



71-0804  
72-1007  
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July 23, 2003  
BFS/NRC 03-011  
Docket Nos. 72-1007,  
72-1026, 71-9276  
File Nos. WEP-09,  
CMPC.0006.1

U.S. Nuclear Regulatory Commission  
Washington, DC 20555-0001

ATTN: Document Control Desk

**Subject: Revision 10 to BNFL Fuel Solutions Quality Assurance Manual**

- References:
- 1) USNRC Quality Assurance Program Approval Certificate 71-0804, Revision 3 dated December 20, 2000
  - 2) USNRC Quality Assurance Program Approval Certificate 71-0804, Revision 4 dated December 6, 2002

Dear Sir or Madam:

BNFL Fuel Solutions Corporation (BFS) has prepared and submits herewith Revision 10 of "Manual of Quality Assurance for BNFL Fuel Solutions" (BFS QA Manual). BFS hereby requests that the NRC approve the enclosed BFS QA Manual (Enclosure 1) in accordance with 10 CFR 72 Subpart G and 10 CFR 71 Subpart H.

BFS received NRC approval of Revision 9 of the BFS QA Manual for 10 CFR 71 Subpart H in Reference 1. At the end of 2002, BFS completed a relocation of our offices and a refocus of our business unit. We have adjusted our organization and processes while maintaining our NRC-accepted Quality Assurance Program. The approval certificate was revised to incorporate the change in address of BFS' offices (Reference 2). All quality-related work currently being conducted at BFS is being performed under the current Revision 9 of the BFS QA Manual.

To complete our transition and complete these adjustments related to refocusing our business, BFS is proposing a revision to its QA Program Description as documented in the enclosed Revision 10 of the BFS QA Manual dated 7/23/03 (Enclosure 1). Changes in Revision 10 of the BFS QA Manual fall into the following categories:

Mmss01

- Corrections of grammar and sentence constructions to more clearly describe the statements of requirement (These corrections constitute the majority of the proposed changes)
- Changes related to reassignment and redistribution of functions and responsibilities in our current organization
- Changes associated with adoption of more efficient business processes such as records and signatures in electronic media
- Changes to remove Quality Assurance from in-line functions in order maintain the independence of QA overview

Also enclosed is a copy of the revised BFS QA Manual that is annotated to indicate the changes, along with a summary of changes that provides an explanation and evaluation of the significance of each change, to facilitate review (Enclosure 2).

Please note that the Manual has been reformatted into a two-column landscape form to facilitate use electronically. For your information, BFS has enclosed an electronic version of Revision 10 of the BFS QA Manual on CD (Enclosure 3).

If there are any questions, please contact Doug Brown at 815-342-6806 or the undersigned at 408-558-3508.

Sincerely,



Robert D. Quinn  
President & CEO

Enclosures

- 1) Manual of Quality Assurance for BNFL Fuel Solutions, Revision 10
- 2) Informational annotated version of revised BFS QA Manual and summary of changes from Revision 9 to Revision 10
- 3) CD containing electronic Manual of Quality Assurance for BNFL Fuel Solutions, Revision 10

cc: Mr. L. W. Camper, NRC NMSS w/o enclosures  
Mr. R. J. Lewis, NRC NMSS, w/ enclosures  
Ms. M. J. Ross-Lee, NRC NMSS, w/o enclosures  
Mr. S. C. O'Connor, NRC NMSS, w/o enclosures

**BFS/NRC 03-011**  
**Enclosure 1**

**ENCLOSURE 1**

**Manual of Quality Assurance  
For  
BNFL Fuel Solutions  
Revision 10**

**MANUAL OF QUALITY ASSURANCE**  
**FOR**  
**BNFL FUEL SOLUTIONS**

Approved By:

*Douglas A. Brown*  
Douglas A. Brown,  
Quality Assurance Manager

Date:

7/23/03

Approved By:

*Robert D. Quinn*  
Robert D. Quinn,  
President/Chief Executive Officer

Date:

7/23/2003

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## RECORD OF REVISIONS

Issue Date	Revision Number	Change(s)		Description
		Page(s)	Paragraph	
10/00	9	--	--	See previous revision for revision history
7/03	10	ii	N/A	Title of QAM Section 7 revised to reflect 10 CFR 71 & 72 title for Criteria 7.
		xii	3	Deleted "project, engineering and."
		xiii	N/A	Deleted former 4 <sup>th</sup> paragraph: "Quality Assurance is recognized by corporate management . . . to the applicable requirements."
		1	1	Deleted second sentence, "Management responsibilities . . . (QA, Projects, Operations, etc.)."
		1	4	Added comma.
		1, 2	(listed below)	Relocated and clarified the requirement to annually review the QA Program as follows:
		1	2	<ul style="list-style-type: none"> <li>Deleted "review of the status and adequacy of"; "and must assure this review occurs annually." Added "and its compliance with the applicable requirements."</li> </ul>
		2	2	<ul style="list-style-type: none"> <li>Added "The Quality Assurance Manager will review the status, adequacy and implementation of the QA Program at least annually and report this status to the President."</li> </ul>
		2	2	Deleted comma.
		2	5	Deleted commas.
		2	6	Added "corrective action" to duties of Manager of Operations. Deleted "of the" and changed "authority" to "authorities."

## RECORD OF REVISIONS

Issue Date	Revision Number	Change(s)		Description
		Page(s)	Paragraph	
		2	8	Revised the duties of the Manager of Projects to add the following: "This includes review of purchase orders received by BFS to supply items or services to assure quality and technical requirements are included in new projects."
		5	5, 6	Revised description of how QAM revisions are indicated as follows. Deleted "Manual revisions are"; "by a vertical line (change bar) in the right margin. This change bar is not required." Added "with changes"; "in the text"; "Changes . . . and relocated text resulting from page reformatting are not considered revisions and are not highlighted as such." Deleted "Change bars are not required when a revision to the Manual requires page reformatting resulting in text which is relocated but not changed. Previous revision change bars are removed when a new revision is issued." Replaced "in addition to being indicated on the title page, is also indicated in the lower left hand corner of each page" with "is indicated on each page."
		5	6	Deleted the page reference for the Record of Revisions.
		5	7	Deleted sections entitled "Transmittal Control" and "Control Log." Added section entitled "Distribution Control" describing electronic distribution control of QAM. Control mechanism is equivalent and reflects change in administrative practices.
		6	1	Deleted "The Training Manager, who reports to." Deletion of position. Restructured sentence.
		7-11	N/A	Revised and corrected list of typical QA Procedures used to implement QA Program.

## RECORD OF REVISIONS

Issue Date	Revision Number	Change(s)		Description
		Page(s)	Paragraph	
		12	N/A	Deleted 3 <sup>rd</sup> paragraph: "The Manager of Projects is responsible for all aspects of project implementation including the preparation of a list of task assignments along with a schedule of milestone completion dates, for providing each designated project participant with a copy, as appropriate, and for in-progress project meetings to track the project and assure the proper design interface."
		12	3	Added "Preparation of licensing documents" to list of general design activities covered by procedure.
		12	4 (1 <sup>st</sup> bullet)	Deleted "QA personnel are a part of the design review process. This is done to assure adherence to all applicable design procedures. This activity is accomplished through review and approval of design documents as specified in QA procedures."
		12	4 (2 <sup>nd</sup> bullet)	Changed "test" to "tests."
		14	2	Added "[quality] assurance programs" to scope of what this QAM section addresses.
		14	2	Changed "inspection" to "inspections" and deleted "all."
		14	4	Deleted "Quality Assurance requirements, when applicable, are included with request for quotes." Added "including the applicability of Part 21 when required." Deleted "always" and "the."
		14	5	Deleted "job site"; "as applicable to BFS." Replace "which" with "that."
		14	7	Deleted "affiliate's or a" and added "of" to clarify list of typical procurement documentation.



## RECORD OF REVISIONS

Issue Date	Revision Number	Change(s)		Description
		Page(s)	Paragraph	
		14	9	Deleted "The Procurement documents are reviewed" and restructured sentence.
		15	1	Added "the Quality Assurance Manager and the President" to complete the list of those who approve procedures.
		15	2	Deleted "Quality Assurance and" from inline review process for fabrication documents.
		16	1	Deleted "policy for"; "establishes review and approval cycles and sequences,"; "requires that." Added comma; "are controlled by quality procedures. Revisions are"; and "as initial issuances."
		16	1	Added "Documents may be authenticated electronically (e.g., digital signatures), manually (e.g., signature and date), or by a combination thereof."
		16	2	Added "Controlled documents may be distributed either electronically or in hard-copy format. Electronic distribution shall make available only the current versions of documents (unless the user takes specific actions to obtain historical versions); hence, there is no requirement for transmittal control and receipt acknowledgement."
		16	2	Replaced "If hard copy distribution is utilized" with "For hard-copy controlled distribution."
		16	N/A	Deleted former 2 <sup>nd</sup> paragraph: "The Manager of Projects shall assure that the documentation listings are maintained specifying the title, number, and current revision for all drawings, procedures, specifications and purchase orders."

## RECORD OF REVISIONS

Issue Date	Revision Number	Change(s)		Description
		Page(s)	Paragraph	
		17	1	Revised final sentence to "Document lists are maintained listing the title, identification number and current revision for all controlled documents."
		18	N/A	Corrected Title of Section to agree with title of corresponding section of 10 CFR 71 & 72.
		18	1	Added "and its customers" to include the total set of requirements considered.
		18	1	Added "Suppliers may be utilized for a customer's work based on a letter from the customer authorizing such use. This is limited only to work for the customer providing such approvals."
		18	2	Added comma. Deleted "QA"; "the."
		18	3	Deleted "and suppliers approved in writing by BFS customers."
		18	4	Deleted "which is."
		19	2 (2 <sup>nd</sup> bullet)	Added period.
		20	2	Added "The."
		21	1	Relocated "Other"; deleted comma; added comma; deleted "or."
		22	5	Deleted "The"; "procedures and instructions include inspection"; and "with." Added "shall include" and "as necessary."
		23	1	Deleted "the."

## RECORD OF REVISIONS

Issue Date	Revision Number	Change(s)		Description
		Page(s)	Paragraph	
		25	3	Deleted "departure, and arrival time and destination data recording"; "to be."
		26	1	Deleted "The use of"; "at or for BFS." Added "are used"; "and." Replaced "is" with "are."
		26	2	Deleted "interoffice memoranda"; "and audit"; "and that"; "are being satisfactorily used." Added "and"; "satisfactory use of"; and "is verified by audit or surveillance."
		27	1	Added "marking and/or." Deleted comma; "these." Restructured sentence.
		27	2	Deleted "The signatures of"; "are placed on the"; "approval." Added "review and approve"; "acceptance."
		27	3	Clarified statement of requirement as follows: added "sufficient"; deleted "indicate and."
		27	4	Added "when required." Substituted "equivalent" for "at least equal."
		28	1	Deleted "The documentation of." Added "is documented in a Condition Report and." Deleted "also."
		28	1	Deleted "The Quality Assurance Manager also logs the documentation of each condition adverse to quality." Substituted "A log of Condition Reports is maintained." Added comma.
		28	1	Added "continued" as a modifier to corrective action effectiveness.

## RECORD OF REVISIONS

Issue Date	Revision Number	Change(s)		Description
		Page(s)	Paragraph	
		28	2	Deleted "establish quality trends." Substituted "identify causal factors." Deleted "the"; "at that level"; "Copies of these reports and analyses are also provided to the Quality Assurance Manager for review."
		29	1	Deleted "is"; "agency." Changed "material's" to "materials."
		29	1	Added "condition reports" to list of typical quality records.
		29	2	Deleted "Shall be"; "commission."
		29	2	Deleted "but no more than five years."
		29	3, 4	Relocated the following from the 2 <sup>nd</sup> paragraph and separated into two paragraphs:  "Additionally, records of use, for all transport packages, shall be maintained for a period of three years after the shipment.  Records are identified by project number, part number, contract number, or drawing number as appropriate to the record type. BFS maintains a complete list of QA records to provide identification and location information."

## RECORD OF REVISIONS

Issue Date	Revision Number	Change(s)		Description
		Page(s)	Paragraph	
		30	1 <sup>st</sup> & 2 <sup>nd</sup> bullet	<p>Deleted the following:</p> <p>"To minimize the risk of damage from fire, flooding and abnormal deterioration, two sets of identical records are maintained at separate and equivalent storage locations with access control and security; or</p> <p>The official copies of all QA records are maintained in approved fireproof files or vaults, at a single location."</p> <p>Replaced statement of requirement with [Protection for QA records is provided by using either one of the following storage methods:]</p> <p>"Single Storage in a facility or container that minimizes the risk of damage or destruction from natural disasters, environmental conditions, and biological infestation, or</p> <p>Dual Storage in locations sufficiently remote from each other as to eliminate or minimize the chance of exposure to a simultaneous hazard."</p>
		31	1	Added "BFS carries out a comprehensive system of planned and periodic audits by personnel qualified in accordance with this QA Program to verify compliance with all aspects of the quality assurance program and to determine the effectiveness of the program."
		31	2	Deleted "auditor" and substituted "audit team."

## RECORD OF REVISIONS

Issue Date	Revision Number	Change(s)		Description
		Page(s)	Paragraph	
		31	2	Added "All audits are performed under the direction of a qualified Audit Team Leader."
		31	4	Relocated former 5 <sup>th</sup> paragraph (See deleted text on page 34, paragraph 1). Added "and Audit Team Leaders."
		33	5	Relocated former 1 <sup>st</sup> paragraph with new subtitle, "Internal Audits."
		31	5	Deleted "by personnel qualified in accordance with the requirements of the BFS QA Program." Deleted "and"; substituted "These audits."
		31	6	Deleted "first" as editorial correction.
		31	7	Deleted "auditors" and changed verb tense for "performs."
		31	8	Deleted former 7 <sup>th</sup> paragraph.
		31	1	Deleted "prescribed." Substituted "determined."

## PREFACE

This manual has been developed for and applies to BNFL Fuel Solutions and any wholly or partially owned subsidiary, affiliate or partnership engaged in the supply of spent fuel storage and/or transportation systems. The owner of the design and Certificate of Compliance for the VSC-24 Ventilated Storage System is Pacific Sierra Nuclear Associates (PSNA), a partnership between BNFL Fuel Solutions Corporation (BFS) and Sierra Nuclear Corporation (SNC). Both BFS and SNC are wholly owned subsidiaries of BNFL Inc.

The Quality Assurance Manual (QAM) sections contained herein describe BNFL Fuel Solutions' basic policy for the control of quality for products and services being provided by BNFL Fuel Solutions and meets the requirements of Title 10 Code of Federal Regulations, Part(s), 71 Subpart H, 72 Subpart G, and 50 Appendix B, and other comparable industry standards such as ANSI/ASME NQA-1.

The QAM is supported by quality procedures, which provide detailed requirements for implementing this corporate quality assurance policy. Procedural coverage is included for design and product quality assurance. Operating and maintenance requirements are included in the licensed product's Safety Analysis Report. The application of this program uses the "graded" approach, as defined in Regulatory Guide 7.10, depending on the complexity, criticality, and safety requirements of each project or component.

The initial release of the QAM and all subsequent revisions will be transmitted with a memo approved by the Quality Assurance Manager or equivalent position. Additional procedures will be prepared under appropriate sections or in subsequently identified sections for special coverage as required for contracts, if not adequately covered in the basic manual.

## STATEMENT OF MANAGEMENT POLICY

The Quality Assurance Program described herein is applicable to all spent fuel storage and/or transportation products and services provided by BNFL Fuel Solutions and any applicable wholly or partially owned subsidiary, affiliate or partnership to customers requiring a Quality Program meeting the requirements of Title 10 Code of Federal Regulations Part(s) 50 Appendix B, 71 Subpart H, and 72 Subpart G, or other comparable industry standards such as ANSI/ASME NQA-1.

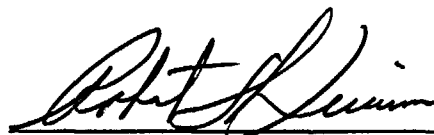
The executive management of BNFL Fuel Solutions is devoted to the support of this program and charges all personnel involved in activities affecting quality with the responsibility of upholding and abiding by the Quality Assurance requirements in this manual. The Quality Assurance organization is authorized sufficient freedom to identify quality problems; initiate, recommend or provide solutions; verify implementation of solutions; and control further processing of service(s) or delivery of a nonconforming item, deficiency or unsatisfactory condition until proper disposition has been completed.

While it is the responsibility of everyone at BNFL Fuel Solutions to assure that quality and reliability objectives are achieved, the overall responsibility for the development, maintenance and assurance of the implementation of the Quality Assurance Program has been assigned to the Quality Assurance Manager, who

reports directly to the President and Chief Executive Officer of BNFL Fuel Solutions.

The Quality Assurance Manager has the complete support of Corporate Management in the performance of required duties and, by organizational arrangement, has no responsibility for production costs or schedules. The authority, as defined herein, extends to all activities performed by or for BNFL Fuel Solutions that may affect product quality. Decisions made by the Quality Assurance Manager within the scope of duties, responsibilities and authority as defined in this program may be changed or modified only by direction of the President.

All personnel assigned to operations subject to the requirements of this program shall be required to familiarize themselves with the policies and objectives set forth in this program. They shall be responsible for executing those policies, explicitly or implied, pertinent to their assignments.



Robert D. Quinn  
President/Chief Executive Officer  
BNFL Fuel Solutions

7/23/2003  
Date



## **SECTION 1 – ORGANIZATION**

### **Organizational Structure**

BNFL Fuel Solutions (BFS) is organized as shown in Figure 1.1.

The President is responsible for management of BFS, setting overall company policy and identification of long-term company goals and resources. The President retains ultimate authority and responsibility for the Quality Assurance Program and its compliance with the applicable requirements.

The assurance of quality at BFS is an interdisciplinary function that involves, as applicable, all organizations. Furthermore, quality assurance encompasses many diversified functions and activities and extends to various job levels within these organizations, including all executives and all employees whose activities affect quality. The implementation of quality assurance throughout the various functions of design, procurement, construction, operation and services at BFS must, therefore, be considered the direct responsibility of the organization performing the work and cannot be considered the sole domain of any single quality assurance group.

Persons or organizations charged with the development, enforcement or measurement and the adequacy and effectiveness of the quality assurance program shall have the authority and organizational freedom

necessary to effectively discharge those responsibilities. Such persons or organizations shall be independent of direct pressures of cost, schedule or production, and their authority and organizational freedom shall be sufficient to: (1) identify quality problems; (2) initiate, recommend or provide solutions; (3) verify implementation of solutions; and (4) withhold and segregate nonconforming material or other action, including stopping work, to maintain program integrity. Furthermore, they shall have direct access to responsible management at a level where appropriate action can be mandated.

Persons performing quality assurance functions such as checking, verifying or reviewing the work of others (functions that do not encompass the development, enforcement or measurement of the adequacy or effectiveness of BFS' Quality Assurance Program) shall have authority and organizational freedom to a degree sufficient to properly discharge their assigned quality assurance responsibilities. However, when authority and organizational freedom are restricted for any person performing quality assurance functions, an established line of communication to responsible management must exist sufficient to prevent suppression of those quality assurance functions and/or to resolve any disputes.

Managers have the organizational freedom to identify issues related to their organization directly to the President.

Final responsibility for the effectiveness and adequacy of BFS' Quality Assurance Program resides with BFS. However, BFS may delegate the establishment and execution of the program, or any part thereof, to other organizations. Those organizations may, in turn, delegate responsibility for applicable portions of the Program to other organizations.

The President of BFS has overall responsibility for assuring the development and maintenance of an effective quality assurance program for BFS. Responsibility for the establishment, training, administration, and enforcement of the BFS Quality Assurance Program has been delegated by the President to the Quality Assurance Manager. The Quality Assurance Department functions as a staff position reporting to the President of BFS and is independent of all other organizations within BFS. The Quality Assurance Department assumes line responsibility for assuring compliance with BFS' Quality Assurance Policy. The Quality Assurance Manager will review the status, adequacy and implementation of the QA program at least annually and report this status to the President. BNFL Corporate Quality Assurance provides general guidelines and oversight and corporate support to the BFS Quality Assurance Manager.

The Quality Assurance Manager may delegate any of the functions assigned to him by this Manual to another individual, but he shall retain the responsibility for accomplishment of the function in accordance with the provisions of this Manual. The Quality Assurance Manager may obtain support/resources from BNFL Inc.

and receives QA functional input from the BNFL Corporate QA Department.

Any dispute over Quality Assurance with the management of other functions that cannot be resolved with the respective manager shall be referred to the President for resolution.

BFS shall verify the accomplishment of Quality through scheduled and/or unscheduled audits of in-house functions and, as applicable, at sub-vendors and/or at suppliers.

The Manager of Operations is responsible for the design, engineering, product development, corrective action, licensing, and regulatory management of BFS activities and systems important to safety. The specific functions, authorities, and duties of persons and organizations performing activities affecting the functions of structures, systems, and components that are important to safety are delineated in the implementing procedures.

### **Project Organization**

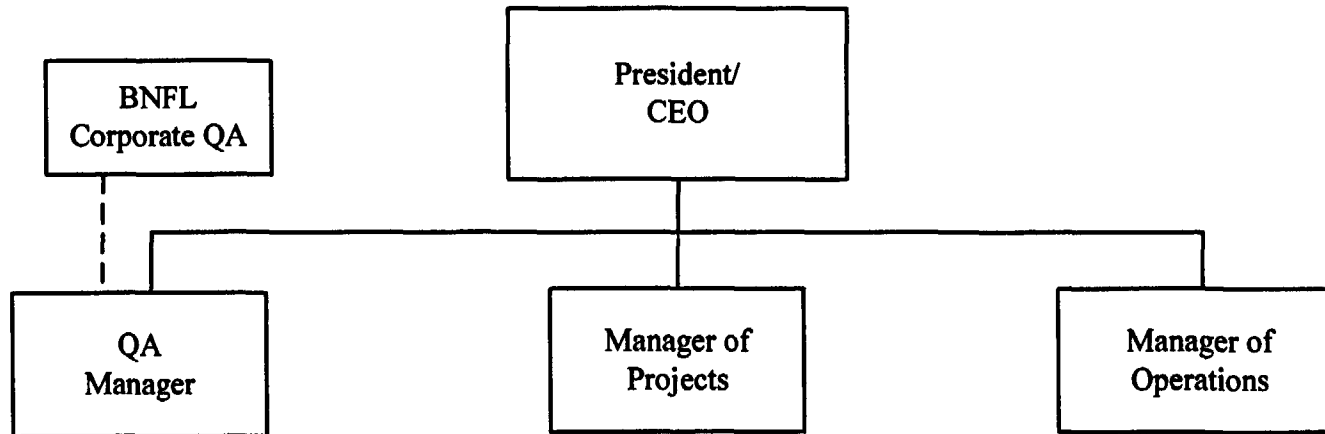
The Manager of Projects has the overall programmatic responsibility for the strategic planning, direction, compliance with technical requirements, procurement, fabrication and construction activities for all projects, and may serve as the Project Manager for one or more projects.

The Manager of Projects is responsible for the quality and commercial aspects of projects. This includes

review of purchase orders received by BFS to supply items or services to assure that quality and technical requirements are included in new projects. The Manager of Projects may assign a project staff, supported by a Project Engineer and by managers that are matrixed from their respective organizations. The Manager of

Projects is responsible for interface control. In a small, single discipline project, the Project Manager and the Project Engineer may be the same person reporting to the Manager of Projects.

Figure 1  
BFS Organization Chart



## SECTION 2 - QUALITY ASSURANCE PROGRAM

This Quality Assurance Program shall apply to all activities that are important-to-safety (or nuclear safety-related) and require compliance with any or all of the documents listed below.

- 10 CFR 71, Subpart H
- 10 CFR 50, Appendix B
- 10 CFR 72, Subpart G
- ANSI N45.2
- ANSI/ASME NQA-1

Conditions that may be reportable either as deficiencies affecting the ability of important-to-safety structures, systems and components to perform their intended safety function per 10CFR72.242 or as "substantial safety hazards" under 10CFR21, shall be reported in accordance with applicable Quality Assurance Procedures.

### Manual Review and Approval

The BFS Quality Assurance Program is fully described in and implemented in accordance with this document, the BFS Quality Assurance Manual. The Manual is reviewed annually or more frequently as directed by the President. The intent of this review is to keep the Manual current with the documents specified above. Revisions to the

Manual required for compliance to the referenced documents are authorized by the President.

Approval of this Manual, and revisions thereto, is documented by the signature of the President on the title page with the respective date of approval. All revisions to the Manual are issued for implementation by the President within thirty (30) days of approval of the revision by the NRC.

### Revision Control

The QA Manual shall be revised and issued in its entirety, with changes highlighted in the text. Changes in the footer of each page or on the title page and relocated text resulting from page reformatting are not considered revisions and are not highlighted as such.

A history of revisions is maintained for the QA Manual as indicated on the Record of Revisions. The current revision of the Manual is indicated on each page.

### Distribution Control

The Manual may be distributed electronically or in hard-copy form. Electronic distribution channels shall limit access to only the current version of the Manual; hence, there is no requirement for transmittal control and receipt acknowledgement. Hard-copy distribution of Controlled Manuals shall be performed using transmittal forms with

required receipt acknowledgement and follow-up on delinquent acknowledgements. Both electronic and hard-copy distribution shall be performed in accordance with the BFS Quality Assurance procedures for document control.

### **Indoctrination and Training**

Each manager will assure that all personnel performing activities affecting quality are indoctrinated, trained and qualified according to their level of responsibility and assigned functions. Indoctrination and training shall consist of informal, on-the-job activities under the guidance of trained personnel, self study and/or formal meetings, classes, lectures, and seminars. The Quality Assurance Manager shall assist the managers in implementing this responsibility including providing training courses, materials and standards. Formal training shall be documented and the associated record maintained as a Quality Assurance Record in accordance with Section 17.

### **Qualification and Certification of Personnel**

BFS performs inspections, examinations or tests for which a formal BFS program of training, qualification and

certification is required per QAM Section 10 and Section 11. When these inspections, examinations or test activities are performed, they shall be performed by appropriately certified personnel.

Surveys and audits for which BFS is responsible are conducted by Lead Auditors who are qualified as specified in ANSI/ASME N45.2.23; 10 CFR 50, Appendix B; and ANSI/ASME NQA-1. Records of Lead Auditor qualification are maintained in the BFS files (refer to Section 18).

### **Quality Assurance Program Implementation**

Quality Assurance Procedures (QAP) are developed to implement the requirements defined by this Quality Assurance Manual. Additional QAPs, or project specific procedures, may be developed for each project because of different interface requirements between customers and suppliers. These project specific procedures shall be part of the project plan. In all cases, the QAPs shall conform to the requirements specified in this Quality Assurance Manual.

The following table identifies the relationships among the 18 criteria and the BFS Quality Assurance Manual and implementing Quality Assurance Procedures.

## RELATIONSHIP OF 18 CRITERIA TO BFS QA PROGRAM

Criteria of:

10 CFR 50 Appendix B

10 CFR 71 Subpart H

10 CFR 72 Subpart G

Corresponding QA Manual Section  
QA Procedures<sup>1</sup>

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I.	Organization	QAM Section 1 and Organization Charts
		QAP 1.0: Order Entry and Project Planning
		QAP 1.1: Project QA Plans and Project-Specific QA Procedures
		QAP 1.2: Readiness Reviews
		QAP 1.3: Organization

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II.	Quality Assurance Program	QAM Section 2
		QAP 2.1: Control and Distribution of BFS Quality Assurance Procedures
		QAP 2.2: Certification of Inspection Personnel
		QAP 2.4: Quality Assurance Program Assessment and Reporting
		QAP 2.5: Indoctrination and Training of Personnel
		QAP 2.6: Personnel Qualifications

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<sup>1</sup> This listing and the content of these Quality Assurance Procedures may change as needed to provide procedural direction applicable to BFS' commercial activities, or as necessary to reflect changes in governing standards/regulations. These changes may be made without revision of the Quality Assurance Manual (QAM) providing the QAM requirements are maintained.

Criteria of:  
10 CFR 50 Appendix B  
10 CFR 71 Subpart H  
10 CFR 72 Subpart G

Corresponding QA Manual Section  
QA Procedures<sup>1</sup>

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III. Design Control

QAM Section 3

- QAP 3.0: Design Control
- QAP 3.1: Design Input
- QAP 3.2: Calculations
- QAP 3.3: Drawings
- QAP 3.4: Specifications
- QAP 3.5: Technical Reports
- QAP 3.6: Safety Analysis Reports
- QAP 3.7: Quality Category Assessment
- QAP 3.8: Engineering Change Notice
- QAP 3.9: Safety Review and Evaluation
- QAP 3.10: System Design Verification
- QAP 3.11: Receipt of Engineering and Fabrication Deliverables
- QAP 3.12: Computer Software Development, Installation and Revisions
- QAP 3.13: Computer Software Control and Usage Tracking
- QAP 3.14: Identification and Control of Computer Errors
- QAP 3.15: 10CFR72.48 Evaluation
- QAP 3.16: 10CFR71 Change Evaluation
- QAP 3.17: Processing of 10CFR72.48 Records



Criteria of:  
10 CFR 50 Appendix B  
10 CFR 71 Subpart H  
10 CFR 72 Subpart G

Corresponding QA Manual Section  
QA Procedures<sup>1</sup>

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IV.	Procurement Document Control	QAM Section 4 QAP 4.0: Procurement Control
V.	Instructions, Procedures and Drawings	QAM Section 5 QAP 5.2: Process Control
VI.	Document Control	QAM Section 6 QAP 6.0: Document Control
VII.	Control of Purchased Materials, Equipment and Services	QAM Section 7 QAP 7.1: Supplier Evaluation QAP 7.2: Source Inspection QAP 7.3: Receipt Inspection QAP 7.5: Commercial Grade Dedication
VIII.	Identification and Control of Materials, Parts and Components	QAM Section 8 QAP 8.0: Identification and Control of Materials, Parts and Components QAP 8.1: Certificate of Conformance

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Criteria of:

10 CFR 50 Appendix B  
10 CFR 71 Subpart H  
10 CFR 72 Subpart G

Corresponding QA Manual Section  
QA Procedures<sup>1</sup>

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IX.	Control of Special Processes	QAM Section 9 QAP 9.0: Control of Special Processes
X.	Inspection	QAM Section 10 QAP 10.0: Inspection
XI.	Test Control	QAM Section 11 QAP 11.0: Test Control
XII.	Control of Measuring and Testing Equipment	QAM Section 12 QAP 12.0: Control of Measuring and Test Equipment
XIII.	Handling, Storage and Shipping	QAM Section 13 QAP 13.0: Handling, Storage and Shipping
XIV.	Inspection, Test and Operating Status	QAM Section 14 QAP 14.0: Inspection and Test Status

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Criteria of:

10 CFR 50 Appendix B  
10 CFR 71 Subpart H  
10 CFR 72 Subpart G

Corresponding QA Manual Section  
QA Procedures<sup>1</sup>

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XV. Nonconforming Material, Parts or Components	QAM Section 15
	QAP 15.0: Nonconforming Material, Parts, Components or Services
	QAP 15.2: Reporting of Defects and Noncompliances

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XVI. Corrective Action	QAM Section 16
	QAP 16.0: Corrective Action Process
	QAP 16.1: Cause Analysis
	QAP 16.3: Effectiveness Reviews

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XVII. Quality Assurance Records	QAM Section 17
	QAP 17.0: Quality Records

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XVIII. Audits	QAM Section 18
	QAP 18.0: Audits and Surveys
	QAP 18.1: Qualification and Certification of QA Audit Personnel
	QAP 18.2: Quality Assurance Surveillance of Suppliers
	QAP 18.3: Internal Surveillance

## **SECTION 3 - DESIGN CONTROL**

The purpose of this section is to establish the basic minimum requirements to provide control of design activities including program planning, design and design verification from initial concepts through completion of design, manufacturing, inspection and planning for BFS and customer-based projects. BFS provides designs, investigations, analyses and reports based on specific project requirements.

Before any quality affecting work, including design input, conclusion, or review remarks, can be provided on a project, the Manager of Projects shall prepare a "Project Plan". The Project Plan lists all of the intended activities required to accomplish/support specific project needs for BFS and/or customer based projects, including all design bases and/or regulatory requirement documents applicable to the project. Design interfaces and quality requirements shall be described in the Project Plan.

The Manager of Operations is responsible for assuring the technical adequacy and correctness of the design and that the final design meets the BFS, customer and regulatory requirements. Procedures have been developed to assist in assuring and documenting the quality of the design output. These procedures cover the following:

- Preparation of calculations
- Review and checking of calculations and reports
- Computer program control and usage

- Drawing and specification preparation
- Design verification
- Change control
- Procured design services
- Preparation of licensing documents

BFS Quality Assurance Procedures (QAPs) have been developed, approved and implemented to control the design process in such a manner to assure that:

- The design activity is planned, controlled and documented.
- The design documents contain Quality Assurance requirements for inspections and tests that will assure control, inspection and testing of design characteristics.
- Deviations from quality requirements are controlled.
- Design verification is performed by qualified personnel independent of the design activity, but with a skill level at least equal to that of the original design personnel. These verifications may include tolerance studies, alternate calculations or tests. Qualification tests are conducted in accordance with approved test programs and procedure.

- The design verification method selection is based on regulatory and contractual requirements, level of complexity of the design and "state-of-the-art" considerations, i.e., materials, fabrication processes, etc., and operating conditions.
- Interface control is established and adequate to assure that the review, approval, release, distribution and revision of design documents involving interfaces are performed with all cognizant design personnel.

- Design and specification changes are reviewed and approved by the same organization(s) as the original issue.
- Design errors and deficiencies are documented and appropriate corrective action is taken.

## **SECTION 4 - PROCUREMENT DOCUMENT CONTROL**

The QA Program provides controls to assure that all purchased material, components, equipment, and services adhere to design specifications, regulatory and contractual requirements.

Evaluation and selection of suppliers, objective evidence of supplier quality assurance programs, assignment of quality requirements to procurement documents, and related design documents, and source, in-process and receiving inspections are administered and controlled in accordance with this section of the Quality Assurance Manual and approved procedures.

Procurement is performed under the supervision of the Manager of Projects. Changes to procurement documents shall be prepared, reviewed, approved and authorized for use in the same manner as established for the original issue of the document.

Quality Assurance requirements, including the applicability of Part 21 when required, are provided with purchase orders and/or applicable specifications.

BFS may procure any design, manufacturing, inspection, testing, auditing or construction activity described in this Manual. Procurement documents for these services shall include requirements that assure that the requirements of this Manual will be met by the subcontractor. BFS retains final responsibility to assure the service is acceptable for the BFS project.

Contract documents such as Purchase Orders, drawings and specifications are reviewed to assure the inclusion of all requirements. Personnel qualification requirements are either defined or verified by reference on a procurement document. Review also includes verification of the suitability of standard items for the use required by the applicable drawings and design specifications with the inclusion of valid industry standards, references, and related data, when applicable.

The Manager of Projects assures that requirements for acceptance of hardware and documentation, such as the supplier's submittal and retention of instructions appropriate to the contract, are included in procurement documentation.

BFS maintains the right of access to all supplier facilities and documentation for source inspection and/or audit activities. A statement to this effect is included on procurement documentation when it is appropriate to the contract.

BFS QA personnel check procurement documents for completeness and the inclusion of quality requirements in accordance with written procedures. Procurement documents require the approval of the BFS Quality Assurance Manager.

## **SECTION 5 - INSTRUCTIONS, PROCEDURES AND DRAWINGS**

Procedures and instructions are developed by qualified personnel assigned by the responsible manager. Procedures are developed for activities requiring design and/or fabrication, performance verification, witnessing, measurements, testing or other Quality Assurance related activities. These procedures are approved by the responsible manager, the Quality Assurance Manager and the President.

All fabrication documents (i.e., drawings, specifications, special processes, test and calibration procedures, etc.) are reviewed by a qualified engineer as assigned by the Manager of Operations. The fabrication documents are also referenced in inspection procedures as necessary to assure adherence to package, system or other design approvals and the applicable regulatory and contractual requirements.

The inspection procedures also include appropriate acceptance criteria such as dimensions, tolerances, operating limits, workmanship standards, and other qualitative and quantitative measures.

All instructions, procedures, and drawings are developed, reviewed, approved, utilized and controlled in accordance with approved procedures.

Changes to instructions, procedures and drawings shall be prepared, reviewed, approved and authorized for use in the same manner as established for the original issue of the document.

## SECTION 6 - DOCUMENT CONTROL

The review, approval, release and revision of quality related documents, as well as revisions/changes to all such approved documents, are controlled by quality procedures. Revisions are subjected to the same approval cycle and sequence as initial issuances. Provisions are made for identifying individuals/organizations responsible for review and approval of controlled documents in the Quality Assurance Procedure applicable to the controlled document. Documents may be authenticated electronically (e.g., digital signatures), manually (e.g., signature and date), or by a combination thereof. Document control responsibilities and distribution requirements are also addressed in procedures.

Controlled documents may be distributed either electronically or in hard-copy format. Electronic distribution shall make available only the current versions of documents (unless the user takes specific actions to obtain historical versions); hence, there is no requirement for transmittal control and receipt acknowledgement. For hard-copy controlled distribution, transmittal sheets with provisions for acknowledging receipt are utilized to provide proper records of the transmittal and receipt of controlled documents and subsequent revisions.

Controlled documents include but are not limited to:

- Design Specifications

- Calculations
- Analyses
- Safety Analysis Report(s)
- Drawings
- Specifications (Procurement, Equipment, etc.)
- Special Process Procedures (Welding, Forming, Heat Treating, NDE, Etc.)
- Inspection Procedures
- QA Manuals and Procedures
- Source Surveillance and Inspection Reports
- Test Procedures and Reports
- Operational Test and Inspection Reports
- Subvendor Procedures, Specifications and Drawings
- Customer Specifications, Procedures and Drawings

When documents being revised appear in other documents as references, supplements or include the attribute being changed, an impact assessment will be conducted and depending upon the results, either:



- A process to control the revision of that document will be provided, or
- That document will be revised prior to release of the approved change.

Document lists are maintained listing the title, identification number and current revision for all controlled documents.

## **SECTION 7 - CONTROL OF PURCHASED MATERIALS, EQUIPMENT AND SERVICES**

It is the policy of BFS that all suppliers of materials, components, systems or services, receive controlled and approved procurement documents that contain or reference all applicable regulatory requirements, appropriate design/engineering drawings and specifications, and other requirements necessary to produce a product or service that meets the quality requirements of BFS and its customers. In addition, procurement documents shall contain provisions that require suppliers and their subtier suppliers to execute quality assurance programs in a manner and to the extent specified by BFS. Furthermore, procurement documents shall provide for the right of BFS to audit its contractors as well as their subtier suppliers, on their implementation of these controls. All procurements will be made only from BFS approved suppliers based on their past history, pre-award and/or post-award audits and surveys. Suppliers may be utilized for a customer's work based on a letter from the customer authorizing such use. This is limited only to work for the customer providing such approvals. BFS shall maintain an Approved Suppliers List (ASL).

As directed by the Quality Assurance Manager, evaluations are conducted by BFS QA qualified personnel to further assure supplier acceptability and performance. These evaluations are based on the following criteria:

- The capability of the supplier to comply with the requirements of 10CFR72 Subpart G, 10CFR71 Subpart H, 10CFR50 Appendix B, ANSI N45.2,

ANSI/ASME NQA-1, or other requirements appropriate to the contract as determined by BFS .

- A review of previous records and performance of the supplier by BFS Quality Assurance.
- A survey/audit by QA, assisted by Operations and Projects as appropriate, of the supplier's facilities and Quality Program to determine their capability to supply a product that meets design, manufacturing, and quality requirements.

Suppliers shall be evaluated by audit except for Regulatory Agencies/Nationally Recognized Standards Laboratories.

Results of the supplier evaluations and audits are appropriately recorded and included as part of the vendor's history file retained by Quality Assurance.

Audits are conducted at active supplier's facilities during the performance of activities, to assure continued adherence to the imposed Quality Assurance, design and contract performance criteria. These audits are conducted at least once every three years (during active periods) or more often as directed by the Quality Assurance Manager.

As an alternative to the aforementioned requirements, dedication of commercial grade items and services may be performed in accordance with approved procedures.

As directed by the Quality Assurance Manager, source and/or receiving inspections are performed by qualified personnel to assure the following:

- The material, component, or equipment is properly identified, refers to applicable codes, standards and specifications, and corresponds with the identification on receiving documentation.
- Prior to their use or installation, materials, components, equipment and acceptance records are inspected and are accepted in accordance with appropriate contractual requirements.

- Inspection records and/or certificates of conformance are available that attest to the acceptance of materials and components prior to their installation or use.
- Items accepted and released are identified as to their inspection status prior to forwarding to a controlled storage area or release for further work.

All described activities are delineated in approved BFS Quality Assurance Procedures.

## **SECTION 8 - IDENTIFICATION AND CONTROL OF MATERIALS, PARTS AND COMPONENTS**

A process for identifying and controlling materials, parts, components and completed and in-process assemblies is administered by Quality Assurance Manager in accordance with approved Quality Assurance Procedures. These procedures address quality status tags, marking, and/or stamping to assure maintenance of material identification, traceability, and part identification, to related documentation. Some of the details of these procedures are as follows:

- Material identification procedures included in Quality Assurance inspection instructions and fabrication drawings require that identification of material, components, and/or hardware be maintained on the item or in traceable records to prevent use of incorrect or defective material.
- Specifications, procurement documentation, fabrication and inspection records, discrepancy

reports and material test data are also periodically audited to assure continued adherence to design, regulatory and contractual requirements.

- Identification requirements, such as method and size, may be specified on applicable drawings or in applicable procurement/equipment specifications. Such identification shall not interfere with fit, interface or performance.

The Quality Assurance Manager shall assure that materials and equipment are controlled, protected, stored, handled, operated and packaged so that identification, traceability and condition are maintained. Some or all of the material control functions described herein may be delegated to approved suppliers.

## **SECTION 9 - CONTROL OF SPECIAL PROCESSES**

This section delineates the policies and practices established for special processes that control or verify quality, such as those used in welding, heat treating, and non-destructive examination. Examples of other processes that may be considered a special process, include coating, painting, and lead pouring. Special processes developed by suppliers and/or BFS are documented, reviewed and approved by the responsible technical personnel within BFS, and/or customer organizations. In addition, special process equipment is identified, inspected and performance tested prior to use.

All procedures for special processes are performed in accordance with applicable codes, standards,

specifications and contract requirements. The personnel performing such processes are trained and qualified in accordance with approved procedures. Both the procedures and personnel are subjected to full review and approval cycles as defined herein, by personnel qualified and approved by the Quality Assurance Manager for the subject matter relating to the special process.

Qualification records and support data are retained in the Quality Assurance files.

All documentation shall be administered and controlled in accordance with the requirements of the BFS Quality Assurance Program.

## **SECTION 10 – INSPECTION**

Receiving, source, test, in-process, shipping and in-service inspection activities are performed in accordance with the requirements of this manual and approved procedures. Inspection personnel and/or organization qualifications are reviewed and accepted by the Quality Assurance Manager prior to inspection activity. The inspection activity is performed to verify conformance to drawings, procedures and/or specifications.

Inspection personnel report to the Quality Assurance Manager.

The qualifications of inspection personnel are based on their capability to perform the required inspection functions in accordance with applicable codes and standards. Qualification reviews are performed

periodically to maintain personnel proficiency and assure current qualification.

Inspection procedures and instructions include hold points, inspection equipment requirements, accept-reject criteria, personnel requirements, characteristics to inspect, variable attributes, recording instructions, reference documentation and other requirements, as appropriate.

Inspection results shall include supporting information such as variables, attributes, data, test results, NDE records, welding information, certified materials test report (and/or certification), special process data, discrepancy reports, related dispositions and resultant reinspection data as necessary.

## **SECTION 11 - TEST CONTROL**

A quality related test control program is defined by approved test procedures. Prerequisites, accept/reject criteria, data recording criteria, instrumentation calibration, environmental conditions, documentation and evaluation requirements, etc., are defined in test procedures.

The Manager of Operations assures that the service conditions described in applicable design, regulatory and contractual documents are verified by testing activities. Changes to test procedures are required to be reviewed/approved by the same organization(s) as the original issue.

Whenever equipment, components, and/or assemblies require modification, repairs, or replacement that could result in requirements for re-test or additional testing, the Manager of Projects shall assure that original or new test inspection instructions are prepared and adhered to as appropriate.

Test results are documented, evaluated and accepted by the Manager of Operations as required by the test procedure prepared for the test under the cognizance of the Manager of Projects.

## **SECTION 12 - CONTROL OF MEASURING AND TESTING EQUIPMENT**

Calibration of measuring equipment and instrumentation is established by the Quality Assurance Manager. The calibration process assures that all standard measuring instruments used in the acceptance of material, equipment, and assemblies are calibrated and properly adjusted at specified intervals to maintain accuracy within pre-determined limits.

Calibrated equipment is identified and is traceable to the calibration test data. Identification includes the equipment property number, next calibration due date and

inspector's or calibrator's signature or initials attesting to the accuracy and validity of the calibration.

Calibration accuracy is maintained by utilizing standards traceable to the National Institute of Standards Technology (NIST), derived from accepted values for natural physical constants, or by the ratio type of self-calibration.



## **SECTION 13 - HANDLING, STORAGE AND SHIPPING**

Requirements for handling, storage and shipping shall be documented in project specific procedures or specifications. These requirements are designed to prevent damage or deterioration of material and equipment. Information pertaining to shelf life, environment, packaging, temperature, cleaning, handling, preservation, etc., is included as required to meet design, regulatory and/or customer requirements.

Inspection procedures and instructions contain assessment of criteria for handling, storage, preservation and shipping requirements.

Shipping documentation preparation is also addressed, when applicable. The requirements pertaining to shipping must be met prior to release for shipment.

## **SECTION 14 - INSPECTION, TEST AND OPERATING STATUS**

Inspection status tags, quality inspection stamps, and other means are used to indicate inspection and test status and are described in project specific procedures or fabrication travelers.

These documents provide that indications of status are clear, inspection and/or test steps are not bypassed, and removal or modification of status indicators are

prohibited, except with Manager of Projects and/or Quality Assurance Manager approval. The Quality Assurance Manager assures via procedure and training sessions that personnel are aware of and understand the meaning and uses of status indicators on hardware, material, and test setups. The satisfactory use of status indicators is verified by audit or surveillance.

## **SECTION 15 - NONCONFORMING MATERIAL, PARTS OR COMPONENTS**

Material, components, and equipment that do not conform to requirements are controlled to prevent their inadvertent use. This control is through identification, marking and/or segregation. Discrepancy reporting, disposition of nonconformances by authorized individuals and reinspection activities are performed and controlled in accordance with written procedures.

Nonconformance Reports (NCRs) are utilized and logged to identify discrepant items, describe the discrepancy and provide disposition and reinspection requirements. Authorized, cognizant personnel review and approve NCRs to signify acceptance of the disposition.

NCRs are reviewed by the Manager of Projects, Manager of Operations and Quality Assurance Manager to assure that "use-as-is" or "repair" dispositions include sufficient technical justification to assure continued compliance with design, regulatory and contractual requirements. When appropriate, copies of dispositions are forwarded to the owners and users of the affected equipment.

In conjunction with "repair" or "rework" dispositions, Quality Assurance personnel assure that supplemental inspections are performed to verify compliance with the NCR disposition when required. This assures that the item is re-tested and/or reinspected to a degree equivalent to the original acceptance level.

## SECTION 16 - CORRECTIVE ACTION

Conditions adverse to quality, such as failures, malfunctions, deficiencies and deviations in material, components, equipment and services, are identified, documented, and reported to BFS Management. Significant conditions adverse to quality will be reported to the President. Each condition adverse to quality is documented in a Condition Report and is forwarded to the Quality Assurance Manager for review and analysis. A log of Condition Reports is maintained. For significant conditions adverse to quality the cause of the condition

and the corrective action necessary to prevent recurrence is identified, implemented and when required, followed up to verify continued corrective action effectiveness.

Analyses of Identified conditions are conducted within thirty days of their submittal or as otherwise approved by the Quality Assurance Manager and/or the President. These analyses identify causal factors and help to pin-point areas in need of corrective action. Quality trends and related reports are prepared and presented to the President for review and action.

## SECTION 17 - QUALITY ASSURANCE RECORDS

BFS' QA records system is established and administered in accordance with approved BFS QA Procedures. The purpose of the QA records system is to assure that documented evidence pertaining to quality related activities is maintained and available for use by company, customer, and/or regulatory personnel, as appropriate. QA records include, but are not limited to, design related records (calculations, drawings, research, development test reports, and design reviews), inspection and test records (including identification of inspectors and data recorders), audit reports, condition reports, quality personnel qualification(s), quality related procurement data, supplier evaluation reports, materials analyses (certified material test reports or certificates of compliance as applicable), fabrication/manufacturing records, modification records, repair records, and maintenance records.

The retention period for the above identified records is as follows: 1) Transportation Packaging - Life of the packaging plus three years; 2) Spent Fuel Storage Packaging - Maintained by or under the control of the licensee until the NRC terminates the license. For all other equipment, quality related records are retained for a minimum of three years unless otherwise specified by applicable regulatory, code, standard or contractual requirements.

Additionally, records of use, for all transport packages, shall be maintained for a period of three years after the shipment.

Records are identified by project number, part number, contract number, or drawing number as appropriate to the record type. BFS maintains a complete list of QA records to provide identification and location information.

Inspection records retained in the QA records system provide the following data when applicable:

- Inspection type, i.e., in-process, in-service, testing, receiving and shipping.
- Evidence of completion and verification of manufacturing, inspection or test operation.
- The date and results of the inspection or test.
- Information related to noted discrepancies.
- Inspector or data recorder identification.
- Evidence of acceptance.

Protection for QA records is provided by using either one of the following storage methods:

- Single Storage in a facility or container that minimizes the risk of damage or destruction from natural disasters, environmental conditions, and biological infestation, or

- Dual Storage in locations sufficiently remote from each other as to eliminate or minimize the chance of exposure to a simultaneous hazard.

## SECTION 18 – AUDITS

BFS carries out a comprehensive system of planned and periodic audits by personnel qualified in accordance with this QA Program to verify compliance with all aspects of the quality assurance program and to determine the effectiveness of the program.

Audit Logs, Audit Plans and Audit Checklists are prepared and utilized by the audit team. All audits are performed under the direction of a qualified Audit Team Leader. At the completion of each audit, the Quality Assurance Manager evaluates the planning sheets and checklists to confirm that the audit effectively addressed all the appropriate Program elements.

Audit results and corrective action activities are documented in an Audit Report by the Quality Assurance Manager and transmitted to the responsible management personnel of the audited organization, the President and the Manager of Operations. Responsible management personnel are required to respond to audit findings with the necessary action to correct the noted deficiencies.

Records of audits and the qualifications of Auditors and Audit Team Leaders are maintained by the Quality Assurance Manager.

### **Internal Audits**

Internal Program audits are performed annually (or more often, if deemed necessary by the Quality Assurance

Manager). These audits may be project specific or cover multiple projects. These audits provide comprehensive, independent verification and evaluation of the implementation of the entire Quality Assurance system established in response to the appropriate requirements of 10CFR72 Subpart G, 10CFR71 Subpart H, 10CFR50 Appendix B, ANSI N45.2, ANSI/ASME NQA-1, and other applicable codes, standards, specifications and requirements.

Areas found deficient during these audits are re-audited on a priority basis to verify corrective action implementation and effectiveness.

### **External Audits**

BFS performs audits of active suppliers once every three years to assure continued adherence to imposed design, procurement and quality requirements.

Written audit results are reviewed with the affected supplier, and appropriate and mutually accepted corrective actions are determined. Corrective action implementation and effectiveness is evaluated by designated personnel as part of subsequent audits to review the supplier for continued approval.

**ENCLOSURE 2**

**Informational annotated version  
of  
Revised BFS QA Manual**

**and**

**Summary of changes  
from  
Revision 9 to Revision 10**



**For Information Only**



*MANUAL OF QUALITY ASSURANCE  
FOR  
BNFL FUEL SOLUTIONS*

Approved By: \_\_\_\_\_  
Douglas A. Brown,  
Quality Assurance Manager

Date: \_\_\_\_\_

Approved By: \_\_\_\_\_  
Robert D. Quinn,  
President/Chief Executive Officer

Date: \_\_\_\_\_

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## RECORD OF REVISIONS

Issue Date	Revision Number	Change(s)		Description
		Annotated Page(s)	Annotated Paragraph	
10/00	9	--	--	See previous revision for revision history
7/03	10	ii	N/A	Title of QAM Section 7 revised to reflect 10 CFR 71 & 72 title for Criteria 7.
		xii	3	Deleted "project, engineering and."
		xiii	4	Deleted former 4 <sup>th</sup> paragraph: "Quality Assurance is recognized by corporate management . . . to the applicable requirements."
		1	1	Deleted second sentence, "Management responsibilities . . . (QA, Projects, Operations, etc.)."
		1	4	Added comma.
		1, 2	(listed below)	Relocated and clarified the requirement to annually review the QA Program as follows:
		1	2	• Deleted "review of the status and adequacy of"; "and must assure this review occurs annually." Added "and its compliance with the applicable requirements."
		2	3	• Added "The Quality Assurance Manager will review the status, adequacy and implementation of the QA Program at least annually and report this status to the President."
		2	3	Deleted comma.
		2	6	Deleted commas.
		2	7	Added "corrective action" to duties of Manager of Operations. Deleted "of the" and changed "authority" to "authorities."

## RECORD OF REVISIONS

Issue Date	Revision Number	Change(s)		Description
		Annotated Page(s)	Annotated Paragraph	
		3	1	Revised the duties of the Manager of Projects to add the following: "This includes review of purchase orders received by BFS to supply items or services to assure quality and technical requirements are included in new projects."
		5	5, 6	Revised description of how QAM revisions are indicated as follows. Deleted "Manual revisions are"; "by a vertical line (change bar) in the right margin. This change bar is not required." Added "with changes"; "In the text"; "Changes . . . and relocated text resulting from page reformatting are not considered revisions and are not highlighted as such." Deleted "Change bars are not required when a revision to the Manual requires page reformatting resulting in text which is relocated but not changed. Previous revision change bars are removed when a new revision is issued." Replaced "in addition to being indicated on the title page, is also indicated in the lower left hand corner of each page" with "is indicated on each page."
		5	6	Deleted the page reference for the Record of Revisions.
		6	1-5	Deleted sections entitled "Transmittal Control" and "Control Log." Added section entitled "Distribution Control" describing electronic distribution control of QAM. Control mechanism is equivalent and reflects change in administrative practices.
		6	6	Deleted "The Training Manager, who reports to." Deletion of position. Restructured sentence.
		8-12	N/A	Revised and corrected list of typical QA Procedures used to implement QA Program.

## RECORD OF REVISIONS

Issue Date	Revision Number	Change(s)		Description
		Annotated Page(s)	Annotated Paragraph	
		13	3	Deleted 3 <sup>rd</sup> paragraph: "The Manager of Projects is responsible for all aspects of project implementation including the preparation of a list of task assignments along with a schedule of milestone completion dates, for providing each designated project participant with a copy, as appropriate, and for in-progress project meetings to track the project and assure the proper design interface."
		13	4	Added "Preparation of licensing documents" to list of general design activities covered by procedure.
		13	5 (1 <sup>st</sup> bullet)	Deleted "QA personnel are a part of the design review process. This is done to assure adherence to all applicable design procedures. This activity is accomplished through review and approval of design documents as specified in QA procedures."
		14	1 <sup>st</sup> bullet	Changed "test" to "tests."
		15	2	Added "[quality] assurance programs" to scope of what this QAM section addresses.
		15	2	Changed "inspection" to "inspections" and deleted "all."
		15	4	Deleted "Quality Assurance requirements, when applicable, are included with request for quotes." Added "including the applicability of Part 21 when required." Deleted "always" and "the."
		15	5	Deleted "job site"; "as applicable to BFS." Replace "which" with "that."
		15	7	Deleted "affiliate's or a" and added "of" to clarify list of typical procurement documentation.

## RECORD OF REVISIONS

Issue Date	Revision Number	Change(s)		Description
		Annotated Page(s)	Annotated Paragraph	
		15	9	Deleted "The Procurement documents are reviewed" and restructured sentence.
		17	1	Added "the Quality Assurance Manager and the President" to complete the list of those who approve procedures.
		17	2	Deleted "Quality Assurance and" from inline review process for fabrication documents.
		18	1	Deleted "policy for"; "establishes review and approval cycles and sequences,"; "requires that." Added comma; "are controlled by quality procedures. Revisions are"; and "as initial issuances."
		18	1	Added "Documents may be authenticated electronically (e.g., digital signatures), manually (e.g., signature and date), or by a combination thereof."
		18	2	Added "Controlled documents may be distributed either electronically or in hard-copy format. Electronic distribution shall make available only the current versions of documents (unless the user takes specific actions to obtain historical versions); hence, there is no requirement for transmittal control and receipt acknowledgement."
		18	2	Replaced "If hard copy distribution is utilized" with "For hard-copy controlled distribution."
		18	3	Deleted "The Manager of Projects shall assure that the documentation listings are maintained specifying the title, number, and current revision for all drawings, procedures, specifications and purchase orders."

## RECORD OF REVISIONS

Issue Date	Revision Number	Change(s)		Description
		Annotated Page(s)	Annotated Paragraph	
		19	2	Revised final sentence to "Document lists are maintained listing the title, identification number and current revision for all controlled documents."
		20	N/A	Corrected Title of Section to agree with title of corresponding section of 10 CFR 71 & 72.
		20	1	Added "and its customers" to include the total set of requirements considered.
		20	1	Added "Suppliers may be utilized for a customer's work based on a letter from the customer authorizing such use. This is limited only to work for the customer providing such approvals."
		20	2	Added comma. Deleted "QA"; "the."
		20	3	Deleted "and suppliers approved in writing by BFS customers."
		20	4	Deleted "which is."
		21	2 (2 <sup>nd</sup> bullet)	Added period.
		22	2	Added "The."
		23	1	Relocated "Other"; deleted comma; added comma; deleted "or."
		24	5	Deleted "The"; "procedures and instructions include inspection"; and "with." Added "shall include" and "as necessary."
		25	1	Deleted "the."

## RECORD OF REVISIONS

Issue Date	Revision Number	Change(s)		Description
		Annotated Page(s)	Annotated Paragraph	
		27	3	Deleted "departure, and arrival time and destination data recording"; "to be."
		28	1	Deleted "The use of"; "at or for BFS." Added "are used"; "and." Replaced "is" with "are."
		28	2	Deleted "interoffice memoranda"; "and audit"; "and that"; "are being satisfactorily used." Added "and"; "satisfactory use of"; and "is verified by audit or surveillance."
		29	1	Added "marking and/or." Deleted comma; "these." Restructured sentence.
		29	2	Deleted "The signatures of"; "are placed on the"; "approval." Added "review and approve"; "acceptance."
		29	3	Clarified statement of requirement as follows: added "sufficient"; deleted "indicate and."
		29	4	Added "when required." Substituted "equivalent" for "at least equal."
		30	1	Deleted "The documentation of." Added "is documented in a Condition Report and." Deleted "also."
		30	1	Deleted "The Quality Assurance Manager also logs the documentation of each condition adverse to quality." Substituted "A log of Condition Reports is maintained." Added comma.
		30	1	Added "continued" as a modifier to corrective action effectiveness.



## RECORD OF REVISIONS

Issue Date	Revision Number	Change(s)		Description
		Annotated Page(s)	Annotated Paragraph	
		30	2	Deleted "establish quality trends." Substituted "identify causal factors." Deleted "the"; "at that level"; "Copies of these reports and analyses are also provided to the Quality Assurance Manager for review."
		31	1	Deleted "is"; "agency." Changed "material's" to "materials."
		31	1	Added "condition reports" to list of typical quality records.
		31	2	Deleted "Shall be"; "commission."
		31	3	Deleted "but no more than five years."
		31	4, 5	Relocated the following from the 2 <sup>nd</sup> paragraph and separated into two paragraphs:  "Additionally, records of use, for all transport packages, shall be maintained for a period of three years after the shipment.  Records are identified by project number, part number, contract number, or drawing number as appropriate to the record type. BFS maintains a complete list of QA records to provide identification and location information."

## RECORD OF REVISIONS

Issue Date	Revision Number	Change(s)		Description
		Annotated Page(s)	Annotated Paragraph	
		32	1	<p>Deleted the following:</p> <p>"To minimize the risk of damage from fire, flooding and abnormal deterioration, two sets of identical records are maintained at separate and equivalent storage locations with access control and security; or</p> <p>The official copies of all QA records are maintained in approved fireproof files or vaults, at a single location."</p> <p>Replaced statement of requirement with [Protection for QA records is provided by using either one of the following storage methods:]</p> <p>"Single Storage in a facility or container that minimizes the risk of damage or destruction from natural disasters, environmental conditions, and biological infestation, or</p> <p>Dual Storage in locations sufficiently remote from each other as to eliminate or minimize the chance of exposure to a simultaneous hazard."</p>
		33	1	<p>Added "BFS carries out a comprehensive system of planned and periodic audits by personnel qualified in accordance with this QA Program to verify compliance with all aspects of the quality assurance program and to determine the effectiveness of the program."</p>
		33	2	<p>Relocated former 1<sup>st</sup> paragraph with new subtitle, "Internal Audits."</p>

## RECORD OF REVISIONS

Issue Date	Revision Number	Change(s)		Description
		Annotated Page(s)	Annotated Paragraph	
		33	3	Deleted "auditor" and substituted "audit team."
		33	3	Added "All audits are performed under the direction of a qualified Audit Team Leader."
		33	5	Relocated former 5 <sup>th</sup> paragraph (See deleted text on page 34, paragraph 1). Added "and Audit Team Leaders."
		33	6	Deleted "by personnel qualified in accordance with the requirements of the BFS QA Program." Deleted "and"; substituted "These audits."
		33	7	Deleted "first" as editorial correction.
		34	2	Deleted "auditors" and changed verb tense for "performs."
		34	3	Deleted former 7 <sup>th</sup> paragraph.
		34	4	Deleted "prescribed." Substituted "determined."

## PREFACE

This manual has been developed for and applies to BNFL Fuel Solutions and any wholly or partially owned subsidiary, affiliate or partnership engaged in the supply of spent fuel storage and/or transportation systems. The owner of the design and Certificate of Compliance for the VSC-24 Ventilated Storage System is Pacific Sierra Nuclear Associates (PSNA), a partnership between BNFL Fuel Solutions Corporation (BFS) and Sierra Nuclear Corporation (SNC). Both BFS and SNC are wholly owned subsidiaries of BNFL Inc.

The Quality Assurance Manual (QAM) sections contained herein describe BNFL Fuel Solutions' basic policy for the control of quality for products and services being provided by BNFL Fuel Solutions and meets the requirements of Title 10 Code of Federal Regulations, Part(s), 71 Subpart H, 72 Subpart G, and 50 Appendix B, and other comparable industry standards such as ANSI/ASME NQA-1.

The QAM is supported by ~~project, engineering and quality~~ procedures, which provide detailed requirements for implementing this corporate quality assurance policy. Procedural coverage is included for design and product quality assurance. Operating and maintenance requirements are included in the licensed product's Safety Analysis Report. The application of this program uses the "graded" approach, as defined in Regulatory Guide 7.10, depending on the complexity, criticality, and safety requirements of each project or component.

The initial release of the QAM and all subsequent revisions will be transmitted with a memo approved by the Quality Assurance Manager or equivalent position. Additional procedures will be prepared under appropriate sections or in subsequently identified sections for special coverage as required for contracts, if not adequately covered in the basic manual.

## STATEMENT OF MANAGEMENT POLICY

The Quality Assurance Program described herein is applicable to all spent fuel storage and/or transportation products and services provided by BNFL Fuel Solutions and any applicable wholly or partially owned subsidiary, affiliate or partnership to customers requiring a Quality Program meeting the requirements of Title 10 Code of Federal Regulations Part(s) 50 Appendix B, 71 Subpart H, and 72 Subpart G, or other comparable industry standards such as ANSI/ASME NQA-1.

The executive management of BNFL Fuel Solutions is devoted to the support of this program and charges all personnel involved in activities affecting quality with the responsibility of upholding and abiding by the Quality Assurance requirements in this manual. The Quality Assurance organization is authorized sufficient freedom to identify quality problems; initiate, recommend or provide solutions; verify implementation of solutions; and control further processing of service(s) or delivery of a nonconforming item, deficiency or unsatisfactory condition until proper disposition has been completed.

While it is the responsibility of everyone at BNFL Fuel Solutions to assure that quality and reliability objectives are achieved, the overall responsibility for the development, maintenance and assurance of the implementation of the Quality Assurance Program has been assigned to the Quality Assurance Manager, who reports directly to the President and Chief Executive Officer of BNFL Fuel Solutions.

~~Quality Assurance is recognized by corporate management as an interdisciplinary function for which the Quality Assurance Manager is charged by the President with the responsibility for establishing, implementing and maintaining a system to assure the conformance of BNFL Fuel Solutions' activities to the applicable requirements.~~

The Quality Assurance Manager has the complete support of Corporate Management in the performance of required duties and, by organizational arrangement, has no responsibility for production costs or schedules. The authority, as defined herein, extends to all activities performed by or for BNFL Fuel Solutions that may affect product quality. Decisions made by the Quality Assurance Manager within the scope of duties, responsibilities and authority as defined in this program may be changed or modified only by direction of the President.

All personnel assigned to operations subject to the requirements of this program shall be required to familiarize themselves with the policies and objectives set forth in this program. They shall be responsible for executing those policies, explicitly or implied, pertinent to their assignments.

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Robert D. Quinn  
President/Chief Executive Officer  
BNFL Fuel Solutions

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Date

## SECTION 1 – ORGANIZATION

### Organizational Structure

BNFL Fuel Solutions (BFS) is organized as shown in Figure 1.1. ~~Management responsibilities are identified by management level (manager, lead, etc.) and department (QA, Projects, Operations, etc.).~~

The President is responsible for management of BFS, setting overall company policy and identification of long-term company goals and resources. The President retains ultimate authority and responsibility for ~~review of the status and adequacy of the Quality Assurance Program and its compliance with the applicable requirements, and must assure this review occurs annually.~~

The assurance of quality at BFS is an interdisciplinary function that involves, as applicable, all organizations. Furthermore, quality assurance encompasses many diversified functions and activities and extends to various job levels within these organizations, including all executives and all employees whose activities affect quality. The implementation of quality assurance throughout the various functions of design, procurement, construction, operation and services at BFS must, therefore, be considered the direct responsibility of the organization performing the work and cannot be considered the sole domain of any single quality assurance group.

Persons or organizations charged with the development, enforcement or measurement and the adequacy and effectiveness of the quality assurance program shall have the authority and organizational freedom necessary to effectively discharge those responsibilities. Such persons or organizations shall be independent of direct pressures of cost, schedule or production, and their authority and organizational freedom shall be sufficient to: (1) identify quality problems; (2) initiate, recommend or provide solutions; (3) verify implementation of solutions; and (4) withhold and segregate nonconforming material or other action, including stopping work, to maintain program integrity. Furthermore, they shall have direct access to responsible management at a level where appropriate action can be mandated.

Persons performing quality assurance functions such as checking, verifying or reviewing the work of others (functions that do not encompass the development, enforcement or measurement of the adequacy or effectiveness of BFS' Quality Assurance Program) shall have authority and organizational freedom to a degree sufficient to properly discharge their assigned quality assurance responsibilities. However, when authority and organizational freedom are restricted for any person performing quality assurance functions, an established line of communication to responsible management must

exist sufficient to prevent suppression of those quality assurance functions and/or to resolve any disputes.

Managers have the organizational freedom to identify issues related to their organization directly to the President.

Final responsibility for the effectiveness and adequacy of BFS' Quality Assurance Program resides with BFS. However, BFS may delegate the establishment and execution of the program, or any part thereof, to other organizations. Those organizations may, in turn, delegate responsibility for applicable portions of the Program to other organizations.

The President of BFS has overall responsibility for assuring the development and maintenance of an effective quality assurance program for BFS. Responsibility for the establishment, training, administration, and enforcement of the BFS Quality Assurance Program has been delegated by the President to the Quality Assurance Manager. The Quality Assurance Department functions as a staff position reporting to the President of BFS and is independent of all other organizations within BFS. The Quality Assurance Department assumes line responsibility for assuring compliance with BFS' Quality Assurance Policy. The Quality Assurance Manager will review the status, adequacy and implementation of the QA program at least annually and report this status to the President. BNFL Corporate Quality Assurance provides general guidelines and oversight, and corporate support to the BFS Quality Assurance Manager.

The Quality Assurance Manager may delegate any of the functions assigned to him by this Manual to another individual, but he shall retain the responsibility for accomplishment of the function in accordance with the provisions of this Manual. The Quality Assurance Manager may obtain support/resources from BNFL Inc. and receives QA functional input from the BNFL Corporate QA Department.

Any dispute over Quality Assurance with the management of other functions that cannot be resolved with the respective manager shall be referred to the President for resolution.

BFS shall verify the accomplishment of Quality, through scheduled and/or unscheduled audits, of in-house functions and, as applicable, at sub-vendors and/or at suppliers.

The Manager of Operations is responsible for the design, engineering, product development, corrective action, licensing, and regulatory management of BFS activities and systems important to safety. The specific functions, ~~of the authorities,~~ and duties of persons and organizations performing activities affecting the functions of structures, systems, and components that are important to safety are delineated in the implementing procedures.

### **Project Organization**

The Manager of Projects has the overall programmatic responsibility for the strategic planning, direction,

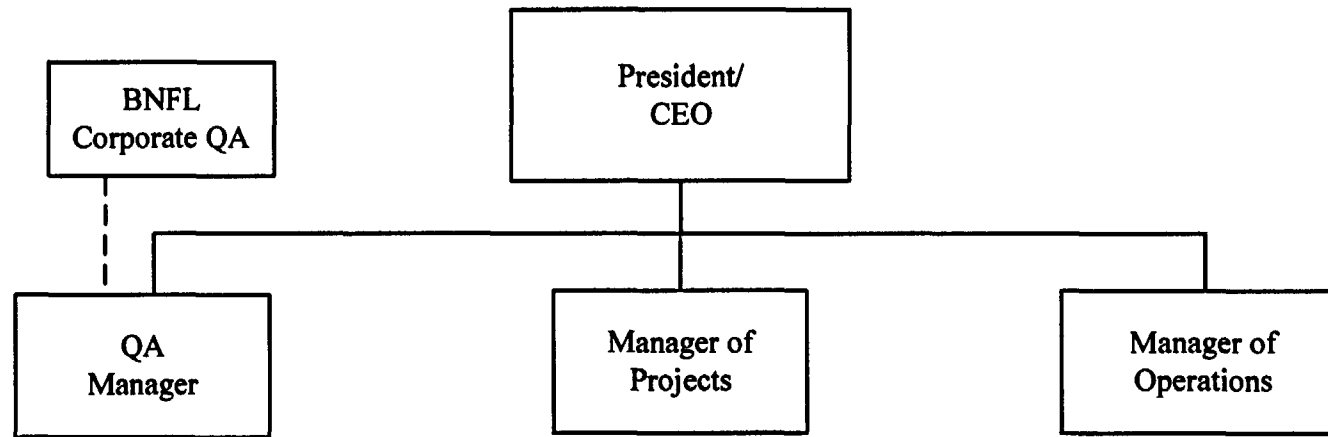
compliance with technical requirements, procurement, fabrication and construction activities for all projects, and may serve as the Project Manager for one or more projects.

The Manager of Projects is responsible for the quality and commercial aspects of projects. This includes review of purchase orders received by BFS to supply items or services to assure that quality and technical requirements are included in new projects. The Manager of Projects may assign a project staff, supported by a

Project Engineer and by managers that are matrixed from their respective organizations. The Manager of Projects is responsible for interface control. In a small, single discipline project, the Project Manager and the Project Engineer may be the same person reporting to the Manager of Projects.



Figure 1  
BFS Organization Chart



## SECTION 2 - QUALITY ASSURANCE PROGRAM

This Quality Assurance Program shall apply to all activities that are important-to-safety (or nuclear safety-related) and require compliance with any or all of the documents listed below.

- 10 CFR 71, Subpart H
- 10 CFR 50, Appendix B
- 10 CFR 72, Subpart G
- ANSI N45.2
- ANSI/ASME NQA-1

Conditions that may be reportable either as deficiencies affecting the ability of important-to-safety structures, systems and components to perform their intended safety function per 10CFR72.242 or as "substantial safety hazards" under 10CFR21, shall be reported in accordance with applicable Quality Assurance Procedures.

### Manual Review and Approval

The BFS Quality Assurance Program is fully described in and implemented in accordance with this document, the BFS Quality Assurance Manual. The Manual is reviewed annually or more frequently as directed by the President. The intent of this review is to keep the Manual current with the documents specified above. Revisions to the

Manual required for compliance to the referenced documents are authorized by the President.

Approval of this Manual, and revisions thereto, is documented by the signature of the President on the title page with the respective date of approval. All revisions to the Manual are issued for implementation by the President within thirty (30) days of approval of the revision by the NRC.

### Revision Control

The QA Manual shall be revised and issued in its entirety, with changes. Manual revisions are highlighted in the text. ~~by a vertical line (change bar) in the right margin. This change bar is not required. Changes in the footer of each page or on the title page and relocated text resulting from page reformatting are not considered revisions and are not highlighted as such. Change bars are not required when a revision to the Manual requires page reformatting resulting in text which is relocated but not changed. Previous revision change bars are removed when a new revision is issued.~~

A history of revisions is maintained for the QA Manual as indicated on the Record of Revisions ~~(page iii)~~. The current revision of the Manual is indicated on each page, ~~in addition to being indicated on the title page, is also indicated in the lower left hand corner of each page.~~

## **Transmittal-Distribution Control**

The Manual may be distributed electronically or in hard-copy form. Electronic distribution channels shall limit access to only the current version of the Manual; hence, there is no requirement for transmittal control and receipt acknowledgement. Hard-copy distribution of Controlled Manuals shall be performed using transmittal forms with required receipt acknowledgement and follow-up on delinquent acknowledgements. Both electronic and hard-copy distribution shall be performed in accordance with the BFS Quality Assurance procedures for document control.

~~The recipient of the Controlled Manual verifies the receipt of the Manual and subsequent revisions and certifies that his/her Manual is complete, by signing and returning the BFS Quality Assurance Controlled Document Transmittal. The recipient is required to return the completed Controlled Document Transmittal Form to the designated BFS person. The recipient shall be responsible for the destruction of the obsolete manual(s).~~

~~The Quality Assurance Manager shall take appropriate measures to secure delinquent BFS Quality Assurance Controlled Document Transmittal Forms. Except for BFS personnel, delinquent Transmittals shall result in uncontrolling the subject Manual after thirty (30) days. Transmittals not returned from BFS personnel within thirty days after transmittal date shall be investigated by the designated QA personnel and followed up with corrective action as necessary.~~

## **Control Log**

~~The Quality Assurance Department maintains a Control Log that records the holders of Controlled Manuals.~~

~~Holders of Uncontrolled Manuals receive an information copy of the Manual that is current at the time of issue, but will not receive subsequent revisions to the Manual. Holders of Controlled Manuals automatically receive future revisions to the Manual.~~

## **Indoctrination and Training**

Each manager will assure that all personnel performing activities affecting quality are indoctrinated, trained and qualified according to their level of responsibility and assigned functions. Indoctrination and training shall consist of informal, on-the-job activities under the guidance of trained personnel, self study and/or formal meetings, classes, lectures, and seminars. ~~The Training Manager, who reports to~~ The Quality Assurance Manager, shall assist the managers in implementing this responsibility including providing training courses, materials and standards. Formal training shall be documented and the associated record maintained as a Quality Assurance Record in accordance with Section 17.

## **Qualification and Certification of Personnel**

BFS performs inspections, examinations or tests for which a formal BFS program of training, qualification and certification is required per QAM Section 10 and Section 11. When these inspections, examinations or test

activities are performed, they shall be performed by appropriately certified personnel.

Surveys and audits for which BFS is responsible are conducted by Lead Auditors who are qualified as specified in ANSI/ASME N45.2.23; 10 CFR 50, Appendix B; and ANSI/ASME NQA-1. Records of Lead Auditor qualification are maintained in the BFS files (refer to Section 18).

### **Quality Assurance Program Implementation**

Quality Assurance Procedures (QAP) are developed to implement the requirements defined by this Quality

Assurance Manual. Additional QAPs, or project specific procedures, may be developed for each project because of different interface requirements between customers and suppliers. These project specific procedures shall be part of the project plan. In all cases, the QAPs shall conform to the requirements specified in this Quality Assurance Manual.

The following table identifies the relationships among the 18 criteria and the BFS Quality Assurance Manual and implementing Quality Assurance Procedures.

## RELATIONSHIP OF 18 CRITERIA TO BFS QA PROGRAM

Criteria of:  
 10 CFR 50 Appendix B  
 10 CFR 71 Subpart H  
 10 CFR 72 Subpart G

Corresponding QA Manual Section  
 QA Procedures<sup>1</sup>

Criteria of:	Corresponding QA Manual Section QA Procedures <sup>1</sup>
I. Organization	QAM Section 1 and Organization Charts QAP 1.0: <del>Project Organization</del> Order Entry and Project Planning QAP 1.1: <del>Control and Distribution of Project</del> QA Plans and Project-Specific QA Procedures QAP 1.2: Readiness Reviews QAP 1.3: <del>BFS</del> Organization
II. Quality Assurance Program	QAM Section 2 QAP 2.1: Control and Distribution of BFS Quality Assurance Procedures QAP 2.2: Certification of Inspection Personnel QAP 2.4: Quality Assurance Program Assessment and Reporting QAP 2.5: Indoctrination and Training of Personnel QAP 2.6: Personnel Qualifications

<sup>1</sup> This listing and the content of these Quality Assurance Procedures may change as needed to provide procedural direction applicable to BFS' commercial activities, or as necessary to reflect changes in governing standards/regulations. These changes may be made without revision of the Quality Assurance Manual (QAM) providing the QAM requirements are maintained.

Criteria of:  
10 CFR 50 Appendix B  
10 CFR 71 Subpart H  
10 CFR 72 Subpart G

Corresponding QA Manual Section  
QA Procedures<sup>1</sup>

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III. Design Control

QAM Section 3

- QAP 3.0: Design Control
- QAP 3.1: Design Input
- QAP 3.2: Calculations
- QAP 3.3: Drawings
- QAP 3.4: Specifications
- QAP 3.5: Technical Reports
- QAP 3.6: Safety Analysis Reports
- QAP 3.7: Quality Category Assessment
- QAP 3.8: Engineering Change Notice
- QAP 3.9: Safety Review and Evaluation
- QAP 3.10: System Design Verification
- QAP 3.11: Receipt of Engineering and Fabrication Deliverables
- QAP 3.12: Computer Software Development, Installation and Revisions
- QAP 3.13: Computer Software Control and Usage Tracking
- QAP 3.14: Identification and Control of Computer Errors
- QAP 3.15: 10CFR72.48 Evaluation
- QAP 3.16: 10CFR71 Change Evaluation
- QAP 3.17: Processing of 10CFR72.48 Records

Criteria of:

10 CFR 50 Appendix B  
10 CFR 71 Subpart H  
10 CFR 72 Subpart G

Corresponding QA Manual Section  
QA Procedures<sup>1</sup>

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IV.	Procurement Document Control	QAM Section 4 QAP 4.0: Procurement Control
V.	Instructions, Procedures and Drawings	QAM Section 5 QAP 5.2: Process Control
VI.	Document Control	QAM Section 6 QAP 6.0: <del>Project</del> -Document Control
VII.	Control of Purchased Materials, <u>Equipment and Services</u> <del>Parts and Components</del>	QAM Section 7 QAP 7.1: Supplier Evaluation QAP 7.2: Source Inspection QAP 7.3: Receipt Inspection QAP 7.5: Commercial Grade Dedication
VIII.	Identification and Control of Materials, Parts and Components	QAM Section 8 QAP 8.0: Identification and Control of Materials, Parts and Components <u>QAP 8.1: Certificate of Conformance</u>

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Criteria of:

10 CFR 50 Appendix B  
10 CFR 71 Subpart H  
10 CFR 72 Subpart G

Corresponding QA Manual Section  
QA Procedures<sup>1</sup>

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IX.	Control of Special Processes	QAM Section 9 QAP 9.0: Control of Special Processes
X.	Inspection	QAM Section 10 QAP 10.0: Inspection
XI.	Test Control	QAM Section 11 QAP 11.0: Test Control
XII.	Control of Measuring and Testing Equipment	QAM Section 12 QAP 12.0: Control of Measuring and Test Equipment
XIII.	Handling, Storage and Shipping	QAM Section 13 QAP 13.0: Handling, Storage and Shipping
XIV.	Inspection, Test and Operating Status	QAM Section 14 QAP 14.0: Inspection and Test Status

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Criteria of:  
10 CFR 50 Appendix B  
10 CFR 71 Subpart H  
10 CFR 72 Subpart G

Corresponding QA Manual Section  
QA Procedures<sup>1</sup>

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XV. Nonconforming Material, Parts or Components	QAM Section 15
	QAP 15.0: <u>Nonconforming Material, Parts, or Components or Services</u>
	QAP 15.2: Reporting of Defects and Noncompliances

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XVI. Corrective Action	QAM Section 16
	QAP 16.0: Corrective Action Process
	QAP 16.1: Cause Analysis
	<del>QAP 16.2: Lessons Learned</del> QAP 16.3: <u>Effectiveness Reviews</u>

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XVII. Quality Assurance Records	QAM Section 17
	QAP 17.0: Quality Records

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XVIII. Audits	QAM Section 18
	QAP 18.0: Audits and Surveys
	QAP 18.1: Qualification and Certification of QA Audit Personnel
	QAP 18.2: Quality Assurance Surveillance of Suppliers
	QAP 18.3: Internal Surveillance

## SECTION 3 - DESIGN CONTROL

The purpose of this section is to establish the basic minimum requirements to provide control of design activities including program planning, design and design verification from initial concepts through completion of design, manufacturing, inspection and planning for BFS and customer-based projects. BFS provides designs, investigations, analyses and reports based on specific project requirements.

Before any quality affecting work, including design input, conclusion, or review remarks, can be provided on a project, the Manager of Projects shall prepare a "Project Plan". The Project Plan lists all of the intended activities required to accomplish/support specific project needs for BFS and/or customer based projects, including all design bases and/or regulatory requirement documents applicable to the project. Design interfaces and quality requirements shall be described in the Project Plan.

~~The Manager of Projects is responsible for all aspects of project implementation including the preparation of a list of task assignments along with a schedule of milestone completion dates, for providing each designated project participant with a copy, as appropriate, and for in-progress project meetings to track the project and assure the proper design interface.~~

The Manager of Operations is responsible for assuring the technical adequacy and correctness of the design and that the final design meets the BFS, customer and regulatory

requirements. Procedures have been developed to assist in assuring and documenting the quality of the design output. These procedures cover the following:

- Preparation of calculations
- Review and checking of calculations and reports
- Computer program control and usage
- Drawing and specification preparation
- Design verification
- Change control
- Procured design services
- Preparation of licensing documents

BFS Quality Assurance Procedures (QAPs) have been developed, approved and implemented to control the design process in such a manner to assure that:

- ~~QA personnel are a part of the design review process. This is done to assure adherence to all applicable design procedures. This activity is accomplished through review and approval of design documents as specified in QA procedures.~~ The design activity is planned, controlled and documented.

- The design documents contain Quality Assurance requirements for inspections and tests that will assure control, inspection and testing of design characteristics.
- Deviations from quality requirements are controlled.
- Design verification is performed by qualified personnel independent of the design activity, but with a skill level at least equal to that of the original design personnel. These verifications may include tolerance studies, alternate calculations or tests. Qualification tests are conducted in accordance with approved test programs and procedure.
- The design verification method selection is based on regulatory and contractual requirements, level of complexity of the design and "state-of-the-art"

considerations, i.e., materials, fabrication processes, etc., and operating conditions.

- Interface control is established and adequate to assure that the review, approval, release, distribution and revision of design documents involving interfaces are performed with all cognizant design personnel.
- Design and specification changes are reviewed and approved by the same organization(s) as the original issue.
- Design errors and deficiencies are documented and appropriate corrective action is taken.

## SECTION 4 - PROCUREMENT DOCUMENT CONTROL

The QA Program provides controls to assure that all purchased material, components, equipment, and services adhere to design specifications, regulatory and contractual requirements.

Evaluation and selection of suppliers, objective evidence of supplier quality assurance programs, assignment of quality requirements to procurement documents, and related design documents, and source, in-process and receiving inspections are all administered and controlled in accordance with this section of the Quality Assurance Manual and approved procedures.

Procurement is performed under the supervision of the Manager of Projects. Changes to procurement documents shall be prepared, reviewed, approved and authorized for use in the same manner as established for the original issue of the document.

~~Quality Assurance requirements, when applicable, are included with request for quotes. Quality Assurance requirements, including the applicability of Part 21 when required, are always provided with the purchase orders and/or applicable specifications.~~

BFS may procure any design, manufacturing, inspection, testing, auditing or ~~job site construction activity~~ described in this Manual. Procurement documents for these services shall include requirements, which that assure that the requirements of this Manual, ~~as applicable to BFS,~~ will be

met by the subcontractor. BFS retains final responsibility to assure the service is acceptable for the BFS project.

Contract documents such as Purchase Orders, drawings and specifications are reviewed to assure the inclusion of all requirements. Personnel qualification requirements are either defined or verified by reference on a procurement document. Review also includes verification of the suitability of standard items for the use required by the applicable drawings and design specifications with the inclusion of valid industry standards, references, and related data, when applicable.

The Manager of Projects assures that requirements for acceptance of hardware and documentation, such as the ~~affiliate's or a supplier's~~ submittal and retention of instructions appropriate to the contract, are included in procurement documentation.

BFS maintains the right of access to all supplier facilities and documentation for source inspection and/or audit activities. A statement to this effect is included on procurement documentation when it is appropriate to the contract.

BFS QA personnel check procurement documents for completeness and the inclusion of quality requirements. ~~The procurement documents are reviewed in accordance with written procedures, and~~ Procurement documents

require the approval of the BFS Quality Assurance  
Manager.



## SECTION 5 - INSTRUCTIONS, PROCEDURES AND DRAWINGS

Procedures and instructions are developed by qualified personnel assigned by the responsible manager. Procedures are developed for activities requiring design and/or fabrication, performance verification, witnessing, measurements, testing or other Quality Assurance related activities. These procedures are approved by the responsible manager, the Quality Assurance Manager and the President.

All fabrication documents (i.e., drawings, specifications, special processes, test and calibration procedures, etc.) are reviewed by ~~Quality Assurance and~~ a qualified engineer as assigned by the Manager of Operations. The fabrication documents are also referenced in inspection procedures as necessary to assure adherence to package,

system or other design approvals and the applicable regulatory and contractual requirements.

The inspection procedures also include appropriate acceptance criteria such as dimensions, tolerances, operating limits, workmanship standards, and other qualitative and quantitative measures.

All instructions, procedures, and drawings are developed, reviewed, approved, utilized and controlled in accordance with approved procedures.

Changes to instructions, procedures and drawings shall be prepared, reviewed, approved and authorized for use in the same manner as established for the original issue of the document.

## SECTION 6 - DOCUMENT CONTROL

The ~~policy for review, approval, release and revision of quality related documents establishes review and approval cycles and sequences, as well as requires that revisions/changes to all such approved documents, are controlled by quality procedures. Revisions are~~ be subjected to the same approval cycle and sequence as initial issuances. Provisions are made for identifying individuals/organizations responsible for review and approval of controlled documents in the Quality Assurance Procedure applicable to the controlled document. Documents may be authenticated electronically (e.g., digital signatures), manually (e.g., signature and date), or by a combination thereof. Document control responsibilities and distribution requirements are also addressed in procedures.

Controlled documents may be distributed either electronically or in hard-copy format. Electronic distribution shall make available only the current versions of documents (unless the user takes specific actions to obtain historical versions); hence, there is no requirement for transmittal control and receipt acknowledgement. For hard-copy controlled distribution, if hard-copy distribution is utilized, ~~Transmittal sheets with provisions for acknowledging receipt are utilized to provide proper records of the transmittal and receipt of controlled documents and subsequent revisions.~~

~~The Manager of Projects shall assure that documentation listings are maintained specifying the title, number and current revision for all drawings, procedures, specifications and purchase orders.~~

Controlled documents include but are not limited to:

- Design Specifications
- Calculations
- Analyses
- Safety Analysis Report(s)
- Drawings
- Specifications (Procurement, Equipment, etc.)
- Special Process Procedures (Welding, Forming, Heat Treating, NDE, Etc.)
- Inspection Procedures
- QA Manuals and Procedures
- Source Surveillance and Inspection Reports
- Test Procedures and Reports
- Operational Test and Inspection Reports

- Subvendor Procedures, Specifications and Drawings
- Customer Specifications, Procedures and Drawings

When documents being revised appear in other documents as references, supplements or include the attribute being changed, an impact assessment will be conducted and depending upon the results, either:

- A process to control the revision of that document will be provided, or
- That document will be revised prior to release of the approved change.

Documentation listings are maintained listing the title, ~~document~~identification number and current revision for all controlled documents.



## **SECTION 7 - CONTROL OF PURCHASED MATERIALS, ~~PARTS AND COMPONENTS~~ EQUIPMENT AND SERVICES**

It is the policy of BFS that all suppliers of materials, components, systems or services, receive controlled and approved procurement documents that contain or reference all applicable regulatory requirements, appropriate design/engineering drawings and specifications, and other requirements necessary to produce a product or service that meets the quality requirements of BFS and its customers. In addition, procurement documents shall contain provisions that require suppliers and their subtier suppliers to execute quality assurance programs in a manner, and to the extent, specified by BFS. Furthermore, procurement documents shall provide for the right of BFS to audit its contractors as well as their subtier suppliers, on their implementation of these controls. All procurements will be made only from BFS approved suppliers based on their past history, pre-award and/or post-award audits and surveys. Suppliers may be utilized for a customer's work based on a letter from the customer authorizing such use. This is limited only to work for the customer providing such approvals. BFS shall maintain an Approved Suppliers List (ASL).

As directed by the Quality Assurance Manager, evaluations are conducted by BFS QA qualified personnel to further assure supplier acceptability and performance. These evaluations are based on the following criteria:

- The capability of the supplier to comply with the requirements of 10CFR72 Subpart G, 10CFR71 Subpart H, 10CFR50 Appendix B, ANSI N45.2, ANSI/ASME NQA-1, or other requirements appropriate to the contract as determined by BFS QA.
- A review of previous records and performance of the supplier by BFS Quality Assurance.
- A survey/audit by QA, assisted by Operations and Projects as appropriate, of the supplier's facilities and Quality Program to determine their capability to supply a product that meets ~~the~~ design, manufacturing, and quality requirements.

Suppliers shall be evaluated by audit except for Regulatory Agencies/Nationally Recognized Standards Laboratories, ~~and suppliers approved in writing by BFS customers.~~

Results of the supplier evaluations and audits are appropriately recorded and included as part of the vendor's history file, ~~which is~~ retained by Quality Assurance.

Audits are conducted at active supplier's facilities during the performance of activities, to assure continued adherence to the imposed Quality Assurance, design and

contract performance criteria. These audits are conducted at least once every three years (during active periods) or more often as directed by the Quality Assurance Manager.

As an alternative to the aforementioned requirements, dedication of commercial grade items and services may be performed in accordance with approved procedures.

As directed by the Quality Assurance Manager, source and/or receiving inspections are performed by qualified personnel to assure the following:

- The material, component, or equipment is properly identified, refers to applicable codes, standards and specifications, and corresponds with the identification on receiving documentation.

- Prior to their use or installation, materials, components, equipment and acceptance records are inspected and are accepted in accordance with appropriate contractual requirements.

- Inspection records and/or certificates of conformance are available that attest to the acceptance of materials and components prior to their installation or use.

- Items accepted and released are identified as to their inspection status prior to forwarding to a controlled storage area or release for further work.

All described activities are delineated in approved BFS Quality Assurance Procedures.

## **SECTION 8 - IDENTIFICATION AND CONTROL OF MATERIALS, PARTS AND COMPONENTS**

A process for identifying and controlling materials, parts, components and completed and in-process assemblies is administered by Quality Assurance Manager in accordance with approved Quality Assurance Procedures. These procedures address quality status tags, marking, and/or stamping to assure maintenance of material identification, traceability, and part identification, to related documentation. Some of the details of these procedures are as follows:

- Material identification procedures included in Quality Assurance inspection instructions and fabrication drawings require that identification of material, components, and/or hardware be maintained on the item or in traceable records to prevent use of incorrect or defective material.
- Specifications, procurement documentation, fabrication and inspection records, discrepancy

reports and material test data are also periodically audited to assure continued adherence to design, regulatory and contractual requirements.

- Identification requirements, such as method and size, may be specified on applicable drawings or in applicable procurement/equipment specifications. Such identification shall not interfere with fit, interface or performance.

The Quality Assurance Manager shall assure that materials and equipment are controlled, protected, stored, handled, operated and packaged so that identification, traceability and condition are maintained. Some or all of the material control functions described herein may be delegated to approved suppliers.

## SECTION 9 - CONTROL OF SPECIAL PROCESSES

This section delineates the policies and practices established for special processes that control or verify quality, such as those used in welding, heat treating, and non-destructive examination. ~~Other~~ Examples of other processes, that may be considered a special process, include coating, ~~or~~ painting, and lead pouring. Special processes developed by suppliers and/or BFS are documented, reviewed and approved by the responsible technical personnel within BFS, and/or customer organizations. In addition, special process equipment is identified, inspected and performance tested prior to use.

All procedures for special processes are performed in accordance with applicable codes, standards,

specifications and contract requirements. The personnel performing such processes are trained and qualified in accordance with approved procedures. Both the procedures and personnel are subjected to full review and approval cycles as defined herein, by personnel qualified and approved by the Quality Assurance Manager for the subject matter relating to the special process.

Qualification records and support data are retained in the Quality Assurance files.

All documentation shall be administered and controlled in accordance with the requirements of the BFS Quality Assurance Program.

## SECTION 10 – INSPECTION

Receiving, source, test, in-process, shipping and in-service inspection activities are performed in accordance with the requirements of this manual and approved procedures. Inspection personnel and/or organization qualifications are reviewed and accepted by the Quality Assurance Manager prior to inspection activity. The inspection activity is performed to verify conformance to drawings, procedures and/or specifications.

Inspection personnel report to the Quality Assurance Manager.

The qualifications of inspection personnel are based on their capability to perform the required inspection functions in accordance with applicable codes and standards. Qualification reviews are performed periodically to maintain personnel proficiency and assure current qualification.

Inspection procedures and instructions include hold points, inspection equipment requirements, accept-reject criteria, personnel requirements, characteristics to inspect, variable attributes, recording instructions, reference documentation and other requirements, as appropriate.

~~The inspection procedures and instructions include inspection results~~ shall include with supporting information such as variables, attributes, data, test results, NDE records, welding information, certified materials test report (and/or certification), special process data, discrepancy reports, related dispositions and resultant reinspection data as necessary.

## SECTION 11 - TEST CONTROL

A quality related test control program is defined by approved test procedures. Prerequisites, accept/reject criteria, data recording criteria, instrumentation calibration, environmental conditions, documentation and evaluation requirements, etc., are defined in the test procedures.

The Manager of Operations assures that the service conditions described in applicable design, regulatory and contractual documents are verified by testing activities. Changes to test procedures are required to be reviewed/approved by the same organization(s) as the original issue.

Whenever equipment, components, and/or assemblies require modification, repairs, or replacement that could result in requirements for re-test or additional testing, the Manager of Projects shall assure that original or new test inspection instructions are prepared and adhered to as appropriate.

Test results are documented, evaluated and accepted by the Manager of Operations as required by the test procedure prepared for the test under the cognizance of the Manager of Projects.

## **SECTION 12 - CONTROL OF MEASURING AND TESTING EQUIPMENT**

Calibration of measuring equipment and instrumentation is established by the Quality Assurance Manager. The calibration process assures that all standard measuring instruments used in the acceptance of material, equipment, and assemblies are calibrated and properly adjusted at specified intervals to maintain accuracy within pre-determined limits.

Calibrated equipment is identified and is traceable to the calibration test data. Identification includes the equipment property number, next calibration due date and

inspector's or calibrator's signature or initials attesting to the accuracy and validity of the calibration.

Calibration accuracy is maintained by utilizing standards traceable to the National Institute of Standards Technology (NIST), derived from accepted values for natural physical constants, or by the ratio type of self-calibration.

## SECTION 13 - HANDLING, STORAGE AND SHIPPING

Requirements for handling, storage and shipping shall be documented in project specific procedures or specifications. These requirements are designed to prevent damage or deterioration of material and equipment. Information pertaining to shelf life, environment, packaging, temperature, cleaning, handling, preservation, etc., is included as required to meet design, regulatory and/or customer requirements.

Inspection procedures and instructions contain assessment of criteria for handling, storage, preservation and shipping requirements.

Shipping documentation preparation, ~~departure, and arrival time and destination data recording~~ is also to be addressed, when applicable. The requirements pertaining to shipping must be met prior to release for shipment.



## SECTION 14 - INSPECTION, TEST AND OPERATING STATUS

~~The use of~~ Inspection status tags, quality inspection stamps, and other means are used to indicate inspection and test status and ~~at or for BFS,~~ are described in project specific procedures or fabrication travelers.

These documents provide that indications of status are clear, inspection and/or test steps are not bypassed, and removal or modification of status indicators are

prohibited, except with Manager of Projects and/or Quality Assurance Manager approval. The Quality Assurance Manager assures via procedure, ~~interoffice memoranda,~~ and training sessions, ~~and audit,~~ that personnel are aware of and understand the meaning and uses of status indicators on hardware, material, and test setups. ~~and that~~ The satisfactory use of status indicators is verified by audit or surveillance. ~~are being satisfactorily used.~~

## SECTION 15 - NONCONFORMING MATERIAL, PARTS OR COMPONENTS

Material, components, and equipment that do not conform to requirements are controlled to prevent their inadvertent use. This control is through identification, marking and/or segregation. ~~Discrepancy reporting, disposition of nonconformances by authorized individuals and reinspection activities.~~ These are performed and controlled in accordance with written procedures.

Nonconformance Reports (NCRs) are utilized and logged to identify discrepant items, describe the discrepancy and provide disposition and reinspection requirements. ~~The signatures of an Authorized, cognizant personnel review and approve are placed on the NCRs~~ to signify approval acceptance of the disposition.

NCRs are reviewed by the Manager of Projects, Manager of Operations and Quality Assurance Manager to assure that "use-as-is" or "repair" dispositions include sufficient technical justification to ~~indicate and~~ assure continued compliance with design, regulatory and contractual requirements. When appropriate, copies of dispositions are forwarded to the owners and users of the affected equipment.

In conjunction with "repair" or "rework" dispositions, Quality Assurance personnel assure that supplemental inspections are performed to verify compliance with the NCR disposition when required. This assures that the item is re-tested and/or reinspected to a degree equivalent-at least equal to the original acceptance level.

## SECTION 16 - CORRECTIVE ACTION

Conditions adverse to quality, such as failures, malfunctions, deficiencies and deviations in material, components, equipment and services, are identified, documented, and reported to BFS Management. Significant conditions adverse to quality will be reported to the President. ~~The documentation of e~~Each condition adverse to quality is documented in a Condition Report and is also forwarded to the Quality Assurance Manager for review and analysis. A log of Condition Reports is maintained. ~~The Quality Assurance Manager also logs the documentation of each condition adverse to quality.~~ For significant conditions adverse to quality the cause of the condition and the corrective action necessary to prevent

recurrence is identified, implemented and when required, followed up to verify continued corrective action effectiveness.

Analyses of identified conditions are conducted within thirty days of their submittal or as otherwise approved by the Quality Assurance Manager and/or the President. These analyses identify causal factors ~~establish quality trends~~ and help to pin-point areas in need of corrective action. Quality ~~The quality trends and related reports are prepared and presented to the President for review and action, at that level. Copies of these reports and analyses are also provided to the Quality Assurance Manager for review.~~

## SECTION 17 - QUALITY ASSURANCE RECORDS

BFS' QA records system is established and is administered in accordance with approved BFS QA Procedures. The purpose of the QA records system is to assure that documented evidence pertaining to quality related activities is maintained and available for use by company, customer, and/or regulatory agency personnel, as appropriate. QA records include, but are not limited to, design related records (calculations, drawings, research, development test reports, and design reviews), inspection and test records (including identification of inspectors and data recorders), audit reports, condition reports, quality personnel qualification(s), quality related procurement data, supplier evaluation reports, material's analyses (certified material test reports or certificates of compliance as applicable), fabrication/manufacturing records, modification records, repair records, and maintenance records.

The retention period for the above identified records is as follows: 1) Transportation Packaging - Life of the packaging plus three years; 2) Spent Fuel Storage Packaging - ~~Shall be maintained~~ by or under the control of the licensee until the ~~commission (NRC)~~ terminates the license. ~~Additionally, records of use, for all transport packages, shall be maintained for a period of three years after the shipment. Records are identified by project number, part number, contract number, or drawing number as appropriate to the record type. BFS maintains~~

~~a complete list of QA records to provide identification and location information.~~

For all other equipment, quality related records are retained for a minimum of three years, ~~but no more than five years~~ unless otherwise specified by applicable regulatory, code, standard or contractual requirements.

Additionally, records of use, for all transport packages, shall be maintained for a period of three years after the shipment.

Records are identified by project number, part number, contract number, or drawing number as appropriate to the record type. BFS maintains a complete list of QA records to provide identification and location information.

Inspection records retained in the QA records system provide the following data when applicable:

- Inspection type, i.e., in-process, in-service, testing, receiving and shipping.
- Evidence of completion and verification of manufacturing, inspection or test operation.
- The date and results of the inspection or test.
- Information related to noted discrepancies.

- Inspector or data recorder identification.
- Evidence of acceptance.

Protection for QA records is provided by using either one of the following storage methods:

- Single Storage in a facility or container that minimizes the risk of damage or destruction from natural disasters, environmental conditions, and biological infestation, or
- Dual Storage in locations sufficiently remote from each other as to eliminate or minimize the chance of exposure to a simultaneous hazard.

~~☐ To minimize the risk of damage from fire, flooding and abnormal deterioration, two sets of identical records are maintained at separate and equivalent storage locations with access control and security; or~~

~~☐ The official copies of all QA records are maintained in approved fireproof files or vault, at a single location.~~

## SECTION 18 – AUDITS

BFS carries out a comprehensive system of planned and periodic audits by personnel qualified in accordance with this QA Program to verify compliance with all aspects of the quality assurance program and to determine the effectiveness of the program.

~~Internal Program audits are performed annually (or more often, if deemed necessary by the Quality Assurance Manager), by personnel qualified in accordance with the requirements of the BFS QA Program. These audits and may be project specific or cover multiple projects. These audits provide comprehensive, independent verification and evaluation of the implementation of the entire Quality Assurance system established in response to the appropriate requirements of 10CFR72 Subpart G, 10CFR71 Subpart H, 10CFR50 Appendix B, ANSI N45.2, ANSI/ASME NQA-1, and other applicable codes, standards, specifications and requirements.~~

Audit Logs, Audit Plans and Audit Checklists are prepared and utilized by the audit team/auditor. All audits are performed under the direction of a qualified Audit Team Leader. At the completion of each audit, the Quality Assurance Manager evaluates the planning sheets and checklists to confirm that the audit effectively addressed all the appropriate Program elements.

Audit results and corrective action activities are documented in an Audit Report by the Quality Assurance Manager and transmitted to the responsible management

personnel of the audited organization, the President and the Manager of Operations. Responsible management personnel are required to respond to audit findings with the necessary action to correct the noted deficiencies.

Records of audits and the qualifications of Auditors and Audit Team Leaders are maintained by the Quality Assurance Manager.

### Internal Audits

Internal Program audits are performed annually (or more often, if deemed necessary by the Quality Assurance Manager), by personnel qualified in accordance with the requirements of the BFS QA Program. These audits and may be project specific or cover multiple projects. These audits provide comprehensive, independent verification and evaluation of the implementation of the entire Quality Assurance system established in response to the appropriate requirements of 10CFR72 Subpart G, 10CFR71 Subpart H, 10CFR50 Appendix B, ANSI N45.2, ANSI/ASME NQA-1, and other applicable codes, standards, specifications and requirements.

Areas found deficient during these audits are re-audited on a first-priority basis to verify corrective action implementation and effectiveness.

~~Records of audits and the qualifications of Auditors are maintained by the Quality Assurance Manager.~~

### **External Audits**

~~BFS auditors performs audits of active suppliers once every three years to assure continued adherence to imposed design, procurement and quality requirements.~~

~~Written audit checklists are utilized during all supplier audits conducted by Quality Assurance personnel approved by the Quality Assurance Manager.~~

Written audit results are reviewed with the affected supplier, and appropriate and mutually accepted corrective actions are determined prescribed. Corrective action implementation and effectiveness is evaluated by designated personnel as part of subsequent audits to review the supplier for continued approval.

<u>Annotated Page</u>	<u>QAM Section</u>	<u>Annotated Paragraph</u>	<u>Change</u>	<u>Comment</u>
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Note: The page formatting of the BFS QA Manual has been changed to two columns on a landscape oriented page. Page numbers and paragraph numbers from Revision 9 are therefore not relevant when QA Manual is formatted as Revision 10.

ii	Table of Contents	N/A	Title of QAM Section 7 revised to reflect 10 CFR 71 & 72 title for Criteria 7	No change in commitment
xii	Preface	3	Deleted "project, engineering and."	Primary implementation of this QA Program is by quality procedures - No change in commitment.
xiii	Statement of Management Policy	4	Deleted former 4th paragraph: "Quality Assurance is recognized by corporate management . . . to the applicable requirements."	Redundant to preceding and following paragraphs. No change in commitment
1	Section 1 - Organization	1	Deleted second sentence, "Management responsibilities .... (QA, Projects, Operations, etc.)."	No change in commitment, redundant to following paragraphs.
1	Section 1 - Organization	1	Added comma.	Grammar/sentence correction - No change in commitment



<u>Annotated Page</u>	<u>QAM Section</u>	<u>Annotated Paragraph</u>	<u>Change</u>	<u>Comment</u>
1, 2	Section 1 - Organization	(listed below)	Relocated and clarified the requirement to annually review the QA Program as follows: - Deleted "review of the status and adequacy of"; "and must assure this review occurs annually." Added "and its compliance with the applicable requirements." - Added "The Quality Assurance Manager will review the status, adequacy and implementation of the QA Program at least annually and report this status to the President."	This is a relocation and clarification of the requirement to annually review the QA Program - No change in commitment
1		2		
2		3		
2	Section 1 - Organization	3	Deleted comma.	Grammar/sentence correction - No change in commitment
2	Section 1 - Organization	6	Deleted commas.	Grammar/sentence correction - No change in commitment
2	Section 1 - Organization	7	Added "corrective action" to duties of Manager of Operations. Deleted "of the" and changed "authority" to "authorities."	Clarified list of duties and corrected sentence construction. No change in commitment.
3	Section 1 - Organization	1	Revised the duties of the Manager of Projects to add the following: "This includes review of purchase orders received by BFS to supply items or services to assure quality and technical requirements are included in new projects."	Clarification of duties - No change in commitment

<u>Annotated Page</u>	<u>QAM Section</u>	<u>Annotated Paragraph</u>	<u>Change</u>	<u>Comment</u>
5	Section 2 - Quality Assurance Program	5, 6	Revised description of how QAM revisions are indicated as follows. Deleted "Manual revisions are"; "by a vertical line (change bar) in the right margin. This change bar is not required." Added "with changes"; "in the text"; "Changes . . . and relocated text resulting from page reformatting are not considered revisions and are not highlighted as such." Deleted "Change bars are not required when a revision to the Manual requires page reformatting resulting in text which is relocated but not changed. Previous revision change bars are removed when a new revision is issued." Replaced "in addition to being indicated on the title page, is also indicated in the lower left hand corner of each page" with "is indicated on each page."	No change in commitment
5	Section 2 - Quality Assurance Program	6	Deleted the page reference for the Record of Revisions.	No change in commitment
6	Section 2 - Quality Assurance Program	1 thru 5	Deleted sections entitled "Transmittal Control" and "Control Log." Added section entitled "Distribution Control" describing electronic distribution control of QAM. Control mechanism is equivalent and reflects change in administrative practices.	Control mechanisms are equivalent - No change in commitment

<u>Annotated Page</u>	<u>QAM Section</u>	<u>Annotated Paragraph</u>	<u>Change</u>	<u>Comment</u>
6	Section 2 - Quality Assurance Program	6	Deleted "The Training Manager, who reports to" Deletion of position. Restructured sentence.	Training Manager's responsibility reassigned to Quality Assurance Manager. Organization change only - no reduction in commitment.
12-Aug	Section 2 - Quality Assurance Program	N/A	Revised and corrected list of typical QA Procedures used to implement QA Program	List is provided as an example only per footnote on page 8 - No change in commitment
13	Section 3 - Design Control	3	Deleted 3rd paragraph: "The Manager of Projects is responsible for all aspects of project implementation including the preparation of a list of task assignments along with a schedule of milestone completion dates, for providing each designated project participant with a copy, as appropriate, and for in-progress project meetings to track the project and assure the proper design interface."	This is redundant to paragraph 14 of QAM Section 1 - Organization - Project Organization and is not consistent with this section which describes design control measures - No change in commitment.
13	Section 3 - Design Control	4	Added "Preparation of licensing documents" to list of general design activities covered by procedure.	No change in commitment
13	Section 3 - Design Control	5 (first bullet)	Deleted "QA personnel are a part of the design review process. This is done to assure adherence to all applicable design procedures. This activity is accomplished through review and approval of design documents as specified in QA procedures."	Removed QA from inline participation in design review - requirement for QA to audit all aspects of QA program including design control and design reviews remains in effect per QAM Section 18. Acceptable change in commitment resulting in more independence of QA overview.

<u>Annotated Page</u>	<u>QAM Section</u>	<u>Annotated Paragraph</u>	<u>Change</u>	<u>Comment</u>
15	Section 4 - Procurement Document Control	2	Added "[quality] assurance programs" to scope of what this QAM section addresses.	Clarification - No change in commitment
15	Section 4 - Procurement Document Control	2	Changed "inspection" to "inspections" and deleted "all."	Editorial corrections - No change in commitment
15	Section 4 - Procurement Document Control	4	Deleted "Quality Assurance requirements, when applicable, are included with request for quotes." Added "including the applicability of Part 21 when required." Deleted "always" and "the" for grammar correction.	Removed discussion of quotes from manual as this is a commercial process only; added Part 21 applicability for clarification of regulatory requirement; corrected grammar and sentence construction for clarity. No change in commitment.
15	Section 4 - Procurement Document Control	5	Deleted "job site"; "which"; "as applicable to BFS." Replace "which" with "that."	Grammar/sentence correction and clarification of statement of requirement - No change in commitment
15	Section 4 - Procurement Document Control	7	Deleted "affiliate's or a" and added "of" to clarify list of typical procurement documentation.	No change in commitment
15	Section 4 - Procurement Document Control	9	Deleted "The Procurement documents are reviewed" and restructured sentence.	Grammar/sentence correction - No change in commitment
17	Section 5 - Instructions, Procedures, and Drawings	1	Added "the Quality Assurance Manager and the President" to complete the list of those who approve procedures.	Clarification - No change in commitment

<u>Annotated Page</u>	<u>QAM Section</u>	<u>Annotated Paragraph</u>	<u>Change</u>	<u>Comment</u>
17	Section 5 - Instructions, Procedures, and Drawings	2	Deleted "Quality Assurance and" from inline review process for fabrication documents.	Removed QA from inline participation in fabrication document approval - requirement for QA to audit all aspects of fabrication including work control documents remains in effect per QAM Section 18. Acceptable change in commitment resulting in more independence of QA overview.
18	Section 6 - Document Control	1	Deleted "policy for"; "establishes review and approval cycles and sequences,"; requires that." Added comma; "are controlled by quality procedures. Revisions are"; and "as initial issuances."	Restructuring of sentences to clarify what processes are described - No reduction of commitment.
18	Section 6 - Document Control	1	Added "Documents may be authenticated electronically (e.g., digital signatures), manually (e.g., signature and date), or by a combination thereof."	Control mechanism is equivalent and reflects change in administrative practices - No change in commitment.
18	Section 6 - Document Control	2	Added "Controlled documents may be distributed either electronically or in hard-copy format. Electronic distribution shall make available only the current versions of documents (unless the user takes specific actions to obtain historical versions); hence, there is no requirement for transmittal control and receipt acknowledgment"	Control mechanism is equivalent and reflects change in administrative practices No change in commitment.
18	Section 6 - Document Control	2	Replaced " If hard copy distribution is utilized," with "For hard-copy controlled distribution."	Grammar/sentence correction - No change in commitment

<u>Annotated Page</u>	<u>QAM Section</u>	<u>Annotated Paragraph</u>	<u>Change</u>	<u>Comment</u>
18	Section 6 - Document Control	3	Deleted "The Manager of Projects shall assure that the documentation listings are maintained specifying the title, number, and current revision for all drawings, procedures, specifications and purchase orders "	Removal of redundant statement of requirement from paragraph 6 (see below) - No change in commitment
19	Section 6 - Document Control	2	Revised final sentence to "Document lists are maintained listing the title, identification number and current revision for all controlled documents."	Clarified sentence construction - No change in commitment.
20	Section 7 - Identification and Control of Materials, Equipment and Services	N/A	Corrected Title of Section to agree with title of corresponding section of 10 CFR 71 & 72.	Clarification - No change in commitment
20	Section 7 - Control of Purchased Materials, Equipment and Services	1	Added "and its customers" to include the total set of requirements considered.	Clarified statement of requirement - No change in commitment
20	Section 7 - Control of Purchased Materials, Equipment and Services	1	Added "Suppliers may be utilized for a customer's work based on a letter from the customer authorizing such use. This is limited only to work for the customer providing such approvals."	Relocation and restatement of requirement from paragraph 3 (see below)- No change in commitment.
20	Section 7 - Control of Purchased Materials, Equipment and Services	2	Added comma. Deleted "QA"; "the."	Clarified that the BFS organization determines requirements not just QA and corrected grammar/sentence construction - No change in commitment.
20	Section 7 - Control of Purchased Materials, Equipment and Services	3	Deleted "and suppliers approved in writing by BFS customers."	Relocation, clarification and restatement of requirement to paragraph 1 (see above)- No change in commitment.

<u>Annotated Page</u>	<u>OAM Section</u>	<u>Annotated Paragraph</u>	<u>Change</u>	<u>Comment</u>
20	Section 7 - Control of Purchased Materials, Equipment and Services	4	Deleted "which is."	Correction of grammar - No change in commitment.
21	Section 7 - Control of Purchased Materials, Equipment and Services	2 (2nd bullet)	Added period.	Correction of grammar - No change in commitment.
22	Section 8 - Identification and Control of Materials, Equipment and Services	2	Added "The."	Grammar correction - No change on commitment
23	Section 9 - Control of Special Processes	1	Relocated "Other"; deleted comma; added comma; deleted "or."	Grammar and sentence correction - No change in commitment
24	Section 10 - Inspection	5	Deleted "The"; "procedures and instructions include inspection"; and "with." Added "shall include" and "as necessary."	Grammar/sentence construction revised to clarify statement of requirement and what needs to be provided to support inspection results - No change in commitment.
25	Section 11 - Test Control	1	Deleted "the."	Grammar correction - No change on commitment
27	Section 13 - Handling, Storage and Shipping	3	Deleted "departure, and arrival time and destination data recording"; "to be."	Grammar/sentence construction revised to eliminate commercial considerations for shipping - No change in commitment.
28	Section 14 - Inspection, Test, and Operating Status	1	Deleted "The use of"; "at or for BFS." Added "are used"; "and." Replaced "is" with "are."	Grammar/sentence construction correction only - No change in commitment.
28	Section 14 - Inspection, Test, and Operating Status	2	Deleted "interoffice memoranda,"; "and audit"; "and that"; "are being satisfactorily used." Added "and"; satisfactory use of"; "is verified by audit and surveillance."	Grammar/sentence construction and clarified statement of requirement - No change in commitment.

<u>Annotated Page</u>	<u>QAM Section</u>	<u>Annotated Paragraph</u>	<u>Change</u>	<u>Comment</u>
29	Section 15 - Nonconforming Material, Parts, or Components	1	Added "marking and/or." Deleted comma; "these." Restructured sentence.	Added marking as an acceptable means of controlling inadvertent use. Grammar/sentence construction and clarified statement of requirement - No change in commitment.
29	Section 15 - Nonconforming Material, Parts, or Components	2	Deleted "The signatures of"; "are placed on the"; "approval." Added "review and approve"; "acceptance."	Grammar/sentence construction and clarified statement of requirement - No change in commitment.
29	Section 15 - Nonconforming Material, Parts, or Components	3	Clarified statement of requirement as follows: added "sufficient"; deleted "indicate and."	Clarified statement of requirement - No change in commitment
29	Section 15 - Nonconforming Material, Parts, or Components	4	Added "when required." Substituted "equivalent" for "at least equal."	Clarified statement of requirement - No change in commitment
30	Section 16 - Corrective Action	1	Deleted "The documentation of." Added "is documented in a Condition Report and." Deleted "also."	Grammar/sentence construction and clarified statement of requirement. Clarifies what document is used by name - No change in commitment.
30	Section 16 - Corrective Action	1	Deleted "The Quality Assurance Manager also logs the documentation of each condition adverse to quality." Substituted "A log of Condition Reports is maintained." Added comma.	Clarified statement of requirement - allowed for others to maintain a log of Condition Reports - No change in commitment
30	Section 16 - Corrective Action	1	Added "continued" as a modifier to corrective action effectiveness.	Clarified statement of requirement - No change in commitment



<u>Annotated Page</u>	<u>QAM Section</u>	<u>Annotated Paragraph</u>	<u>Change</u>	<u>Comment</u>
30	Section 16 - Corrective Action	2	Deleted "establish quality trends." Substituted "identify causal factors." Deleted "the"; "at that level"; "Copies of these reports and analyses are also provided to the Quality Assurance Manager for review."	Clarified statement of requirement - No change in commitment
31	Section 17 - Quality Assurance Records	1	Deleted "is"; "agency." Changed "material's" to "materials."	Grammar correction - No change on commitment
31	Section 17 - Quality Assurance Records	1	Added "condition reports" to list of typical quality records.	Clarified statement of requirement - No change in commitment
31	Section 17 - Quality Assurance Records	2	Deleted "Shall be"; "commission."	Grammar/sentence construction and clarified statement of requirement - No change in commitment.
31		3	Deleted "but no more than five years."	Removed unnecessary restriction on long-term record retention.
31	Section 17 - Quality Assurance Records	4, 5	Relocated the following from the second paragraph and separated into two paragraphs: "Additionally, records of use, for all transport packages, shall be maintained for a period of three years after the shipment.  Records are identified by project number, part number, contract number, or drawing number as appropriate to the record type. BFS maintains a complete list of QA records to provide identification and location information."	Relocation of requirement for better statement of requirement - No change in requirement.

<u>Annotated Page</u>	<u>OAM Section</u>	<u>Annotated Paragraph</u>	<u>Change</u>	<u>Comment</u>
32	Section 17 - Quality Assurance Records	1	<p>Deleted the following:            "To minimize the risk of damage from fire, flooding and abnormal deterioration, two sets of identical records are maintained at separate and equivalent storage locations with access control and security; or</p> <p>The official copies of all QA records are maintained in approved fireproof files or vaults, at a single location."</p> <p>Replaced statement of requirement with [Protection for QA records is provided by using either one of the following storage methods:] "Single Storage in a facility or container that minimizes the risk of damage or destruction from natural disasters, environmental conditions, and biological infestation, or</p>	Clarified statement of requirement to better align with ASME NQA-1 - No change in commitment.
33	Section 18 - Audits	1	Added "BFS carries out a comprehensive system of planned and periodic audits by personnel qualified in accordance with this QA Program to verify compliance with all aspects of the quality assurance program and to determine the effectiveness of the program."	Strengthened statement of requirement to better align with 10 CFR 71 & 72 - No change in commitment.
33	Section 18 - Audits	2	Relocated former first paragraph with new subtitle, "Internal Audits."	Relocated statement of requirement to better align with internal audit requirements to better align with 10 CFR 71 & 72 - No change in requirement.

<u>Annotated Page</u>	<u>QAM Section</u>	<u>Annotated Paragraph</u>	<u>Change</u>	<u>Comment</u>
33	Section 18 - Audits	3	Deleted "auditor" and substituted "audit team."	Clarified statement of requirement to better align with ASME NQA-1 - No change in commitment.
33	Section 18 - Audits	3	Added "All audits are performed under the direction of a qualified Audit Team Leader."	Clarified and strengthened statement of requirement to better align with ASME NQA-1 - No change in commitment.
33	Section 18 - Audits	5	Relocated former fifth paragraph (See deleted text on page 34, paragraph 1). Added "and Audit Team Leaders."	Relocated paragraph to better align with description of overall audit program and ASME NQA-1 - No change in requirement.
33	Section 18 - Audits	6	Deleted "by personnel qualified in accordance with the requirements of the BFS QA Program." Deleted "and"; substituted "These audits."	Grammar correction - No change on commitment
33	Section 18 - Audits	7	Deleted "first."	Editorial correction - No change on commitment
34	Section 18 - Audits	2	Deleted "auditors" and changed verb tense for "performs."	Clarified statement of requirement - No change in commitment
34	Section 18 - Audits	3	Deleted former seventh paragraph.	Requirement is covered by introductory paragraphs of Section 18.
34	Section 18 - Audits	4	Deleted "prescribed." Substituted "determined."	Grammar correction only - No change in commitment.

**BFS/NRC 03-011**  
**Enclosure 3**

**ENCLOSURE 3**

**CD Containing Electronic  
Manual of Quality Assurance  
for  
BNFL Fuel Solutions**

**Revision 10**