment, structures, systems, or method of operation are to be audited at least once per six months.

Exception/Interpretation

See Item 3a for the exception to this requirement.

16b. RG 1.144, Section C3_a(2)

QUALITY PROGRAM DESCRIPTION FOR BIG ROCK POINT NUCLEAR POWER PLANTS

~~PART 1 - BIG ROCK POINT NUCLEAR PLANT~~

Requirement

Applicable elements of an organization's quality assurance program (for "design and construction phase activities") should be audited at least annually or at least once within the life of the activity, whichever is shorter.

Exception/Interpretation

Since most modifications are straightforward, they are not audited individually. Instead, selected controls over modifications are audited periodically.

16c. RG 1.144, SecC3_b(1)

Requirement

This section identifies procurement contracts that are exempted from being audited.

Exception/Interpretation

In addition to the exemptions of RG 1.144, ~~Consumers Energy~~Big Rock Point considers that Authorized Inspection Agencies, National Institute of Standards and Technology or other State and Federal Agencies which may provide services to ~~Consumers Energy~~Big Rock Point are not required to be audited.

16d. RG 1.144, Section C.3.b(2), second paragraph

Requirement

A documented evaluation of the supplier should be performed annually. Where applicable, this evaluation should take into account (1) review of supplier-furnished documents such as certificates of conformance, non-conformance notices, and corrective actions, (2) results of previous source verifications, audits and receiving inspections, (3) operating experience of identical or similar products furnished by the same supplier, and (4) results of audits from other sources (i.e., customer, ASME or NRC Audits).

Exception/Interpretation

~~Consumers Energy~~Big Rock Point will review the information described in the second paragraph of Section C.3.b(2) of Regulatory Guide 1.144, Revision 1, 1980, as it becomes available through the ~~Company's~~ ongoing receipt inspection, operating experience, and supplier evaluation programs, in lieu of performing a specific evaluation on an annual basis. The results of the reviews are promptly considered for effect on a supplier's continued qualification and adjustments made as necessary (including corrective actions, adjustments of supplier audit plans, and input to third party auditing entities as warranted). In addition, results are reviewed periodically to determine if, as a whole, they constitute a significant condition adverse to quality requiring additional action.

17a. N45.2.13, Section 3.2.2

Requirement

QUALITY PROGRAM DESCRIPTION FOR BIG ROCK POINT NUCLEAR POWER PLANTS

PART 1 - BIG ROCK POINT NUCLEAR PLANT

N45.2.13 requires that technical requirements be specified in procurement documents by reference to technical requirement documents. Technical requirement documents are to be prepared, reviewed and released under the requirements established by ANSI N45.2.11.

Exception/Interpretation

For replacement parts and materials, ~~Consumers Energy~~ Big Rock Point follows ANSI N18.7, Section 5.2.13, Subitem 1, which states: "Where the original item or part is found to be commercially 'off-the-shelf' or without specifically identified QA requirements, spare and replacement parts may be similarly procured, but care shall be exercised to ensure at least equivalent performance."

17b. N45.2.13, Section 3.2.3

Requirement

"Procurement documents shall require that the supplier have a documented quality assurance program that implements portions of ANSI N45.2 as well as applicable quality assurance program requirements of other nationally recognized codes and standards."

Exception/Interpretation

Refer to Item 2l.

17c. N45.2.13, Section 3.3(a)

Requirement

Reviews of procurement documents shall be performed prior to release for bid and contract award.

Exception/Interpretation

Documents may be released for bid or contract award before completing the necessary reviews. However, these reviews are completed before the item or service is put into service or before work has progressed beyond the point where it would be impractical to reverse the action taken.

17d. N45.2.13, Section 3.3(b)

Requirement

"Changes made in the procurement documents as a result of the bid evaluations or precontract negotiations shall be incorporated into the procurement documents. The review of such changes and their effects shall be completed prior to contract award."

Exception/Interpretation

This requirement applies only to quality related changes (i.e., changes to the procurement document provisions identified in ANSI N18.7, Section 5.2.13.I, Subitems 1 through 5). The timing of reviews will be the same as for review of the original procurement document.

QUALITY PROGRAM DESCRIPTION FOR BIG ROCK POINT NUCLEAR POWER PLANTS

PART 1 - BIG ROCK POINT NUCLEAR PLANT

17e. N45.2.13, Section 7.5

Requirement

"Personnel responsible for performing verification activities shall be qualified in accordance with ANSI N45.2.6 as applicable."

Exception/Interpretation

~~Consumers Energy~~ Big Rock Point qualifies audit personnel according to N45.2.23. Thus, personnel performing source verification audits may not be certified according to N45.2.6. Personnel performing inspection as part of source verification will be certified to N45.2.6 or qualified in accordance with Paragraphs 10.2.3, 10.2.7, or 10.2.10. However, personnel performing source surveillances may not be certified to any of those requirements.

17f. N45.2.13, Section 10.1

Requirement

"Where required by code, regulation or contract requirement, documentary evidence that items conform to procurement documents shall be available at the nuclear power plant site prior to installation or use of such items, regardless of acceptance methods."

Exception/Interpretation

Refer to Item 2m.

17g. N45.2.13, Section 10.3.4 (as modified by RG 1.123, C6e)

Requirement

"Post-installation test requirements and acceptance documentation shall be mutually established by the purchaser and supplier."

Exception/Interpretation

In exercising its ultimate responsibility for its Quality Program, ~~Consumers Energy~~ Big Rock Point establishes post-installation test requirements, giving due consideration to supplier recommendations.

18a. ANSI N45.2.23-1978, Section 2.3.4

Requirement

The prospective lead auditor shall have participated in a minimum of five (5) quality assurance audits within a period of time not to exceed three (3) years prior to the date of qualification, one audit of which shall be a nuclear quality assurance audit within the year prior to his qualification.

Exception/Interpretation

QUALITY PROGRAM DESCRIPTION FOR BIG ROCK POINT NUCLEAR POWER PLANTS

PART 1—BIG ROCK POINT NUCLEAR PLANT

The prospective lead auditor shall demonstrate his ability to properly implement the audit process defined by this Standard and ~~Consumers Energy~~Big Rock Point program/procedure, to effectively lead an audit team, and to effectively organize and report results, including participation in at least one nuclear quality assurance audit within the year preceding date of certification.

~~19a.—RG 1.26, General~~

Requirement

~~RG 1.26 establishes a system for classifying pressure boundary items into four quality groups, which are then correlated with ASME B&PV Code and ANSI Standards requirements.~~

Exception/Interpretation

~~Regulatory Guide 1.26 is not useful for determining the quality classification of ISFSI structures, systems and components and will no longer be utilized for any quality program activities at Big Rock Point. However, Table 2.1-1 of the Storage System SAR, WSNF-220, does provide quality classifications for dry fuel storage system structures, systems, components (SSCs), and support equipment. Some ISFSI SSCs are not classified in Table 2.1-1, but are classified within individual sections of WSNF-220. For example, the quality classification of the concrete ISFSI pad is provided in Section 1.2 of WSNF-220. WSNF-223, W74 Canister SAR, also provides quality classification information.~~

~~WSNF-220 and WSNF-223 will be used as the basis for determining the quality classification of ISFSI structures, systems, components, and support equipment.~~

~~20a.—This exception/interpretation no longer applies and has been deleted~~

~~21a.—RG 1.29, Section C, Regulatory Position~~

Requirement

~~The Regulatory Position states that the identified structures, systems, and components are to be designated Seismic Category 1 and should be designed to withstand the SSE.~~

Exception/Interpretation

~~Regulatory Guide 1.29 is not useful for determining seismic criteria to apply to structures, systems and components at the ISFSI, and will no longer be used for this purpose. The Storage System and Canister SARs, WSNF-220 and WSNF-223, respectively, provide the seismic criteria to which the dry fuel storage system structures, systems and components have been designed. These documents also show compliance to regulatory requirements, such as those contained in 10 CFR 72.102(f), and indicate the extent to which applicable regulatory guidance documents have been followed. As a result, the Storage System and Canister SARs will be used to identify applicable seismic design criteria.~~

~~21b.—RG 1.29, General~~

Requirement

QUALITY PROGRAM DESCRIPTION FOR BIG ROCK POINT NUCLEAR POWER PLANTS

PART 1—BIG ROCK POINT NUCLEAR PLANT

~~Apply pertinent Quality Assurance requirements of 10 CFR 50, Appendix B.~~

Exception/Interpretation

~~The pertinent quality requirements for ISFSI systems, structures and components will be determined in a graded manner using documents such as the Dry Fuel Storage SARs and Technical Specifications, and other docketed analyses to determine the degree to which Appendix B of 10 CFR 50 and Subpart G of 10 CFR 72 apply.~~

2219. ANSI/ANS 3.1 - 1987

Exception/Interpretation

The commitment to ANSI/ANS 3.1-1987 is limited to requirements that apply to persons performing the independent safety review function as specified in Appendix C to this QPD quality program.

20. ANSI N18.1-1971

Exception/Interpretation

The individual responsible for radiation protection functions shall meet the minimum requirements of Regulatory Guide 1.8, September 1975. As applied to this specification, "equivalent," as used in Regulatory Guide 1.8 for the bachelor's degree requirement, may be met with four years of any one or combination of the following: (a) formal training in science engineering or (b) operational or technical experience and training in nuclear power.

QUALITY PROGRAM DESCRIPTION FOR BIG ROCK POINT NUCLEAR POWER PLANTS

PART 1—BIG ROCK POINT NUCLEAR PLANT

APPENDIX B

SAFETY REVIEW

B1. FUNCTION

Safety Reviewers shall function to advise the Site General Manager on all matters important to nuclear safety of administrative controls and quality assurance associated with safety-related activities and/or important-to-safety structures, systems, or components. The Safety Reviewer ensures activities do not require U.S. Nuclear Regulatory Commission approval pursuant to 10 CFR 50.59 or 10 CFR 72.48 prior to implementation.

B2. COMPOSITION

The Site General Manager shall assign Safety Reviewers in writing. Safety Reviewers shall be competent in the activity under review and shall not review their own work.

B3. QUALIFICATIONS

Safety Reviewers shall be knowledgeable in the subject area being reviewed.

B4. MEETING FREQUENCY

Meetings are not required for performance of Safety Review functions described in this appendix.

B5. QUORUM

Safety Reviews are to be performed by at least one Safety Reviewer.

B6. RESPONSIBILITIES

Safety Reviewers shall be responsible for ~~nuclear safety~~ review of:

- a. All procedures and programs specified by the ~~Technical Specifications~~ Quality Program Description, Section 5.0, INSTRUCTIONS, PROCEDURES, AND DRAWINGS, and changes thereto, and any other procedures or changes thereto as determined by the Site General Manager ~~to affect nuclear safety~~; all proposed tests or experiments ~~that affect nuclear safety~~; and all proposed changes or modifications to the ISFSI that affect administrative controls and quality assurance associated with safety-related activities and/or important-to-safety structures, systems, or components. ~~nuclear safety.~~
- b. All proposed changes to Operating License, ~~the ISFSI License, Technical Specifications,~~ and the Spent Fuel Storage System Certificate of Compliance.

QUALITY PROGRAM DESCRIPTION FOR BIG ROCK POINT NUCLEAR POWER PLANTS

~~PART 1 BIG ROCK POINT NUCLEAR PLANT~~

- ~~c. Results of investigations of all violations of the Technical Specifications (a report shall be prepared covering evaluation and recommendations to prevent recurrence and be forwarded to the Vice President, NFHO, the Quality Assurance Lead, and the ISRC).~~
- ~~d. ISFSI operations to detect potential safety hazards.~~
- ec. Reports of special reviews and investigations as requested by the Site General Manager, the Quality Assurance Lead, or ISRC.
- f. ~~Site Emergency Plan and implementing procedures.~~
- gd. Reportable events defined by 10 CFR 50.72, 50.73, 71.95, 72.74, and 72.75. A report shall be prepared covering evaluation and recommendations to prevent recurrence and shall be forwarded to the Site General Manager, the Quality Assurance Lead, the ISRC, and the Vice President, NFHO.
- ~~h. Review of any accidental, unplanned or uncontrolled radioactive release including the preparation of reports covering evaluation, recommendations and disposition of the corrective action to prevent recurrence and the forwarding of these reports to the Site General Manager, the Quality Assurance Lead, and ISRC.~~

B7. AUTHORITY

- a. Safety Reviewers shall:
 - 1. Recommend in writing to the Site General Manager approval or disapproval of items considered under B6.a and, b and f.
 - 2. Render determinations in writing whether or not items considered under B6.a and, b, and f require prior NRC approval; alternatively, if the Site General Manager meets the qualification requirements of B3, this determination may be made by the Site General Manager prior to Site General Manager approval of the item.
- b. The Site General Manager shall:
 - 1. Provide written notification within 24 hours to the Senior Vice President, NFHO, the Quality Assurance Lead, and ISRC of any disagreement between the recommendation of a Safety Reviewer and the decision of the Site General Manager; however the Site General Manager shall have authority for resolution of such disagreements.

B8. RECORDS

Written records of Safety Reviews shall be maintained; these records shall contain or identify any documents reviewed, and shall be available for ISRC review.

QUALITY PROGRAM DESCRIPTION FOR BIG ROCK POINT NUCLEAR POWER PLANTS

~~PART 1 BIG ROCK POINT NUCLEAR PLANT~~

APPENDIX C
INDEPENDENT SAFETY REVIEW COMMITTEE

The following exceptions/interpretations in Appendix A, Part 2, are relevant to implementation of the requirements of this section of the QPD quality program:

<u>Paragraph</u>	<u>Exceptions/Interpretations</u>
C1.	2, 2x2b
C2	2, 2219
C3	2, 2b, 2219
C4.1	2c
C4.1(c)	2d
C4.1(g)	2e, 2f

C1. FUNCTION

The Independent Safety Review Committee (ISRC) shall collectively have competence in the disciplines specified below, although the ISRC may obtain additional expertise as provided for in C3.

- a. ISFSI operations
- b. Packaging of spent nuclear fuel for transportation
- c. Engineering
- d. Radiation protection
- e. Quality assurance and administrative controls

C2. COMPOSITION

The ISRC shall report to the Senior Vice President, NFHO and shall consist of a Chairman and at least one members appointed by the Senior Vice President – NFHO. ISRC members shall meet or exceed the qualifications described in Section 4.7 of ANSI/ANS 3.1-1987. The ISRC members shall have no direct responsibility for activities subject to their review.

C3. SUPPORT PERSONNEL

If sufficient expertise is not available within the ISRC to review particular issues, the ISRC shall have the authority to utilize consultants or other qualified organizations for expert advice. Support personnel shall meet or exceed the qualifications described in Section 4.7 of ANSI/ANS 3.1-1987. Support personnel shall have no direct responsibility for activities they review.

QUALITY PROGRAM DESCRIPTION FOR BIG ROCK POINT NUCLEAR POWER PLANTS

~~PART 1—BIG ROCK POINT NUCLEAR PLANT~~

C4. RESPONSIBILITIES

C4.1 Review Requirements

The ISRC shall provide independent review of:

- a. Written 10 CFR 50.59 evaluations and Big Rock Point initiated 10 CFR 72.48 written evaluations of changes in the facility ~~as described in the Safety Analysis Reports, changes in~~ procedures as described in the Safety Analysis Reports, the quality program, and tests or experiments not described in the Safety Analysis Reports Updated Final Hazards Summary Report that have been performed without prior NRC approval under the provisions of 10 CFR 50.59 or 10 CFR 72.48.

This review, includes a review of a sample of the written 10 CFR 50.59, 10 CFR 10.82, and 10 CFR 72.48 screening evaluations, to verify that none of the sample evaluations required evaluation under the provisions of 10 CFR 50.59 or 10 CFR 72.48. This sampling verifies that the process for screening 10 CFR 50.59 and 10 CFR 72.48 evaluations is effective.

ISRC shall review all 10 CFR 50.59 and Big Rock Point ~~Plant Site~~ initiated 10 CFR 72.48 determinations that screen into the evaluation process.

- b. Activities that require prior NRC approval pursuant to 10 CFR 50.59 or 10 CFR 72.48. Such reviews shall be performed prior to implementation ~~submission to the NRC~~ of the change to the facility, change to a procedure, or the test or experiment.
- c. Proposed changes to the Operating License conditions or Cask Storage System Certificate of Compliance ~~or Defueled Technical Specifications~~ prior to the proposed change being submitted to the NRC.
- d. Violations, deviations and reportable events requiring written notification to the NRC within 24 hours ~~or of having nuclear safety~~ safety-related activities and/or important to safety systems, structures, or components ~~significance~~, such as:
- (1) Violations of applicable codes, regulations, orders, Technical Specifications, license requirements, Cask Storage System Certificate of Compliance, or of internal procedures or instructions requiring written notification to the NRC within 24 hours or having that affect nuclear safety ~~significance~~ are safety-related activities and/or important to safety systems, structures, or components.
 - (2) Significant operating abnormalities, events or deviations from normal and expected performance of ISFSI equipment that affect safety-related activities and/or important to safety systems, structures, or components ~~nuclear safety.~~
 - (3) ~~Events requiring written notification to the NRC within 24 hours or having nuclear safety significance.~~
- e. Reports of audits performed as specified in Appendix D.

QUALITY PROGRAM DESCRIPTION FOR BIG ROCK POINT NUCLEAR POWER
PLANTS

~~PART 1 BIG ROCK POINT NUCLEAR PLANT~~

- f. Any other matter involving safe operation of the ISFSI that an ISRC member deems appropriate for consideration, or that is referred to the ISRC by the onsite operating organization or by the Quality Assurance ~~Organization~~ Lead.

QUALITY PROGRAM DESCRIPTION FOR BIG ROCK POINT NUCLEAR POWER PLANTS

~~PART 1—BIG ROCK POINT NUCLEAR PLANT~~

C4.2 Review Methodology and Meeting Requirements

ISRC review of the subjects in C4.1 shall be performed by members or support personnel selected on the basis of technical expertise relative to the subject being reviewed. If the assigned reviewer determines the need for interdisciplinary review, a committee consisting of the ISRC Chairman, or his designate, and at least one other ISRC member or qualified support personnel shall be assigned. The committee shall meet as conditions requiring interdisciplinary review arise, but not less than annually.

C5 AUTHORITY

The ISRC shall report to and advise the Senior Vice-President, NFHO of significant findings associated with the reviews specified in C4.1 and Appendix D, Audit Frequencies.

C6 RECORDS

Records of ISRC activities shall be maintained. Reports shall be prepared and distributed as indicated below:

- a. The results of reviews performed pursuant to C4.1 shall be reported to the Senior Vice President, NFHO, following each meeting of the ISRC. Significant findings with respect to reviews performed in accordance with C4.1 shall be reported immediately to the Senior Vice President, NFHO, with written follow-up not later than the following meeting report.

QUALITY PROGRAM DESCRIPTION FOR BIG ROCK POINT NUCLEAR POWER PLANTS

PART 1 – BIG ROCK POINT NUCLEAR PLANT

APPENDIX D
AUDIT FREQUENCIES

The following exceptions/interpretations in Appendix A, Part 2, are relevant to implementation of the requirements of this section of the QPD-quality program:

<u>Paragraph</u>	<u>Exceptions/Interpretations</u>
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D1.	3a, 3b, 3c, 16a
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D1. AUDITS

Audits of decommissioning activities and ISFSI operations subject to this Program are performed by the Quality Assurance Organization Lead under the cognizance of the ISRC. These audits encompass:

- a. The conformance of plant-site operation to provisions contained within the Technical Specifications, applicable operating license conditions, and the Spent Fuel Storage Cask System Certificate of Compliance at least once per 24 months.
- b. The performance, training and qualifications of those members of the facility staff who perform quality activities defined in this QPD-quality program at least once per 24 months.
- c. The performance of activities and administrative controls required by the QPD-quality program and the Fire Protection Plan for Nuclear Power Plants (CPC-2A) to meet the criteria of 10-CFR-50, Appendix B at least once per 24 months.
- d. The Site-Independent Spent Fuel Storage Installation (ISFSI) Emergency Plan and implementing procedures:
 - (1) At intervals not to exceed 12 months or,
 - (2) As necessary, based on an assessment by the Quality Assurance Organization against performance indicators, and as soon as reasonably practicable after a change occurs in personnel, procedures, equipment, or facilities that potentially could adversely affect emergency preparedness, but no longer than 12 months after the change. In any case, all elements of the emergency preparedness program must be reviewed at least once every 24 months.
- e. The Site Security Plan and implementing procedures shall be audited at intervals specified in the Security Plan.
- f. Any other area of decommissioning or ISFSI operation considered appropriate by the Quality Assurance Organization or the Senior Vice President, NFHO.

QUALITY PROGRAM DESCRIPTION FOR BIG ROCK POINT NUCLEAR POWER PLANTS

PART 1 - BIG ROCK POINT NUCLEAR PLANT

- g. ~~The plant Fire Protection Program and implementing procedures at least once per 24 months.~~
- h. ~~Radiological environmental monitoring program and the results thereof at least once per 24 months.~~
- ig. ~~The Radiation Protection Program, including the Offsite ~~FFSITE~~ Dose ~~OSE~~ Calculation ~~ALCULATION~~ Manual ~~ANUAL~~ (ODCM) and implementing procedures the Process Control Manual and their implementing procedures at least once per 24 months.~~
- j. ~~The PROCESS CONTROL PROGRAM and implementing procedures for processing and packaging of radioactive wastes at least once per 24 months.~~

Audit reports encompassed by D1 shall be forwarded to the Quality Assurance Lead and Management positions responsible for the areas audited within thirty (30) days after completion of the audit.

QUALITY PROGRAM DESCRIPTION FOR BIG ROCK POINT NUCLEAR POWER PLANTS

~~PART 1 - BIG ROCK POINT NUCLEAR PLANT~~

APPENDIX E
RECORD RETENTION

- E1. In addition to the applicable record retention requirements of Title 10, Code of Federal Regulations, the following records shall be retained for at least the minimum period indicated. Where 10 CFR 72 or the Part 72 license conditions do not specify a retention period for a record, the records shall be retained until the NRC terminates the license.
- E2. The following records shall be retained for at least five years:
- a. Records and logs of facility operation covering time interval at each power level.
 - b. Records and logs of principal maintenance activities, inspections, repair and replacement of principal items of equipment related to nuclear safety.
 - c. All reportable events as defined in 10 CFR 50.72, 50.73, 72.74, and 72.75.
 - d. ~~Records of surveillance activities, inspections and calibrations required by Plant Technical Specifications.~~ Big Rock Point Operating License or quality program.
 - e. ~~Records of changes made to the procedures required by Plant Technical Specifications.~~ Big Rock Point Operating License or this quality program.
 - f. Records of radioactive shipments.
 - g. Records of sealed source leak tests and results.
 - h. Records of annual physical inventory of all source material of record.
- E3. The following records shall be retained for the duration of the Facility 10 CFR 50 or Part 72 License:
- a. Record and drawing changes reflecting facility design modifications made to systems and equipment described in the Big Rock Point UFHSR.
 - b. Records of new and irradiated fuel inventory, fuel transfers and assembly burnup histories.
 - c. Records of quarterly radiation exposure for all individuals entering radiation control areas.
 - d. Records of gaseous and liquid radioactive material released to the environs.
 - e. Records of transient or operational cycles for those facility components designed for a limited number of transients or cycles.

QUALITY PROGRAM DESCRIPTION FOR BIG ROCK POINT NUCLEAR POWER PLANTS

PART 1—BIG ROCK POINT NUCLEAR PLANT

- f. Records of in-service inspections performed pursuant to Plant Technical Specifications, the Operating License or Cask Certificate of Compliance.
 - g. Records of Quality Assurance activities required by the QPD quality program.
 - h. Records of reviews performed for changes made to procedures or equipment, or reviews of tests and experiments pursuant to 10 CFR 50.59, 10 CFR 50.82 and 10 CFR 72.48.
 - i. Records of reviews performed by Safety Reviewers and the ISRC, according to Appendices B and C.
 - j. Records of monthly facility radiation and contamination surveys.
 - k. Records for environmental qualifications that are covered under the provisions of 10 CFR 50.49.
 - l. Records of training and qualifications for members of the plant-site staff.
 - m. Records of reactor tests and experiments.
 - n. Records of reviews performed for changes made to the OFFSITE DOSE CALCULATION MANUAL Off-site Dose Control Manual and the PROCESS CONTROL PROGRAM Process Control Program.
- E4. The following records shall be retained as long as the associated material is stored and for a period of five years after the material is transferred out of the ISFSI:
- a. Records of receipt, inventory (including location), disposal, acquisition, and transfer of all spent fuel and high level waste in storage.
- E5. The following records shall be retained until the NRC terminates the 10 CFR Part 72 General License for the ISFSI:
- a. Records of the current inventory of all spent fuel and high-level waste.
 - b. Current material control and accounting procedures.
 - c. ISFSI and Cask Storage System records pertaining to the design, fabrication, erection, testing, maintenance, and use of structures systems and components important to safety.
- E6. The following records shall be retained and forwarded to the appropriate NRC Regional Office prior to the ISFSI General License termination:

QUALITY PROGRAM DESCRIPTION FOR BIG ROCK POINT NUCLEAR POWER
PLANTS

PART 1—BIG ROCK POINT NUCLEAR PLANT

- a. Records of spills or other unusual occurrences involving the spread of contamination in and around the facility, equipment or site. These records may be limited to instances when contamination remains after any clean-up procedures or when there is a reasonable likelihood that contaminants may have spread to inaccessible areas as in the case of possible seepage into porous materials such as concrete. The records must include any known information on identification of involved nuclides, quantities, forms, and concentrations.
- b. As-built drawings and modifications of structures and equipment in restricted areas where radioactive materials are used and/or stored, and of locations of possible inaccessible contamination such as buried pipes which may be subject to contamination. If required drawings are referenced, each relevant document need not be indexed individually. If drawings are not available, the licensee shall substitute appropriate records of available information concerning these areas and locations.
- c. A list contained in a single document and updated no less than every 2 years of the following:
 - (1) All areas designated and formerly designated as restricted areas as defined under 10 CFR 20.1003; and
 - (2) All areas outside of restricted areas that require documentation under 10 CFR 72.30(d)(1).
- d. Records of the cost estimate performed for the decommissioning funding plan or of the amount certified for decommissioning, and records of the funding method used for assuring funds if either a funding plan or certification is used.
- e. Records of the results of measurements and calculations used to evaluate the release of radioactive effluents to the environment. This includes those records of the results of measurements and calculations used to evaluate the release of radioactive effluents to the environment under the standards for protection against radiation in effect prior to January 1, 1994.

Attachment 3
Big Rock Point Plant
Dockets 50-155 and 72-043

February 28, 2006

**Justification for Changes to CPC-2A, Revision 22, Quality Program
Description**

23 Pages

**Attachment 3
JUSTIFICATION FOR CHANGES
Revision 22
Quality Program Description for Big Rock Point**

#	QPD SECTION	REVISION	JUSTIFICATION OF NO REDUCTION IN COMMITMENT
1	Title	<p>Revised title from "Quality Program Description for Nuclear Power Plants, Part 1 – Big Rock Point Nuclear Plant," to: "Quality Program Description for Big Rock Point."</p> <p>Note: Throughout the Quality Program Description for Big Rock Point, editorial revisions from "Quality Program" or "Program" to "quality program" or "program" were made without note in this attachment.</p>	Administrative – Revised title reflects the applicability of this QPD. Formerly, the QPD applied to both Big Rock and Palisades. Palisades is under the Quality Plan for the NMC fleet.
2	1.1 First Paragraph	<p>Added the following sentence, "Quality assurance functions performed by such delegates may be completed under the requirements of either this Quality Program Description or the delegates' comparable, NRC approved, Quality Program Description." After existing sentence: " Consumers Energy may delegate the authority for development and maintenance of the Quality Program Description (QPD) and execution of certain quality assurance functions to others who are independent and qualified, such as contractors, agents, or consultants."</p> <p>Revised "Quality Program" to "quality program" throughout.</p>	<p>Added sentence clarifies the Quality requirements and provides flexibility in utilization of outside entities at the site, while continuing to meet all applicable 10 CFR requirements.</p> <p>Editorial.</p>
3	1.1 Second Paragraph	Deleted "during decommissioning" in sentence on responsibility of activities "affecting radiological safety."	Broadens the scope of the responsibilities for radiological safety to apply to the ISFSI and site, once decommissioning of the former plant area is completed.
4	1.1 Third Paragraph	Revised "Quality Assurance Organization" to "Quality Assurance Lead" and added a reference to the Audit frequency in Appendix D.	QA Organization consists of only a single person, the "QA Lead." Reference to Appendix D is editorial.

**Attachment 3
JUSTIFICATION FOR CHANGES
Revision 22
Quality Program Description for Big Rock Point**

#	QPD SECTION	REVISION	JUSTIFICATION OF NO REDUCTION IN COMMITMENT
5	1.1 Fourth paragraph	Added Exceptions 2, 2b, 2c, 2t, 18a, 19 and 20 to apply to section 1.2.2. Deleted Exception 2g. Deleted paragraph 1.2.3 from exceptions list (no such paragraph exists).	Exception 19 is currently contained in Big Rock Point Defueled Technical Specifications. It applies to the Qualifications of the Radiation Protection Manager. See justification for revision of section Appendix B, B6. The responsibilities of the Radiation Protection Manager have been added to section 1.2.2.d. Exception 20 adds a NEW commitment to ANSI N18.1-1971, which is a commitment from the DTS, along with the RP Manager exception. Other revisions are a result of paragraph numbering changes within the chapter.
6	1.2.1 and 1.2.2.a	Revised title of "President and Chief Executive Office, Electric of Consumers Energy," to : "President and Chief Executive Officer, Consumers Energy."	Editorial.
7	1.2.2.a	Added report function of ISRC and cross-reference to Appendix C under the responsibilities of the Senior Vice President, NFHO.	Editorial.
8	1.2.2.b Various Places	Revised "plant" or "plant/ISFSI" to "site" and "decommissioning and ISFSI personnel" to "site personnel."	Editorial revisions. QPD applies to the BRP site, both former plant area undergoing decommissioning and the ISFSI Facility.

**Attachment 3
JUSTIFICATION FOR CHANGES
Revision 22
Quality Program Description for Big Rock Point**

#	QPD SECTION	REVISION	JUSTIFICATION OF NO REDUCTION IN COMMITMENT
		Move former 1.2.2.c (9), "Maintenance of the Quality Program Description for Big Rock Point" from the responsibility of Quality Assurance to the Site General Manager. Delete redundant 1.2.2.b(19) it is the same as RPM 1.2.2.d(5). Encompassed by 1.2.2b first paragraph – SGM responsible for compliance with licenses.	Administrative revision.
9	1.2.2.b. (3)	Added, "implementing the special nuclear material control program" as part of the site licensing activities. Added second paragraph on SGM responsibility to provide written notification – from Appendix B Safety Review disagreements.	Editorial. Formerly implied. Duty was spelled-out since it is one of prominent remaining licensing activities for a stand-alone ISFSI.
10	1.2.2.b.(20)	Reassigned, "Maintenance of the Quality Program Description for Big Rock Point" from the QA Organization [formerly 1.2.2.c.(9)] to the Site General Manager.	Former QA Organization and the SGM were both direct reports to the Sr. VP, NFHO (See Figure 1). Delegating this responsibility to the SGM is not a reduction in commitment; it is an Administrative change.
11	1.2.2.c (9)	Revised title consistent with QA "Lead" title, rather than former QA Organization. Former sub items (1), (11) and (12) were made into paragraphs, renumbered subsequent sub items. Re-assigned former sub item (9) to the Site General Manager.	Editorial. Editorial. See justification for section 1.2.2.b (20).
12	1.2.2.d	Deleted: "Responsibilities of the Environmental and Laboratory Services Department The Radiation Protection Manager is responsible for: radiation protection, control of radioactive materials (except special nuclear materials), and the ALARA program.	Environmental and Laboratory Services (E&LS) is an off-site entity that no longer operates under this QPD. The use of E&LS to perform important-to-

**Attachment 3
JUSTIFICATION FOR CHANGES
Revision 22
Quality Program Description for Big Rock Point**

#	QPD SECTION	REVISION	JUSTIFICATION OF NO REDUCTION IN COMMITMENT
		<p>His duties include:</p> <ol style="list-style-type: none"> (1) Administration of radioactive waste, storage, packaging, shipping, and disposal activities. (2) Issuing a Stop Work Order upon identifying the potential for excessive or unplanned radiation exposure or loss of contamination control. (3) Assisting and providing recommendations to maintain radiation parameters in accordance with licenses, permits and industry standards. (4) Accounting for radioactive materials on-site other than special nuclear material. (5) Packaging and transportation of radioactive materials. <p>The individual responsible for radiation protection functions shall meet the minimum requirements of Regulatory Guide 1.8, September 1975. As applied to this specification, "equivalent," as used in Regulatory Guide 1.8 for the bachelor's degree requirement, may be met with four years of any one or combination of the following: (a) formal training in science engineering or (b) operational or technical experience and training in nuclear power."</p> <p>Revised to: "Responsibilities of the Radiation Protection Manager.</p> <p>The Radiation Protection Manager is responsible for: radiation protection, control of radioactive materials (except special nuclear materials), and the ALARA program. His duties include:</p> <ol style="list-style-type: none"> (1) Administration of radioactive waste, storage, packaging, shipping, and disposal activities. (2) Issuing a Stop Work Order upon identifying the potential for excessive or unplanned radiation exposure or loss of contamination control. (3) Assisting and providing recommendations to maintain radiation parameters in accordance with licenses, permits and industry standards. 	<p>safety activities requires prior evaluation and acceptance of E&LS as a qualified supplier.</p> <p>Radiation Protection Manager was added for three reasons. 1. Currently, Big Rock Point Defueled Technical Specification (DTS) section 6.3 has a qualification/training exception for this position, which is better defined in this document; 2. Although currently redundant to the DTS, information from the DTS has been added to the QPD with the future expectation of an amendment and deletion of this section; and 3. Future staffing at the site is anticipated to require an individual with these qualifications. Also see Revision to Appendix A, Part 2, Exception 4a and 5a.</p> <p>Since the information is consistent with, and redundant to current DTS section, which takes precedent until amended,</p>

**Attachment 3
JUSTIFICATION FOR CHANGES
Revision 22
Quality Program Description for Big Rock Point**

#	QPD SECTION	REVISION	JUSTIFICATION OF NO REDUCTION IN COMMITMENT
		<p>(4) Accounting for radioactive materials on-site other than special nuclear material. (5) Packaging and transportation of radioactive materials. (6) Ensuring Radiation Protection Programs and Reports are prepared and controlled in accordance with the requirements of this QPD and the Defueled Technical Specifications.</p> <p>The individual responsible for radiation protection functions shall meet the minimum requirements of Regulatory Guide 1.8, September 1975. As applied to this specification, "equivalent," as used in Regulatory Guide 1.8 for the bachelor's degree requirement, may be met with four years of any one or combination of the following: (a) formal training in science engineering or (b) operational or technical experience and training in nuclear power."</p>	<p>this is not a reduction in commitment of the QPD.</p> <p>Item (6) was added to provide a cross reference and delegate responsibility to DTS.</p>
13	1.2.2.e	Added an new second paragraph: "Independent Safety Review Committee function, composition, responsibilities, and authority is discussed in Appendix C of this QPD.	Editorial cross-reference to Appendix C.
14	Figure 1	Deleted "Manger Environmental and Laboratory Services", and Added "Radiation Protection Manager."	Consistent with revision to section 1.2.2.d.
15	2.1 First paragraph	Revised title and "plant" to "site."	Editorial.
16	2.1 Fourth paragraph	Deleted exceptions 19a, 21a, and 21b.	See revisions to Appendix A, Part 2. These exceptions were associated with guidance to which Big Rock Point is no longer committed, and were deleted.
17	2.2.1	Corrected CEO title and deleted "Plant."	Editorial.
18	2.2.2	Revised "Consumers Energy" to "Big Rock Point."	Editorial – QPD is specific to BRP.

**Attachment 3
JUSTIFICATION FOR CHANGES
Revision 22
Quality Program Description for Big Rock Point**

#	QPD SECTION	REVISION	JUSTIFICATION OF NO REDUCTION IN COMMITMENT
19	2.2.3.a (4)	Defined "life of BRP" by revising sentence wording, "life of BRP U.S. Nuclear Regulatory Commission license."	Editorial.
20	2.2.3.b	<p>Deleted: "Because the Big Rock Point reactor will no longer be operated, and prior to implementation of this revised QPD, fuel and high-level radioactive waste will be stored only at the ISFSI, application of Quality Program requirements to the in-plant structures, systems and components formerly associated with either of these functions will no longer be required. Quality Program requirements will be applied to structures, systems and components at the ISFSI that are defined in the Quality List as being required for safe storage of spent nuclear fuel and high-level radioactive waste. Quality Program requirements will also be applied to selected activities and programs defined in the Quality List as being required for decommissioning or operation of the ISFSI; for example, packaging and transportation of radioactive materials, and activities required to achieve compliance with 10 CFR 20."</p> <p>Revised to: "This QPD applies to those structures, systems and components (SSCs), and programs or activities that are Important to Safety, as described in 10CFR72, and assure one or more of the following functions:</p> <ul style="list-style-type: none"> a. To maintain the conditions required to store spent fuel, high-level radioactive waste, or reactor-related waste safely; b. To prevent damage to the spent fuel, high-level radioactive waste, reactor-related waste container during handling and storage; or c. To provide reasonable assurance that spent fuel, high-level radioactive waste, or reactor-related waste can be received, handled, packaged, stored and retrieved without undue risk to the health and safety of the public. <p>Big Rock Point Volume 35A-11, Quality List, lists ISFSI structures, systems, and components to which quality program elements are applicable. Applicable elements of</p>	Administrative revision. Deleted passage referred to the "Quality List." Revision is specific in its reference to Big Rock Volume 34A-11.

**Attachment 3
JUSTIFICATION FOR CHANGES
Revision 22
Quality Program Description for Big Rock Point**

#	QPD SECTION	REVISION	JUSTIFICATION OF NO REDUCTION IN COMMITMENT
		<p>the Quality Program are applied to the emergency, security, and fire protection and radiation protection plans and programs for site activities and ISFSI operation.</p> <p>Big Rock Point Volume 35A-11, Quality List, also applies to activities performed at BRP pursuant to 10CFR71, Subpart H, Quality Assurance for Packaging and transportation of Radioactive Waste."</p>	<p>Added 10 CFR Part 71 for consistency with scope of QPD as stated in the cover letter.</p>
21	2.2.4	<p>Various editorial revisions including title of QPD changes, revision of "Consumers Energy" to "Big Rock Point" and correcting Appendix A references to indicate "Part 1" and "Part 2."</p>	<p>Editorial.</p>
22	2.2.5	<p>Deleted: "c. Applicable elements of the Quality Program are applied to the emergency, security, and fire protection plans and radiation protection procedures for decommissioning and ISFSI operation. These plans describe quality controls applicable to associated equipment and activities."</p>	<p>Incorporated into revision to 2.2.3.b, above.</p>
23	2.2.6 First paragraph	<p>Revised title reference and "Consumers Energy" to "Big Rock Point."</p>	<p>Editorial.</p>
24	2.2.6.a	<p>Added acronym "(ITS)"</p>	<p>Editorial.</p>
25	2.2.6.b	<p>Deleted "the Technical Specifications" as something to which the QPD applies. The Technical Specifications are an appendix to the Big Rock Point License, and is therefore part of "applicable regulations."</p>	<p>Editorial revision in preparation for DTS amendment to delete Technical Specifications from the BRP License DPR-6.</p>
26	2.2.6 Last paragraph	<p>Revised the means of classification and identification of items from a "Q-List", electronic database, or other controlled means to solely the "Quality List."</p>	<p>Administrative. Reflects revision of the Quality List to include an ISFSI and site with all source term removed from the former protected area. Editorial, see above. Dry Fuel</p>

**Attachment 3
JUSTIFICATION FOR CHANGES
Revision 22
Quality Program Description for Big Rock Point**

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		Deleted DTS and Dry Fuel Technical Specifications from list of example documents used to determine extent of Quality Controls.	Storage Technical Specifications are part of the Storage System and Canister SARs.
27	2.2.7.b	Revised "technical specifications" to "License Conditions or Cask Storage System Certificate of Compliance."	License appendix currently is the Technical Specifications. See 2.2.6, last paragraph revisions, above. CoC contains site-specific analyses that must be considered commensurate with License Conditions.
28	2.2.10	Status and adequacy of the Quality Program are assessed by the Quality Assurance Lead.	Revision is editorial. CE Management defined in Figure 1.
29	3.2.2	Added cross-reference to Section 16.0 in discussion of Corrective Actions (actions taken to assure errors and deficiencies are corrected).	Editorial.
30	3.2.5	Deleted "Consumers Energy organization" and left only "organization" in the following sentence: "Decisions and problem resolution involving design interfaces are made by the organization having responsibility for engineering direction of the design effort."	Consistent with new sentence added in section 1.1. Revised sentence clarifies the quality requirement responsibility and provides flexibility in utilization of outside entities at the site, while continuing to meet all applicable 10 CFR requirements.

**Attachment 3
JUSTIFICATION FOR CHANGES
Revision 22
Quality Program Description for Big Rock Point**

#	QPD SECTION	REVISION	JUSTIFICATION OF NO REDUCTION IN COMMITMENT
31	3.2.8 Third Paragraph	Revised "plant" to "site."	Editorial.
32	3.2.9	Revised "His/He" to "The Supervisor/ The Supervisor's"; "QA Organization" to "QA Lead."	Editorial.
33	4.2.1 Second Paragraph	Deleted specific method of review and approval of procurement packages.	Administrative. Site working level procedures define these responsibilities – ultimately the (continued) responsibility of the Site General Manager.
34	4.2.3.e and h	Revised "Consumers Energy" to "Big Rock Point."	Editorial.
35	5.1, Second Paragraph	Added reference to exceptions 2v and 2w and revised Paragraph 5.2, item 10 to item 12 due to renumbering.	Editorial. These exceptions were approved in Revision 21 of the QPD (NRC SER dated 10/28/2003). However, they were not included within the QPD.
36	5.2 Fourth paragraph	Revised "Consumers Energy" to "Big Rock Point."	QPD is specific to BRP site.
37	5.2 Fourth paragraph first subitem	Revised "Administrative Procedures" to "Administrative Procedures implementing the requirements of this Quality Program Description."	Provides specific guidance on which procedures implement the Quality Program and are under the requirements of the quality program. Administrative revision to differentiate former operating plant "Administrative Procedures" from those

**Attachment 3
JUSTIFICATION FOR CHANGES
Revision 22
Quality Program Description for Big Rock Point**

#	QPD SECTION	REVISION	JUSTIFICATION OF NO REDUCTION IN COMMITMENT
			procedures needed to implement the QPD.
38	5.2 Fourth Paragraph Subitems 4 through 8, and re-numbered 10, and 11	Minor editorial and formatting revisions – added commas, “or” and “and” as appropriate.	Editorial.
39	5.2, Fourth Paragraph, NEW Sub Items 9, 10, and 11	Revised #9 to include the ISFSI Emergency Plan (with the IEP implementing procedures). Added ISFSI Security Plan Implementing Procedures; and Fire Protection Plan.	From DTS section 6.5.1.1.
40	5.2 Fourth paragraph Re-numbered Sub item 13.d (formerly 11.d)	Deleted “onsite” from “Control of onsite quality-related modification...”	QPD is specific to BRP site.
41	5.2 Fourth paragraph Subitem 12.	Deleted “Decommissioning procedures when needed to provide for controlled dismantlement of BRP and restoration of the plant site.”	Activities (including radiation protection and other Q-program interfaces) required during the decommissioning process are addressed through procedures implementing the QPD.
42	6.2.2.e	Spelled-out Updated Final Hazards Summary Report.	Editorial.

**Attachment 3
JUSTIFICATION FOR CHANGES
Revision 22
Quality Program Description for Big Rock Point**

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43	6.2.2.f	Revised "BNFL" to "BNG" and added "Dry Fuel Storage Technical Specifications to list of BNG and Dry Fuel Storage documents.	Editorial. DFS Technical Specifications are derived from the SARs.
44	6.2.2.h	Revised "Defueled Technical Specifications" to "Big Rock Point U.S. Nuclear Regulatory Commission License conditions or Cask Storage System Certificate of Compliance."	Editorial. See justification for section 2.2.6, last paragraph and section 2.2.7.
45	6.2.2.i	Deleted "Dry Fuel Storage Technical Specifications."	Added in 6.2.2.f.
46	7.2.2	Revised "Consumers Energy" to "Big Rock Point."	Editorial – QPD specific to BRP.
47	9.1, Second paragraph	Deleted exception 6c.	See below, for deletion of Appendix A, Part 2, Exception 6 c. Exception was consistent with requirement of ANSI N45.2.1, Section 5, and was deleted.
48	10.2.2	Revised first sentence from, "Inspections are applied to procurement, maintenance, modification, testing, fuel transfer operations, and decommissioning to verify that items and activities conform to specified requirements." To: "Inspections are applied to procurement, maintenance, modification, testing, fuel transfer operations, and other site activities to verify that Quality-List items and activities conform to specified requirements. "	Revision references revised site Quality List and expands the applicability of the inspections to site activities, not just decommissioning activities.
49	10.2.3 First paragraph	Added acronym "(SGM)" after "Site General Manger."	Editorial.
50	10.2.3 Second Paragraph	Deleted the paragraph: "Training and qualification programs for Environmental and Laboratory Services (E&LS) personnel who perform inspections, including nondestructive examination, are documented in E&LS procedures."	See justification for revision of section 1.2.2.d.

**Attachment 3
JUSTIFICATION FOR CHANGES
Revision 22
Quality Program Description for Big Rock Point**

#	QPD SECTION	REVISION	JUSTIFICATION OF NO REDUCTION IN COMMITMENT
51	10.2.3 Third paragraph	Revised sentence from: "Qualifications and certifications of inspection and NDE personnel are maintained." To: "Qualifications and certifications of inspection and NDE personnel are maintained by the entity performing in inspection in accordance with the recordkeeping requirements in the approved quality plan for than entity."	Editorial. Reflect recordkeeping requirements of either BRP QPD or approved supplier, contractor, outside entity quality program.
52	10.2.7	Revised "Consumers Energy" to "Big Rock Point."	Editorial – QPD specific to BRP.
53	10.2.10.a	Revised formatting error.	Editorial.
54	12.2.4	Revised "consumers Energy" to "Big Rock Point."	Editorial.
55	14.1 First paragraph	Revised first sentence from: "Operating status of structures, systems, and components to which this Program applies according to Section 2.0, QUALITY PROGRAM, is indicated by tagging of valves and switches, or by other special means, in such a manner as to prevent inadvertent operation." to: "Operating status of structures, systems, and components to which this Program applies according to Section 2.0, QUALITY PROGRAM, is indicated by tagging in such a manner as to prevent inadvertent operation."	Quality-List SSC's for the ISFSI are passive, with no valves or switches.
56	18.2.9 and 18.2.10	"Revised "Quality Assurance Organization" to "Quality Assurance Lead."	Consistent with Figure 1 title and section 1.2.2.c (1).
57	Appendix A, Part 1 First paragraph	Revised "Consumers Energy" to "Big Rock Point."	Editorial – QPD specific to BRP.
58	Appendix A, New Sub Item 19	Added a commitment for ANSI N18.1-1971, American National Standard for Selection and Training of Nuclear Power Plant Personnel.	Consistent with DTS Section 6.3.

**Attachment 3
JUSTIFICATION FOR CHANGES
Revision 22
Quality Program Description for Big Rock Point**

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59	Appendix A, Part 2 Exception 1	Revised "Consumers Energy" to "Big Rock Point."	Editorial – QPD specific to BRP.
60	Appendix, Part 2, Exception 2a	Revised "BRP/ISFSI" to "BRP."	Editorial – QPD specific to BRP.
61	Appendix A, Part 2, Exception 2d	Revised "Technical Specification Changes" to "License Condition or Cask Storage System Certificate of Compliance changes."	Editorial – License conditions include Technical Specifications as an attachment. Consistent with sections 2.2.6.b and 2.2.7 changes.
62	Appendix A, Part 2, Exception 2e	Deleted "during decommissioning and ISFSI operation."	Editorial – QPD specific to BRP. Applies as long as BRP is licensed.
63	Appendix A, Part 2, Exception 2g	Deleted exception.	Exception was made and reviewed in revision 21 (NRC SER dated 10/28/2003). However, it is not included or referenced in any of the 12 criteria QPD exceptions/interpretation sections.
64	Appendix A, Part 2, Exception 2h	Revised "Consumers Energy" to "Big Rock Point." Revised citation of applicability from procedures in the Plant Technical Specifications and to Security Plan and Emergency Plan implementing procedures to: "Big Rock Point considers that this requirement applies only to procedures identified in this Quality Program Description."	Technical Specification procedures, Security Plan and implementing procedures, and emergency plan implementing procedures are addressed in section 5.2 of this QPD In addition, the activities requiring

**Attachment 3
JUSTIFICATION FOR CHANGES
Revision 22
Quality Program Description for Big Rock Point**

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			procedures due to Quality List (Volume 34A-11) interface are inferred in section 2.2.3 of this QPD.
65	Appendix A, Part 2, Exceptions 2i, 2j, 2p, 2q, and 2r	Revised "Consumers Energy" to "Big Rock Point."	Editorial – QPD specific to BRP.
66	Appendix A, Part 2, Exception 2v	Revised "the Big Rock Point site" to "Big Rock Point."	Editorial.
67	Appendix A, Part 2, Exception 2w	Added "ANSI N18.7 sections" in front of "5.3.4.1, 5.3.4.2, and 5.3.4.3" in the first sentence of the Exception/interpretation and added "ANSI N18.7 sections" in front of "5.4.3.4 through 5.3.4.10" to clarify the exception.	Editorial.
68	Appendix A, Part 2, Exception 2x	Deleted exception to N18.7, Section 4.3.1.	Redundant to exception 2b in Appendix A, Part 2.
69	Appendix A, Part 2, Exceptions 3b and 3c	Revised "Consumers Energy" to "Big Rock Point." In 3b, also revised "Defueled Technical Specifications" to "Operating License conditions and Cask Storage System Certificate of Compliance" or "Operating License conditions or Cask Storage System Certificate of Compliance/ QPD Appendix F" and deleted "LCO for Operation and Surveillance Requirements.	Editorial – QPD specific to BRP. Editorial – License conditions include Technical Specifications as an attachment. Consistent with sections 2.2.6.b and 2.2.7 changes. Only LCO's currently in BRP DTS are for the inspection of Sources. The last remaining source on-site was

Attachment 3
JUSTIFICATION FOR CHANGES
Revision 22
Quality Program Description for Big Rock Point

#	QPD SECTION	REVISION	JUSTIFICATION OF NO REDUCTION IN COMMITMENT
			shipped to DOE in January of 2006.
70	Appendix A, Part 2, Exceptions 4a and 5a	Revised: "Other personnel are trained and qualified as designated in the Defueled Technical Specifications and the Dry Fuel Storage Technical Specifications." To: "Other personnel are trained and qualified as designated in Section 1.0 of the Quality Program Description for Big Rock Point"	All training and qualification of personnel from the DTS has been verified to be included in this QPD. Reference revision to 1.2.2c.
71	Appendix A, Part 2, Exception 5b	Revised "Consumers Energy" to "Big Rock Point" Re-worded to indicate Site employees include, Consumers Energy Employees (both from on and offsite) and contract and temporary personnel.	Editorial – QPD specific to BRP.
72	Appendix A, Part 2, Exception 6a	Revised "Consumers Energy" to "Big Rock Point."	Editorial – QPD specific to BRP.
73	Appendix A, Part 2, Exception 6c	Deleted exception.	Interpretation was consistent with the requirements.
74	Appendix A, Part 2, Exceptions 8a, 9b, and 10a	Revised "Consumers Energy" to "Big Rock Point."	Editorial – QPD specific to BRP.
75	Appendix A, Part 2, Exception 10b	Revised "Consumers Energy" to "Big Rock Point" and "plant" to "site."	Editorial.
76	Appendix A, Part 2, Exception 11a	Revised "Qualification of plant personnel who are involved with testing associated with plant operation is provided in specific plant specifications." To: "Qualification of personnel who are involved with testing associated with ISFSI operation is provided in specific procedures."	Revision from plant to ISFSI and generic "personnel" rather than "plant personnel" is editorial. Site QPD

**Attachment 3
JUSTIFICATION FOR CHANGES
Revision 22
Quality Program Description for Big Rock Point**

#	QPD SECTION	REVISION	JUSTIFICATION OF NO REDUCTION IN COMMITMENT
			implementation (Administrative) procedures specify site personnel qualifications.
77	Appendix A, Part 2, Exceptions 12a, 12b, and 12c	Revised "Consumers Energy" to "Big Rock Point."	Editorial.
78	Appendix A, Part 2, Exception 13a	Revised "plant" to "site." Revised "applicable qualification criteria of the Technical Specifications" to "... applicable qualification criteria of the procedures."	Editorial. Site QPD implementation (Administrative) procedures specify site personnel qualifications.
79	Appendix A, Part 2, Exceptions 13c, 14c, 15a, 16c, 16d, and 17a	Revised "Consumers Energy" to "Big Rock Point." Exception 16d, also revised "... the Company's ongoing receipt inspection..." to "... ongoing receipt inspection..."	Editorial. 16d: Other's programs must meet ANSI N45.2.23, as evaluated in the Approved Suppliers lists. Reference change to Section 1.1 paragraph 1 of the QPD.
80	Appendix A, Part 2, Exceptions 17g and 18a	Revised "Consumers Energy" to "Big Rock Point"	Editorial.
81	Appendix A, Part 2, exceptions 19a,	Deleted these exceptions. They refer to Regulatory Guides to which Big Rock Point is no longer committed (See list in Appendix A, Part 1).	Editorial.

**Attachment 3
JUSTIFICATION FOR CHANGES
Revision 22
Quality Program Description for Big Rock Point**

#	QPD SECTION	REVISION	JUSTIFICATION OF NO REDUCTION IN COMMITMENT
	20a, 21a, and 21b		
82	Appendix A, Part 2, Exception 22	Re-numbered to 19 due to deleted exceptions.	Editorial.
83	Appendix A, Part 2, NEW Exception 20	Added NEW exception 20, "The individual responsible for radiation protection functions shall meet the minimum requirements of Regulatory Guide 1.8, September 1975. As applied to this specification, "equivalent," as used in Regulatory Guide 1.8 for the bachelor's degree requirement, may be met with four years of any one or combination of the following: (a) formal training in science engineering or (b) operational or technical experience and training in nuclear power."	Consistent with DTS 6.3 footnote.
84	Appendix B, B.1	Defined "matters important to nuclear safety" by removing the term and replacing it with, "...matters of administrative controls and quality assurance associated with safety-related activities and/or important-to-safety structures, systems, or components. The Safety Reviewer ensures activities do not require U.S. Nuclear Regulatory Commission approval pursuant to 10 CFR 50.59 or 10 CFR 72.48 prior to implementation."	Administrative Revision. Reference 64 FR 53582 (Federal Register notice of 10/4/1999). This revision to 10 CFR 50.59 (and 10 CFR 72.48) deleted the term "unreviewed safety question (USQ)." "Nuclear Safety" are those items (SSCs or activities) that have to potential to result in an USQ should a change be implemented to the SSC or activity. The purpose of the use of the

**Attachment 3
JUSTIFICATION FOR CHANGES
Revision 22
Quality Program Description for Big Rock Point**

#	QPD SECTION	REVISION	JUSTIFICATION OF NO REDUCTION IN COMMITMENT
			<p>term "nuclear safety" was to specify those activities/SSC's to which the QPD apply. And for which secondary review is required. This section formerly defined the function of the "Plant (Safety) Review Committee."</p> <p>Big Rock Point Procedure 34A-05, specifies a screening process to ensure the activity being performed (procedure revision, modification, test, proposed License or CoC amendment) is reviewed against the QPD, License Conditions, or Part 72 CoC conditions to ensure no "USQ" results and that proper secondary "Safety Review" is performed.</p> <p>Review of reportable events is part of the Condition Report process, which requires secondary review (SGM and other qualified Safety Reviewer.)</p>

**Attachment 3
JUSTIFICATION FOR CHANGES
Revision 22
Quality Program Description for Big Rock Point**

#	QPD SECTION	REVISION	JUSTIFICATION OF NO REDUCTION IN COMMITMENT
85	Appendix B, B6	<p>Revised from:</p> <p>"Safety Reviewers shall be responsible for nuclear safety review of:</p> <ul style="list-style-type: none"> a. All procedures and programs specified by the Technical Specifications and changes thereto, and any other procedure or changes thereto as determined by the Site General Manager to affect nuclear safety; all proposed tests or experiments that affect nuclear safety; and all proposed changes or modifications to the ISFSI that affect nuclear safety. b. All proposed changes to the Operating License, the ISFSI License, Technical Specifications, and the Spent Fuel Storage System Certificate of Compliance. c. Results of investigations of all violations of the Technical Specifications (a report shall be prepared covering evaluation and recommendations to prevent recurrence and be forwarded to the Vice President, NFHO, the Quality Assurance Lead, and the ISRC.) d. ISFSI operations to detect potential safety hazards. e. Reports of special reviews and investigations as requested by the Site General Manager, the Quality Assurance Lead, or ISRC. f. Site Emergency Plan and implementing procedures. g. Reportable events defined by 10 CFR 50.72, 50.73, 71.95, 72.74, and 72.75. h. Review of any accidental, unplanned or uncontrolled radioactive release including the preparation of reports covering evaluation, recommendations and disposition of the corrective action to prevent recurrence and the forwarding of these reports to the Site General Manager, the Quality Assurance Lead, and the ISRC." <p>To:</p> <p>"Safety Reviewers shall be responsible for review of:</p> <ul style="list-style-type: none"> a. All procedures and programs specified by the Quality Program Description, Section 5.0, Instructions, Procedures, and Drawings, and changes thereto. b. All procedures and programs specified by the Quality Program Description 	<p>See justification for revision of Section Appendix B, B1, above.</p> <p>Procedures or programs in the QPD or activities affecting the License Conditions, or CoC are screened in the Safety Review process. (And now include Site Emergency Plan).</p> <p>Reportable events encompass former B.6.e, and B.6.h. ISFSI operations to detect potential safety hazards are documented in the Corrective Action process.</p>

**Attachment 3
JUSTIFICATION FOR CHANGES
Revision 22
Quality Program Description for Big Rock Point**

#	QPD SECTION	REVISION	JUSTIFICATION OF NO REDUCTION IN COMMITMENT
		<p>Appendix F, Radiation Protection Program and Reports, and changes thereto.</p> <ul style="list-style-type: none"> c. Any other procedures or changes thereto, as determined by the Site General Manager. d. All proposed changes, tests or experiments, or modifications to Q-Listed Structures, Systems, or Components. e. All proposed changes to the Operating License Conditions or the Spent Fuel Storage System Certificate of Compliance. f. Reportable events defined by 10 CFR 50.72, 50.73, 71.95, 72.74, and 72.75. g. Reports or special reviews and investigations as requested by the Site General Manager, the Quality Assurance Lead, or ISRC." 	
86	Appendix B, B.7	Revised reference to re-numbered items in section 6.B.	Editorial.
87	Appendix C, Exceptions	Revised exceptions to match re-numbered and deleted 2x (replaced with 2b, which is equivalent).	Editorial.
88	Appendix C, C2.	Defined the Quorum of ISRC as "Chairman and at least one member appointed by the Senior Vice President – NFHO."	Editorial. Reference NRC SER of 10/28/2003 – revision 21 of the BRP QPD. This number is consistent with the number specified in section C4.2.
89	Appendix C, C4.1.b	Revised ISRC review of activities that require prior NRC approval to "prior to submittal" rather than "prior to implementation."	Open item from ISRC comments of July 2005. Also consistent with QPD Appendix A, Part 2, Exception 2d.
90	Appendix C, C4.1.c	Deleted "Defueled Technical Specifications and inserted "conditions or Cask Storage System Certificate of Compliance" after "Operating License."	Consistent with changes in section 2.2.6 and 2.2.7.

**Attachment 3
JUSTIFICATION FOR CHANGES
Revision 22
Quality Program Description for Big Rock Point**

#	QPD SECTION	REVISION	JUSTIFICATION OF NO REDUCTION IN COMMITMENT
91	Appendix C, C4.1.d	<p>Revised: "Violations, deviations and reportable events requiring written notification to the NRC within 24 hours or having nuclear safety significance, such as:</p> <ol style="list-style-type: none"> (1) Violations of applicable codes, regulations, orders, Technical Specifications, license requirements, Cask Storage System Certificate of Compliance, or of internal procedures or instructions requiring written notification to the NRC within 24 hours or having nuclear safety significance. (2) Significant operating abnormalities or deviations from normal and expected performance of ISFSI equipment that affect nuclear safety. (3) Events requiring written notification to the NRC within 24 hours or having nuclear safety significance." <p>To: "Violations, deviations and reportable events requiring written notification to the NRC within 24 hours of safely-related activities and/or important-to-safety systems, structures, or components, such as:</p> <ol style="list-style-type: none"> (1) Violations of applicable codes, regulations, orders, license requirements, Cask Storage System Certificate of Compliance, or of internal procedures or instructions that are safety-related activities and/or important-to-safety systems, structures, or components. (2) Significant operating abnormalities, events or deviations from normal and expected performance of ISFSI equipment that affect safety-related activities and/or important-to-safety systems, structures, or components." 	<p>Consistent with changes in Appendix C to eliminate use of the term "nuclear safety." Affect nuclear safety is equivalent to "safety-related activities and/or important-to-safety SSCs." These are defined in BRP Quality List and in Section 5.0 and Appendix F of the QPD.</p>
92	Appendix D, D1	Revised QA Organization to QA Lead and deleted "under the cognizance of the ISRC.	<p>Editorial, consistent with previous QPD changes.</p> <p>All QA Lead audit results are reviewed by ISRC (C4.1.e).</p>

**Attachment 3
JUSTIFICATION FOR CHANGES
Revision 22
Quality Program Description for Big Rock Point**

#	QPD SECTION	REVISION	JUSTIFICATION OF NO REDUCTION IN COMMITMENT
93	Appendix D, D1a	Revised "plant" to "site" and "the Technical Specifications, applicable license conditions..." to "operating license."	Editorial, consistent with previous QPD changes.
94	Appendix D, D1.c	<p>Revised from: "The performance of activities required by the QPD for Nuclear Power Plants (CPC-2A) to met the criteria of 10 CFR 50, Appendix B at least once per 24 months."</p> <p>To: "The performance of activities and administrative controls required by the QPD and the Fire Protection Plan at least once per 24 months."</p>	<p>Editorial – revision of the title of the QPD.</p> <p>Included the Fire Protection Plan (due to deletion below). ISFSI Fire Program SSC's are passive. Plan and administrative fire controls (per 10 CFR 72.212 evaluation) are better inspected as part of procedure/administrative audits.</p>
95	Appendix D, D1.g through j	<p>Revise from:</p> <ul style="list-style-type: none"> "g. The plant Fire Protection Program and implementing procedures at least once per 24 months. h. Radiological environmental monitoring program and the results thereof at least once per 24 months. i. The OFFSITE DOSE CALCULATION MANUAL and implementing procedures at least once per 24 months. j. The PROCESS CONTROL PROGRAM and implementing procedures for processing and packaging of radioactive wastes at least once per 24 months." 	<p>Fire Protection program is included in D.1.e. (Fire SSCs are passive components; fire load is administratively controlled).</p> <p>The radiological environmental monitoring program is included in the ODCM.</p> <p>Remaining radiation protection programs (ODCM and PCP) have been combined in one audit.</p>

**Attachment 3
JUSTIFICATION FOR CHANGES
Revision 22
Quality Program Description for Big Rock Point**

#	QPD SECTION	REVISION	JUSTIFICATION OF NO REDUCTION IN COMMITMENT
		To: "g. The Radiation Protection Program, including the Offsite Dose Calculation Manual (ODCM) and the Process Control Manual and their implementing procedures at least once per 24 months."	
96	Appendix E, E2.d and E2.e	Replaced "Plant Technical Specifications" with "Big Rock Point Operating License or this QPD."	TS are a condition of the operating license. Reflects addition of New Appendix F.
97	Appendix E, E3.a	Spelled-out "BRP."	Editorial.
98	Appendix E, E3.f	Deleted "Plant Technical Specifications" and replaced it with, "the Operating License or Cask Storage System Certificate of Compliance."	TS are a condition of the operating license. Consistent with changes in sections 2.2.6 and 2.2.7.
99	Appendix E, E3.l	Replaced "plant" with "site."	

Attachment 4
Big Rock Point Plant
Dockets 50-155 and 72-043

February 28, 2006

Copy of the Complete Quality Program, Revision 22

86 Pages

QUALITY PROGRAM DESCRIPTION FOR BIG ROCK POINT

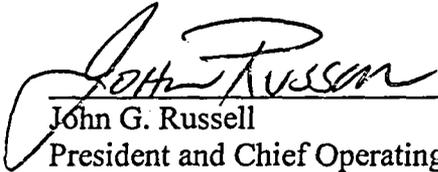
**SUBJECT: STATEMENT OF RESPONSIBILITY AND AUTHORITY REGARDING
THE QUALITY PROGRAM FOR BIG ROCK POINT**

As President and Chief Operating Officer of Consumers Energy, I have the ultimate management authority for the Big Rock Point quality program. The quality program for Big Rock Point complies with the quality assurance requirements contained in Appendix B of 10 CFR 50, "Quality Assurance Criteria for Nuclear Power Plants and Fuel Reprocessing Plants. The quality program responds to the additional guidance contained in ANSI N18.7, and to the ANSI N45.2 series of standards and corresponding Regulatory Guides within the context of applicability imposed by ANSI N18.7. In addition to activities governed by 10 CFR 50 Appendix B, this quality program applies to activities governed by 10 CFR 71 Subpart H "Quality Assurance for Packaging and Transportation of Radioactive Waste", and 10 CFR 72 Subpart G "Quality Assurance for Independent Storage of Spent Nuclear Fuel and High-Level Radioactive Waste".

Because the Big Rock Point reactor has been shipped offsite for disposal, and fuel and high-level radioactive waste are stored only at the Independent Spent Fuel Storage Installation (ISFSI), application of quality program requirements to the in-plant structures, systems and components formerly associated with operating functions will no longer be required. Quality Program requirements will be applied to structures, systems and components at the ISFSI that are required for safe storage of spent nuclear fuel and high-level radioactive waste. Quality program requirements will also be applied to selected activities and programs as long as they are required for decommissioning or operation of the ISFSI.

I have delegated responsibility for establishing, maintaining and implementing the Quality Program Description to the Senior Vice President, Nuclear, Fossil and Hydro Operations. This Quality Program Description describes the Consumers Energy and Big Rock Point organizations responsible for implementation.

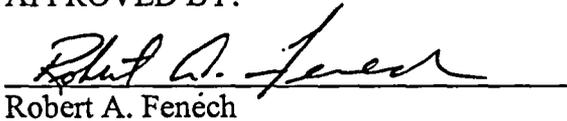
The quality program contains mandatory requirements which must be implemented and enforced by all responsible organizations and individuals.



John G. Russell
President and Chief Operating Officer, Consumers Energy

2-23-06
Date

APPROVED BY:



Robert A. Fenéch
Senior Vice President, Nuclear, Fossil, and
Hydro Operations, Consumers Energy

2-20-06
Date

QUALITY PROGRAM DESCRIPTION FOR BIG ROCK POINT

CONTENTS

<u>Section</u>	<u>Title</u>	<u>Page</u>
	Statement of Responsibility and Authority and Approval	1
	Contents	2
1.0	ORGANIZATION.....	4
2.0	QUALITY PROGRAM.....	11
3.0	DESIGN CONTROL.....	17
4.0	PROCUREMENT DOCUMENT CONTROL.....	21
5.0	INSTRUCTIONS, PROCEDURES AND DRAWINGS.....	23
6.0	DOCUMENT CONTROL.....	26
7.0	CONTROL OF PURCHASED MATERIAL, EQUIPMENT AND SERVICES.....	28
8.0	IDENTIFICATION AND CONTROL OF ITEMS.....	31
9.0	CONTROL OF SPECIAL PROCESSES.....	32
10.0	INSPECTION.....	33
11.0	TEST CONTROL.....	36
12.0	CONTROL OF MEASURING AND TEST EQUIPMENT.....	38
13.0	HANDLING, STORAGE AND SHIPPING.....	40
14.0	INSPECTION, TEST AND OPERATING STATUS.....	41
15.0	NONCONFORMING MATERIALS, PARTS OR COMPONENTS.....	42
16.0	CORRECTIVE ACTION.....	44
17.0	QUALITY RECORDS.....	45
18.0	AUDITS.....	47

QUALITY PROGRAM DESCRIPTION FOR BIG ROCK POINT

APPENDIX A, PART 1, REGULATORY GUIDE AND ANSI STANDARD
COMMITMENTS 49

APPENDIX A, PART 2, BIG ROCK POINT EXCEPTIONS TO OPERATING PHASE
STANDARDS AND REGULATORY GUIDES 51

APPENDIX B, SAFETY REVIEW 77

APPENDIX C, INDEPENDENT SAFETY REVIEW COMMITTEE 79

APPENDIX D, AUDIT FREQUENCIES 82

APPENDIX E, RECORD RETENTION 84

FIGURE

1 Consumers Energy Organization Chart for Big Rock Point Quality Program.....10

QUALITY PROGRAM DESCRIPTION FOR BIG ROCK POINT

1.0 ORGANIZATION

1.1 REQUIREMENTS

Consumers Energy is responsible for establishing and implementing the quality program, as described herein, for Big Rock Point (BRP) and its Independent Spent Fuel Storage Installation (ISFSI). Consumers Energy may delegate the authority for development and maintenance of the quality program and execution of certain quality assurance functions to others who are independent and qualified, such as contractors, agents or consultants. Quality assurance functions performed by such delegates may be completed under the requirements of either this quality program or the delegates' comparable, NRC approved, quality program. Although authority for development and execution of some parts of the program may be delegated to others, Consumers Energy retains overall responsibility.

This section of the quality program identifies the responsibilities of Consumers Energy and other organizations for activities: 1) affecting radiological safety; 2) related to packaging and transportation of radioactive materials; and 3) affecting safe operation of the ISFSI. It addresses responsibilities for attaining quality objectives; for establishing and maintaining the quality program; and for assessing the performance of activities affecting quality.

Quality assessment functions, such as audits, surveillances and supplier evaluations are performed by personnel who report to the Quality Assurance Lead or by members of other organizations selected by the Quality Assurance Lead. Audit frequency is outlined in Appendix D of this quality program. The reporting level of the Quality Assurance Lead affords sufficient authority and organizational freedom, including sufficient independence from the cost and schedule impacts of quality assurance actions, to enable the Quality Assurance Lead to identify quality problems; to initiate, recommend, or provide solutions; and to verify implementation of solutions.

The following exceptions/interpretations in Appendix A, Part 2, are relevant to implementation of the requirements of this section of the quality program:

<u>Paragraph</u>	<u>Exceptions/Interpretations</u>
1.2.1	2a
1.2.2	2, 2b, 2c, 2t, 18a, 19, 20

QUALITY PROGRAM DESCRIPTION FOR BIG ROCK POINT

1.2 IMPLEMENTATION

1.2.1 Source of Authority

The President and Chief Operating Officer, Consumers Energy (see Figure 1, Company Organization Chart) is responsible for safe decommissioning of Big Rock Point and safe operation of the ISFSI. Authority and responsibility for establishing and implementing the quality program are delegated to the Senior Vice President - Nuclear, Fossil, and Hydro Operations (NFHO). This delegation is formalized in a STATEMENT OF RESPONSIBILITY AND AUTHORITY signed by the President and Chief Operating Officer, Consumers Energy. Other quality-related functions are provided by other organizations as described herein.

1.2.2 Responsibility for Attaining Quality Objectives at Big Rock Point

a. Senior Vice President, Nuclear, Fossil and Hydro Operations (NFHO)

The Senior Vice President, NFHO is responsible to the President and Chief Operating Officer, Consumers Energy, for decommissioning BRP and operation of the ISFSI. Managers who report to the Senior Vice President, NFHO have responsibilities as indicated for directing the performance of activities that affect safe decommissioning and ISFSI operation, and/or functions of structures, systems and components of the ISFSI that are important to safety in accordance with quality program requirements. The Independent Safety Review Committee (ISRC) reports to the Senior Vice President, NFHO. ISRC function, composition, responsibility, and authority are described in Appendix C of this quality program.

b. Big Rock Point Site General Manager

The BRP Site General Manager (see Figure 1) is responsible to the Senior Vice President NFHO for decommissioning BRP and operation and maintenance of the ISFSI in a manner that achieves compliance with licenses, applicable regulations and the quality program. The Site General Manager delegates to appropriate staff personnel in his organization responsibility for carrying out applicable controls required by the quality program. Quality program activities performed on the authority of the Site General Manager include:

- (1) Preparation, review, and approval of methods to identify ISFSI structures, systems and components, and ISFSI/site activities to which this quality program apply, as described in Section 2.0, QUALITY PROGRAM.
- (2) Establishing, implementing and documenting the appropriate training of site personnel, including quality program indoctrination and training.

QUALITY PROGRAM DESCRIPTION FOR BIG ROCK POINT

- (3) Accomplishing site licensing activities including maintaining licensing documents up-to-date, interfacing with the NRC, accomplishing and/or tracking licensing commitments and coordinating internal action on NRC bulletins, generic letters, etc., implementing the special nuclear material control program, and performing reviews specified in Appendix B, SAFETY REVIEW.

The Site General Manager shall provide written notification within 24 hours to the Senior Vice President, NFHO, the Quality Assurance Lead, and ISRC of any disagreement between the recommendation of a Safety Reviewer and the decision of the Site General Manager; however the Site General Manager has authority for resolution of such disagreements.

- (4) Functioning as the ISFSI design and configuration control authority for compliance of ISFSI modifications and design changes to existing ISFSI design criteria.
- (5) Performing the engineering, construction, inspection and testing associated with ISFSI modification projects.
- (6) Procurement, including preparation, reviews and approval of purchase requests for spare parts, replacement items, consumables, materials, items and services, and submittal of purchase requests to the purchasing organization. Planning and execution of vendor source surveillance or inspection, receiving inspection, and review of supplier quality-related documentation.
- (7) Preparation, review, approval and control of required procedures and instructions.
- (8) Developing, maintaining and implementing security, fire protection and emergency plans.
- (9) Providing for handling, storage, protection, and preservation of identification of purchased materials and items awaiting disposition after removal from service.
- (10) Qualification of appropriate site personnel, including certification of inspection personnel.
- (11) Performing necessary surveillance testing.
- (12) Inspection of ISFSI maintenance and testing, fuel transfer operations, activities associated with packaging and transportation of radioactive material, and activities required to achieve compliance with 10 CFR 20.

QUALITY PROGRAM DESCRIPTION FOR BIG ROCK POINT

- (13) Control, calibration, and use of Measuring and Test Equipment (M&TE) and installed instrumentation.
- (14) Maintaining equipment status control.
- (15) Stopping unsatisfactory work to control further processing, delivery or installation of nonconforming materials or items.
- (16) Assuring that nonconforming items are identified, segregated and dispositioned.
- (17) Implementing the Corrective Action process.
- (18) Preparation, protection and retention of quality records.
- (19) Maintenance of the Quality Program Description for Big Rock Point

c. Responsibilities of the Quality Assurance Lead

The Quality Assurance Lead, (see Figure 1) is directly responsible to the Senior Vice President, NFHO, for:

- (1) Assessment of the effectiveness of the Big Rock Point quality program by performing Audits as specified in Appendix D of this quality program.
- (2) Supplier surveys and evaluation including review/approval of supplier QA programs, and maintenance of the Qualified Suppliers List.
- (3) Preparation, review, approval and implementation of departmental procedures governing nuclear assessment activities.
- (4) Assuring that assessments are done by personnel not directly responsible for the work being performed.
- (5) Assessment of on-site and off-site programs and activities including follow-up on corrective action for audit findings.
- (6) Review of performance trends associated with site activities including corrective actions.
- (7) Analysis of new and/or changed regulatory direction, codes and standards to determine their effect on the quality program.
- (8) Reporting audit findings relative to follow-up on corrective actions and the effectiveness of the quality program to Consumers Energy management.

QUALITY PROGRAM DESCRIPTION FOR BIG ROCK POINT

In fulfilling the above responsibilities, the Quality Assurance Lead may use a combination of Consumers Energy employees and others who are qualified and independent, including contractors, agents or consultants. The Quality Assurance Lead is provided with "Stop Work" authority whereby he can suspend any quality related activity or process that may, in his opinion, adversely affect public safety, the safe decommissioning of BRP, or safe fuel storage operations. When a Stop Work Order that would result in suspension of in-process activities related to spent fuel transfer operations or storage operations is given, the persons responsible for the operation in question shall ensure stored fuel is in a safe condition before stopping work.

The Quality Assurance Lead has no other duties or responsibilities that would prevent his attention to quality program matters, is sufficiently free from schedule and cost pressures to give appropriate weight to quality considerations in his decisions and recommendations, and has direct access to high enough levels of management to obtain resolution of quality problems.

d. Responsibilities of the Radiation Protection Manager

The Radiation Protection Manager is responsible for: radiation protection, control of radioactive materials (except special nuclear materials), and the ALARA program. His duties include:

- (1) Administration of radioactive waste, storage, packaging, shipping, and disposal activities.
- (2) Issuing a Stop Work Order upon identifying the potential for excessive or unplanned radiation exposure or loss of contamination control.
- (3) Assisting and providing recommendations to maintain radiation parameters in accordance with licenses, permits and industry standards.
- (4) Accounting for radioactive materials on-site other than special nuclear material.
- (5) Packaging and transportation of radioactive materials.
- (6) Ensuring radiation protection programs and reports are prepared and controlled in accordance with the requirements of this quality program and the Defueled Technical Specifications.

If qualified, the Site General Manager may perform the function of the Radiation Protection Manager.

QUALITY PROGRAM DESCRIPTION FOR BIG ROCK POINT

The individual responsible for radiation protection functions shall meet the minimum requirements of Regulatory Guide 1.8, September 1975. As applied to this specification, "equivalent," as used in Regulatory Guide 1.8 for the bachelor's degree requirement, may be met with four years of any one or combination of the following: (a) formal training in science engineering or (b) operational or technical experience and training in nuclear power.

- e. Responsibility for Attaining Quality Objectives Outside Nuclear, Fossil, and Hydro Operations

Certain functions that constitute part of the quality program may be performed by Consumers Energy organizational units outside the Nuclear, Fossil and Hydro Operations Department. However, when off-site organizations perform quality activities in support of Big Rock Point, they do so under the provisions of this Quality Program Description for Big Rock Point, and the activities or services performed are subject to acceptance by the Site General Manager or designate.

Independent Safety Review Committee responsibilities, composition and function are described in Appendix C of this quality program.

QUALITY PROGRAM DESCRIPTION FOR BIG ROCK POINT

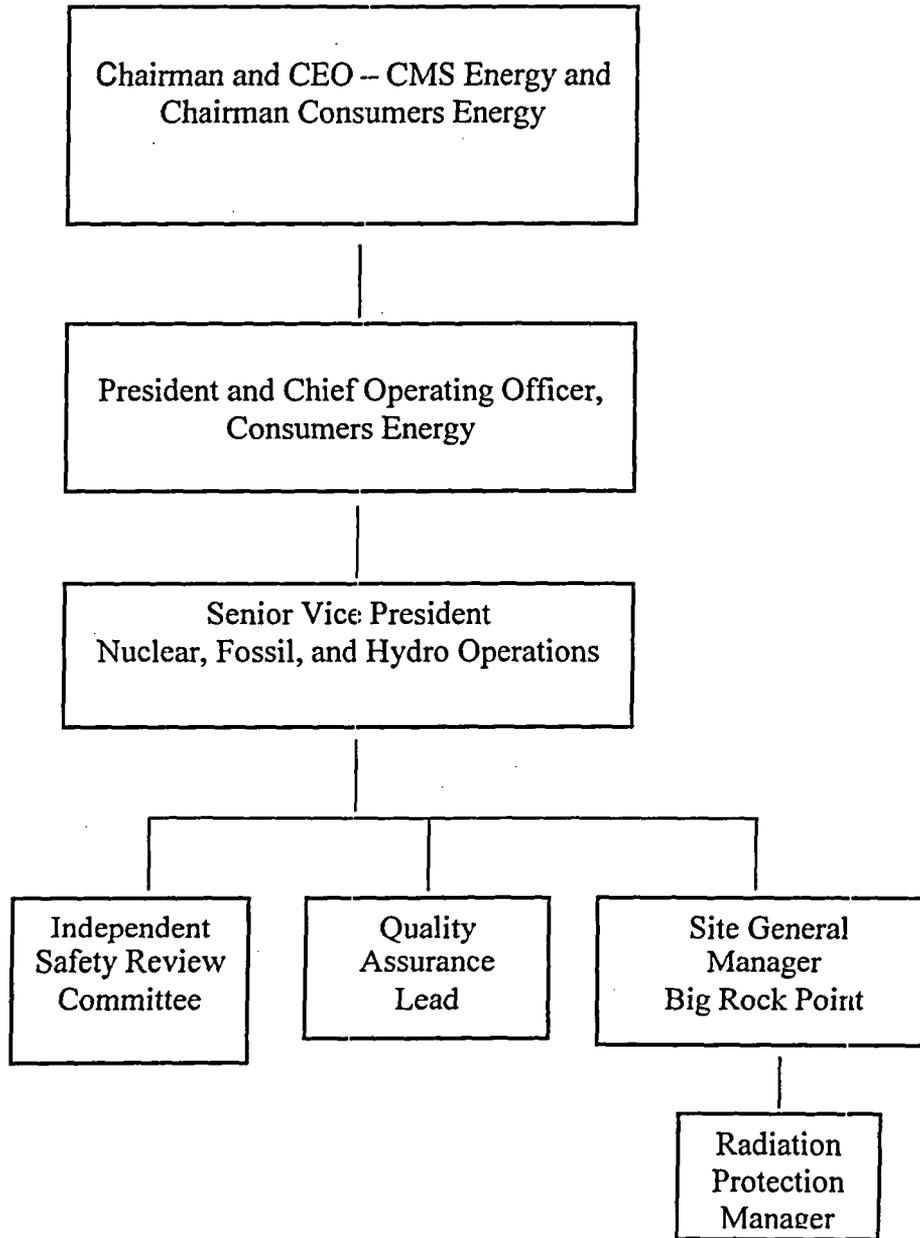


Figure 1 – Consumers Energy Organization for Big Rock Point Quality Program

QUALITY PROGRAM DESCRIPTION FOR BIG ROCK POINT

2.0 QUALITY PROGRAM

2.1 REQUIREMENTS

Policies that define and establish the quality program for Big Rock Point are stated in the individual sections of this document. The program is implemented through procedures and instructions responsive to provisions of the quality program and will be carried out for the life of BRP and its associated ISFSI. Site/ISFSI life is defined as the period covered by a valid license under 10 CFR 50 and/or 10 CFR 72.

Quality controls apply to activities affecting the quality of structures, systems and components, to an extent based on the importance of those structures, systems, or components to safety. Such activities are performed under suitably controlled conditions, including the use of appropriate equipment, maintenance of proper environmental conditions, assignment of qualified personnel and assurance that all applicable prerequisites have been met.

Quality program status, scope, adequacy and compliance with 10 CFR 50, Appendix B, 10 CFR 71 Subpart H, and 10 CFR 72 Subpart G are regularly reviewed by Consumers Energy Management through reports, meetings and review of audit results.

The following exceptions/interpretations in Appendix A, Part 2, are relevant to implementation of the requirements of this section of the quality program:

<u>Paragraph</u>	<u>Exceptions/Interpretations</u>
2.2.6	1
2.2.9	2j, 4a, 5a, 5b, 6a, 7b, 10a, 11a, 12a, 12b, 12c, 12d, 13a, 17e
2.2.10	2e, 2f

2.2 IMPLEMENTATION

- 2.2.1 The President and Chief Operating Officer, Consumers Energy, has stated in a formal STATEMENT OF RESPONSIBILITY AND AUTHORITY, signed by him, that it is corporate policy to comply with the provisions of applicable legislation and regulations pertaining to quality assurance as defined by 10 CFR 50, Appendix B, 10 CFR 71 Subpart H, and 10 CFR 72 Subpart G, as they apply to decommissioning and operation of the ISFSI. The statement makes this quality program and the associated implementing procedures and instructions mandatory and requires compliance by all responsible organizations and individuals. It identifies the management positions in the Company vested with responsibility and authority for implementing the quality program and assuring its effectiveness.
- 2.2.2 The quality program at Big Rock Point consists of controls exercised by organizations responsible for attaining quality objectives and by organizations responsible for quality assessment functions (see Section 1.0, ORGANIZATION).

QUALITY PROGRAM DESCRIPTION FOR BIG ROCK POINT

2.2.3 The effective dates and applicability of this quality program are as follows:

a. Effective Dates

- (1) For Big Rock Point, the quality program became effective on April 1, 1982, with full implementation on January 1, 1983.
- (2) By letter dated February 1, 2002, the Nuclear Regulatory Commission notified Consumers Energy Company that NRC had approved the Big Rock Point Plant quality assurance program for radioactive material packages. The NRC indicated that the QA Program approval contained in their February 1, 2002 letter satisfied the approval requirements of 10 CFR 71.101(c).
- (3) In accordance with 10 CFR 72.4, the NRC Spent Fuel Project Office was notified by letter dated February 17, 2000 of Consumers Energy's intent to apply this quality program to the ISFSI and spent fuel storage cask activities as required by 10 CFR Part 72.140.
- (4) The quality program described in this Quality Program Description for Big Rock Point is intended to apply for the life of BRP U.S. Nuclear Regulatory Commission license and its associated ISFSI.

b. Applicability

This quality program applies to those structures, systems and components (SSCs), and programs or activities that are Important to Safety, as described in 10 CFR 72, and assure one or more of the following functions:

- a. To maintain the conditions required to store spent fuel, high-level radioactive waste, or reactor-related waste safely;
- b. To prevent damage to the spent fuel, high-level radioactive waste, reactor-related waste container during handling and storage; or
- c. To provide reasonable assurance that spent fuel, high-level radioactive waste, or reactor-related waste can be received, handled, packaged, stored and retrieved without undue risk to the health and safety of the public.

Big Rock Point Volume 35A-11, Quality List, identifies ISFSI structures, systems, and components to which quality program elements are applicable. Applicable elements of the quality program are applied to the emergency, security, and fire protection and radiation protection plans and programs for site activities and ISFSI operation.

QUALITY PROGRAM DESCRIPTION FOR BIG ROCK POINT

Big Rock Point Volume 35A-11, Quality List, also applies to activities performed at BRP pursuant to 10 CFR 71 Subpart H, Quality Assurance for Packaging and Transportation of Radioactive Waste.

- 2.2.4 The Quality Program Description for Big Rock Point organized around the 18 criteria of 10 CFR 50, Appendix B, states Big Rock Point requirements for each of the criteria and describes how the controls pertinent to each are carried out. Any changes made to this quality program that do not reduce the commitments previously accepted by the NRC must be submitted to the NRC as specified by 10 CFR 50.71.e. Any changes made to this quality program that do reduce the commitments previously accepted by the NRC must be submitted to the NRC and receive NRC approval prior to implementation in accordance with the requirements of 10 CFR 50.54(a)(4).

Appendix A, Part 1, to this quality program lists the ANSI Standards and Regulatory Guides to which Consumers Energy commits. Appendix A, Part 2, also describes necessary exceptions and clarifications to the requirements of those documents.

The program described in this quality program will not be changed in any way that would prevent it from meeting the criteria of 10 CFR 50, Appendix B.

- 2.2.5 Documents used for implementing the provisions of the quality program include the following:
- a. Administrative procedures specify the standard methods of accomplishing quality program activities. Because the quality program is an integral part of these activities, the methods for implementing quality program controls are integrated into these documents.
 - b. When contractors perform work under their own quality assurance programs, these programs are reviewed for compliance with the requirements of 10 CFR 50, Appendix B, 10 CFR 71 Subpart H, and 10 CFR 72 Subpart G, as applicable; and the contract, and are approved by Consumers Energy prior to the start of work.
- 2.2.6 Provisions of the quality program for Big Rock Point apply to activities affecting the quality of structures, systems, components and related consumables that are within the scope of the program. Big Rock Point uses the following criteria in the selection of structures, systems, components, and activities to which the quality program is applied. Application of the quality program assures that such structures, systems, components, and activities are monitored and controlled in a manner sufficient to provide reasonable assurance that they are capable of fulfilling their intended functions.

QUALITY PROGRAM DESCRIPTION FOR BIG ROCK POINT

- a. The quality program shall be applied to structures, systems, components, and activities selected based on evaluations that use quality classification criteria of the FuelSolutions™ Storage System Final Safety Analysis Report and FuelSolutions™ W74 Canister Final Safety Analysis Report (SARs) (documents WSNF-220 and WSNF-223) to determine those items and activities whose function is important to safe operation of the ISFSI. These items and activities are commonly referred to as “Important to Safety (ITS).”
- b. The quality program shall be applied to radiation protection requirements that are required to meet applicable regulations.
- c. The quality program shall be applied to activities related to packaging and transportation of radioactive material.

Application of these criteria in performing an evaluation of an activity or an item's function results in its classification and identification as being either subject or not subject to the quality program. Identification is via the “Quality-List.” Identification is maintained current as conditions change. This information is available for inquiry by individuals involved in site activities. The extent to which controls specified in the Quality Program are applied is determined for each item considering its relative importance to the above criteria. Such determinations are based on information in such documents as the Updated Final Hazards Summary Report (UFHSR), and the Storage System and Canister SARs.

2.2.7 Activities affecting quality of items within the scope of this program are accomplished under controlled conditions. Preparations for such activities include confirmation that prerequisites have been met, such as:

- a. Assigned personnel are qualified.
- b. Work has been planned to the proper revisions of applicable engineering and/or License Conditions or Cask Storage System Certificate of Compliance.
- c. Specified equipment and/or tools, if any, are on hand to be used.
- d. Materials and items are in an acceptable status.
- e. Systems, components, or structures on which work is to be performed are in the proper condition for the task.
- f. Authorized current instructions/procedures for the work are available for use.
- g. Items and facilities that could be damaged by the work have been protected, as required.

QUALITY PROGRAM DESCRIPTION FOR BIG ROCK POINT

- h. Provisions have been made for special controls, processes, tests and verification methods.
- 2.2.8 Development, control, and use of computer programs affecting design and operation of the ISFSI and activities important to quality are subject to quality program design control.
- 2.2.9 Responsibility and authority for planning and implementing indoctrination and training are designated in Section 1.0, ORGANIZATION.
- a. The training and indoctrination program provides for ongoing training and periodic refamiliarization with this quality program.
 - b. Personnel who perform inspection and examination functions are qualified in accordance with requirements of Regulatory Guide 1.58, SNT TC-1A, or the ASME Code, or Section 10.2.3 of this quality program, as applicable.
 - c. Personnel who lead audits are qualified in accordance with Regulatory Guide 1.146. Others are either qualified to ANSI N45.2.23 or have detailed expertise in the area being audited.
 - d. Personnel assigned duties such as special cleaning processes, welding, etc., are qualified in accordance with applicable codes, standards and regulatory guides.
 - e. The training/qualification program for personnel leading audits includes provisions for retraining, re-evaluation and recertification to ensure that proficiency is maintained.
 - f. Training and qualification records including documentation of objectives, content of program, attendees and dates of attendance are maintained at least as long as the personnel involved are performing activities to which the training/qualification is relevant.
 - g. Personnel responsible for performing activities that affect quality are instructed as to the requirements identified in applicable quality related manuals, instructions and procedures.
- 2.2.10 Status and adequacy of the quality program are regularly assessed by the Quality Assurance Lead. The following activities constitute formal elements of that assessment:
- a. Audit reports, including follow-up on corrective action accomplishment and effectiveness, are distributed to appropriate levels of management (see Section 18.0, AUDITS).

QUALITY PROGRAM DESCRIPTION FOR BIG ROCK POINT

- b. The Independent Safety Review Committee assesses nuclear safety performance as described in Appendix C. Conclusions and recommendations are reported to the Senior Vice President, NFHO.
- c. Corrective actions in response to recommendations are tracked in the corrective action tracking system (see Section 16.0, CORRECTIVE ACTION).

QUALITY PROGRAM DESCRIPTION FOR BIG ROCK POINT

3.0 DESIGN CONTROL

3.1 REQUIREMENTS

Modifications to structures, systems and components to which this program applies according to Section 2.0, QUALITY PROGRAM, are accomplished in accordance with approved designs. Activities to develop such designs are controlled. Depending on the type of modification, these activities include design and field engineering; the performance of physics, seismic, stress, thermal, hydraulic, and radiation analyses; UFHSR and storage system and canister SAR accident analyses; the development and control of associated computer programs; studies of material compatibility; accessibility for inspection and maintenance; and determination of quality standards. The controls apply to preparation and review of design documents, including the correct translation of applicable regulatory requirements and design bases into design, procurement and procedural documents.

The following exceptions/interpretations in Appendix A, Part 2, are relevant to implementation of the requirements of this section of the quality program:

<u>Paragraph</u>	<u>Exceptions/Interpretations</u>
3.1	9a, 13b
3.2.9	15a
3.2.10	13d

3.2 IMPLEMENTATION

3.2.1 Authority and responsibility for modification activities are described in Section 1.0, ORGANIZATION. This authority and responsibility includes the preparation, review, approval and verification of the following design documents: (a) Equipment descriptions in the storage system and canister SARs; (b) Design input and criteria; (c) Drawings and specifications; and (d) Engineering analyses and associated computer programs.

3.2.2 Errors and deficiencies in approved design documents or in design methods (such as computer codes) that could adversely affect structures, systems and components are documented. Action is taken to assure that the errors and deficiencies are corrected. Section 16.0 of this quality program describes Corrective Action requirements, responsibilities, and controls.

QUALITY PROGRAM DESCRIPTION FOR BIG ROCK POINT

- 3.2.3 Materials, parts and processes that are essential to functions that are important to safety are selected and specified, based on the requirements of applicable codes and standards or on known, successful use under similar conditions. This includes standard commercial materials, parts and processes. Alternatively, materials, parts and processes may be qualified for use through qualification testing (see Item 3.2.8). The adequacy of the selected materials, parts and processes is assured through the required design verifications or approvals.
- 3.2.4 Exceptions and waivers to or deviations from the engineering (quality) standards (i.e., the required dimensions, material properties, features and other characteristics specified for modifications) are required by procedure and by contract, when applicable, to be documented and controlled (see, also, Section 15 concerning the approval of "repair" or "use as is" dispositions of nonconformances).
- 3.2.5 When modifications involve design interfaces between internal or external design organizations or across technical disciplines, these interfaces are controlled. Procedures are used for the review, approval, release, distribution and revision of documents involving design interfaces to ensure that structures, systems and components are compatible geometrically, functionally and with processes and environment. Lines of communication are established for controlling the flow of needed design information across design interfaces, including changes to the information as work progresses. Decisions and problem resolutions involving design interfaces are made by the organization having responsibility for engineering direction of the design effort.
- 3.2.6 Checks are performed and documented to verify the dimensional accuracy and completeness of design drawings and specifications (i.e., the products of a design process).
- 3.2.7 Modification design document packages are reviewed to assure that the documents that they contain have been prepared, verified, reviewed and approved in accordance with Company procedures and that they contain the necessary quality requirements. These requirements include the inspection and test requirements, quantitative and/or qualitative acceptance criteria and the requirements for documenting inspection and test results.
- 3.2.8 The extent of and methods for design verification are documented. The extent of design verification performed is a function of the importance of the item to safety, design complexity, degree of standardization, the state-of-the-art and similarity with previously proven designs. Methods for design verification include evaluation of the applicability of standardized or previously proven designs, alternate calculations, qualification testing and design reviews. These methods may be used singly or in combination, depending on the needs for the design under consideration.

When design verification is done by evaluating standardized or previously proven designs, the applicability of such designs is confirmed. Any differences from the proven design are documented and evaluated for the intended application.

QUALITY PROGRAM DESCRIPTION FOR BIG ROCK POINT

Qualification testing of prototypes, components or features is used when the ability of an item to perform an essential function that is important to safety cannot otherwise be adequately substantiated. This testing is performed before site equipment installation where possible, but always before reliance upon the item to perform a function that is important to safety. Qualification testing is performed under conditions that simulate the most adverse design conditions, considering all relevant operating modes. Test requirements, procedures and results are documented. Results are evaluated to assure that test requirements have been satisfied. Modifications shown to be necessary through testing are made, and any necessary retesting or other verification is performed. Scaling laws are established and verified, when applicable. Test configurations are clearly documented.

Design reviews are performed by multi-organizational or interdisciplinary groups or by single individuals. Criteria are established to determine when a formal group review is required and when review by an individual is sufficient.

Unless otherwise stated, the verification of design addresses all information conveyed by the design document. When the verification is limited to certain areas or features, the scope or extent and any limitations on the verification are documented.

3.2.9 Persons representing applicable technical disciplines are assigned to perform design verifications. These persons are qualified by appropriate education or experience but are not directly responsible for the design. The designer's immediate supervisor may perform the verification, provided that:

- a. The supervisor is the only technically qualified individual available, and
- b. The supervisor has not specified a singular design approach, ruled out certain design considerations or established the design inputs for the particular design aspect being verified, and
- c. The supervisor's review is either:
 - (1) Approved in advance by the supervisor's management, with documentation of the approval included in the design package, or
 - (2) Controlled by a procedure that provides specific limitations regarding the types of design work that may or may not be verified by a designer's supervisor, and shall provide for clear documentation that the supervisor performed the design verification.

Independent audits by the Quality Assurance Lead cover the frequency, effectiveness, and technical adequacy of the use of supervisors as design verifiers to guard against abuse.

QUALITY PROGRAM DESCRIPTION FOR BIG ROCK POINT

- 3.2.10 When designs must be released for use before they have been fully completed or before they have been verified, the incomplete or unverified parts of the design and the hold point to which work may proceed are identified. This hold point occurs before the work becomes irreversible or before the item is relied on to perform a function that is important to safety. Justification for such early release is documented.
- 3.2.11 Computer codes used in design are appropriately documented, verified, certified for use and controlled. Their use is specified.
- 3.2.12 Changes to design output documents, including field changes, are controlled in a manner commensurate with that used for the original design. Such changes are evaluated for impact. Those that affect fit, form, or function are reviewed and approved by the same, or equivalent, organizations that approved the original design. Information on approved changes is transmitted to all affected organizations.

QUALITY PROGRAM DESCRIPTION FOR BIG ROCK POINT

4.0 PROCUREMENT DOCUMENT CONTROL

4.1 REQUIREMENTS

Procurement documents for structures, systems, components and services to which this Program applies according to Section 2.0, QUALITY PROGRAM, define the characteristics of item(s) to be procured, identify requirements of applicable regulatory and industry codes and standards and specify supplier quality assurance program requirements to the extent necessary to assure adequate quality.

The following exceptions/interpretations in Appendix A, Part 2, are relevant to implementation of the requirements of this section of the quality program:

<u>Paragraph</u>	<u>Exceptions/Interpretations</u>
4.2.1	17c, 17d
4.2.3	2l, 17a, 17b
4.2.5	17d

4.2 IMPLEMENTATION

4.2.1 Responsibilities and authorities for procurement planning and for preparation, review and approval of procurement documents are described in Section 1.0, ORGANIZATION.

Procurement request packages are reviewed and approved. Review includes verification that the necessary quality requirements are specified.

Bids are evaluated by an individual or organization having appropriate knowledge related to the item or service being procured.

4.2.2 Supplier selection is described in Section 7.0, CONTROL OF PURCHASED MATERIALS, EQUIPMENT AND SERVICES.

4.2.3 The content of a procurement document varies according to the item or service being purchased and its function. Provisions of this quality program are considered for application to suppliers. As applicable, procurement documents include:

- a. Scope of work to be performed.
- b. Technical requirements, with applicable drawings, specifications, codes and standards identified by title, document number, revision, and date. Required procedures, such as special process instructions, will be identified.
- c. Regulatory, administrative and reporting requirements.

QUALITY PROGRAM DESCRIPTION FOR BIG ROCK POINT

- d. Quality requirements appropriate to the complexity and scope of the work, including necessary tests and inspections.
- e. A requirement for a documented quality program, subject to Big Rock Point review and written concurrence prior to the start of work.
- f. A requirement for the supplier to invoke applicable quality requirements on sub-tier suppliers.
- g. Provisions for access to supplier and sub-tier supplier facilities and records for inspections, surveillances and audits.
- h. Identification of documentation to be provided by the supplier, identification of documents to be compatible with the records system, the schedule of submittals and identification of documents requiring Big Rock Point approval.

4.2.4 Trained, qualified personnel perform and document reviews of procurement request packages to assure that:

- a. Quality requirements (see 4.2.3 of this Section) are correctly stated, inspectable, and controllable.
- b. Adequate acceptance and rejection criteria are included.
- c. The procurement documents have been prepared, reviewed, and approved per Quality Program requirements.

4.2.5 Changes to the technical or quality requirements in procurement documents are controlled in a manner commensurate with that used for the original requirements. Those changes that could affect fit, form, function or assurance of quality are reviewed and approved by the same, or equivalent, organizations that approved the original procurement request packages.

QUALITY PROGRAM DESCRIPTION FOR BIG ROCK POINT

5.0 INSTRUCTIONS, PROCEDURES AND DRAWINGS

5.1 REQUIREMENTS

Activities affecting the quality of structures, systems and components to which this Program applies according to Section 2.0, QUALITY PROGRAM, are accomplished using instructions, procedures and drawings appropriate to the circumstances that include acceptance criteria for determining if an activity has been satisfactorily completed.

The following exceptions/interpretations in Appendix A, Part 2, are relevant to implementation of the requirements of this section of the quality program:

<u>Paragraph</u>	<u>Exceptions/Interpretations</u>
5.1	2v, 2w, 9a, 13b
5.2, item 5	2r, 2s, 8a
5.2, item 12	6b

5.2 IMPLEMENTATION

The authority and responsibility for performing activities affecting the quality of structures, systems and components are described in Section 1.0, ORGANIZATION. Management personnel assigned these responsibilities assure that the instructions, procedures, and drawings necessary to accomplish the activity are prepared and implemented.

Instructions, procedures and drawings incorporate (1) a description of the activity to be accomplished and (2) appropriate quantitative acceptance criteria, such as tolerances and operating limits, and/or qualitative acceptance criteria, such as workmanship standards, sufficient to determine that the activity has been satisfactorily accomplished.

Temporary procedures may be issued to provide management instructions that have short-term applicability. Temporary procedures include a designation of the time period during which they may be used.

The procedures used by Big Rock Point to control its activities include the following:

1. Administrative Procedures implementing the requirements of this quality program.
2. Procedures as needed to describe operation of ISFSI equipment.
3. Process monitoring procedures that provide for monitoring system performance and which, as appropriate, identify limits for significant process parameters.

QUALITY PROGRAM DESCRIPTION FOR BIG ROCK POINT

4. Spent fuel management procedures that provide for activities such as:
 - a. Fuel accountability,
 - b. Preparation of fuel for transportation,
 - c. Nuclear safety measures, or
 - d. Fuel transfer operations.
5. Maintenance procedures that provide for:
 - a. Preparation for maintenance,
 - b. Performance of maintenance,
 - c. Post-maintenance and operability checks and tests, and
 - d. Use of supporting maintenance documents
6. Radiation Protection Program procedures that provide for:
 - a. Implementation of the radiation control program including the acquisition of radiation data,
 - b. Identification of equipment for performing radiation surveys, or
 - c. Measurement, evaluation and assessment of radiation hazards.
7. Calibration and test procedures that provide for:
 - a. Periodic calibration and testing of instrumentation and control systems, or
 - b. Calibration of portable measuring and test equipment used in activities affecting safety.
8. Chemical-radiochemical control procedures that provide for activities including:
 - a. Control of deleterious agents,
 - b. Control, treatment and management of radioactive wastes, and
 - c. The control of radioactive calibration sources.

QUALITY PROGRAM DESCRIPTION FOR BIG ROCK POINT

9. Independent Spent Fuel Storage Installation (ISFSI) Emergency Plan and Implementing Procedures.

The ISFSI Emergency Plan meets the requirements of 10 CFR 50.47 and 10 CFR Part 50, Appendix E, as modified by U.S. Nuclear Regulatory Commission (NRC) approved exemptions of September 30, 1998 and Safety Evaluation Report of October 13, 2005.

10. ISFSI Security Plan and Implementing Procedure.

11. Fire Protection Plan.

12. Inspection, test and examination procedures that identify:

- a. Objectives,
- b. Acceptance criteria,
- c. Prerequisite and special conditions,
- d. Limiting conditions,
- e. Test or inspection instructions,
- f. Any required special equipment or calibration,
- g. Hold and Witness points, as appropriate.

13. Modification procedures that provide for:

- a. Administrative control and technical support during ISFSI modifications,
- b. The basis for a consistent method of performing recurring engineering, construction and quality activities,
- c. Control of the interfaces between Big Rock Point and its suppliers, and
- d. Control of quality-related modification activities that assure the quality program is implemented and its effectiveness is assessed and reported.

QUALITY PROGRAM DESCRIPTION FOR BIG ROCK POINT

6.0 DOCUMENT CONTROL

6.1 REQUIREMENTS

Documents controlling activities within the scope defined in Section 2.0, QUALITY PROGRAM, are issued and changed according to established procedures. Documents such as instructions, procedures and drawings, including changes thereto, are reviewed for adequacy, approved for release prior to implementation by authorized personnel and are distributed and used at the location where a prescribed activity is performed.

Changes to controlled documents are reviewed and approved by the same organizations that performed the original review and approval or by other qualified, responsible organizations specifically designated in accordance with the procedures governing these documents.

The following exceptions/interpretations in Appendix A, Part 2, are relevant to implementation of the requirements of this section of the quality program:

<u>Paragraph</u>	<u>Exceptions/Interpretations</u>
6.1	2h
6.2.3	2h, 2s, 12b

6.2 IMPLEMENTATION

6.2.1 The authority and responsibility for the control of documents are described in Section 1.0, ORGANIZATION.

6.2.2 Controls are established for approval, issue and change of documents in the following categories:

- a. Design documents (i.e., calculations, drawings, specifications, analyses) including documents related to computer codes
- b. As-built drawings (record drawings) and related documents
- c. Procurement documents
- d. Instructions and procedures for activities such as fabrication, construction, modification, installation, inspection, test, ISFSI maintenance and operation, and decommissioning which implement the quality program.
- e. Big Rock Point Updated Final Hazards Summary Report (UFHSR).

QUALITY PROGRAM DESCRIPTION FOR BIG ROCK POINT

- f. BNG FuelSolutions™ Storage System and W74 Canister SARs, WSNF-220 and WSNF-223, and the associated Dry Fuel Storage Exceptions Document and Dry Fuel Storage Technical Specifications.
 - g. Reports of nonconformances
 - h. Big Rock Point U.S. Nuclear Regulatory Commission License Conditions or Cask Storage System Certificate of Compliance.
- 6.2.3 The review, approval, issue and change of the above documents are controlled by:
- a. Establishment of criteria to ensure that adequate technical and quality requirements are incorporated.
 - b. Identification of the organizations responsible for review, approval, issue and revision.
 - c. Review of changes to documents by the organizations designated in accordance with the procedure governing the review and approval of specific types of documents, including quality aspects.
- 6.2.4 Controlled documents are issued and distributed so that:
- a. The documents are available at the work location prior to commencing work.
 - b. Obsolete or superseded documents are removed from work areas and replaced by applicable revisions in a timely manner.
- 6.2.5 Master lists or equivalent controls are used to identify the current revision of instructions, procedures, specifications, drawings and procurement documents. When master lists are used they are updated and distributed to designated personnel who are responsible for maintaining current copies of the lists.
- 6.2.6 Accurate as-built drawings (record drawings) and related documentation are prepared in a timely manner.

QUALITY PROGRAM DESCRIPTION FOR BIG ROCK POINT

7.0 CONTROL OF PURCHASED MATERIAL, EQUIPMENT AND SERVICES

7.1 REQUIREMENTS

Activities that implement approved procurement requests for material, equipment and services used in systems, structures, and components to which this program applies according to Section 2.0, QUALITY PROGRAM, are controlled to assure conformance with procurement document requirements. Controls include a system of supplier evaluation and selection, source inspection, examination and acceptance of items and documents upon delivery, and periodic assessment of supplier performance. Objective evidence of quality that demonstrates conformance with specified procurement document requirements is available prior to reliance on equipment, material or services.

The following exceptions/interpretations in Appendix A, Part 2, are relevant to implementation of the requirements of this section of the quality program:

<u>Paragraph</u>	<u>Exceptions/Interpretations</u>
7.1	2i
7.2.2	16d
7.2.3	7b, 17e
7.2.5	2m, 7e, 17f
7.2.6	2m, 9b, 13c, 13d, 17f

7.2 IMPLEMENTATION

7.2.1 Authority and responsibility for implementing the controls outlined herein are described in Section 1.0, ORGANIZATION.

7.2.2 Big Rock Point qualifies suppliers by performing a documented evaluation of their capability to provide items or services specified by procurement documents. To remain qualified, suppliers involved in active procurements are evaluated continuously and are audited triennially. If an audit is acquired from an external source, the audit is evaluated prior to its use.

Supplier evaluation and triennial audits are not necessary when the items or services supplied are all of the following:

- a. Relatively simple and standard in design, manufacture and test, and
- b. Adaptable to standard or automated inspections or tests of the end product to verify quality characteristics after delivery, and
- c. Such that receiving inspection does not require operations that could adversely affect the integrity, function or cleanness of the item.

QUALITY PROGRAM DESCRIPTION FOR BIG ROCK POINT

In the above cases, source and/or receipt inspection provides the necessary assurance of an acceptable item or service.

- 7.2.3 Supplier activities that affect quality are verified in accordance with written procedures. These procedures provide the method of verifying (such as audit, surveillance or inspection) and documenting that the characteristics or processes meet the requirements of the procurement document. For commercial "off-the-shelf" items where the requirements for a specific quality assurance program appropriate for nuclear applications cannot be imposed in a practical manner, source verification is used to provide adequate assurance of acceptability unless the quality of the item can be adequately verified upon receipt.
- 7.2.4 Spare and replacement parts are procured in such a manner that their performance and quality are at least equivalent to those of the parts that will be replaced.
- a. Specifications and codes referenced in procurement documents for spare or replacement items are at least equivalent to those for the original items or to properly reviewed and approved revisions.
 - b. Parts intended as spares or replacements for "off-the-shelf" items, or other items for which quality requirements were not originally specified, are evaluated for performance at least equivalent to the original.
 - c. Where quality requirements for the original items cannot be determined, requirements and controls are established by evaluation performed by qualified individuals. The evaluation assures there is no adverse effect on interfaces, interchangeability, safety, fit, form, function, or compliance with applicable regulatory or code requirements. Evaluation results are documented.
 - d. Any additional or modified design criteria, imposed after previous procurement of the item(s), are identified and incorporated.
- 7.2.5 Receipt inspections are performed to verify that items are undamaged and properly identified, that they conform to procurement requirements not previously verified by source surveillance or inspection and that required supplier furnished documentation is available. Items inspected are identified as to their acceptance status prior to their storage or release for installation.
- 7.2.6 Suppliers are required to furnish the following records:
- a. Applicable drawings and related engineering documentation that identify the purchased item and the specific procurement requirements (i.e., codes, standards, and specifications) met by the item.

QUALITY PROGRAM DESCRIPTION FOR BIG ROCK POINT

- b. Documentation identifying any procurement requirements that have not been met.
- c. A description of those nonconformances from the procurement requirements dispositioned "accept as is" or "repair."
- d. Quality records as specified in the procurement requirements.

The acceptability of these documents is evaluated during source and/or receipt inspection.

7.2.7 Supplier's certificates of conformance are periodically evaluated by audits, independent inspections, or tests to assure that they are valid. The results of these evaluations are documented.

QUALITY PROGRAM DESCRIPTION FOR BIG ROCK POINT

8.0 IDENTIFICATION AND CONTROL OF ITEMS

8.1 REQUIREMENTS

Materials, parts and components (items) used in structures, systems, and components to which this program applies according to Section 2.0, QUALITY PROGRAM, are identified and controlled to prevent their inadvertent use. Identification of items is maintained either on the items, their storage areas or containers, or on records traceable to the items.

The following exceptions/interpretations in Appendix A, Part 2, are relevant to implementation of the requirements of this section of the quality program:

<u>Paragraph</u>	<u>Exceptions/Interpretations</u>
8.2.2	7d, 7g
8.2.3	7a

8.2 IMPLEMENTATION

8.2.1 Controls are established that provide for the identification and control of materials (including consumables), parts and components (including partially fabricated assemblies). Authority and responsibility for the identification and control of items are described in Section 1.0, ORGANIZATION.

8.2.2 Items are identified by physically marking the item, its storage area or its container or by maintaining records traceable to the item. The method of identification is such that the quality of the item is not degraded.

8.2.3 Items are traceable to applicable drawings, specifications, or other pertinent documents to ensure that only correct and acceptable items are used. Verification of traceability is performed and documented prior to release for fabrication, assembly, or installation.

QUALITY PROGRAM DESCRIPTION FOR BIG ROCK POINT

9.0 CONTROL OF SPECIAL PROCESSES

9.1 REQUIREMENTS

Special processes affecting structures, systems, and components to which this program applies according to Section 2.0, QUALITY PROGRAM, are controlled and are accomplished by qualified personnel using qualified procedures and equipment in accordance with applicable codes, standards, specifications, criteria, and other special requirements.

The following exceptions/interpretations in Appendix A, Part 2, are relevant to implementation of the requirements of this section of the quality program:

<u>Paragraph</u>	<u>Exceptions/Interpretations</u>
9.2.1	13e

9.2 IMPLEMENTATION

- 9.2.1 Processes subject to special process controls are those for which full verification or characterization by direct inspection is impossible or impractical. Such processes include welding, heat treating, chemical cleaning, application of protective coatings, concrete placement, and nondestructive examination.
- 9.2.2 Authority and responsibility for implementation of special processes and for qualification of procedures, personnel, and equipment used to perform special processes are described in Section 1.0, ORGANIZATION.
- 9.2.3 Special process procedures are prepared by personnel with expertise in the discipline involved. The procedures are reviewed for technical adequacy by other personnel with the necessary technical competence, and are qualified by testing, as necessary.
- 9.2.4 Special process personnel qualification is determined by individuals authorized to administer the pertinent examinations. Certification is based on examination results. Personnel qualification is kept current by performance of the special process and/or re-examination at time intervals specified by applicable codes, specifications, and standards. Unsatisfactory performance or, where applicable, failure to perform within the designated time intervals requires recertification.
- 9.2.5 For special processes that require qualified equipment, such equipment is qualified in accordance with applicable codes, standards and specifications.
- 9.2.6 Qualification records are maintained in accordance with quality program Section 17.
- 9.2.7 The Quality Assurance Lead assesses special process activities, including qualification activities to assure they are satisfactorily performed.

QUALITY PROGRAM DESCRIPTION FOR BIG ROCK POINT

10.0 INSPECTION

10.1 REQUIREMENTS

Activities affecting the quality of structures, systems, and components to which this program applies according to Section 2.0, QUALITY PROGRAM, are inspected to verify their conformance with requirements. Inspections are accomplished by independent verification or process monitoring as necessary. Verification points are used as necessary to ensure that inspections are accomplished at the correct points in the sequence of work activities.

The following exceptions/interpretations in Appendix A, Part 2, are relevant to implementation of the requirements of this section of the quality program:

<u>Paragraph</u>	<u>Exceptions/Interpretations</u>
10.2.2	2p, 2q
10.2.3	2j, 6a
10.2.7	2j, 6a
10.2.10	2j

10.2 IMPLEMENTATION

10.2.1 Authority and responsibility for inspections are described in Section 1.0, ORGANIZATION.

10.2.2 Inspections are applied to procurement, maintenance, modification, testing, fuel transfer operations, and other site activities to verify that Quality-List items and activities conform to specified requirements. Work authorizing documents (i.e.; procedures, instructions, maintenance work orders) are reviewed in accordance with established criteria to do the following as necessary:

- a. Determine the need for inspection(s).
- b. Identify the inspection organization or personnel.
- c. Identify independent verification points.
- d. Determine how and when the inspections are to be performed.
- e. Specify measuring and test equipment of the necessary accuracy for performing inspection.
- f. Provide for documentation of inspection results to provide adequate objective evidence of acceptability.

QUALITY PROGRAM DESCRIPTION FOR BIG ROCK POINT

Independent verification is performed at each operation where it is necessary to verify conformance with requirements.

Process monitoring is used in whole or in part where direct inspection alone is impractical or inadequate.

- 10.2.3 Training and qualification programs for personnel who perform inspections, including nondestructive examination, are established, implemented, and documented in accordance with Section 2.0, QUALITY PROGRAM, and onsite or offsite procedures. These programs meet the requirements of applicable codes and standards. The Site General Manager (SGM) is responsible for review and concurrence with training and qualification programs that are under his direct responsibility.

Qualifications and certifications of inspection and NDE personnel are maintained by the entity performing the inspection in accordance with the recordkeeping requirements in the approved quality plan for that entity.

- 10.2.4 Inspection requirements are specified in procedures, instructions, drawings or checklists and are either provided or concurred with by the organization that performs the inspection planning. The procedures, instructions, drawings or checklists provide for the following as appropriate:

- a. Identification of applicable revisions of required procedures, instructions, drawings and specifications.
- b. Identification of characteristics and activities to be inspected.
- c. Inspection methods (independent verification or process monitoring).
- d. Specification of measuring and test equipment having the necessary accuracy.
- e. Identification of personnel responsible for performing the inspection.
- f. Acceptance criteria.
- g. Recording of the inspection results and the identification of the inspector.

- 10.2.5 Independent verification points are designated when confirmation is needed that critical characteristics are acceptable before the work can be allowed to proceed further. Independent verifications are performed and work is released for further processing or use by assigned verification personnel. Independent verification points may be waived only by the organization that performs the inspection planning.

QUALITY PROGRAM DESCRIPTION FOR BIG ROCK POINT

10.2.6 Independent verifications are performed and documented in accordance with the written instructions provided. The results are evaluated by designated personnel in order to ensure that the results substantiate the acceptability of the item or work. Evaluation and review results are documented.

Independent verification should be designated when the activity/task being verified is necessary to ensure critical characteristics are in conformance with requirements and/or the verification is the result of codes, standards, regulations, or commitments.

10.2.7 Independent verification may be performed by individuals in the same organization as that which performed the work provided:

- a. Qualifications of the independent verifier are equal to or better than the minimum qualifications for persons who can be authorized to perform the task; and
- b. The work is within the skills of Big Rock Point personnel and/or is addressed by Big Rock Point procedures.
- c. If work involves breaching a pressure retaining item, the quality of the work can be demonstrated through a functional test.

When a, b, and c are not met, inspections will be carried out by individuals certified in accordance with ANSI N45.2.6.

The verification is performed by individuals other than the person(s) performing or directly supervising the work.

10.2.8 For independent verification, when acceptance criteria are not met, corrected areas are to be re-verified. Results of independent verification are documented and retained for the purposes of performance trending and analysis.

10.2.9 The independent verifier has the authority to stop work if inspection criteria are not met. Resolution of disagreements between the verifier and worker is resolved by site management.

10.2.10 Contractors may be used as independent verifiers in accordance with Section 10.2.7 provided:

- a. The work is performed using procedures.
- b. Individuals are trained and qualified in accordance with Section 10.2.3.

Otherwise, contractors must be certified to ANSI N45.2.6 to perform inspections.

QUALITY PROGRAM DESCRIPTION FOR BIG ROCK POINT

11.0 TEST CONTROL

11.1 REQUIREMENTS

Testing is performed in accordance with established programs to demonstrate that structures, systems, and components to which this program applies according to Section 2.0, QUALITY PROGRAM, will perform satisfactorily in service. The testing is performed in accordance with written procedures that incorporate specified requirements and acceptance criteria. The test program includes qualification (as applicable), acceptance, surveillance, and maintenance tests. Test parameters, including any prerequisites, instrumentation requirements and environmental conditions are specified and met. Test results are documented and evaluated.

The following exceptions/interpretations in Appendix A, Part 2, are relevant to implementation of the requirements of this section of the quality program:

<u>Paragraph</u>	<u>Exceptions/Interpretations</u>
11.2.2	2k, 17g

11.2 IMPLEMENTATION

11.2.1 Authority and responsibility for testing are described in Section 1.0, ORGANIZATION.

11.2.2 Tests are performed in accordance with programs, procedures, and criteria that designate when tests are required and how they are to be performed. Such testing includes the following:

- a. Qualification tests, as applicable, to verify design adequacy in accordance with Section 3.0, DESIGN CONTROL.
- b. Acceptance tests of equipment and components to assure their proper operation prior to delivery or to pre-operational tests.
- c. Surveillance tests to assure continuing proper and safe operation of systems and equipment.
- d. Maintenance tests after preventive or corrective maintenance.

11.2.3 Test procedures and instructions include provisions for the following, as applicable:

- a. The requirements and acceptance limits contained in applicable design and procurement documents.

QUALITY PROGRAM DESCRIPTION FOR BIG ROCK POINT

- b. Test prerequisites such as calibrated instrumentation, adequate test equipment, and instrumentation including accuracy requirements, completeness of the item to be tested, suitable and controlled environmental conditions, and provisions for data collection and storage.
- c. Instructions for performing the test.
- d. Mandatory inspection hold points for witness by the appropriate authority.
- e. Acceptance and rejection criteria.
- f. Methods of documenting or recording test data and results.
- g. Assuring that test prerequisites have been met.
- h. Verification of completion of modification activities.

Test procedures and instructions are reviewed for technical content and quality aspects, by the site engineering organization, or an offsite technical support organization, as applicable.

When acceptance criteria are not met, corrected areas are to be retested.

QUALITY PROGRAM DESCRIPTION FOR BIG ROCK POINT

12.0 CONTROL OF MEASURING AND TEST EQUIPMENT

12.1 REQUIREMENTS

Measuring and testing equipment used in activities affecting the quality of structures systems, and components to which this program applies according to Section 2.0, QUALITY PROGRAM, are properly identified, controlled, calibrated, and adjusted at specified intervals to maintain accuracy within necessary limits.

The following exceptions/interpretations in Appendix A, Part 2, are relevant to implementation of the requirements of this section of the quality program:

<u>Paragraph</u>	<u>Exceptions/Interpretations</u>
12.2.3	2o, 9c
12.2.4	2o, 9c
12.2.5	10c
12.2.8	10b

12.2 IMPLEMENTATION

12.2.1 Authority and responsibility for the control of measuring and test equipment are described in Section 1.0, ORGANIZATION.

12.2.2 Procedures are established for measuring and test equipment utilized in the measurement, inspection and monitoring of structures, systems and components. These procedures describe calibration technique and frequency and maintenance and control of the equipment.

12.2.3 Measuring and test equipment is uniquely identified and is traceable to its calibration source.

12.2.4 Big Rock Point uses a system of labels to be attached to measuring and test equipment to display the next calibration due date. Where labels cannot be attached, a control system is used that identifies to potential users any equipment beyond the calibration due date.

12.2.5 Measuring and test equipment (M&TE) and installed instrumentation are calibrated at specified intervals based on the required accuracy, purpose, degree of usage, stability characteristics, and other conditions affecting the measurement.

Calibration of M&TE is against standards that have an accuracy of at least four times the required accuracy of the equipment being calibrated or, when this is not possible, have an accuracy that assures the equipment being calibrated will be within required tolerance and the basis of acceptance is documented and authorized by responsible management.

QUALITY PROGRAM DESCRIPTION FOR BIG ROCK POINT

Calibration standards used for installed instrumentation shall normally have greater accuracy than the instrumentation being calibrated. Standards with the same accuracy may be used when shown to be adequate for specific calibration requirements. The basis for this acceptance is documented and is approved by responsible management.

- 12.2.6 Calibrating standards have greater accuracy than standards being calibrated. Calibrating standards with the same accuracy may be used if it can be shown to be adequate for the requirements and the basis of acceptance is documented and authorized by responsible management.
- 12.2.7 Reference and transfer standards are traceable to nationally recognized standards; where national standards do not exist, provisions are established to document the basis for calibration.
- 12.2.8 When measuring and testing equipment used for inspection and test is found to be outside of required accuracy limits at the time of calibration, evaluations are conducted to determine the validity of the results obtained since the most recent calibration. The results of evaluations are documented. Retests or reinspections are performed on suspect items.

QUALITY PROGRAM DESCRIPTION FOR BIG ROCK POINT

13.0 HANDLING, STORAGE AND SHIPPING

13.1 REQUIREMENTS

Activities with the potential for causing contamination or deterioration that could adversely affect the ability of an item (to which this program applies according to Section 2.0, QUALITY PROGRAM) to perform its intended safety functions, and activities necessary to prevent undetected or uncorrectable damage are identified and controlled. These activities include cleaning, packaging, preserving, handling, shipping, and storing. Controls are effected through the use of appropriate procedures and instructions implemented by suitably trained personnel.

The following exceptions/interpretations in Appendix A, Part 2, are relevant to implementation of the requirements of this section of the quality program:

<u>Paragraph</u>	<u>Exceptions/Interpretations</u>
13.2.2	7a, 7d, 7f, 7g, 7h

13.2 IMPLEMENTATION

13.2.1 Authority and responsibility for material cleaning, handling, storing, packaging, preserving, and shipping activities are described in Section 1.0, ORGANIZATION.

13.2.2 Procedures are used to control the cleaning, handling, storing, packaging, preserving, and shipping of materials, components and systems in accordance with design and procurement requirements. These procedures include, but are not limited to, the following functions:

- a. Cleaning, to assure that required cleanliness levels are achieved and maintained.
- b. Packaging and preservation, to provide adequate protection against damage or deterioration. When necessary, these procedures provide for special environments such as inert gas atmospheres, specific moisture content levels, and temperature levels.
- c. Handling, to preclude damage or safety hazards.
- d. Storing, to minimize the possibility of loss, damage to or deterioration of items in storage, including consumables such as chemicals, reagents, and lubricants. Storage procedures also provide methods to assure that specified shelf lives are not exceeded.

QUALITY PROGRAM DESCRIPTION FOR BIG ROCK POINT

14.0 INSPECTION, TEST AND OPERATING STATUS

14.1 REQUIREMENTS

Operating status of structures, systems, and components to which this program applies according to Section 2.0, QUALITY PROGRAM, is indicated by tagging in such a manner as to prevent inadvertent operation. The status of inspections and tests performed on individual items is clearly indicated by markings and/or logging under strict procedural controls to prevent inadvertent bypassing of such inspections and tests.

The following exceptions/interpretations in Appendix A, Part 2, are relevant to implementation of the requirements of this section of the quality program:

<u>Paragraph</u>	<u>Exceptions/Interpretations</u>
14.1	2r
14.2.5	2i

14.2 IMPLEMENTATION

14.2.1 Authority and responsibility for identifying inspection, test and operating status are described in Section 1.0, ORGANIZATION.

14.2.2 For modification activities, including item fabrication, installation and test, procurement documents, service contracts, and procedures specify the degree of control required for the indication of inspection and test status of structures, systems, and components.

14.2.3 Application and removal of inspection and welding stamps and of such status indicators as tags, markings, labels, etc., are controlled by procedures.

14.2.4 The sequence of inspections, tests and other operations important to safety are controlled by procedures. Changes in the approved sequence are subject to the same review and approval as the original, or as specified in administrative procedures if the original organization no longer exists.

14.2.5 The status of nonconforming, inoperable or malfunctioning structures, systems, and components is clearly identified and documented to prevent inadvertent use.

QUALITY PROGRAM DESCRIPTION FOR BIG ROCK POINT

15.0 NONCONFORMING MATERIALS, PARTS OR COMPONENTS

15.1 REQUIREMENTS

Materials, parts, or components for structures, systems and components to which this program applies according to Section 2.0, QUALITY PROGRAM, that do not conform to requirements are controlled in order to prevent their inadvertent use. Nonconforming items are identified, documented, segregated when practical, and dispositioned. Affected organizations are notified of nonconformances

The following exceptions/interpretations in Appendix A, Part 2, are relevant to implementation of the requirements of this section of the quality program:

<u>Paragraph</u>	<u>Exceptions/Interpretations</u>
15.1	2i

15.2 IMPLEMENTATION

15.2.1 Items, services, or activities that are deficient in characteristic, documentation, or procedure that render the quality unacceptable or indeterminate, are identified as nonconforming and any further use is controlled. Nonconformances are documented and dispositioned, and notification is made to affected organizations. Personnel authorized to disposition, conditionally release, and close out nonconformances are designated. The authority and responsibility for the implementation of activities related to the processing and control of nonconforming materials, parts, or components are described in Section 1.0, ORGANIZATION.

- a. Nonconforming items are identified by marking, tagging, or segregating or by documented administrative controls. Documentation describes the nonconformance, the disposition of the nonconformance and the inspection requirements. It also includes signature approval of the disposition.
- b. The original inspection planning authority reviews the disposition of nonconformances, and documents concurrence with the acceptance, conditional release or repair of a nonconforming item.
- c. Items that have been repaired or reworked are inspected and tested in accordance with the original inspection and test requirements or alternatives that have been documented as acceptable and concurred with by the original inspection planning authority.
- d. Items that have the disposition "repair" or "use as is" require documentation justifying acceptability. Any changes made are recorded to denote the as-built condition.

QUALITY PROGRAM DESCRIPTION FOR BIG ROCK POINT

- 15.2.2 Dispositions of conditionally released items are closed out before the items are relied upon to perform functions that are important to safety.
- 15.2.3 Prior to the initiation of preoperational testing on an item, all nonconformances are corrected or dispositioned and evaluated for impact upon the item or the testing program.
- 15.2.4 Nonconformance reports are analyzed to identify quality trends. Trend reports, which highlight significant results, are issued periodically to upper management for review and assessment.

QUALITY PROGRAM DESCRIPTION FOR BIG ROCK POINT

16.0 CORRECTIVE ACTION

16.1 REQUIREMENTS

Conditions adverse to quality of structures, systems, components, or activities to which this program applies according to Section 2.0, QUALITY PROGRAM, such as failures, malfunctions, deficiencies, deviations, defective material, and equipment and nonconformances, are identified promptly and corrected as soon as practical.

For significant conditions adverse to quality, the cause of the condition is determined and corrective action is taken to preclude repetition. In these cases, the condition, cause and corrective action taken is documented and reported to appropriate levels of management for review and assessment.

16.2 IMPLEMENTATION

16.2.1 The responsibility and authority for the control of corrective action are described in Section 1.0, ORGANIZATION.

16.2.2 Controls are established to assure that conditions adverse to quality are identified and documented and that appropriate remedial action is taken.

16.2.3 For significant conditions adverse to quality, necessary corrective action is promptly determined and recorded. Corrective action includes determining the cause and extent of the condition, and taking appropriate action to preclude similar problems in the future. The controls also assure that corrective action is implemented in a timely manner.

QUALITY PROGRAM DESCRIPTION FOR BIG ROCK POINT

17.0 QUALITY RECORDS

17.1 REQUIREMENTS

Records that furnish evidence of activities affecting the quality of structures, systems and components to which this program applies according to Section 2.0, QUALITY PROGRAM, are maintained. They are accurate, complete and legible and are protected against damage, deterioration or loss. They are identifiable and retrievable.

The following exceptions/interpretations in Appendix A, Part 2, are relevant to implementation of the requirements of this section of the quality program:

<u>Paragraph</u>	<u>Exceptions/Interpretations</u>
17.1	14b
17.2.5	14c
17.2.8	14a, 14c

17.2 IMPLEMENTATION

17.2.1 Authority and responsibility for the identification and control of quality records are described in Section 1.0, ORGANIZATION.

17.2.2 Documents that furnish evidence of activities affecting quality are generated and controlled in accordance with the procedures that govern those activities. Upon completion, these documents are considered records. These records include:

- a. Results of reviews, inspections, surveillances, tests, audits, and material analyses
- b. Qualification of personnel, procedures, and equipment
- c. Operating and decommissioning logs
- d. Maintenance and modification procedures and related inspection results
- e. Reportable occurrences
- f. Records required by Appendix E of this quality program
- g. Nonconformance reports
- h. Corrective action reports
- i. Other documentation such as drawings, specifications, procurement documents, calibration procedures, and reports

QUALITY PROGRAM DESCRIPTION FOR BIG ROCK POINT

- 17.2.3 Inspection and test records contain the following where applicable:
- a. A description of the type of observation
 - b. The date and results of the inspection or test
 - c. Information related to conditions adverse to quality
 - d. Inspector or data recorder identification
 - e. Evidence as to the acceptability of the results
 - f. Action taken to resolve any discrepancies noted
- 17.2.4 When a document becomes a record, it is designated as permanent or nonpermanent and then transmitted to file. Nonpermanent records have specified retention times. Permanent records are maintained for the life of the item. Appendix E identifies retention periods for certain specific records.
- 17.2.5 Temporary storage of completed documents during processing to become records is in rated fire-resistant file cabinets.
- 17.2.6 Only authorized personnel may issue corrections or supplements to records.
- 17.2.7 Traceability between the record and the item or activity to which it applies is provided.
- 17.2.8 Records are stored in remote, dual facilities to prevent damage, deterioration, or loss due to natural or unnatural causes. Records that can only be stored as originals, such as radiographs and some strip charts are retained in a four-hour fire-rated facility.

QUALITY PROGRAM DESCRIPTION FOR BIG ROCK POINT

18.0 AUDITS

18.1 REQUIREMENTS

A comprehensive system of audits is carried out to provide independent assessment of performance and effectiveness of the quality program to achieve nuclear safety, including those elements of the program implemented by suppliers and contractors. Audits are performed in accordance with written procedures or checklists by qualified personnel not having direct responsibility in the areas audited. Audit results are documented and are reviewed by management. Follow-up action is taken where indicated.

The following exceptions/interpretations in Appendix A, Part 2, are relevant to implementation of the requirements of this section of the quality program:

<u>Paragraph</u>	<u>Exceptions/Interpretations</u>
18.2.2	3a, 3b, 3c, 16a, 16b
18.2.3	16c
18.2.9	2e

18.2 IMPLEMENTATION

- 18.2.1 Responsibility and authority for the audit program are described in Section 1.0, ORGANIZATION.
- 18.2.2 Internal audits are performed in accordance with established schedules that reflect the status and importance to safety of the activities being performed. Audits are conducted in accordance with frequencies stated in Appendix D, Audit Frequencies.
- 18.2.3 Audits of suppliers and contractors are scheduled based on the status and safety importance of the activities being performed as well as performance of the suppliers and contractors and are initiated early enough to assure effective quality during design, procurement, manufacturing, construction, installation, inspection, and testing.
- 18.2.4 Principal contractors are required to audit their suppliers based on performance and on a schedule based on the status and safety importance of the activities being performed. Such audits shall be initiated early enough to assure an effective quality program on the part of their suppliers.
- 18.2.5 Regularly scheduled audits are supplemented by special audits when significant changes are made in the quality program, when it is suspected that quality is in jeopardy or when an independent assessment of program effectiveness is considered necessary.

QUALITY PROGRAM DESCRIPTION FOR BIG ROCK POINT

- 18.2.6 Audits include an objective evaluation of quality-related practices, procedures, instructions, activities and items, and review of documents and records to confirm that the quality program is effective and properly implemented.
- 18.2.7 Audit procedures and the scope, plans, checklists, and results of individual audits are documented.
- 18.2.8 Personnel selected for auditing assignments have experience or are given training commensurate with the needs of the audit and have no direct responsibilities in the areas audited.
- 18.2.9 Audit data are analyzed by the Quality Assurance Lead. The resulting audit reports identify any quality deficiencies and assess the effectiveness of the Quality Program in the area audited. The reports are distributed to the responsible management of both the audited and auditing organizations.
- 18.2.10 Management of the audited organization identifies and takes appropriate corrective action to correct observed deficiencies and to prevent recurrence of any significant conditions adverse to quality. Follow-up for internal audits is performed by the Quality Assurance Lead to ensure that appropriate corrective action is taken and is effective. Such follow-up includes re-audits when necessary. For vendor audits, such follow-up shall be performed by the organization performing the audit.

QUALITY PROGRAM DESCRIPTION FOR BIG ROCK POINT

APPENDIX A, PART 1 REGULATORY GUIDE AND ANSI STANDARD COMMITMENTS

The Big Rock Point quality program complies with the regulatory position of the Regulatory Guides referenced in this appendix as modified by the exceptions stated in Part 2.

1. Appendix B to 10 CFR, Part 50, Quality Assurance Criteria for Nuclear Power Plants and Fuel Reprocessing Plants
2. 10 CFR 72, Subpart F – General Design Criteria
3. Regulatory Guide 1.8 - (9/80 Draft) - Personnel Qualification and Training - Endorses ANSI/ANS 3.1 - (12/79 Draft) (application limited as described in Exceptions 4a and 5a of Appendix A, Part 2)
4. Regulatory Guide 30 (Safety Guide 30) - (8/11/72) - Quality Assurance Requirements for the Installation, Inspection, and Testing of Instrumentation and Electrical Equipment - Endorses ANSI N45.2.4
5. Regulatory Guide 1.33 - (2/78, Rev 2) - Quality Assurance Program Requirements (Operation) - Endorses ANSI N18.7 - 1976
6. Regulatory Guide 1.37 - (3/16/73) - Quality Assurance Requirements for Cleaning of Fluid Systems and Associated Components of Water-Cooled Nuclear Power Plants - Endorses ANSI N45.2.1 - 1973
7. Regulatory Guide 1.38 - (5/77, Rev 2) - Quality Assurance Requirements for Packaging, Shipping, Receiving, Storage, and Handling of Items for water-Cooled Nuclear Power Plants - Endorses ANSI N45.2.2 - 1972
8. Regulatory Guide 1.39 - (9/77, Rev 2) - Housekeeping Requirements for Water-Cooled Nuclear Power Plants - Endorses ANSI N45.2.3 - 1973
9. Regulatory Guide 1.58 - (9/80, Rev 1) - Qualification of Nuclear Power Plant Inspection, Examination, and Testing Personnel - Endorses N45.2.6 1978
10. Regulatory Guide 1.64 - (6/76, Rev 2) - Quality Assurance Requirements for the Design of Nuclear Power Plants – Endorses N45.2.11 - 1974
11. Regulatory Guide 1.74 - (2/74) - Quality Assurance Requirements Terms and Definitions - Endorses ANSI N45.2.10 - 1973
12. Regulatory Guide 1.88 - (10/76, Rev 2) - Collection, Storage, and Maintenance of Nuclear Power Plant Quality Assurance Records – Endorses N45.2.9 - 1974

QUALITY PROGRAM DESCRIPTION FOR BIG ROCK POINT

13. Regulatory Guide 1.94 - (4/76, Rev 1) - Quality Assurance Requirements for Installation, Inspection, and Testing of Structural Concrete and Structural Steel During the Construction Phase of Nuclear Power Plants - Endorses ANSI N45.2.5 - 1974
14. Regulatory Guide 1.116 - (5/77) - Quality Assurance Requirements for Installation, Inspection, and Testing of Mechanical Equipment and Systems - Endorses ANSI N45.2.8 - 1975
15. Regulatory Guide 1.123 - (7/77, Rev 1) - Quality Assurance Requirements for Control of Procurement of Items and Services for Nuclear Power Plants - Endorses N45.2.13 - 1976
16. Regulatory Guide 1.144 - (9/80, Rev 1) - Auditing of Quality Assurance Programs for Nuclear Power Plants - Endorses N45.2.12 - 1977
17. Regulatory Guide 1.146 - (8/80) - Qualification of Quality Assurance Program Audit Personnel for Nuclear Power Plants - Endorses N45.2.23 -1978
18. ANSI/ANS 3.1-1987, Selection, Qualification, and Training of Personnel for Nuclear Power Plants (application limited as described in Appendix C of this document)
19. ANSI N18.1-1971, American National Standard for Selection and Training of Nuclear Power Plant Personnel.

QUALITY PROGRAM DESCRIPTION FOR BIG ROCK POINT

APPENDIX A, PART 2 BIG ROCK POINT EXCEPTIONS TO OPERATING PHASE STANDARDS AND REGULATORY GUIDES

1. General

Requirement

Certain Regulatory Guides invoke or imply Regulatory Guides and standards in addition to the standard each primarily endorses.

Certain ANSI Standards invoke or imply additional standards.

Exception/Interpretation

The Big Rock Point commitment refers to the Regulatory Guides and ANSI Standards specifically identified in Appendix A, Part 1. Additional Regulatory Guides, ANSI Standards, and similar documents implied or referenced in those specifically identified are not part of this commitment.

Imposition of these Regulatory Guides on Big Rock Point suppliers and sub-tier suppliers will be on a case-by-case basis depending upon the item or service to be procured.

2. N18.7 General

Exception/Interpretation

As permitted by 4.3.3 of ANSI N18.7, Consumers Energy has established an organizational unit, the Independent Safety Review Committee, (ISRC) to perform independent review activities.

The standard numeric and qualification requirements may not be met by the ISRC. Procedures will be established to specify how the ISRC will acquire necessary expertise to carry out its review responsibilities in accordance with Appendix C, Independent Safety Review Committee.

2a. N18.7, Section 3.4.2

Requirement

"The Plant Manager shall have overall responsibility for the execution of the administrative controls and quality assurance program at the plant to assure safety."

QUALITY PROGRAM DESCRIPTION FOR BIG ROCK POINT

Exception/Interpretation

Since Consumers Energy has more than one organization providing services to Big Rock Point, overall responsibility cannot be centralized in a single on-site position. Instead, responsibilities are as designated within the quality program.

2b. N18.7, Section 4.3.1

Requirement

"Personnel assigned responsibility for independent reviews shall be specified in both number and technical disciplines and shall collectively have the experience and competence required to review problems in the following areas:..."

Exception/Interpretation

The ISRC will not have members specified by number or by technical disciplines and its members may not have the experience and competence required to review problems in all areas listed in this section; however, the ISRC will function as described in Appendix C, Independent Safety Review Committee, and will acquire the services of personnel having such experience and competence as necessary.

2c. N18.7, Section 4.3.4

Requirement

"The following subjects shall be reviewed by the independent review body:"

Exception/Interpretation

Subjects requiring review will be as specified in Appendix C, Independent Safety Review Committee.

2d. N18.7, Section 4.3.4(3)

Requirement

Changes in the Technical Specifications or license amendments relating to nuclear safety are to be reviewed by the independent review body prior to implementation, except in those cases where the change is identical to a previously reviewed proposed change.

QUALITY PROGRAM DESCRIPTION FOR BIG ROCK POINT

Exception/Interpretation

The ISRC will not review License Conditions or Cask Storage System Certificate of Compliance changes after NRC approval prior to implementation. The basis for this position is that all License Conditions or Cask Storage System Certificate of Compliance changes are reviewed prior to submittal to the NRC.

2e. N18.7, Section 4.5

Requirement

Written reports of audits specified in ANSI N18.7 shall be reviewed by the independent review body and by appropriate members of Management including those having responsibility in the area audited.

Exception/Interpretation

The ISRC shall review or arrange for reviews of those audits over which it has cognizance, in accordance with Appendix C, Independent Safety Review Committee.

Some audits required are in areas other than those requiring independent review in accordance with ANSI N18.7, Section 4.3.4.

2f. N18.7, Section 4.5

Requirement

Periodic review of the audit program shall be performed by the independent review body or by a management representative at least semiannually to assure that audits are being accomplished in accordance with requirements of technical specifications and of this standard.

Exception/Interpretation

Audits of nuclear facility activities are performed under the cognizance of the ISRC as described in Appendix C, Independent Safety Review Committee.

2g. N18.7, Section 5.2.1

Requirement

"The responsibilities and authorities of the plant operating personnel shall be delineated."

Exception/Interpretation

The exception taken to this section of ANSI N18.7 has been deleted.

QUALITY PROGRAM DESCRIPTION FOR BIG ROCK POINT

2h. N18.7, Section 5.2.2

Requirement

"Temporary changes, which clearly do not change the intent of the approved procedure, shall as a minimum be approved by two members of the plant staff knowledgeable in the areas affected by the procedures. At least one of these individuals shall be the supervisor in charge of the shift and hold a senior operators license on the unit affected."

Exception/Interpretation

Big Rock Point considers that this requirement applies only to procedures identified in this quality program. Temporary changes to these procedures may be made provided:

- a. The intent of the original procedure is not altered;
- b. The change is approved by an individual designated by the Site General Manager; and
- c. The change is documented, reviewed by a safety reviewer as described in Appendix B within 30 days of initial approval, and approved by the Site General Manager.

2i. N18.7, Section 5.2.6

Requirement

"In cases where required documentary evidence is not available, the associated equipment or materials must be considered nonconforming in accordance with Section 5.2.14. Until suitable documentary evidence is available to show the equipment or material is in conformance, affected systems shall be considered to be inoperable and reliance shall not be placed on such systems to fulfill their intended safety functions."

Exception/Interpretation

Big Rock Point initiates appropriate corrective action when it is discovered that documentary evidence does not exist for a test or inspection, which is required to verify equipment acceptability. This action includes a technical evaluation of the equipment's operability status.

QUALITY PROGRAM DESCRIPTION FOR BIG ROCK POINT

2j. N18.7, Section 5.2.7

Requirement

The following standards contain useful guidance concerning design and construction-related activities associated with modifications and shall be applied to those activities that are comparable in nature and extent to related activities occurring during initial plant design and construction: American National Standard Installation, Inspection and Testing of Instrumentation and Electric Equipment During the Construction of Nuclear Power Generation Station, N45.2.4-1972 (IEEE 336-1972) [6]; American National Standard Supplementary Quality Assurance Requirements for Installation, Inspection and Testing of Structural Concrete and Structural Steel During the Construction Phase of Nuclear Power Plants, N45.2.5-1974 [7]; American National Standard Qualifications of Inspection, Examination and Testing Personnel for the Construction Phase of Nuclear Power Plants N45.2.6-1973 [5]; American National Standard Supplementary Quality Assurance Requirements for Installation, Inspection and Testing of Mechanical Equipment and Systems for Construction Phase of Nuclear Power Plants, N45.2.8-1975 [8]; American National Standard Quality Assurance Requirements for the Design of Nuclear Power Plants, N45.2.11 1974 [9]; and American National Standard Quality Assurance for Protective Coating Applied to Nuclear Facilities N101.4-1972 [10]. Considerable care is required in assessing which operational phase activities are comparable in nature and extent to activities normally associated with design and construction.

Exception/Clarification

Work that is within the skills of Consumers Energy personnel and is covered by Big Rock Point procedures may be inspected by independent verifiers qualified in accordance with Sections 10.2.3, 10.2.7 and 10.2.10 of this quality program, rather than ANSI N45.2.6.

2k. N18.7, Section 5.2.8

Requirement

"A surveillance testing and inspection program...shall include the establishment of a master surveillance schedule reflecting the status of all planned in-plant surveillance tests and inspections."

Exception/Interpretation

Separate master schedules may exist for different programs such as storage cask inspection, Defueled Technical Specification surveillance requirements, and Dry Fuel Storage Technical Specification surveillance requirements.

2l. N18.7, Section 5.2.13.1

Requirement

"To the extent necessary, procurement documents shall require suppliers to provide a quality assurance program consistent with the pertinent requirements of ANSI N45.2 - 1971."

QUALITY PROGRAM DESCRIPTION FOR BIG ROCK POINT

Exception/Interpretation

To the extent necessary, procurement documents require that the supplier have a documented quality assurance program consistent with the pertinent requirements of ANSI N45.2 or other nationally recognized codes and standards.

2m. N18.7, Section 5.2.13.2

Requirement

ANSI N18.7 and N45.2.13 specify that where required by code, regulation, or contract, documentary evidence that items conform to procurement requirements shall be available at the nuclear power plant site prior to installation or use of such items.

Exception/Interpretation

The required documentary evidence is available at the site prior to use, but not necessarily prior to installation. This allows installation to proceed while any missing documents are being obtained, but precludes dependence on the item for safety purposes.

2n. N18.7, Section 5.2.15

Requirement

Plant procedures shall be reviewed by an individual knowledgeable in the area affected by the procedure no less frequently than every two years to determine if changes are necessary or desirable.

Exception/Interpretation

The exception taken to this section of ANSI N18.7 has been deleted.

2o. N18.7, Section 5.2.16

Requirement

Records shall be made and equipment suitably marked to indicate calibration status.

Exception/Interpretation

See Item 9c.

2p. N18.7, Section 5.2.17

Requirement

For modifications and non-routine maintenance, inspections shall be conducted in a manner similar (frequency, type, and personnel performing such inspections) to that associated with construction phase activities (see also Section 5.2.7)

QUALITY PROGRAM DESCRIPTION FOR BIG ROCK POINT

Exception/Interpretation

Maintenance and modification activities that are within the skills of Consumers Energy maintenance personnel and are carried out using Big Rock Point procedures may be inspected by independent verifiers qualified in accordance with Sections 10.2.3, 10.2.7, and 10.2.10 of this program description.

2q. N18.7, Section 5.2.17

Requirement

If mandatory inspection hold points are required, the specific hold points shall be indicated in appropriate documents. Information concerning inspection shall be obtained from the related design drawings, specifications, and/or other controlled documents.

Exception/Interpretation

Big Rock Point uses the terminology "independent verification point" as equivalent to a hold point.

2r. N18.7, Section 5.3.5(3)

Requirement

Instructions shall be included, or referenced (in maintenance procedures), for returning the equipment to its normal operating status.

Exception/Interpretation

At Big Rock Point, equipment is returned to its normal operating status, i.e., declared operable, by qualified personnel. Verification of equipment operability will be by line-up verification or appropriate functional testing, and will be documented.

2s. N18.7, Section 5.3.5(4)

Requirement

This section requires that where sections of documents such as vendor manuals, operating and maintenance instructions, or drawings are incorporated directly or by reference into a maintenance procedure, they shall receive the same level of review and approval as operating procedures.

QUALITY PROGRAM DESCRIPTION FOR BIG ROCK POINT

Exception/Interpretation

Such documents are reviewed by appropriately qualified personnel prior to use to ensure that, when used as instructions, they provide proper and adequate information to ensure the required quality of work. Maintenance procedures which reference these documents receive the same level of review and approval as operating procedures.

2t. N18.7, Section 3.4.2

Requirement

This section requires that the onsite operating organization include individuals knowledgeable in nuclear power plant operation, nuclear power plant mechanical, electrical and electronic systems, nuclear engineering, chemistry and radiochemistry, radiation protection, and quality assurance.

Exception/Interpretation

When needed to support ISFSI operations, Consumers Energy Company will retain or contract persons knowledgeable in ISFSI operations, ISFSI structural, and electronic systems, nuclear engineering, radiation protection, and quality assurance. For ISFSI operations, chemistry and radiochemistry controls do not apply after loaded casks have been placed on the ISFSI pad. There are no mechanical or electrical systems directly associated with dry fuel storage casks.

2u. N18.7, Section 5.1

Requirement

If source documents are not compiled in one master document, a summary document shall be compiled to identify the sources, to index the source documents to the requirements of ANSI N18.7 and to provide a consolidated base for description of the program.

Exception/Interpretation

Appendix A of this quality program is the compilation of source documents that apply to the total program for providing administrative controls and quality assurance during decommissioning and ISFSI operation.

QUALITY PROGRAM DESCRIPTION FOR BIG ROCK POINT

2v. N18.7, Section 5.2.1

Requirement

5.2.1(1), (2) and (3) require identification of authority and responsibilities related to reactor shutdown, reactor trip or unexplained operation, and reactor restart.

Exception/Interpretation

Because these reactor events are no longer possible at Big Rock Point, the authority and responsibilities associated with these events will not be addressed in site procedures.

2w. N18.7, Section 5.3.4

Requirement

This section (5.3.4.1 through 5.3.4.10) requires procedures for the integrated operation of a plant.

Exception/interpretation

Some of the procedures, for example, those required by ANSI N18.7 sections 5.3.4.1, 5.3.4.2 and 5.3.4.3, apply only to reactor operation and will not be developed for ISFSI operations. The procedures required by ANSI N18.7 sections 5.3.4.4 through 5.3.4.10 will be developed and will address conditions applicable to ISFSI operation.

3a. RG 1.33, Section C4a

Requirement

The results of actions taken to correct deficiencies that affect nuclear safety and occur in facility equipment, structures, systems, or method of operation are to be audited at least once per six months.

Exception/Interpretation

Performance trends are reviewed by the ISRC. In addition, the corrective action system is audited in accordance with Appendix D, Audit Frequencies.

3b. RG 1.33, Section C4b

Requirement

The conformance of facility operations to provisions contained within the Technical Specifications and applicable license conditions-at least once per 12 months.

QUALITY PROGRAM DESCRIPTION FOR BIG ROCK POINT

Exception/Interpretation

- a. Consistent with NRC Safety Evaluation, Amendment 106, for Millstone Nuclear Power Station Unit 1 (ADAMS Accession Number ML993330283), and NRC Transmittal QA1 99 221 dated November 18, 1999 (ADAMS Accession Number ML993310022) and NRC Administrative Letter 95-06 dated December 12, 1995, Big Rock Point interprets the commitment to audit License conditions and Cask Storage System Certificate of Compliance conditions contained in 18.2.2 of the quality program, and in Appendix D, Audit Frequencies, as follows:

Big Rock Point maintains a matrix that identifies all applicable Technical Specification line items to be audited. Prior to each audit, the matrix is reviewed and updated as required to conform to approved Operating License Conditions or Cask Storage System Certificate of Compliance changes. During each 24-month period, a selected sample of line items is audited.

The items to be audited during each 24-month period are selected from the following sections of the Operating License Conditions or Cask Storage System Certificate of Compliance and Dry Fuel Storage Technical Specifications:

- Operating License Conditions
 - Cask Storage System Certificate of Compliance
 - Dry Fuel Storage Technical Specifications:
 - 1) Functional and Operating Limits
 - 2) Limiting Conditions for Operation and Surveillance Requirements
 - 3) Administrative Controls
- b. The previously approved quality plan required that Technical Specification audits be scheduled so that all line items are covered within a maximum period of five years. This interval was noted to be consistent with guidance presented in NRC letters dated March 29, 1983 (RLSpessard to JMTaylor) and January 30, 1984 (JGPartlow to RLSpessard), and was accepted by the NRC in an NRC letter dated August 2, 1989 (Goeffrey C. Wright to David P. Hoffman).

Audits are scheduled so that all line items are covered within a maximum period of 5 years. The audit period for any of the above elements may be reduced depending on compliance history.

QUALITY PROGRAM DESCRIPTION FOR BIG ROCK POINT

3c. RG 1.33, Section C4c

Requirement

The performance, training, and qualifications of the facility staff (should be audited) - at least once per 12 months.

Exception/Interpretation

Consistent with NRC Safety Evaluation, Amendment 106, for Millstone Nuclear Power Station Unit 1 (ADAMS Accession Number ML993330283), and NRC Transmittal QA1-99-221 dated November 18, 1999 (ADAMS Accession Number ML993310022) and NRC Administrative Letter 95-06 dated December 12, 1995, Big Rock Point interprets the commitment to audit performance, training, and qualifications of the facility staff contained in 18.2.2 of this quality program, and in Appendix D, Audit Frequencies, as once per 24 months.

4a. ANS 3.1, General

Exception/Interpretation

The commitment to ANS 3.1 (12/79, draft) is limited to the requirements that apply to the training and qualification of persons performing independent quality assurance functions, except for Lead Auditors. Lead auditors are trained and qualified to Regulatory Guide 1.146 (8/80)/ANSI 45.2.23-1978. Other personnel are trained and qualified as designated in Section 1.0 of the Quality Program Description for Big Rock Point.

5a. RG 1.8, C.3.1, General

Exception/Interpretation

The commitment to Regulatory Guide 1.8 (9/80, draft) is limited to the requirements that apply to the training and qualification of persons performing independent quality assurance functions, except for Lead Auditors. Lead Auditors are trained and qualified to Regulatory Guide 1.146 (8/80)/ANSI N45.2.23-1978. Other personnel are trained and qualified as designated in Section 1.0 of the Quality Program Description for Big Rock Point.

QUALITY PROGRAM DESCRIPTION FOR BIG ROCK POINT

5b. RG 1.8, C1.2.2

Requirement

"When an individual is hired to temporarily function as a plant employee, such as for contracted services, evidence of previous education, experience, and training should be provided and reviewed by the appropriate professional-technical group leaders. The appropriate group leaders should then determine the content for that individual's training, including plant-specific training. As a minimum, each individual should receive General Employee Training."

Exception/Interpretation

Big Rock Point understands that this requirement applies to site employees, Consumers Energy employees from another site, and to contract personnel who are temporarily assigned to BRP either as replacements for regular employees or to augment the staff. Employees so assigned possess the required qualifications as a prerequisite to the assignment and the review is waived. The qualifications of contract personnel are reviewed and arrangements made for any necessary training. Temporarily assigned personnel requiring unescorted access receive the site general orientation as embodied in General Employee Training.

6a. N45.2.1, Section 2.4

Requirement

Those personnel who perform inspection, examination, or testing activities required by this standard shall be qualified in accordance with ANSI N45.2.6 Qualifications of Inspection, Examination and Testing Personnel for the Construction Phase of Nuclear Power Plants.

Exception/Interpretation

Big Rock Point certifies its inspectors in accordance with Paragraphs 10.2.3, 10.2.7 and 10.2.10 of this quality program unless the work is comparable in nature and extent to original construction (see Item 2j).

6b. N45.2.1, Section 3.1

Requirement

N45.2.1 establishes criteria for classifying items into "cleanness levels," and requires that items be so classified.

QUALITY PROGRAM DESCRIPTION FOR BIG ROCK POINT

Exception/Interpretation

Instead of using the cleanliness level classification system of N45.2.1, the required cleanliness for specific items and activities is addressed on a case-by-case basis.

Cleanliness is maintained, consistent with the work being performed, so as to prevent the introduction of foreign material. As a minimum, cleanliness inspections are performed prior to system closure. Such inspections are documented.

7a. N45.2.2, General

Requirement

N45.2.2 establishes requirements and criteria for classifying items subject to this program into protection levels.

Exception/Interpretation

Instead of classifying items subject to this program into protection levels, controls over the packaging, shipping, handling, and storage of such items are established on a case-by-case basis with due regard for the item's complexity, use, and sensitivity to damage. Prior to installation or use, the items are inspected and serviced as necessary to assure that no damage or deterioration exists which could affect their function.

7b. N45.2.2, Section 2.4

Requirement

"...Offsite inspection, examination or testing shall be audited and monitored by personnel who are qualified in accordance with N45.2.6."

Exception/Interpretation

Offsite inspection, examination, or testing activities are audited or inspected by persons qualified and certified in accordance with ANSI N45.2.23-1978, as endorsed by Regulatory Guide 1.146, or by personnel meeting the requirements of paragraphs 10.2.3, 10.2.7 or 10.2.10. Monitoring activities not involving audit or inspection may be conducted by persons trained and qualified to effectively carry out such tasks, but not necessarily certified to either ANSI N45.2.23, N45.2.6 or Paragraph 10.2.7.

7c. This exception/interpretation no longer applies and has been deleted.

QUALITY PROGRAM DESCRIPTION FOR BIG ROCK POINT

7d. N45.2.2, Section 3.9 and Appendix A 3.9

Requirement

"The item and the outside of containers shall be marked."

(Further criteria for marking and tagging are given in the appendix.)

Exception/Interpretation

These requirements were originally written for items packaged and shipped to construction projects. Full compliance is not always necessary in the case of items shipped to operating plants and may, in some cases, increase the probability of damage to the item. The requirements are implemented to the extent necessary to assure traceability and integrity of the item.

7e. N45.2.2, Section 5.2.2

Requirement

"The inspections shall be performed in an area equivalent to the level of storage."

Exception/Interpretation

Receiving inspection area environmental controls may be less stringent than storage environmental requirements for an item. However, such inspections are performed in a manner and in an environment that do not endanger the required quality of the item.

7f. N45.2.2, Section 6.2.4

Requirement

"The use or storage of food, drinks, and salt tablet dispensers in any storage area shall not be permitted."

Exception/Interpretation

Packaged food for emergency or extended overtime use may be stored in material stock rooms. The packaging assures that materials are not contaminated. Food will not be "used" in these areas.

QUALITY PROGRAM DESCRIPTION FOR BIG ROCK POINT

7g. N45.2.2, Section 6.3.4

Requirement

"All items and their containers shall be plainly marked so that they are easily identified without excessive handling or unnecessary opening of crates and boxes."

Exception/Interpretation

See N45.2.2, Section 3.9 (Exception 7d).

7h. N45.2.2, Section 6.4.1

Requirement

"Inspections and examinations shall be performed and documented on a periodic basis to assure that the integrity of the item and its container...is being maintained."

Exception/Interpretation

The requirement implies that all inspections and examinations of items in storage are to be performed on the same schedule. Instead, the inspections and examinations are performed and documented in accordance with material storage procedures that identify the characteristics to be inspected and include the required frequencies. These procedures are based on technical considerations that recognize that inspections and frequencies needed vary from item to item.

8a. N45.2.3, Section 2.1

Requirement

Cleanliness requirements for housekeeping activities shall be established on the basis of five zone designations.

Exception/Interpretation

Instead of the five-level zone designation system referenced in ANSI N45.2.3, Big Rock Point bases its controls over housekeeping activities on a consideration of what is necessary and appropriate for the activity involved. The controls are effected through procedures or instructions, which, in the case of maintenance or modifications work, are developed on a case-by-case basis. Factors considered in developing the procedures and instructions include cleanliness control, personnel safety, fire prevention and protection, radiation control, and security. The procedures and instructions make use of standard janitorial and work practices to the extent possible. However, in preparing these procedures, consideration is also given to the recommendations of Section 2.1 of ANSI N45.2.3.

QUALITY PROGRAM DESCRIPTION FOR BIG ROCK POINT

9a. N45.2.4, Section 2.2

Requirement

Section 2.2 establishes prerequisites that must be met before the installation, inspection, and testing of instrumentation and electrical equipment may proceed. These prerequisites include personnel qualification, control of design, conforming and protected materials, and availability of specified documents.

Exception/Interpretation

During the decommissioning phase, this requirement is considered to be applicable to modifications and initial start-up of electrical equipment. For routine or periodic inspection and testing, the prerequisite conditions will be achieved as necessary.

9b. N45.2.4, Section 2.2(5)

Requirement

Section 2.2(5) of ANSI N45.2.4 lists documents that are to be available at the construction site.

Exception/Clarification

All of the documents listed are not necessarily required at the site for installation and testing. Big Rock Point assures that they are available to the site as necessary.

9c. N45.2.4, Section 6.2.1

Requirement

"Items requiring calibration shall be tagged or labeled on completion, indicating date of calibration and identity of person that performed the calibration."

Exception/Interpretation

If the physical size or location of installed instrumentation prevents calibration labels or tags from being affixed to the instrument, each instrument is uniquely identified and is traceable to its calibration record.

A scheduled calibration program assures that each instrument's calibration is current.

QUALITY PROGRAM DESCRIPTION FOR BIG ROCK POINT

10a. N45.2.5, Section 2.4

Requirement

"Persons charged with engineering managerial responsibility of the inspection and testing organization at the site in either a resident or non-resident capacity shall be certified for Level III capability."

Exception/Interpretation

This standard (N45.2.5) was written for the construction phase of nuclear power plants; as such, it presumes significant activity in the areas of concrete and structural steel that do not generally occur at an Independent Spent Fuel Storage Installation or decommissioning site. At Big Rock Point, persons having engineering managerial responsibility for inspections and tests¹ may be certified to Level III, or may meet other qualification criteria established for the position, including, but not limited to, nuclear power and management experience. For major modifications involving significant concrete or structural steel work, the services of a properly qualified Level III individual will be obtained in at least an advisory capacity.

10b. N45.2.5, Section 2.5.2

Requirement

"When discrepancies, malfunctions, or inaccuracies in inspection and testing equipment are found during calibration, all items inspected with that equipment since the last previous calibration shall be considered unacceptable until an evaluation has been made by the responsible authority and appropriate action taken."

Exception/Interpretation

Big Rock Point uses the requirements of N18.7, Section 5.2.16, rather than N45.2.5, Section 2.5.2. The N18.7 requirements are more applicable to ISFSI operation and a site undergoing decommissioning.

10c. N45.2.5, Section 5.4

Requirement

"Hand torque wrenches used for inspection shall be controlled and must be calibrated at least weekly and more often if deemed necessary. Impact torque wrenches used for inspection must be calibrated at least twice daily."

¹ Within the scope of N45.2.5.

QUALITY PROGRAM DESCRIPTION FOR BIG ROCK POINT

Exception/Interpretation

Torque wrenches are controlled as measuring and test equipment in accordance with ANSI N18.7, Section 5.2.16. Calibration intervals are based on use and calibration history rather than N45.2.5.

11a. N45.2.6, Section 1.2

Requirement

"The requirements of this standard apply to personnel who perform inspections, examinations, and tests during fabrication prior to and during receipt of items at the construction site, during construction, during preoperational and start-up testing, and during operational phases of nuclear power plants."

Exception/Interpretation

See Exception/Interpretation 2j for those inspectors who must be certified to ANSI N45.2.6. Others are qualified to Paragraphs 10.2.3, 10.2.7 and 10.2.10 of this quality program.

Qualification of personnel who are involved with testing associated with ISFSI operation is provided in specific procedures. In addition, personnel participating in inspection or testing who take data or make observations, where special training is not required to perform this function, need not be qualified in accordance with ANSI N45.2.6 but need only be trained to the extent necessary to perform the assigned function.

12a. RG 1.58, Section C.1

Requirement

"However, for qualification of personnel (1) who approve preoperational, start-up and operational test procedures and test results and (2) who direct or supervise the conduct of individual preoperational, start-up and operational tests, the guidelines contained in Regulatory Guide 1.8, Personnel Selection and Training, should be followed in lieu of the Guidelines of ANSI N45.2.6 - 1978."

Exception/Interpretation

Big Rock Point endorses this position, as also stated in 11 a, above, except that offsite support organizations involved in testing may apply ANSI N45.2.6. Some of these departments have already developed their qualification programs based on ANSI N45.2.6, and provide services throughout decommissioning of Big Rock Point and operation of the ISFSI.

QUALITY PROGRAM DESCRIPTION FOR BIG ROCK POINT

12b. RG 1.58, Section C.5

Requirement

"In addition, the individual should be capable of reviewing and approving inspection, examination and testing procedures and of evaluating the adequacy of such procedures to accomplish the inspection, examination and test objectives."

Exception/Interpretation

While a Level III individual should be capable of reviewing and approving inspection, examination and testing procedures and of evaluating the adequacy of such procedures to accomplish the inspection, examination and test objectives, this is not construed by Big Rock Point as requiring personnel who review, approve or evaluate such procedures to be certified as Level III personnel.

12.c. RG 1.58, Section C.6

Requirement

"Since only one set of recommendations is provided for the education and experience of personnel, a commitment to comply with the regulatory position of this guide in lieu of providing an alternative to the recommendations of the standard means that the specified education and experience recommendations of the standard will be followed."

Exception/Interpretation

The content of the Big Rock Point qualification and certification program is based upon the recommendations of ANSI N45.2.6, and satisfactory completion of capability testing is required prior to certification. Therefore, it is our position that a candidate should not be required to be a high school graduate or have earned the GED equivalent.

12.d RG 1.58, Section C.10

Requirement

"Use of the measures outlined in these actions to establish that an individual has the required qualifications in lieu of required education and experience should result in documented evidence (i.e., procedure and record of written test) demonstrating that the individual indeed does have comparable or equivalent competence to that which would be gained from having the required education and experience."

Exception/Interpretation

We will maintain documented objective evidence that demonstrates that an individual does have "comparable" or "equivalent" competence to that which would be gained from having the required education and experience. However, this may take the form of documentation other than "procedures and records of written test" such as documentation of oral tests and on-the-job performance demonstrations.

QUALITY PROGRAM DESCRIPTION FOR BIG ROCK POINT

13a. N45.2.8, Section 2.7

Requirement

Section 2.7 requires that personnel performing inspection and test activities be qualified according to ANSI N45.2.6.

Exception/Interpretation

See Exception/Interpretation 2j, 11a, and 12a. Test personnel who are part of the site staff need not be certified to N45.2.6, provided they meet applicable qualification criteria of the procedures.

13b. N45.2.8, Section 2.9

Requirement

Section 2.9 establishes prerequisites that must be met before the installation, inspection and testing of mechanical equipment may proceed. These prerequisites include personnel and procedure qualification, control of design, material selection and fabrication, and availability of specified documents.

Exception/Interpretation

During the decommissioning phase, this requirement is considered to be applicable to modifications of mechanical equipment. For routine or periodic inspection and testing, the prerequisites will be achieved as necessary.

13c. N45.2.8, Section 2.9e

Requirement

Section 2.9e of N45.2.8 lists documents relating to the specific stage of installation activity which are to be available at the construction site.

Exception/Interpretation

All of the documents listed are not necessarily required at the site for installation and testing. Big Rock Point assures that they are available to the site as necessary.

13d. N45.2.8, Section 2.9e

Requirement

Evidence that engineering or design changes are documented and approved shall be available at the construction site prior to installation.

QUALITY PROGRAM DESCRIPTION FOR BIG ROCK POINT

Exception/Interpretation

Equipment may be installed before final approval of engineering or design changes. However, the system is not declared operable until such changes are documented and approved.

13e. N45.2.8, Section 4.5.1

Requirement

"Installed systems and components shall be cleaned, flushed, and conditioned according to requirements..." (requirements are given for chemical conditioning, flushing and process controls).

Exception/Interpretation

Systems and components are cleaned, flushed and conditioned as determined on a case-by-case basis. Measures are taken to help preclude the need for cleaning, flushing, and conditioning through good practices during maintenance or modification activities.

14a. N45.2.9, Section 5.4, Item 2

Requirement

Records shall not be stored loosely. They shall be firmly attached in binders or placed in folders or envelopes for storage on shelving in containers. Steel cabinets are preferred.

Exception/Interpretation

Records are suitably stored in steel file cabinets or on shelving in containers. Methods other than binders, folders or envelopes (for example, dividers or electronic media) may be used to organize the records for storage.

14b. N45.2.9, Section 6.2

Requirement

"A list shall be maintained designating those personnel who shall have access to the files."

Exception/Interpretation

Rules are established governing access to and control of files as provided for in ANSI N45.2.9, Section 5.3, Item 5. These rules do not always include a requirement for a list of personnel who are authorized access. It should be noted that duplicate files and/or microforms exist for general use and backup.

QUALITY PROGRAM DESCRIPTION FOR BIG ROCK POINT

14c. RG 1.88, C2

Requirement

"Two methods of protection of quality assurance records from the hazards of fire are described in Subdivision 5.6 of ANSI N45.2.9-1974. NFPA No 232-1975...also contains provisions for records protection equipment and records handling techniques that provide protection from the hazards of fire. This standard, within its scope of coverage, is considered by the NRC staff to provide an acceptable alternative to the fire protection provisions listed in Subdivision 5.6...When NFPA 232-1975 is used, quality assurance records should be classified as NFPA Class 1 records...."

Exception/Interpretation

Big Rock Point adheres to ANSI N45.2.9-1974, Subdivision 5.6 for the facility for permanent storage of non-duplicated records. Temporary storage of documents after completion and during processing as records is in file cabinets selected in accordance with provisions of NFPA 232-1975 for Class 1 records (usually NFPA Class C, 1 hour or UL-Class 350).

15a. RG 1.64, C2

Requirement

"Regardless of their title, individuals performing design verification should not (1) have immediate supervisory responsibility for the individual performing the design...."

Exception/Interpretation

Big Rock Point follows the requirements of ANSI N45.2.11-1974, Section 6.1, and the guidance of Section 3E4(a) of the Standard Review Plan, with the exception that use of supervisors as design verifiers may be controlled by a procedure instead of individually approved in advance in each case (see Section 3.2.9, herein). This approach is necessary to allow small organizational units (having limited numbers of technically qualified staff, or having the only technically qualified staff available in the Company) the flexibility needed to most effectively accomplish their assigned tasks.

16a. RG 1.144, Section C3.a(1)

Requirement

This section requires that for operational phase activities, RG 1.33 "Quality Assurance Program Requirements (Operations)" are to be followed. One of the RG 1.33 requirements is that the results of actions taken to correct deficiencies that affect nuclear safety and occur in facility equipment, structures, systems, or method of operation are to be audited at least once per six months.

Exception/Interpretation

See Item 3a for the exception to this requirement.

QUALITY PROGRAM DESCRIPTION FOR BIG ROCK POINT

16b. RG 1.144, Section C3.a(2)

Requirement

Applicable elements of an organization's quality assurance program (for "design and construction phase activities") should be audited at least annually or at least once within the life of the activity, whichever is shorter.

Exception/Interpretation

Since most modifications are straightforward, they are not audited individually. Instead, selected controls over modifications are audited periodically.

16c. RG 1.144, Sec C3.b(1)

Requirement

This section identifies procurement contracts that are exempted from being audited.

Exception/Interpretation

In addition to the exemptions of RG 1.144, Big Rock Point considers that Authorized Inspection Agencies, National Institute of Standards and Technology or other State and Federal Agencies which may provide services to Big Rock Point are not required to be audited.

16d. RG 1.144, Section C.3.b(2), second paragraph

Requirement

A documented evaluation of the supplier should be performed annually. Where applicable, this evaluation should take into account (1) review of supplier-furnished documents such as certificates of conformance, non-conformance notices, and corrective actions, (2) results of previous source verifications, audits and receiving inspections, (3) operating experience of identical or similar products furnished by the same supplier, and (4) results of audits from other sources (i.e., customer, ASME or NRC Audits).

Exception/Interpretation

Big Rock Point will review the information described in the second paragraph of Section C.3.b(2) of Regulatory Guide 1.144, Revision 1, 1980, as it becomes available through ongoing receipt inspection, operating experience, and supplier evaluation programs, in lieu of performing a specific evaluation on an annual basis. The results of the reviews are promptly considered for effect on a supplier's continued qualification and adjustments made as necessary (including corrective actions, adjustments of supplier audit plans, and input to third party auditing entities as warranted). In addition, results are reviewed periodically to determine if, as a whole, they constitute a significant condition adverse to quality requiring additional action.

QUALITY PROGRAM DESCRIPTION FOR BIG ROCK POINT

17a. N45.2.13, Section 3.2.2

Requirement

N45.2.13 requires that technical requirements be specified in procurement documents by reference to technical requirement documents. Technical requirement documents are to be prepared, reviewed and released under the requirements established by ANSI N45.2.11.

Exception/Interpretation

For replacement parts and materials, Big Rock Point follows ANSI N18.7, Section 5.2.13, Subitem 1, which states: "Where the original item or part is found to be commercially 'off-the-shelf' or without specifically identified QA requirements, spare and replacement parts may be similarly procured, but care shall be exercised to ensure at least equivalent performance."

17b. N45.2.13, Section 3.2.3

Requirement

"Procurement documents shall require that the supplier have a documented quality assurance program that implements portions of ANSI N45.2 as well as applicable quality assurance program requirements of other nationally recognized codes and standards."

Exception/Interpretation

Refer to Item 21.

17c. N45.2.13, Section 3.3(a)

Requirement

Reviews of procurement documents shall be performed prior to release for bid and contract award.

Exception/Interpretation

Documents may be released for bid or contract award before completing the necessary reviews. However, these reviews are completed before the item or service is put into service or before work has progressed beyond the point where it would be impractical to reverse the action taken.

17d. N45.2.13, Section 3.3(b)

Requirement

"Changes made in the procurement documents as a result of the bid evaluations or pre-contract negotiations shall be incorporated into the procurement documents. The review of such changes and their effects shall be completed prior to contract award."

QUALITY PROGRAM DESCRIPTION FOR BIG ROCK POINT

Exception/Interpretation

This requirement applies only to quality related changes (i.e., changes to the procurement document provisions identified in ANSI N18.7, Section 5.2.13.1, Subitems 1 through 5). The timing of reviews will be the same as for review of the original procurement document.

17e. N45.2.13, Section 7.5

Requirement

"Personnel responsible for performing verification activities shall be qualified in accordance with ANSI N45.2.6 as applicable."

Exception/Interpretation

Big Rock Point qualifies audit personnel according to N45.2.23. Thus, personnel performing source verification audits may not be certified according to N45.2.6. Personnel performing inspection as part of source verification will be certified to N45.2.6 or qualified in accordance with Paragraphs 10.2.3, 10.2.7, or 10.2.10. However, personnel performing source surveillances may not be certified to any of those requirements.

17f. N45.2.13, Section 10.1

Requirement

"Where required by code, regulation or contract requirement, documentary evidence that items conform to procurement documents shall be available at the nuclear power plant site prior to installation or use of such items, regardless of acceptance methods."

Exception/Interpretation

Refer to Item 2m.

17g. N45.2.13, Section 10.3.4 (as modified by RG 1.123, C6e)

Requirement

"Post-installation test requirements and acceptance documentation shall be mutually established by the purchaser and supplier."

Exception/Interpretation

In exercising its ultimate responsibility for its Quality Program, Big Rock Point establishes post-installation test requirements, giving due consideration to supplier recommendations.

QUALITY PROGRAM DESCRIPTION FOR BIG ROCK POINT

18a. ANSI N45.2.23-1978, Section 2.3.4

Requirement

The prospective lead auditor shall have participated in a minimum of five (5) quality assurance audits within a period of time not to exceed three (3) years prior to the date of qualification, one audit of which shall be a nuclear quality assurance audit within the year prior to his qualification.

Exception/Interpretation

The prospective lead auditor shall demonstrate his ability to properly implement the audit process defined by this Standard and Big Rock Point program/procedure, to effectively lead an audit team, and to effectively organize and report results, including participation in at least one nuclear quality assurance audit within the year preceding date of certification.

19. ANSI/ANS 3.1 - 1987

Exception/Interpretation

The commitment to ANSI/ANS 3.1-1987 is limited to requirements that apply to persons performing the independent safety review function as specified in Appendix C to this quality program.

20. ANSI N18.1-1971

Exception/Interpretation

The individual responsible for radiation protection functions shall meet the minimum requirements of Regulatory Guide 1.8, September 1975. As applied to this specification, "equivalent," as used in Regulatory Guide 1.8 for the bachelor's degree requirement, may be met with four years of any one or combination of the following: (a) formal training in science engineering or (b) operational or technical experience and training in nuclear power.

QUALITY PROGRAM DESCRIPTION FOR BIG ROCK POINT

APPENDIX B SAFETY REVIEW

B1. FUNCTION

Safety Reviewers shall function to advise the Site General Manager on all matters of administrative controls and quality assurance associated with safety-related activities and/or important-to-safety structures, systems, or components. The Safety Reviewer ensures activities do not require U.S. Nuclear Regulatory Commission approval pursuant to 10 CFR 50.59 or 10 CFR 72.48 prior to implementation.

B2. COMPOSITION

The Site General Manager shall assign Safety Reviewers in writing. Safety Reviewers shall be competent in the activity under review and shall not review their own work.

B3. QUALIFICATIONS

Safety Reviewers shall be knowledgeable in the subject area being reviewed.

B4. MEETING FREQUENCY

Meetings are not required for performance of Safety Review functions described in this appendix.

B5. QUORUM

Safety Reviews are to be performed by at least one Safety Reviewer.

B6. RESPONSIBILITIES

Safety Reviewers shall be responsible for review of:

- a. All procedures and programs specified by the Quality Program Description, Section 5.0, INSTRUCTIONS, PROCEDURES AND DRAWINGS, and changes thereto, and any other procedures or changes thereto as determined by the Site General Manager; all proposed tests or experiments; and all proposed changes or modifications to the ISFSI that affect administrative controls and quality assurance associated with safety-related activities and/or important-to-safety structures, systems, or components.
- b. All proposed changes to Operating License and the Spent Fuel Storage System Certificate of Compliance.
- c. Reports of special reviews and investigations as requested by the Site General Manager, the Quality Assurance Lead, or ISRC.

QUALITY PROGRAM DESCRIPTION FOR BIG ROCK POINT

- d. Reportable events defined by 10 CFR 50.72, 50.73, 71.95, 72.74, and 72.75. A report shall be prepared covering evaluation and recommendation to prevent recurrence and shall be forwarded to the Site General Manager, the Quality Assurance Lead, the ISRC, and the Vice President, NFHO.

B7. AUTHORITY

- a. Safety Reviewers shall:
 1. Recommend in writing to the Site General Manager approval or disapproval of items considered under B6.a and b.
 2. Render determinations in writing whether or not items considered under B6.a and b require prior NRC approval; alternatively, if the Site General Manager meets the qualification requirements of B3, this determination may be made by the Site General Manager prior to Site General Manager approval of the item.
- b. The Site General Manager shall:
 1. Provide written notification within 24 hours to the Senior Vice President, NFHO, the Quality Assurance Lead, and ISRC of any disagreement between the recommendation of a Safety Reviewer and the decision of the Site General Manager; however the Site General Manager shall have authority for resolution of such disagreements.

B8. RECORDS

Written records of Safety Reviews shall be maintained; these records shall contain or identify any documents reviewed, and shall be available for ISRC review.

QUALITY PROGRAM DESCRIPTION FOR BIG ROCK POINT

APPENDIX C INDEPENDENT SAFETY REVIEW COMMITTEE

The following exceptions/interpretations in Appendix A, Part 2, are relevant to implementation of the requirements of this section of the quality program:

<u>Paragraph</u>	<u>Exceptions/Interpretations</u>
C1.	2, 2b
C2	2, 19
C3	2, 2b, 19
C4.1	2c
C4.1(c)	2d
C4.1(g)	2e, 2f

C1. FUNCTION

The Independent Safety Review Committee (ISRC) shall collectively have competence in the disciplines specified below, although the ISRC may obtain additional expertise as provided for in C3.

- a. ISFSI operations
- b. Packaging of spent nuclear fuel for transportation
- c. Engineering
- d. Radiation protection
- e. Quality assurance and administrative controls

C2. COMPOSITION

The ISRC shall report to the Senior Vice President, NFHO and shall consist of a Chairman and at least one member appointed by the Senior Vice President – NFHO. ISRC members shall meet or exceed the qualifications described in Section 4.7 of ANSI/ANS 3.1-1987. The ISRC members shall have no direct responsibility for activities subject to their review.

C3. SUPPORT PERSONNEL

If sufficient expertise is not available within the ISRC to review particular issues, the ISRC shall have the authority to utilize consultants or other qualified organizations for expert advice. Support personnel shall meet or exceed the qualifications described in Section 4.7 of ANSI/ANS 3.1-1987. Support personnel shall have no direct responsibility for activities they review.

QUALITY PROGRAM DESCRIPTION FOR BIG ROCK POINT

C4. RESPONSIBILITIES

C4.1 Review Requirements

The ISRC shall provide independent review of:

- a. Written 10 CFR 50.59 evaluations and Big Rock Point initiated 10 CFR 72.48 written evaluations of changes in the facility or procedures as described in the quality program, and tests or experiments not described in the Updated Final Hazards Summary Report that have been performed without prior NRC approval under the provisions of 10 CFR 50.59 or 10 CFR 72.48.

This review, includes a review of a sample of the written 10 CFR 50.59, 10 CFR 10.82, and 10 CFR 72.48 screening evaluations, to verify that none of the sample evaluations required evaluation under the provisions of 10 CFR 50.59 or 10 CFR 72.48. This sampling verifies that the process for screening 10 CFR 50.59 and 10 CFR 72.48 evaluations is effective.

ISRC shall review all 10 CFR 50.59 and Big Rock Point Site initiated 10 CFR 72.48 determinations that screen into the evaluation process.

- b. Activities that require prior NRC approval pursuant to 10 CFR 50.59 or 10 CFR 72.48. Such reviews shall be performed prior to submittal to the NRC of the change to the facility, change to a procedure, or the test or experiment.
- c. Proposed changes to the Operating License conditions or Cask Storage System Certificate of Compliance prior to the proposed change being submitted to the NRC.
- d. Violations, deviations and reportable events requiring written notification to the NRC within 24 hours of safety-related activities and/or important to safety systems, structures, or components, such as:
 - (1) Violations of applicable codes, regulations, orders, license requirements, Cask Storage System Certificate of Compliance, or of internal procedures or instructions that are safety-related activities and/or important to safety systems, structures, or components.
 - (2) Significant operating abnormalities, events or deviations from normal and expected performance of ISFSI equipment that affect safety-related activities and/or important to safety systems, structures, or components.
- e. Reports of audits performed as specified in Appendix D.

QUALITY PROGRAM DESCRIPTION FOR BIG ROCK POINT

- f. Any other matter involving safe operation of the ISFSI that an ISRC member deems appropriate for consideration, or that is referred to the ISRC by the onsite operating organization or by the Quality Assurance Lead.

C4.2 Review Methodology and Meeting Requirements

ISRC review of the subjects in C4.1 shall be performed by members or support personnel selected on the basis of technical expertise relative to the subject being reviewed. If the assigned reviewer determines the need for interdisciplinary review, a committee consisting of the ISRC Chairman, or his designate, and at least one other ISRC member or qualified support personnel shall be assigned. The committee shall meet as conditions requiring interdisciplinary review arise, but not less than annually.

C5 AUTHORITY

The ISRC shall report to and advise the Senior Vice-President, NFHO, of significant findings associated with the reviews specified in C4.1 and Appendix D, Audit Frequencies.

C6 RECORDS

Records of ISRC activities shall be maintained. Reports shall be prepared and distributed as indicated below:

- a. The results of reviews performed pursuant to C4.1 shall be reported to the Senior Vice President, NFHO, following each meeting of the ISRC. Significant findings with respect to reviews performed in accordance with C4.1 shall be reported immediately to the Senior Vice President, NFHO, with written follow-up not later than the following meeting report.

QUALITY PROGRAM DESCRIPTION FOR BIG ROCK POINT

APPENDIX D AUDIT FREQUENCIES

The following exceptions/interpretations in Appendix A, Part 2, are relevant to implementation of the requirements of this section of the quality program:

<u>Paragraph</u>	<u>Exceptions/Interpretations</u>
D1.	3a, 3b, 3c, 16a

D1. AUDITS

Audits of decommissioning activities and ISFSI operations subject to this Program are performed by the Quality Assurance Lead. These audits encompass:

- a. The conformance of site operation to provisions contained within operating license, and the Spent Fuel Storage Cask System Certificate of Compliance at least once per 24 months.
- b. The performance, training and qualifications of those members of the facility staff who perform quality activities defined in this quality program at least once per 24 months.
- c. The performance of activities and administrative controls required by the quality program and the Fire Protection Plan at least once per 24 months.
- d. The Independent Spent Fuel Storage Installation (ISFSI) Emergency Plan and implementing procedures:
 - (1) At intervals not to exceed 12 months or,
 - (2) As necessary, based on an assessment by the Quality Assurance Organization against performance indicators, and as soon as reasonably practicable after a change occurs in personnel, procedures, equipment, or facilities that potentially could adversely affect emergency preparedness, but no longer than 12 months after the change. In any case, all elements of the emergency preparedness program must be reviewed at least once every 24 months.
- e. The Site Security Plan and implementing procedures shall be audited at intervals specified in the Security Plan.
- f. Any other area of decommissioning or ISFSI operation considered appropriate by the Quality Assurance Organization or the Senior Vice President, NFHO.

QUALITY PROGRAM DESCRIPTION FOR BIG ROCK POINT

- g. The Radiation Protection Program, including the Offsite Dose Calculation Manual (ODCM) and the Process Control Manual and their implementing procedures at least once per 24 months.

Audit reports encompassed by D1 shall be forwarded to the Quality Assurance Lead and Management positions responsible for the areas audited within thirty (30) days after completion of the audit.

QUALITY PROGRAM DESCRIPTION FOR BIG ROCK POINT

APPENDIX E RECORD RETENTION

- E1. In addition to the applicable record retention requirements of Title 10, Code of Federal Regulations, the following records shall be retained for at least the minimum period indicated. Where 10 CFR 72 or the Part 72 license conditions do not specify a retention period for a record, the records shall be retained until the NRC terminates the license.
- E2. The following records shall be retained for at least five years:
- a. Records and logs of facility operation covering time interval at each power level.
 - b. Records and logs of principal maintenance activities, inspections, repair and replacement of principal items of equipment related to nuclear safety.
 - c. All reportable events as defined in 10 CFR 50.72, 50.73, 72.74, and 72.75.
 - d. Records of surveillance activities, inspections and calibrations required by Big Rock Point Operating License or quality program.
 - e. Records of changes made to the procedures required by Big Rock Point Operating License or this quality program.
 - f. Records of radioactive shipments.
 - g. Records of sealed source leak tests and results.
 - h. Records of annual physical inventory of all source material of record.
- E3. The following records shall be retained for the duration of the Facility 10 CFR 50 or Part 72 License:
- a. Record and drawing changes reflecting facility design modifications made to systems and equipment described in the Big Rock Point UFHSR.
 - b. Records of new and irradiated fuel inventory, fuel transfers and assembly burnup histories.
 - c. Records of quarterly radiation exposure for all individuals entering radiation control areas.
 - d. Records of gaseous and liquid radioactive material released to the environs.

QUALITY PROGRAM DESCRIPTION FOR BIG ROCK POINT

- e. Records of transient or operational cycles for those facility components designed for a limited number of transients or cycles.
 - f. Records of in-service inspections performed pursuant to the Operating License or Cask Certificate of Compliance.
 - g. Records of Quality Assurance activities required by the quality program.
 - h. Records of reviews performed for changes made to procedures or equipment, or reviews of tests and experiments pursuant to 10 CFR 50.59, 10 CFR 50.82 and 10 CFR 72.48.
 - i. Records of reviews performed by Safety Reviewers and the ISRC, according to Appendices B and C.
 - j. Records of monthly facility radiation and contamination surveys.
 - k. Records for environmental qualifications that are covered under the provisions of 10 CFR 50.49.
 - l. Records of training and qualifications for members of the site staff.
 - m. Records of reactor tests and experiments.
 - n. Records of reviews performed for changes made to the Off-site Dose Control Manual and the Process Control Program.
- E4. The following records shall be retained as long as the associated material is stored and for a period of five years after the material is transferred out of the ISFSI:
- a. Records of receipt, inventory (including location), disposal, acquisition, and transfer of all spent fuel and high level waste in storage.
- E5. The following records shall be retained until the NRC terminates the 10 CFR Part 72 General License for the ISFSI:
- a. Records of the current inventory of all spent fuel and high-level waste.
 - b. Current material control and accounting procedures.
 - c. ISFSI and Cask Storage System records pertaining to the design, fabrication, erection, testing, maintenance, and use of structures systems and components important to safety.

QUALITY PROGRAM DESCRIPTION FOR BIG ROCK POINT

- E6. The following records shall be retained and forwarded to the appropriate NRC Regional Office prior to the ISFSI General License termination:
- a. Records of spills or other unusual occurrences involving the spread of contamination in and around the facility, equipment or site. These records may be limited to instances when contamination remains after any clean-up procedures or when there is a reasonable likelihood that contaminants may have spread to inaccessible areas as in the case of possible seepage into porous materials such as concrete. The records must include any known information on identification of involved nuclides, quantities, forms, and concentrations.
 - b. As-built drawings and modifications of structures and equipment in restricted areas where radioactive materials are used and/or stored, and of locations of possible inaccessible contamination such as buried pipes, which may be subject to contamination. If required drawings are referenced, each relevant document need not be indexed individually. If drawings are not available, the licensee shall substitute appropriate records of available information concerning these areas and locations.
 - c. A list contained in a single document and updated no less than every 2 years of the following:
 - (1) All areas designated and formerly designated as restricted areas as defined under 10 CFR 20.1003; and
 - (2) All areas outside of restricted areas that require documentation under 10 CFR 72.30(d)(1).
 - d. Records of the cost estimate performed for the decommissioning funding plan or of the amount certified for decommissioning, and records of the funding method used for assuring funds if either a funding plan or certification is used.
 - e. Records of the results of measurements and calculations used to evaluate the release of radioactive effluents to the environment. This includes those records of the results of measurements and calculations used to evaluate the release of radioactive effluents to the environment under the standards for protection against radiation in effect prior to January 1, 1994.