



**MICHAEL S. TUCKMAN**  
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October 1, 2003

U. S. Nuclear Regulatory Commission  
Attention: Document Control Desk  
Washington, DC 20555

Subject: Duke Energy Corporation  
Catawba Nuclear Station Units 1 & 2, Docket Nos. 50-413, 50-414  
McGuire Nuclear Station Units 1 & 2, Docket Nos. 50-369, 50-370  
Response to Request for Additional Information Regarding the Use of  
Mixed Oxide Fuel Lead Assemblies (TAC Nos. MB7863, MB7864,  
MB7865, MB7866)

By letter dated February 27, 2003 Duke Energy submitted an application to amend the licenses of McGuire and Catawba to allow the use of four mixed oxide fuel lead assemblies. In a subsequent submittal dated September 23, 2003, Duke notified the Nuclear Regulatory Commission of the decision to focus the lead assembly program on Catawba only. As part of the review of this application the Nuclear Regulatory Commission staff in a letter dated August 13, 2003 requested that Duke provide additional information related to the application. The requested information is contained in Attachment 1 to this letter. Also included as Attachment 2 is a copy of the Framatome ANP *Fuel Sector Quality Management Manual* and a letter certifying that the manual is not proprietary.

Inquiries on this matter should be directed to G. A. Copp at (704) 373-5620.

M. S. Tuckman

Attachments

A001

Oath and Affirmation

M. S. Tuckman affirms that he is the person who subscribed his name to the foregoing statement, and that all the matters and facts set forth herein are true and correct to the best of his knowledge.

M.S. Tuckman  
M.S. Tuckman

Subscribed and sworn to before me on this 1<sup>st</sup> day of October, 2003

Mary P. Debus  
Notary Public

My Commission expires:

JAN 22, 2006  
Date



U. S. Nuclear Regulatory Commission  
October 1, 2003  
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cc: w/Attachments

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Senior Resident Inspector  
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w/Attachment 1 only

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Division of Radioactive Waste Management  
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Beverly O. Hall, Section Chief  
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1645 Mail Service Center  
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Attachment 1  
Responses to NRC Request for  
Additional Information dated August 13, 2003  
on Application for MOX Fuel Lead Assemblies

Question 1

Section 3.5.4, "Quality Assurance," states, in part, that "Framatome ANP has the responsibility for the overall Quality Assurance (QA) oversight of the entire fuel assembly fabrication process" and that "Framatome ANP ultimately has the responsibility for certification of the finished fuel assemblies to Duke Power, thru DCS."

- A. Given this oversight role of Framatome ANP, please describe the complete QA oversight process to be employed for the fuel fabrication process. Also, provide a copy of the relevant QA program and process plan to be implemented for that purpose.
- B. Is a QA plan for assembly and certification of the fuel rods and assemblies being developed specifically for those activities?

Response A:

The MOX fuel lead assemblies will be fabricated in accordance with the current Framatome-ANP (FANP) *Fuel Sector Quality Management Manual* (FQM Revision 1, US Version – Applicable July 2003), a copy of which is provided with this submittal as Attachment 2. Framatome ANP is a qualified supplier of nuclear fuel to Duke Power.

The *Fuel Sector Quality Management Manual* defines a Quality Program that applies to the fabrication of components within FANP and items purchased from suppliers. For the MOX fuel lead assemblies, all hardware and/or materials will be purchased from suppliers that have been or will be qualified and approved in accord with this program. The MOX fuel pellets will be manufactured at the COGEMA facility at Cadarache and these will be loaded into fuel rods using standard procedures used in the production of commercial MOX fuel. The lead assemblies will be fabricated at the MELOX facility in accordance with standard FANP practice and the supervision of FANP staff during the fabrication. Audits of the current QA programs at both facilities will be performed to verify that the relevant requirements of the FANP QA program are in place.

Response B:

Yes – The plan is in the process of being developed and will be complete by December 31, 2003. The plan will be based upon programmatic requirements of the *Fuel Sector Quality Management Manual* and the technical and quality requirements of the product specifications. The plan will address the method for surveillance of the pellet, rod, and assembly fabrication as well as the visual and dimensional inspection of those items. In addition, the plan will address the review of pertinent supplier records in order to certify the completed assemblies.

Question 2

Section 3.5.4, "Quality Assurance," states, in part, that "every sub-vendor who operates under the technical requirements by Framatome ANP will be qualified by Framatome ANP as an approved supplier."

- A. Please identify the sub-vendors to be used for this effort. Will all sub-vendors operate under the technical requirements of Framatome ANP? If not, what alternate technical requirements will they use and how will they be qualified?
- B. Please identify the manufacturer(s) of the fuel rods and assemblies, and the locations of manufacture of these components. Provide a detailed schedule for the manufacture of the fuel rods and assemblies. Is the manufacturer(s) required to perform its fabrication activities in accordance with the Framatome ANP QA program or is an alternate QA program(s) going to be used?

Response A:

MOX fuel pellets and rods will be fabricated at the COGEMA facility at Cadarache. The assemblies will be fabricated at the COGEMA facility at MELOX. Note that both COGEMA and Framatome are part of the AREVA group. QA programs at the Cadarache and MELOX facilities will have been approved by a Framatome ANP 10CFR 50 Appendix B audit and will be in effect at the time of fabrication.

Yes – Framatome ANP will provide the technical requirements for procurement and/or fabrication of all components. Tubing, guide tubes, end fittings, grids, etc will be procured from existing suppliers in accord with Framatome ANP technical requirements as typically used in the production of commercial low enriched uranium fuel.

Response B

See the response to 2.A above. The Cadarache facility is located in Provence, France and the MELOX facility is located at Marcoule, France.

The current schedule for the manufacture of the fuel rods and fuel assemblies is as follows:

Fuel rods – October to November, 2004

Fuel assemblies – November to December, 2004

COGEMA will perform the fabrication activities in accordance with its internal QA program. That QA program will be evaluated by a review of the COGEMA Quality Manual for compliance with Framatome ANP requirements (10CFR 50 Appendix B). In addition, Framatome ANP will perform an audit of COGEMA's facilities to verify that the programmatic controls are in place with a subsequent surveillance performed during production to verify implementation of the program for the MOX project.

### Question 3

Section 3.5.4, "Quality Assurance," states, in part, that "Framatome ANP will verify that each of these vendors/facilities meets the requirements of 10CFR 50 Appendix B. This verification may include quality system audits by Framatome ANP, review of audits performed by other Framatome ANP facilities from other regions, and/or surveillance audits by other approved Framatome ANP quality auditors."

- A. Please describe to what extent these three applicable review processes will be implemented to support the entire fuel rod and assembly fabrication process and the ultimate certification of the finished fuel.
- B. Please describe the method(s) to be used to identify, document, and resolve any discrepancies identified with the vendors/facilities as a result of the various verification processes described.
- C. Please describe how the results of these verification activities will be documented and retained in an auditable and retrievable manner.
- D. Will the reporting requirements of 10CFR Part 21 be imposed on each of the vendors/facilities?

### Response A

Suppliers that have been audited, approved, and documented as an approved supplier by any group within the Framatome ANP Fuel Sector may be used to provide product, as applicable, for this project.

Suppliers that have been audited by other Framatome ANP organizations (non Fuel Sector) will be added to the applicable Fuel Sector Supplier List only after a review of the subject audit report confirms that the audit addressed the appropriate Fuel Sector requirements (i.e. 10CFR Part 50, etc.). In addition, the audit team's credentials will be evaluated for compliance with Fuel Sector requirements.

The majority (> 95%) of the suppliers of services, raw material, and product have been audited and approved by the Fuel Sector region. Several suppliers approved by other Framatome organizations will be utilized.

Framatome ANP will perform a system audit of both Cadarache and MELOX. Framatome ANP will perform surveillance activities at both facilities which will include witnessing the fabrication of pellets, rods, and assemblies. In addition, a final review will be made to verify that applicable documentation is available to support the certification that will be issued by Framatome ANP. Finally, an over-check visual and dimensional inspection/surveillance of the fuel assemblies will be completed by a trained quality inspector from Framatome ANP – Lynchburg.

Duke Power will also perform oversight activities at Cadarache and MELOX. These activities will include observation of fabrication activities and documentation reviews.

#### Response B

For raw material and product, the supplier is required by the ordering documentation to notify Framatome ANP of any deviation prior to shipment of product. This notification to Framatome ANP is done in accordance with the supplier's internal procedure. When received, Framatome ANP will issue a "Deviation Report" in accordance with the Fuel Sector Quality Management Manual and supporting procedure(s). The procedure requires an analysis by the applicable Framatome ANP design organization prior to acceptance. In addition, this analysis includes a review by supporting design organizations as well as Duke Power when required. This document is traceable and becomes part of Framatome ANP permanent records.

For programmatic issues related to the audit or surveillance an Audit Finding Report will be issued in accordance with the *Fuel Sector Quality Management Manual* and supporting procedure(s). The procedure requires the supplier to provide a root cause, corrective and preventative action implementation plan within an agreed upon time. This document is traceable and becomes part of Framatome ANP permanent records.

For design deviations related to the surveillance or inspection a "Deviation Report" will be processed as describe in the first paragraph above.

#### Response C

The audit report, surveillance report, and inspection report discussed in Response 3B above become part of the Framatome ANP permanent records. These documents are traceable and retained in accord with the Framatome ANP "Records Retention" procedure. In addition, the Finding Report and Deviation Report described in the response to item 3B above are traceable and retained in accordance with Framatome ANP "Records Retention" procedure.

#### Response D

Yes – The requirements of 10 CFR Part 21 are part of Framatome ANP's standard ordering requirements and will be imposed on each supplier.

The supplier is required to notify Framatome ANP of conditions that may be subject to a 10CFR Part 21 review. Framatome ANP will evaluate the data provided by the supplier and where a Part 21 condition exists, Framatome ANP would notify NRC as required by internal procedures.

Attachment 2



**FRAMATOME ANP**

An AREVA and Siemens Company

**FRAMATOME ANP, Inc.**

September 29, 2003  
JFM:03:026

Mr. Kenneth S. Canady  
Vice President, Nuclear Engineering  
EC08H  
Duke Energy Corp.  
P. O. Box 1006  
Charlotte, NC 28201-1006

**Framatome ANP Fuel Sector Quality Management Manual**

Dear Ken:

Responses to certain questions contained in an RAI concerning an application by Duke Energy for MOX lead test assemblies refer to the Framatome ANP Fuel Sector Quality Management Manual. This manual is attached to the responses and has been characterized as being proprietary on the title page and elsewhere. This marking is incorrect and should be disregarded.

I hereby certify that the Framatome ANP Fuel Sector Quality Management Manual (FQM Revision 1, US Version of July 2003) is not proprietary and does not require any special handling.

Very truly yours,

James F. Mallay, Director  
Regulatory Affairs

cc: George A. Meyer



**FRAMATOME ANP**

**FQM Rev. 1 U. S. Version**

# **FUEL SECTOR**

# **QUALITY MANAGEMENT MANUAL**

**APPLICABLE JULY 2003**

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**A**

FRAMATOME ANP

FQM, Rev. 1 U. S. Version

Fuel Sector

**QM Manual**

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

July 22, 2003

Mr. C. A. Armontrout  
Quality/Management Systems Technical Advisor  
Framatome ANP, Inc.  
P. O. Box 11648  
Lynchburg VA 24506-1646

SUBJECT: QUALITY ASSURANCE PROGRAM APPROVAL FOR RADIOACTIVE  
MATERIAL PACKAGES NO. 0003, REVISION 22

Dear Mr. Armontrout:

Enclosed is the Quality Assurance (QA) Program Approval for Radioactive Material Packages No. 0003, Revision 22. This Approval satisfies the requirements of 10 CFR 71.12(b) and 71.101(c) for a QA Program approved by the Nuclear Regulatory Commission (NRC).

This Approval will remain in effect until the expiration date, indicated in Block No. 3. Termination of your materials license does not cause this Approval to be automatically terminated. If you wish to renew, amend, or terminate this Approval, please request it in writing.

This letter also serves as a reminder that if you are using or planning to use an NRC-approved packaging, you must be registered for use of that packaging with NRC. Registration for use of NRC-approved packagings should be made pursuant to 10 CFR 71.12(c)(3).

Sincerely,

A handwritten signature in black ink, appearing to read "R. J. Lewis".

Robert J. Lewis, Chief  
Transportation and Storage Safety  
and Inspection Section  
Spent Fuel Project Office  
Office of Nuclear Material Safety  
and Safeguards

Docket No.: 71-0003

Enclosure: QA Program Approval No. 0003, Rev. 22



|  |   |                                    |                          |  |  |  |   |
|--|---|------------------------------------|--------------------------|--|--|--|---|
| NRC FORM 311<br>(8-2002)<br>10 CFR 71  |   | U.S. NUCLEAR REGULATORY COMMISSION |                          | 1. APPROVAL NUMBER<br><b>0003</b>              |  |  |   |
| <b>QUALITY ASSURANCE PROGRAM APPROVAL</b><br>FOR RADIOACTIVE MATERIAL PACKAGES   |   |                                    |                          | REVISION NUMBER<br><b>22</b>                   |  |  |   |
| Pursuant to the Atomic Energy Act of 1954, as amended, the Energy Reorganization Act of 1974, as amended, and Title 10, Code of Federal Regulations, Chapter 1, Part 71, and in reliance on statements and representations heretofore made in Item 5 by the organization named in Item 2, the Quality Assurance Program identified in Item 5 is hereby approved. This approval is issued to satisfy the requirements of Section 71.101 of 10 CFR Part 71. This approval is subject to all applicable rules, regulations, and orders of the Nuclear Regulatory Commission now or hereafter in effect and to any conditions specified below.   |   |                                    |                          |  |  |  |   |
| 2. NAME<br><b>Framatome ANP, Inc.</b>  |   |                                    |                          | 3. EXPIRATION DATE<br><b>December 31, 2005</b> |  |  |   |
| STREET ADDRESS<br><b>2101 Horn Rapids Road</b>   |   |                                    |                          | 4. DOCKET NUMBER<br><b>71-0003</b>             |  |  |   |
| CITY<br><b>Richland</b>  |   | STATE<br><b>WA</b>                 | ZIP CODE<br><b>99352</b> |  |  |  |   |
| 5. QUALITY ASSURANCE PROGRAM APPLICATION DATE(S)<br><b>June 30, 2003</b>   |   |                                    |                          |  |  |  |   |
| 6. CONDITIONS  |   |                                    |                          |  |  |  |   |
| <p>1. Activities conducted under applicable criteria of Subpart H of 10 CFR Part 71 are to be executed with regard to transportation packagings. Authorized activities include: design, procurement, fabrication, assembly, testing, modification, maintenance, repair, and use of transportation packagings.</p> <p>2. Records shall be maintained in accordance with the provisions of 10 CFR Part 71. Specifically:</p> <ul style="list-style-type: none"> <li>a. Records of each shipment of licensed material shall be maintained for 3 years after that shipment [10 CFR 71.91(a)].</li> <li>b. Records providing evidence of packaging quality shall be maintained for 3 years after the life of the packaging [10 CFR 71.91(c)].</li> <li>c. Records describing activities affecting packaging quality shall be maintained for 3 years after this Quality Assurance Program Approval is terminated [10 CFR 71.135].</li> </ul> <p>3. Planned and periodic audits of all aspects of the Quality Assurance Program shall be conducted in accordance with written procedures or checklists, by appropriately trained personnel not having direct responsibility in the areas being audited, in accordance with 10 CFR 71.137.</p> <p>This approval is valid at the following locations:</p> <table style="width: 100%; border: none;"> <tr> <td style="width: 50%; text-align: center;"> <b>Framatome ANP, Inc.</b><br/> <b>2101 Horn Rapids Road</b><br/> <b>Richland, WA 99352-0130</b> </td> <td style="width: 50%; text-align: center;"> <b>Framatome ANP, Inc.</b><br/> <b>1724 Mount Athos Road, PO Box 11646</b><br/> <b>Lynchburg, VA 24506-1646</b> </td> </tr> </table> |   |                                    |                          |  |  | <b>Framatome ANP, Inc.</b><br><b>2101 Horn Rapids Road</b><br><b>Richland, WA 99352-0130</b> | <b>Framatome ANP, Inc.</b><br><b>1724 Mount Athos Road, PO Box 11646</b><br><b>Lynchburg, VA 24506-1646</b> |
| <b>Framatome ANP, Inc.</b><br><b>2101 Horn Rapids Road</b><br><b>Richland, WA 99352-0130</b>   | <b>Framatome ANP, Inc.</b><br><b>1724 Mount Athos Road, PO Box 11646</b><br><b>Lynchburg, VA 24506-1646</b> |                                    |                          |  |  |  |   |
| FOR THE U.S. NUCLEAR REGULATORY COMMISSION   |   |                                    |                          |  |  |  |   |
| SIGNATURE<br>   |   |                                    |                          | DATE<br><b>22 July 2003</b>                    |  |  |   |
| ROBERT J. LEWIS, CHIEF<br>TRANSPORTATION AND STORAGE SAFETY AND INSPECTION SECTION<br>SPENT FUEL PROJECT OFFICE<br>OFFICE OF NUCLEAR MATERIAL SAFETY AND SAFEGUARDS  |   |                                    |                          |  |  |  |   |

NRC FORM 311 (8-2002)

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FRAMATOME ANP

FQM, Rev. 1 U. S. Version

Fuel Sector

**QM Manual**

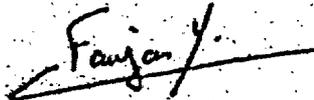
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Prepared:

  
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D. D. Sheilburne  
Manager, Fuel America Quality/Management Systems

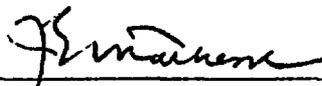
6/12/03  
Date

Reviewed:

  
\_\_\_\_\_  
Yves Fanjas, FS QM Manager  
Framatome ANP

6-19-03  
Date

Approved:

  
\_\_\_\_\_  
J. E. Matheson, Senior Vice President  
Fuel America

6/23/03  
Date

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**Summary of Changes**

| Item | Page | Description and Justification  |
|------|------|--|
|      | All  | General updating: replacement of the former acronyms by the new ones (FBG becomes FS, BU becomes LU, Line become BU). Replacement of "Framatome ANP Quality Vice President" by "Framatome ANP Sustainable Development and Continuous Improvement Vice President". Added reference to Corporate and FS quality procedures. Other titles changed as follows: Director, Quality, Nuclear Fuel, U.S. Business Unit to Manager, Fuel America Quality/Management Systems, Senior Vice President, Nuclear Fuel to Senior Vice President, Fuel America, Manager, Quality Engineering to Manager, Richland Site Quality, and Manager, Quality Systems to Manager, Lynchburg Fuel Site Quality     |
| 1    |      | The name of former Business Groups is replaced by the Sectors names: Project and Engineering, Nuclear Services, Nuclear Fuel and Mechanical Equipment respectively become Plants, Services, Fuel and Equipment.  |
| 6    |      | In "Develop new products",<br><ul style="list-style-type: none"> <li>- replaced "Define product development actions" by " Manage development project portfolio"</li> <li>- Added: "Stimulate innovative technical ideas"</li> </ul>  |
| 7    |      | Replaced "Plan the contract" by "Plan manufacturing"   |
| 10   |      | In §1.2 – Replaced "are to be implemented by the LUs" by "shall be transferred into LUs" lower tier procedures"<br>Added in §1.2 "For specific projects, Quality Assurance Plans (QAP) can be issued under the responsibility of the project manager. Preparation, review and approval are described in procedure FQP 01."<br>In §1.3:<br><ul style="list-style-type: none"> <li>- Added reference to procedure FQP 01</li> <li>- Suppressed "by the users" in "Identification by the users of the applicable revisions of documents or data"</li> <li>- In last sentence, replaced "previous revision" by necessary information for review (such as the previous revision)."</li> </ul> |
| 13   |      | Added "Sustainable Development principles" in the Quality Policy   |
| 17   |      | § 2.4.1 Replaced "The FBG will be managed" by "The FS is managed"  |
| 22   |      | § 2.5 Added "as available" before "self assessments"   |
| 24   |      | § 4.1 Added "Planning of product realization includes....meet the acceptance criteria".  |
| 28   |      | §4.4.1 "Assessment issued by a BU of the NFBG or by another BG of Framatome ANP is deemed valid for the other Bus of the NFBG. An assessed Vendors List or data bases is (are) maintained and is (are) applicable to all Bus" replaced by "Assessment issued by a LU (from the FS or another Sector) complying ... Information related to the status of suppliers is made available to all the LU of the FS."  |
|      |      | "The renewal is based on QM system audits and periodical evaluations." replaced by "The renewal is based on one or a combination of methods used for the initial evaluation."  |
| 29   |      | § 4.4.3 Added "People in charge ... to Corporate procedure Q 104."   |
| 29   |      | § 4.4.4 Added "QM system requirements...from the final customer if any."   |
| 33   |      | § 4.5.4 "Where non conformances are detected...of product use" replaced by "Precautions are taken to preclude damage...control of quality records"   |
| 35   |      | § 5.2.2 Added: "Internal audits at the FS level...LU QM units' activity"<br>"and the timing of audits. The schedules...to the FS QM manager."<br>"Third party audits: Coordination...responsibility of the FS QM Manager."   |



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| Sub-division of previous § 5.2.3 into § 5.2.3 and 5.2.4

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## 0. INTRODUCTION

### 0.1. Scope and Purpose

This Quality Management Manual describes the Quality Management System implemented within the Nuclear Fuel Sector. It applies to the Framatome ANP Fuel Sector at the locations of Paris, Lyon, Romans-sur-Isère, Pierrelatte, Dessel, Paimboeuf, Rugles, Montreuil-Juigné, Ugine, Jarrie, Lynchburg, Richland, Erlangen, Lingen, Duisburg and Karlstein.

It is based on the Quality Management Directives of Framatome ANP, which are implemented within Framatome ANP for all Sectors (including their subsidiaries):

- Plants
- Services
- Fuel
- Equipment

and the Corporate Departments, such as the technical center as applicable, when they supply products to the Sectors or their own external customers.

The QM Manual fulfills the requirements of the following codes, standards and regulations:

|                            |   |
|----------------------------|---|
| ISO 9001:2000              | Quality Management Systems – Requirements;<br>(ISO – International Organization for Standardization)  |
| IAEA 50 – C - Q (1996)     | Quality Assurance for Safety in Nuclear Power Plants and other<br>Nuclear Installations<br>(IAEA – International Atomic Energy Agency)<br>Note: IAEA 50-C-QA also applies |
| KTA 1401 (06/96)           | Allgemeine Forderungen an die Qualitätssicherung;<br>(KTA-German Nuclear Safety Standards Commission)   |
| Arrêté Qualité             | Arrêté du 10 août 1984 relatif à la qualité de la conception de la<br>construction et de l'exploitation des installations nucléaires de base;<br>(French Regulation)      |
| ANSI/ASME NQA-1<br>1a-1983 | Quality Assurance Program Requirements for Nuclear Facilities   |
| 10 CFR 50, App. B          | Quality Assurance Criteria for Nuclear Power Plants and Fuel<br>Reprocessing Plants (US Regulation)   |
| 10 CFR 71, Subpart H       | Quality Assurance Requirements for Packaging & Transportation of<br>Radioactive Material  |

Where additional standards are to be used or exceptions to these standards are taken, these conditions will be noted in Appendix II and further defined in lower tier documents.

The extent to which the QM measures are applied is consistent with the decision of the Management and with the importance to nuclear safety, of the particular product or process. A graded approach is used, which satisfies the applicable requirements and ensures the required safety and quality.

### **0.2. Applicability**

The QM System of the FS, as described in this Manual, is applicable for sales and marketing, development and design, procurement, manufacturing, inspection, testing of materials, parts, components or assemblies for use in reactor and shipment. It also applies to related engineering services and technical support including irradiated fuel inspection, repair or reconstruction of irradiated fuel, in-core monitoring hardware and software and nuclear plant analyses.

In the U.S., the QM System also applies to radioactive material shipping containers (10 CFR 71 Subpart H regulations).

### **0.3. Responsibility**

The FS QM Manager is responsible for defining the content and changes to the QM System and QM Manual in conjunction with the LU QM Managers. LU specific requirements, including description of LU organization structure, are provided in manual attachments or sub-tier documents.

### **0.4. Terms and Definitions**

Quality related terms are used as defined in ISO 9000:2000, "Quality Management Systems-Fundamentals and vocabulary." Additional and deviating definitions used in this document:

|                             |   |
|-----------------------------|---|
| <b>Sectors</b>              | Part of Framatome ANP which is responsible for the world wide business of particular scope of products                                      |
| <b>Business Unit</b>        | Part of Fuel Sector comprising several Local Units of different regions   |
| <b>Local Unit/Company</b>   | Part of Fuel Sector and Regional Sector   |
| <b>Corporate Department</b> | Department that supports in the field of its missions, the whole of Framatome ANP   |
| <b>Customer</b>             | Client of Framatome ANP and its subsidiaries  |
| <b>Fuel related product</b> | Materials, parts, components and assemblies for use in the reactor  |
| <b>Nonconformance</b>       | A deficiency in a characteristic, documentation or procedure that renders the quality of a product or process unacceptable or indeterminate |



---

|                  |   |
|------------------|---|
| Procedure        | A document that specifies or describes how an activity is to be performed (document = any written or pictorial information describing, defining, specifying, reporting or certifying activities, requirements, procedures or results) |
| Product          | Result of a process which may be a hardware product, a software product or service activities   |
| Regional Sector  | Part of Framatome ANP located in one of the three administrative regions France, Germany and United States or in a country linked to one of these regions   |
| Supplier         | Any individual or organization that furnishes a product in accordance with a procurement document. An all inclusive term used in place of e.g. Subcontractor, Vendor  |
| Software Product | Set of computer programs, procedures and possibly associated documents and data; a software product may be designated for delivery, an integral part of another product or used in the design and development process                 |

**0.5. Abbreviations**

|               |   |
|---------------|---|
| Framatome ANP | Framatome Advanced Nuclear Power and its subsidiaries |
| FS            | Fuel Sector   |
| BU            | Business Unit   |
| LU            | Local Unit or Company                                 |
| NDT           | Non Destructive Testing                               |
| QM            | Quality Management                                    |

## 1. QUALITY MANAGEMENT SYSTEM

### 1.1. Process Management

- I The FS has established, documented, implemented and maintains a QM System and continually improves its effectiveness in accordance with the applicable national and international standards, customer requirements and Framatome ANP quality policy and objectives.

The QM System assures that:

- a) Processes and their application are identified and managed
- b) The sequence and interaction of these processes are defined
- c) Criteria and methods are defined which are needed for an effective operation and control of these processes
- d) Resources and data necessary to support the operation and control of these processes are available
- e) Processes are monitored, measured and analyzed
- f) Actions necessary to achieve planned results and continual improvement of these processes are implemented

Processes to be identified and managed are of three types:

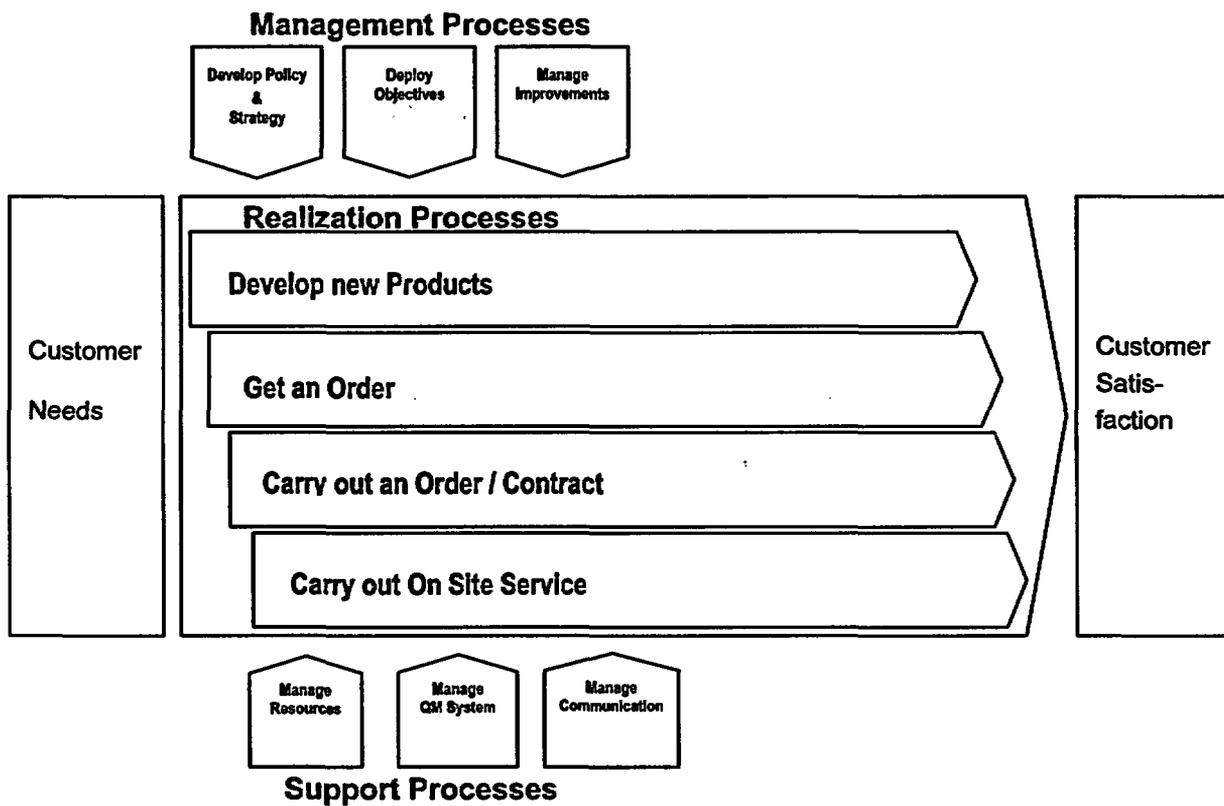
- Management Processes contributing to the determination of Quality policy and objectives. They provide guidance and consistency for realization processes and support processes
- Realization Processes generating products to satisfy customer requirements
- Support Processes providing necessary resources for the performance of realization processes

At the FS, BU or LU level, as appropriate, the individual processes are documented by process descriptions and/or procedures which include the necessary information regarding the sequence of the steps, main interactions between the processes and criteria or indicators to control the effectiveness of these processes.

Process owners are designated by the management at FS, BU or LU level.

The main responsibilities of the process owners are:

- Support the application of the processes
- Monitor and implement actions necessary to achieve planned results
- Review regularly the process effectiveness and track process efficiency
- Implement continuous improvement of the process



**Figure 1-1: General View of the FS Process Map**



The following general description gives an overview of the processes and objectives identified by the process map of the FS.

### **Management Processes**

#### **Develop Policy and Strategy**

The aim of this process is to create the policy and the strategic plan in accordance with stakeholders' needs and the visions and missions of the company.

This process includes:

- Analyze stakeholders' needs and internal performance
- Define and review policy and strategic plan
- Deploy policy and strategy

#### **Deploy Objectives**

The aim of this process is to deploy the objectives of the strategic and operative planning process to the different levels of the organization, in order to define and agree on targets that provide direct support to the objectives in such a way that the organizational units / employees are encouraged to take initiative and contribute personally to the benefit of the company.

This process includes:

- Deploy objectives and targets
- Monitor target achievement
- Assess performance, review/adjust targets, decide improvement actions as needed

#### **Manage Improvements**

The aim of this process is to ensure that effective and efficient methods are used to identify areas for improvement of the business including processes / practices and to manage respective activities in order to improve the satisfaction of the customer and other stakeholders.

This process includes:

- Identify and implement methods for improvement
- Identify, implement and control improvement activities
- Verify improvements
- Evaluate the improvements achieved

### **Realization Processes**

#### **Develop New Products**

The aim of this process is to provide to the customers improved and new products meeting their expectations.

This process includes:

- Assess customer and market
- Manage development project portfolio



- Stimulate innovative technical ideas
- Develop a new product, including validation of design and evaluation of performance
- Qualify a new product

#### Get an Order

The aim of this process is to deliver a proposal to the customer meeting all the requirements expressed in the inquiry and containing appropriate approaches to meet also the unexpressed needs of the customer and finally to get an order.

This process includes:

- Plan the offer
- Prepare the proposal
- Negotiate and review the contract

#### Carry out an Order / Contract

The aim of this process is to supply to the customer products that fulfill the customer requirements and expectations in order to improve customer satisfaction.

This process includes:

- Plan manufacturing
- Manage the contract
- Design and engineer the product for the contract
- Procure materials and components
- Produce the product, including inspection and end-of-project review
- Ship the finished product

#### Carry On Site Service

The aim of this process is to provide to the customer all related services on site including the delivery of service equipment that fulfill all customer requirements and expectations in order to improve customer satisfaction.

This process includes:

- Develop on site service / equipment
- Sell a service / equipment
- Perform on site service

### **Support Processes**

#### Manage Resources

The aim of this process is to provide the realization processes with the necessary people resources to achieve product quality for customer satisfaction.

The process includes:

- Determine personnel proficiency needs
- Perform training



- Manage infrastructure (such as equipment, hardware and software)
- Manage work environment

### Manage the QM System

The aim of this process is to provide the realization and management processes with the necessary tools to assure control of the quality of products for the customer satisfaction and provide information for the continual improvement management.

The process includes:

- Handle nonconformances including corrective and preventive actions
- Plan and perform audits
- Coordinate external audits
- Control quality related documents, data and records

### Communication

The aim of this process is to communicate with the customer regarding customer requirements, expectations and feedback. Internal communication shall assure that the customer needs are well known as well as policy, objectives and their accomplishment.

This process includes:

- Plan communication actions
- Perform communication actions

The process will address items such as

- Document quality policy and objectives
- Communicate product related information
- Transmit project information
- Review and communicate customer feedback and complaints
- Evaluate and document effectiveness of the QM System

## **1.2. Documentation of QM System**

The Framatome ANP QM System is structured (see Fig. 1-2) in accordance with ISO 9001:2000 so that fundamental quality requirements are documented, understood and maintained throughout Framatome ANP.

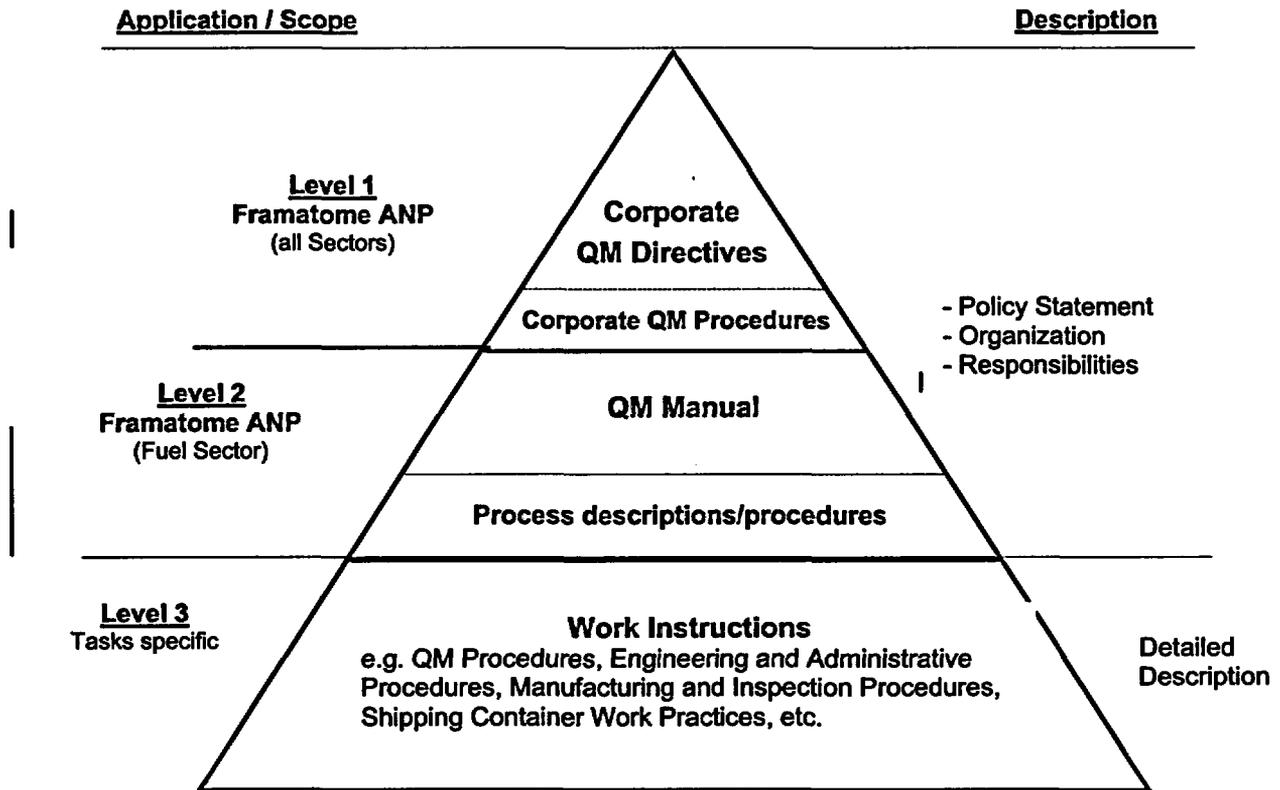


Figure 1-2: Structure of the FS QM System Documentation

This QM Manual is reviewed each calendar year and revised if needed. The FS QM Manager is responsible for collecting proposed changes from the LUs and incorporating appropriate changes. New or revised requirements of the QM Manual shall be transferred into LUs' lower tier procedures within 120 days following the issue of the revision, unless otherwise specified. For revisions that impact our QA Program elements applied to 10 CFR 71 activities, FANP will obtain prior NRC approval before implementation.

The QM System defines requirements for associated quality-related design, procurement, production, inspection, handling and shipping (packaging and transportation) activities. These requirements are propagated through procedures such as engineering procedures, manufacturing procedures, inspection and administrative procedures.

Based on the QM Manual the associated provisions and measures are detailed in procedures. Those procedures can be applicable for the entire Framatome ANP, the FS or specific to the LU. For specific projects, Quality Assurance Plans (QAP) can be issued under the responsibility of the project manager. Preparation, review and approval are described in procedure FQP 01.

The English version is the reference version for the level 1 and level 2 documents. Level 3 documents are issued by each LU in its regional language only.

Corporate Sustainable development and continuous improvement Vice President and FS QM manager respectively are responsible for the translation of these documents in regional languages, when needed (one LU assigned by region).

### **1.3. Control of Documents and Data**

Measures are established and described in procedure FQP 01 and LU procedures, to control documents – including those prepared by customers or external sources, e.g. codes and standards – and electronic data base, which are used for activities that may directly or indirectly affect the quality of products. The measures also assure that changes to documents and databases are appropriately controlled.

Procedures cover the following aspects for:

- Preparation, review, approval of and change of documents
- Release and distribution in order that applicable documents are available at the location where documents are used
- Identification of changes
- Identification of the applicable revisions of documents or data
- The distribution of e.g., "Advanced Copies," "Temporary Document Revisions" or "Use with restrictions" in order to avoid the unnecessary shutdown of key production operations
- Ensuring that documents remain legible, readily identifiable and retrievable
- Translation and review of translation of documents by competent translator. Translation is identified as such
- Requirements for protection of proprietary information and archiving

Review and approval of changes are performed by the same organizations that reviewed and approved the original or by designated organizations having access to the necessary information for review (such as the previous revision).



#### 1.4. Control of Quality Records

Measures are established and described in procedure FQP 02 and LU procedures to control quality records - including those prepared by customers or external sources- consistent with applicable regulatory or customer requirements. Quality records may be hard copy, microfilm or electronic.

Quality records are retained to provide evidence that quality requirements have been fulfilled and that the QM System functions effectively, e.g., operating logs, results of review, inspections, tests, audits, monitoring of work performance and materials analyses. Associated records from suppliers form part of these records.

Procedures cover the following aspects for:

- Classification of permanent and non-permanent records
- Identification, collection and indexing
- Filing and archiving duration
- Conditions for preservation, retrieval and disposition

The records may also include closely related data such as qualifications of personnel, processes and equipment.

Inspection and test records identify the inspector or data recorder, the type of observation, the results, the acceptability and the action taken in connection with any deficiencies noted. Records are identifiable and retrievable.

Customer records are provided in accordance with contract requirements.

#### 1.5 Shipping Containers

Measures are established to control the design, procurement, fabrication, handling, shipping, cleaning, assembly, inspection, testing, use, maintenance, repair and modification of components of our approved containers used to ship fissile and Type A and Type B quantities of radioactive material.

A matrix of the QA procedures related to 10 CFR 50, Appendix B criteria and 10 CFR 71, Subpart H requirements is shown in Appendix III.

#### 1.6 Classification of Characteristics

In order to place the correct amount of emphasis on the more important fuel related products, LUs may implement a system of classifying quality characteristics in design documents for subsequent use in process qualification and/or product inspection and testing.

For shipping containers, components are classified in accordance with design control procedures that determine their safety significance based upon appropriate regulatory guidance (e.g., NUREG/CR-6407). These classifications, in part, determine the level of quality controls applied to the procurement and use of the components.



## **2. MANAGEMENT RESPONSIBILITY**

### **2.1. Management Commitment and Quality Policy**

Management Commitment is documented in the following "Declaration of the FS Quality Policy" (see Fig. 2-1) which is in compliance with the Quality Policy of Framatome ANP.



## QUALITY POLICY

The purpose of the Fuel Sector (FS) quality policy is to provide products and services that meet and anticipate customer's needs. Our products and services will comply with the applicable national and international regulations, codes and standards, with respect to the stringent safety and reliability requirements imposed in the field of nuclear power.

Our quality management system is based on the ISO 9001 (2000 version) standard and must be consistent throughout our entire Sector i.e. all Business Units and all Local Units and Companies belonging to the Fuel Sector.

Our goal is to always improve the effectiveness and the results of our business processes to the balanced benefit of all our stakeholders: customers, shareholders, employees, and community. This will be achieved through the effective application of Total Quality Management practices and sustainable development principles by all managers in the Fuel Sector. These practices aim at:

- bringing the highest benefit to our customers
- promoting personal development and empowerment of our people as well as teamwork
- continuously improving all our processes
- establishing mutual beneficial partnership with all our partners, including suppliers
- protecting our environment, preserving the natural resources and supporting local communities

Environment is of utmost importance, evidenced by the deployment of an environmental management system meeting ISO 14001 standard requirements.

I am sure that this approach is the only possible way to keep a leading position in the market and a long term economic success to the FS.

As Executive Vice-President, I am directly responsible for the implementation of this policy in the FS and I will check it through the yearly Improvement Action Plan results and through my visits to the various sites.

I give full delegation to the Business Units Managers to act in this way, and I demand full support from all the Managers and Employees in the Business Units, Local Units and Companies.

The FS Quality Manager, as well as all quality teams within the company, will be responsible for translating this policy into actions.

The FS Management Committee will periodically review the effectiveness of the implementation of the quality policy.

Claude Jaouen  
FRAMATOME-ANP  
Fuel Sector  
Executive Vice-President

April 2003

Figure 2-1: Declaration of the FS Quality Policy

All personnel perform their duties in conformance to the requirements set forth in the QM System of the FS and all related documentation.

Persons who are assigned the functions of assuring that the required Quality has been achieved are identified so that they are provided with sufficient organizational freedom and authority to perform their functions.

## **2.2. Customer Focus**

Measures are established to ensure that customer requirements are identified and fulfilled with the aim of enhancing customer satisfaction (see Sect. 4.2 and 5.2.1). Arrangements for communication with customers are defined at the most efficient level in order to collect, analyze and use information for improving customer satisfaction.

In order to achieve customer satisfaction, various activities are performed on a regular basis such as:

- Customer needs and expectations are determined, analyzed and taken into account during proposals
- Meetings with customer
- Management of customer complaints and requests
- Customer opinion survey

## **2.3. Planning**

### **2.3.1. Quality Objectives**

The quality objectives are based on the Quality Policy of the FS (see Fig. 2-1).

Benchmarking with external organizations is an element of the QM System, which will be introduced within the FS. Best-practice sharing within Framatome ANP is also an element of the QM System. Such comparison leads to identification of strengths and areas of improvement that influence the development of quality objectives.

Information on customers' feedback, results of audits and process reviews, Management Review conclusions and product verifications are used as sources for the definition of quality objectives.

Syntheses (summary evaluations of quality objective accomplishment) are established at the LU level and are the basis of reporting to the FS level.

### **2.3.2. QM System Planning**

QM System planning within the FS ensures that quality objectives, including those needed to meet the requirements from customers and quality standards are established at all levels within the organization. This shall be achieved by measures such as:

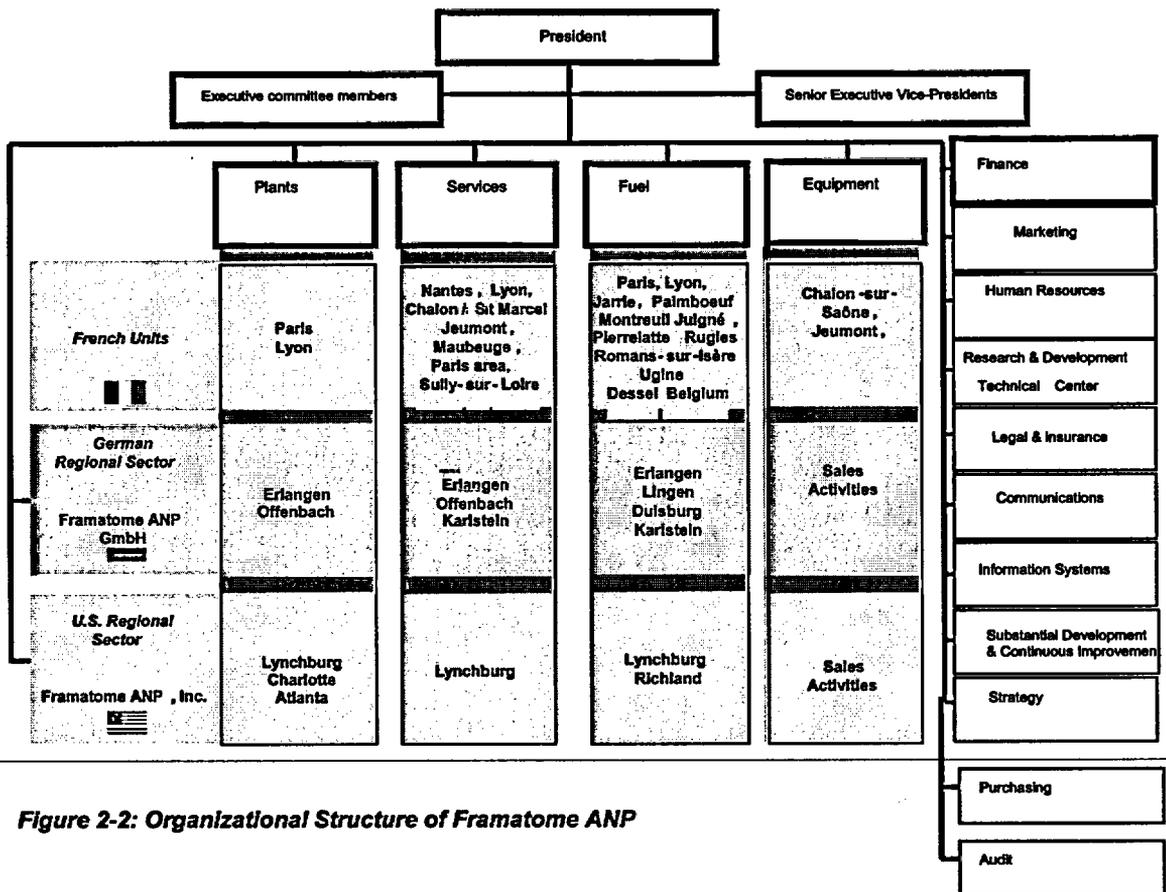
- Identification of customer requirements resulting from contract reviews
- Assurance that the integrity of the QM System is maintained when customer specific changes are required (if needed, those changes are included in a quality plan)



- 
- Provisions of controls, processes, production and inspection equipment, resources and skills
  - Assurance of compatibility between design, production and inspection and applicable documentation
  - QM System assessment during audits, process reviews and Management Reviews
  - Comprehensive training programs for all personnel whose activities affect quality
  - Identification and development of process capability measurement to ensure product and product verification requirements are satisfied
  - Preparation of inspection plans
  - Establishment of acceptance criteria

**2.4. Organization**

Framatome ANP organizational structure is given in Fig. 2-2 and FS organizational structure in Fig. 2-3.



**Figure 2-2: Organizational Structure of Framatome ANP**

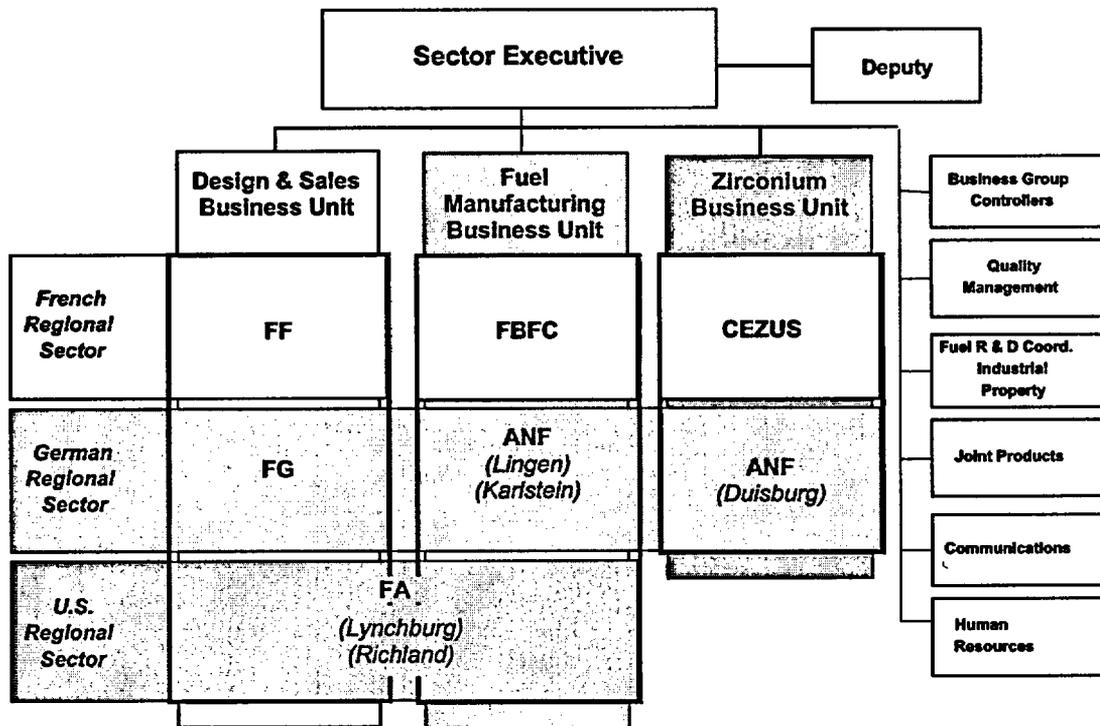


Figure 2-3: Organizational Structure of the FS

#### 2.4.1. Responsibility and Authority

The FS is comprised of the following Regional Sectors.

- The German regional Sector, headquartered in Erlangen consisting of the LU for design, sales and fuel services (Framatome ANP GmbH FG) and the LU for production of fuel related products (Advanced Nuclear Fuels GmbH)
- The U.S. regional Sector, headquartered in Lynchburg, Virginia, consisting of the LU for design, sales, production of fuel related products and fuel services (Framatome ANP, Inc.,FA)
- The French regional Sector, headquartered in Paris consisting of the LU for design, sales and fuel services (Framatome ANP S.A.S., FF), the LU for production of fuel related products (FBFC) and the LU for zirconium based products (CEZUS)

In order to favor integration in the FS, enhance dialogue, develop cross approaches between LUs doing the same kind of activity, the FS is managed according to three Business Units: Design & Sales, Zirconium, Fuel Manufacturing. However, each LU will retain its identity and direct report to the FS Executive. The main target of this management is to achieve global optimization at the FS level.

Each LU maintains its own organizational and management structure. Management accountabilities and responsibilities within the FS are defined, in part, by provisions within this



QM Manual, which defines integrated quality requirements applicable to the worldwide Fuel Sector activities. Further requirements are detailed in procedures for the LUs, taking into account aspects of local authority regulations.

### **2.4.2. Management Representative**

#### **2.4.2.1. FS Quality Management**

The QM Manager of the FS reports to the FS Executive and in addition to the Corporate Sustainable and continuous improvement Vice President. The QM Manager is the Management Representative of the FS. The QM Manager is responsible for providing the assurance that the LUs control and can provide evidence of product quality. The QM Manager is independent and as such has no responsibility for product, engineering or production. This position is responsible for supervising the implementation of the FS quality-related activities including the interpretation of quality requirements and for defining, developing, administering, executing and auditing the QM System for the FS. Specific responsibilities include:

- Preparation and maintenance of the FS QM Manual and procedures in cooperation with the LU QM Managers
- Organization and administration of Management Reviews on the FS level
- Reporting of quality trends and quality-related costs
- Definition of continuous improvement measures of QM and coordination of quality improvement programs between the LUs
- Coordination of audits to verify implementation of the LU QM requirements
- Obtaining and maintaining certification of the QM System by an accredited certification body

The FS QM Manager function is supported by the QM Managers of the LUs. The FS QM Manager may delegate specific tasks and responsibilities to be performed to the respective QM organizations. He has the overall authority to make decisions on interfacing QM matters within the FS. This position has the authority to submit quality-related matters directly to the FS Executive and the Framatome ANP Sustainable Development and Continuous Improvement Vice President. The FS QM Manager will defer to the LU QM Managers for resolution of local regulatory concerns. The FS QM Manager has the organizational freedom and authority to identify and report quality problems; recommend, initiate and provide solutions; verify implementation of solutions and initiate actions to prevent the recurrence of quality problems.

#### **2.4.2.2. LU Quality Management**

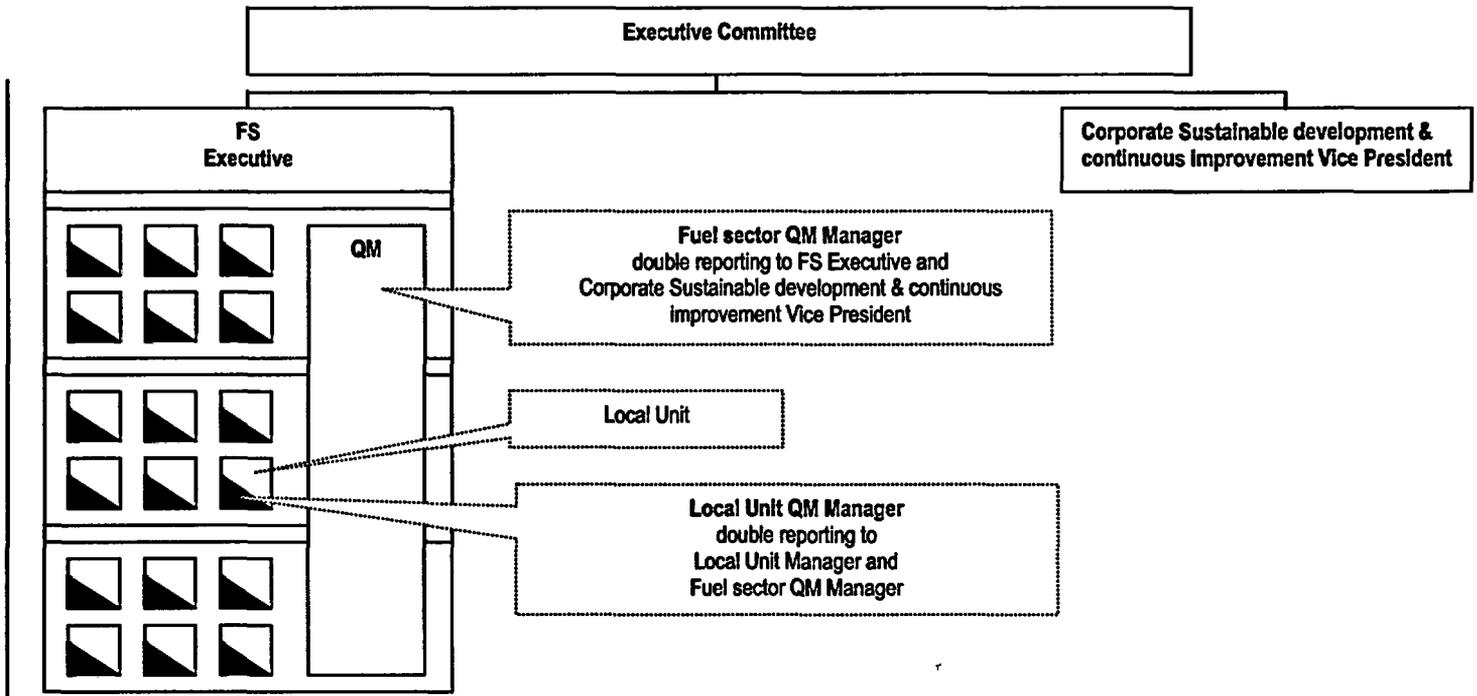
The QM Managers within the various LUs are independent and as such they are charged with no direct product, engineering or production responsibilities. They are responsible for interpreting quality requirements and for the deployment and maintenance of the QM System within their respective organizations. This deployment integrates the inter-organizational functions required to implement the global QM System, as well as define System elements that address local authority regulations and direct customer requirements. In matters of potential conflict, the LU QM Manager shall retain the authority to interpret local regulations consistent with regulatory expectations. The QM Managers of each LU are responsible for implementing comprehensive audit programs to verify compliance with and determine the effectiveness of all



aspects of the QM System. They have stop work authority for their respective facilities and report both to their responsible management and to the FS QM Manager (see Fig. 2-4).

Specific LU QM Manager responsibilities include performing or ensuring that adequate processes are in place for the following:

- Quality control related to the product of the LU. This involves:
  - Preparation/review of product related documents
  - Performance of inspection and surveillance including at suppliers' shop
  - Coordination of disposal of nonconformances
  - Compilation/review of Quality records and product certification
- Preparation and maintenance of the LU specific procedures in compliance with the FS QM Manual and Procedures
- Providing QM indoctrination and training
- Providing program planning and execution of audits within the LU
- Performing supplier evaluation
- Conducting and monitoring corrective actions within the LU
- Interfacing with the other LUs on QM matters
- Conducting Management Reviews within the Regional Sector or LU
- Participating in contract review as required
- Reporting regularly to LU management and to the FS QM Manager on QM System status and quality trends
- Participating in or performing QM audits in other LUs upon request of the FS QM Manager



**Figure 2-4: Functional QM Organization of the FS**

### **2.4.2.3 Manager, Fuel America Quality/Management Systems**

The Manager, Fuel America Quality/Management Systems, reports to the Senior Vice President, Fuel America, and is responsible for providing Quality Assurance and Quality program management for both the Richland and Lynchburg facilities fuel manufacturing, engineering, and transportation activities. The Manager, Fuel America Quality/Management Systems, is responsible for the overall establishment and execution of the Quality Assurance Program for reactor and fuel services, fuel and related component design, fabrication operations, and packaging and transportation activities. The Manager, Fuel America Quality/Management Systems, is responsible for interpreting quality requirements, and for defining, developing, administering, executing, and auditing the Quality Assurance Program in accordance with quality requirements. The Manager, Fuel America Quality/Management Systems, has responsibility for the implementation of the quality assurance-related activities, including stop work authority. In matters pertaining to Quality Assurance and/or Quality, the Manager, Fuel America Quality/Management Systems, also has direct lines of communication to the Fuel America Management Staff. Specific responsibilities include:

- Interpreting and administering the Quality Assurance Program.
- Ordering work stopped when the seriousness of a condition adverse to quality warrants such action in order to maintain the requisite quality.
- Developing an audit program, including follow-up audits, as required, of internal operations and vendor quality assurance programs to assure that quality, engineering, design, manufacturing, purchasing, and other related requirements are being met.
- Developing and implementing quality enhancement initiatives and/or training programs in Quality Assurance requirements and practices to promote the understanding of quality requirements throughout the organization.
- Formulating and implementing Quality Programs to ensure adequate product quality.
- Monitoring and conducting corrective action follow-up for Quality Assurance activities.
- Providing the necessary organization and qualified personnel to carry out the required Quality Assurance/Quality functions.

### **2.4.2.4 Qualification Requirements for Principal Quality Assurance and Quality Management Positions**

Qualification requirements for the Manager, Fuel America Quality/Management Systems, are:

- A bachelor's degree in a technical field.
- At least ten years experience in responsible management of technical or manufacturing activities in the nuclear field, five years of which have been in fields allied to nuclear quality assurance.
- Knowledge of applicable quality-related codes, standards, and regulatory requirements.
- Thorough knowledge of the FANP Quality Assurance Program.

Qualification requirements for the Manager, Richland Site Quality and Manager, Lynchburg Fuel Site Quality are:

- A bachelor's degree in a technical field.
- At least six years experience in responsible management of technical or manufacturing activities in the nuclear field, four years of which have been spent in quality-related nuclear activities.
- Knowledge of applicable quality-related codes, standards, and regulatory requirements.
- Thorough knowledge of the FANP Quality Assurance Program.

#### **2.4.3. Internal Communication**

Internal communication is part of the support process "Communication." Appropriate communication shall be performed at all levels to assure that customer needs as well as policy, objectives and their accomplishment are well known to all involved personal.

### **2.5. Management Review**

The FS Management Review covers the assessment of opportunities for improvement and of the need for changes to the QM System including Quality policy and Quality objectives, to ensure its continued suitability, adequacy and effectiveness. It uses the LU Management Reviews as an input.

In each LU an annual Management Review is held including current performance and improvement opportunities related to the following, if applicable:

- Results of audits and, as available, self assessments
- Customer feedback
- Process performance and product conformance
- Status of preventive and corrective actions
- Follow-up actions from earlier Management Reviews
- Changes that could affect the QM System

Reports including conclusions of these reviews are distributed to the FS QM Manager as sources for the annual FS Management Review. The results of the FS Management Review are documented in reports containing the following topics:

- Improvement of the QM System and processes
- Improvement of products related to customer requirements
- Resources needs

The report of the FS Management Review is distributed to the Corporate Sustainable and continuous improvement Vice President as a source for the Corporate Management Review.

## **3. RESOURCE MANAGEMENT**

### **3.1. Provision of Resources**

Within FS, measures are established to identify and provide the resources, which are needed for

- Implementing and maintaining the QM System and continually improving its effectiveness
- Enhancing customer satisfaction by meeting customer requirements

### 3.2. Human Resources

Comprehensive training programs for all personnel whose activities affect the quality are established in procedures in each of the LUs.

These procedures address:

- Determining training needs taking into account strategic needs and individual needs of the personnel
- Scheduling and performing of training
- Evaluate effectiveness of the training
- Job-related training for the different tasks
- Special training and certification for special processes and audit performance in accordance with applicable codes and standards
- Requirements for retraining and re-certification
- Requirements for establishing and maintaining training records

A general indoctrination session is presented to all persons who perform activities affecting quality. This indoctrination is presented to new personnel shortly after they begin work. The purpose of the indoctrination session is to familiarize personnel with the QM System and with the stringent safety and reliability requirements and make them aware of the importance of their contribution to the achievement of the quality objectives. Re-indoctrination is performed when significant changes to the QM System are made.

### 3.3. Infrastructure and Work Environment

Each LU is responsible for identifying, providing and maintaining suitable infrastructure and adequate work environment to carry out business processes. Infrastructure includes for example, but is not limited to:

- Building, work space and associated utilities
- Process equipment both hardware and software
- Supporting services such as
  - transport and packaging service
  - documentation and archiving service
  - information and communication service

Persons are provided with all tools and resources required to fulfill assigned tasks. The work conditions comply with all relevant safety regulations applicable for the specific work places.



## 4. PRODUCT REALIZATION

### 4.1. Planning of Product Realization

The process model of the FS consists of four main realization processes (see Fig. 1-1). According to the scope of supply of the particular order, the relevant parts of the Process Map shall apply to the production of product for a given contract.

Measures are established for monitoring and controlling the processes for their respective output according to criteria for acceptability. These measures ensure that resources and suitable production facilities are maintained and appropriate reviews and approvals are obtained for product, process and equipment changes.

Planning of product realization includes:

- Establishing Quality Assurance Plans Project Master Plans, Development plans and inspection plans as required
- Design and development planning
- Design reviews, verification and validation
- Control of quality records to provide evidence that the products meet the acceptance criteria.

### 4.2. Customer Related Processes

#### 4.2.1. Determination of Requirements Related to the Product

Contract review ensures that customer requirements are identified including:

- Product requirements specified by the customer, including the requirements for nuclear safety, availability, delivery and support
- Product requirements not specified by the customer but necessary for intended or specified use where known
- Obligations related to the product, including regulatory and legal requirements

#### 4.2.2. Review of Requirements Related to the Product

Product requirements, whether documented by the customer or not, are defined and results of reviews are documented prior to the commitment to supply products to the customer.

Feasibility assessment of all requirements, including applicable regulations, codes, standards and guidelines is performed.

Deviations from the requirements stated in the customer's documents require resolution with other LUs as well as with the customer and – if necessary – with regulatory authorities and are communicated to relevant personnel.

Changes to contractual requirements are expediently addressed in the same manner as the original contract information and requirements.



### **4.2.3. Customer Communication**

Customer communication as part of the support process "Communication" is focused on product and project information as well as customer feedback including customer complaints.

## **4.3. Design and Development**

### **4.3.1. General**

Procedures are established for the preparation and review of design documents, including the correct translation of applicable regulatory and customer requirements and design bases into design and procurement documents. Included are such activities as: physics, seismic, mechanical, thermal, hydraulic, radiation and accident analyses; associated development and maintenance of software programs; establishment of materials compatibility; determination of accessibility for in-service inspection, maintenance and repair; and the development and maintenance of quality standards.

Design organizations are responsible for the preparation, review, approval and verification of design documents for items and services within their respective areas of responsibility. Design documents include such documents as specifications, drawings, analyses and software program documentation. These documents specify technical and quality requirements appropriate to the activities they cover. Wherever practical and applicable, industry standards and specifications are utilized in design specifications for suitable materials, parts, equipment and processes. They are independently reviewed for completeness and technical accuracy. Approved documents are required to procure or produce items.

Errors and nonconformances in approved design documents, including design methods such as computer programs that could adversely affect product performance, are documented and corrected. Deviations from specified quality standards are identified and controlled in accordance with procedures.

### **4.3.2. Design and Development Planning**

Design and development of new products and changes to existing products are carried out as described in procedures. Plans are prepared for each new product design and development activity. They describe or reference these activities and define responsibility for their implementation. The design and development activities are assigned to qualified personnel equipped with adequate resources. The plans are updated as the design evolves.

For software products the design and development process is suitably defined.

### **4.3.3. Design, Organizational and Technical Interfaces**

Procedures establish methods for the identification and control of design, organizational and technical interfaces and for their coordination among participating design organizations. These procedures establish methods for review, approval, distribution and revision of design documents to ensure that the appropriate design, organizational and technical interfaces are considered.



#### ***4.3.4. Design and Development Input***

Design inputs are contained in requirement, criteria and/or contract documents, and design analyses prepared, reviewed, and approved in accordance with procedures. These documents contain applicable regulatory and customer requirements and design bases.

*Incomplete, ambiguous or conflicting requirements are clarified among all affected LUs and, if required, with the customer.*

#### ***4.3.5. Design and Development Output***

Design and development output data are presented to a degree of detail and in a form suitable for verification. As a minimum output documents:

- Satisfy the requirements stipulated in design input
- Provide appropriate information for production and service operations
- Contain or reference product acceptance criteria
- Define the characteristics of the product that are essential to its safe and proper use

Design outputs are documented in design reports, design calculations, drawings, specifications, reload reports and parts lists. Design reports for new products or major changes to existing products demonstrate that design input requirements were met. Parts lists are used to define specific product designs by listing the applicable part structures, part names, part numbers and other information necessary for production and procurement activities. These design output documents are prepared, reviewed and approved as stated in procedures.

#### ***4.3.6. Design and Development Review***

Design reviews are conducted at defined milestones in the design and development processes for new products or major changes to existing products:

- to evaluate the ability to fulfil requirements
- to identify problems and propose solutions

The number of design reviews to be conducted depends on the scope and complexity of the project.

Individuals or groups other than those who performed the original design but who may be from the same LU conduct the design review process. Implementation and documentation of the design review results are specified by procedures.

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

#### ***4.3.7. Design and Development Verification***

Procedures are provided to assure verification of designs. Verification methods include independent review of design documents, design analyses (calculations) and design verification testing. The design organization determines design verification methods to be used.



#### 4.3.7.1. Independent Review of Design Documents

All design documents are independently reviewed for completeness and technical accuracy. The reviewer shall be any technically qualified individual other than the author of the document in compliance with local regulations.

#### 4.3.7.2. Design Analyses

Design analyses (calculations) are used to establish design requirements or to verify the design. The analyst is required to document the calculations as to purpose, assumptions, method, input data, results and conclusions in such a manner that an independent reviewer can verify its technical accuracy independent of the analyst. Design analyses are checked by independent reviewers who are competent in the particular type of analysis being checked.

Computer codes used for design analyses are verified, except for those that can easily be verified by a user, before use as stipulated in procedures.

#### 4.3.7.3 Design Verification Testing

*Design verification by testing is used whenever engineering judgment leads to the conclusion that design analyses or previous experience cannot substantiate a design or design feature.*

Design verification testing is conducted by the test organization using test procedures that incorporate the requirements of design specifications that establish the design limits of the items or features being tested. If verification of a design or design feature is solely by test, the testing is conducted under the most adverse design conditions that can be practically achieved as determined by analysis.

Test results are reviewed by the responsible design organization to determine if they verify the design or design feature tested.

#### **4.3.8. Design and Development Validation**

The suitability of new product designs may be demonstrated by the placement of lead test assemblies or components in reactors to validate their performance under operating conditions.

Validation takes place within the framework of the specified acceptance criteria and procedures with reference to the terms and conditions of use. Acceptance criteria are defined in the design input. Acceptance is performed e.g., during final inspection.

For software products adequate measures are implemented, e.g., validation plan.

#### **4.3.9. Control of Design and Development Changes**

Measures ensure that changes and modifications to designs are identified, documented and controlled. The changes are verified and validated, as appropriate, and approved before implementation.

Design changes to previously approved and issued design documents shall be reviewed and approved in the same manner (unless otherwise specified) as the original documents. If those

required to accept or approve are unable to achieve a unanimous agreement, the items of disagreement are referred to the next higher level of management until resolved.

#### **4.3.10 Shipping Container Modification**

Design control measures are applied to container attributes such as criticality controls, compatibility of materials, accessibility for in-service inspection, and decontamination capability. These attributes are specified in license drawings which accompany certificates of compliance (C of Cs) issued by the USNRC. Changes in the conditions specified in the package approval require USNRC approval.

### **4.4. Purchasing**

#### **4.4.1. Purchasing Process**

Measures are established in procedures to assure that products, including shipping containers, are procured from suppliers that meet the requirements of the FS and those specified in customer contracts. One or combinations of the following methods according to the importance of the purchased product are used for supplier evaluation:

- Supplier's third party certificates and references
- Evaluation of supplier's QM System
- Review of performance data for former products and services of the supplier
- Source, incoming inspection and/or surveillance results

This evaluation leads to an assessment, which contains at least the registered name of the supplier including the location where the work is performed, scope of supply and expiration date as well as the condition under which the supplier is considered approved.

Assessment issued by a LU (from the FS or another Sector) complying with the Corporate Quality Procedure Q DC 4 (Q 101) or FS Procedure complying with the Corporate directives is deemed valid for the other LUs. These assessments are registered in LU and/or FS or regional lists or databases. Information related to the status of suppliers is made available to all the LU of the FS.

In addition, suppliers assessed by other companies may be accepted by the LUs provided the conditions for assessment have been found acceptable by the unit in charge of the assessment.

The assessment is valid for a maximum duration of three years. The renewal is based on one or a combination of methods used for the initial evaluation.

Commercial grade and/or designated products for use in the reactor may be procured from suppliers where specific quality controls for nuclear applications cannot be imposed in a practicable manner. In these instances, an evaluation of the suitability of the item or service for nuclear applications is performed by the responsible process engineering and/or design organization. The critical characteristics of the item or service are also determined and documented as part of this evaluation. Special methods may be needed for verification of these critical characteristics. If needed, these special quality verification methods may include inspections, tests or commercial grade surveys or evaluations of the supplier.

#### **4.4.2. Purchasing Data**

Procurement documents for the purchase of products include or reference the following provisions, as applicable:

- Scope of supply
- Technical requirements
- QM System requirements

Purchase orders are reviewed prior to release by personnel different from those who prepare the order.

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

#### **4.4.3. Verification of Purchased Product**

Measures assure that purchased products, including shipping containers, conform to the procurement documents. These measures include provisions as appropriate, for source evaluation and selection, objective evidence of quality furnished by the supplier, inspection at the source and examination of products upon delivery at intervals consistent with the importance, complexity and quantity of the product or services.

People in charge of the inspection, either at the source or upon delivery are entitled or qualified according to LU procedures. If they perform a source inspection for another sector, they shall be qualified according to Corporate procedure Q 104.

Documentary evidence that purchased products conform to the procurement requirements is retained and must identify the specific requirements such as standards, specifications and drawings.

For design services, the relevant Design group monitors the quality of the required technical documents that are prepared by the supplier. Rules for releasing these documents are defined in procedures. If the supplier uses computer codes for critical studies, the verification actions consist of checking:

- The existence and validity of a calculation note
- The validity of the codes
- The validity of the input data with respect to the applicable ranges
- The validity of the results obtained with respect to the limits set.

#### **4.4.4. Product and Service Transfer between LUs**

For the product and service transfer between the LUs of Framatome ANP, an internal order is used. QM system requirements consist of the implementation of the FS QM system and the requirements from the final customer if any. Product received from another LU is inspected for completeness and possible shipment damage. The quality records are reviewed for compliance with the requirements from the internal order.

Design service documents are reviewed by responsible Design personnel for consistency with the internal order, completeness and quality of documents.



## 4.5. Production and Service Processes

### 4.5.1. Control of Production and Service Processes

#### Fuel related products, including shipping containers

Drawings and specifications issued by Design groups may not be directly usable on the shop floor. On this basis, manufacturing and inspection documents are prepared to determine the chronological sequence and the description of manufacturing and inspections steps. Other documents are issued such as parameter sheets based on qualification of processes.

#### On site service activities

For any work on-site an operation file is issued which includes the planning of the work (schedule, assignment of personnel), the sequential list of operations, the list of applicable documents and the documents themselves. In addition, the necessary documents required on-site, as prerequisites such as personnel accreditations or qualifications of equipment are also included.

### 4.5.2. Qualification or Validation of Production and Service Processes

#### 4.5.2.1. Production Processes

Production processes as required are qualified on the basis of qualification programs which define production output to be evaluated, characteristics to be controlled, acceptance criteria defined or reviewed by the Design function and necessary documentation.

Production processes in which the quality achieved depends on the performance of the process and the results cannot be fully verified by subsequent inspections and tests are considered special processes are covered by more in-depth controls. These special processes are performed under controlled conditions with qualified procedures, trained and qualified personnel and suitable equipment and re-qualified if required.

Typical special processes and tests include welding, liquid penetrant testing, radiography, helium leak testing, ultrasonic testing, eddy current testing and nuclear rod assay.

For technically similar products, small quantities and non-repetitive production, qualification exemptions can be granted providing products or processes undergo more extensive inspection and surveillance.

The qualification process including required documents as well as archiving is described in procedures.

#### 4.5.2.2. On-Site Service

The aim of the qualification is to demonstrate that:

- the functional requirements of the equipment are met
- the desired result for the product subject to the work is obtained
- no irreversible damage occurs to the product subject to the work

The qualification process including required documents as well as archiving is described in procedures.



#### 4.5.2.3. Qualification of NDT Inspectors

Procedures for qualification of NDT inspectors are established and define the following items:

- The qualification levels suited to the tasks, as well as the contents and the duration of the training and corresponding experience
- The terms of the certification tests and examinations, including the medical examinations designed for checking the physical ability of the applicants. These medical examinations, including visual acuity testing, are extended to all personnel performing visual inspection of the products
- The responsibilities for granting certificates
- The validity duration of the certifications and the conditions of their renewal
- The updating and archiving of the certification files

Certification of the personnel is not required for operating automatic inspection equipment and for carrying out, according to procedures, simple and repetitive operations, including frequent calibrations that can be considered as adjustments, providing surveillance is ensured.

#### 4.5.2.4. Maintenance

A maintenance program or maintenance plan is prepared to ensure implementation of preventive maintenance of equipment affecting the quality of the products. The objective of this preventive maintenance is to ensure a continuous and stable process.

For maintenance operations (preventive or corrective) the conditions for restarting shall be defined as appropriate.

#### 4.5.2.5. Software Control

Before application, new and modified software used for the functional and mechanical design of fuel assemblies and other core components, as well as for manufacture and inspection, is subject to appropriate verification and validation to demonstrate suitability for the intended purpose.

### ***4.5.3. Identification, Traceability and Status Control***

Measures are established and documented in procedures for the identification and control of products and shipping containers. These identification and control measures are designed to prevent the use of incorrect or defective products. These measures also assure that sub-components are traceable to finished products throughout production and use. Such traceability also supports warranty evaluations for product failures encountered in use or storage.

Moreover these measures are established to indicate, by the use of markings such as stamps, tags, labels, routing cards or other suitable means, the status of inspections and tests performed upon individual hardware items.

Suitable configuration control measures are implemented for identification, traceability and status control of software products.



#### 4.5.3.1. Identification

Traceability is maintained through receipt of material to final shipment. Procedures require that identification be maintained either on the item or on the package or on the records traceable to the item. Methods of identification and traceability are such that they provide, at all times, a link between the product and the related documentation and prevent the use of nonconforming products or product that have not yet been accepted.

Any fuel related product which loses its identification is considered as potentially nonconforming until such time as the identity can be established or the item is dispositioned by the nonconforming control System (see section 5.3).

#### 4.5.3.2. Inspection and Test Status

Controls are established to assure that the inspection and processing status of items which will become part of the product or are important to the manufacturing process are adequately identified from receipt of the items to end use, in order to prevent inadvertent bypassing of operations or inadvertent use.

The following controls are employed to assure that the status of fuel related products are adequately identified:

- Lot cards, production order routers, station reports, route cards, inspection forms, and/or checklists are utilized to identify and control lots or items and to transfer identification when several items are joined into a single unit
- Inspector or operator identification is entered on the identity/control documentation to signify the completion of operations or inspections
- Hold points may be established at specified points in the process whereby material processing may not proceed until formally inspected and released by authorized personnel and/or the customer. Release points are designated in associated procedures. Releases become part of the quality records
- Conditional release of fuel related products beyond hold points may be initiated by completion of a "Conditional Release" or equivalent. Conditional Releases are not to be used to waive specification requirements. Conditional Releases shall be converted to Full Releases, at the latest, prior to product shipment
- Rejected items are suitably identified (e.g., hold tags) and / or separated from acceptable items to prevent their inadvertent use

#### 4.5.4. Customer Property

Uranium hexafluoride (UF<sub>6</sub>) is an example of customer property of fuel related products. Acceptance of such product is based on quantity and inspection followed by a formal release. Inspection includes visible damage on the packaging or product, review of the documents required to evidence quality and as appropriate, physical and/or chemical analysis.

Engineering analyses, plant data and software are examples of non-hardware types of purchaser property. Acceptance of data and analyses is done through the validation of data or results.



Precautions are taken to preclude damage on customer property. A report is issued for any loss, damage or other limitation according to LU procedures. This report is transmitted to the customer and kept according to LU procedure dealing with the control of quality records.

#### **4.5.5. Preservation of Product**

Procedural controls are established to assure that fuel related products are handled, stored, shipped and preserved in a manner such that quality is not adversely affected. Trained individuals accomplish the special handling, storage and preservation in accordance with procedures. Where special controls are not required for handling, storage and preservation, standard material handling and transportation methods are used to protect against physical damage.

##### **4.5.5.1. Control of Prohibited Materials**

Controls are established to assure that materials detrimental to fuel performance are sufficiently controlled or not used. The measures include control of essential material purchases and evaluation of the process via appropriate analyses, as required to assure that adequate control is maintained over the use of such materials.

##### **4.5.5.2. Packaging and Storage**

Procedures for packaging and storage assure that fuel related products, which are subject to deterioration or damage through exposure to air, moisture and other environments, are protected during procurement, production, interim storage and final shipping.

##### **4.5.5.3. Delivery**

Shipping of nuclear material is performed in accordance with national and international regulations.

As requested by the customer upon receipt of nuclear fuel at the customer's plant, inspection is performed, based on a procedure which is mutually agreed between both parties.

#### **4.6. Control for Measuring and Test Equipment**

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

Procedures for calibration and use of the measuring and test equipment are established and document the basis of calibration. These procedures describe requirements such as:

- Traceability of calibration standards according to national or international standards, where such standards exist. In the event there are no national or international standards, the basis of the calibration is documented
- Equipment within the scope of the calibration and maintenance program is procured, controlled and used to ensure the required degree of accuracy, reproducibility and traceability



- Frequencies of recalibration are established, based on required accuracy usage, stability of the equipment and, where feasible, the calibration status is identified by tag, label or other appropriate means
- Nonconforming equipment is clearly identified and its use prohibited or suitably restricted until repaired or calibrated
- Environmental conditions for calibration
- Handling and safeguarding of equipment
- Use of test hardware (fixtures, templates)

Inspection, measuring and test equipment being used to determine product acceptance that is found to be out of calibration will be removed from service and recalibrated before being used again. Products are then considered as potentially nonconforming.

Calibration records for measuring, inspection and test equipment are maintained. As a minimum, identification number of the equipment, calibration method and results of calibrations are recorded.

## **5. MEASUREMENT, ANALYSIS AND IMPROVEMENT**

### **5.1. Planning of Measurement, Analysis and Improvement**

Measures are established in procedures for planning and implementing measurement, analysis and improvement processes, which are needed:

- to demonstrate product conformity
- to ensure QM System conformity
- to continuously improve the effectiveness of the QM System
- To use statistical techniques as appropriate.

### **5.2. Monitoring and Measurement**

#### **5.2.1. Customer Satisfaction**

Measures are defined for monitoring information on customer feedback including customer complaints as a measurement of the QM System performance as to whether the customer requirements are met.



### 5.2.2. Audits

A comprehensive program of planned and periodic audits is carried out to verify compliance with all aspects of the QM system and to determine the effectiveness of the procedures. The audit process is described in Corporate procedure Q 102. The audits include the evaluation of work areas, activities, quality-related practices and review of documents and records. The audit program includes supplier audits, as well as internal audits. Audit reports are documented and distributed to appropriate management and necessary corrective actions are taken to correct noted deficiencies.

#### Internal Audits

Internal audits are performed at both the FS and LU levels.

Internal audits are scheduled to cover the program elements on a defined frequency and are chartered to identify potential improvements.

Audits are lead by qualified auditors who do not have direct responsibility in the area being audited.

Internal audits at the FS level cover at least interfaces between LUs and LU QM units' activity. They are led by qualified auditors that do not belong to the audited unit. Internal audits are conducted according to the audit schedule taking into consideration the status and importance of activities and areas being audited as well as the results of previous audits. Audit schedules are prepared annually and contain at least the organizations or processes to be audited and the timing of audits. The schedules and yearly synthesis of internal audits are provided to the FS QM Manager

Corrective actions are coordinated with the LUs and documented with an implementation deadline.

The lead auditor, or designee, monitors implementation and verifies the effectiveness of corrective actions. The LU QM Managers ensure that the corrective action program is effectively implemented.

Internal audit findings with global implications are distributed to all LU QM Managers within the FS and to the FS QM Manager.

#### Customer or Authority Audits

Customer or Authority audits are performed at the LUs. Results are evaluated by the audited QM Manager. If the audited LU is not in charge of the contract, the results are transmitted to the appropriate LU QM Manager for resolution. Audit non-conformities with global implications are distributed to all LU QM Managers within the FS and to the FS QM Manager.

#### Third party audits

Coordination of audits and answer to the non conformities or comments from the Certification body audits is under the responsibility of the FS QM Manager.

### 5.2.3. Monitoring and Measurement of Processes

The effectiveness of processes is reviewed at regular intervals with the aim of continuous improvement. The review is based on product and QM System requirements as well as on defined process indicators.

Statistical techniques for measurement and monitoring of processes are applied, if useful, e.g., for the following purposes:

- to determine effectiveness of manufacturing and inspection processes
- to control and monitor those processes by using statistical process control
- to analyze processes in order to improve the process such as increase yield, reduce variability
- to improve product reliability and performance

#### **5.2.4. Monitoring and Measurement of fuel related products**

Inspection procedures are established and executed to verify conformance with specifications and drawings for accomplishing activities affecting quality.

Inspections, which are deemed important for safety and inspections for acceptance of the work will be performed by individuals other than those who performed the activity being inspected. However, certain inspections may be performed by individuals who performed the activities being inspected provided such inspections do not require sensory or human judgement. Examples of inspections which may not require independence are:

- Physical inspections with gages which do not require recording of data, e.g., go/no-go gages
- Automated inspections – automated coordinate measuring machines, gamma scanner, etc.
- Automated processes or “mistake-proof” tools – heat treatment furnace charts, torque wrenches with set breakaway
- Inspection of assembly attributes which are generated by multiple operations and are not readily traceable to an individual operation/operator

Inspection by the manufacturing organization may be applied during production and for final inspection of finished product, provided such inspections are subject to documented surveillance by Quality personnel to assure their acceptability.

Examinations, measurements or tests of product processed are performed for each production step where necessary to assure quality. The provisions of special processes (see section 4.5.2.1) apply if inspection of products is impossible or disadvantageous.

Inspectors are qualified/trained in accordance with procedures.

Procedures for in-process inspections are established to monitor processing parameters and equipment. In-process inspections are documented on production routers/travelers, route cards, computer Systems, etc.

### **5.3. Control of Nonconforming Product**

Measures are established in FS procedure FQP 03 and in LU procedures to control products and shipping containers which do not conform to requirements in order to prevent their inadvertent use. These procedures include, as appropriate, provisions for identification, documentation, segregation, disposition and notification to affected organizations.



Nonconforming products will be reviewed and accepted, repaired or reworked or rejected in accordance with procedures.

Products, which are reworked or repaired, are inspected in accordance with applicable inspection requirements applied to the original items or as specified in applicable rework or repair procedures.

When a nonconforming product is detected after delivery or use has started, actions are taken by the responsible LU, which are appropriate to the effects or potential effects of the nonconformance.

Measures ensure that any defect in fuel related product or any noncompliance with customer requirements which could create a substantial nuclear safety hazard are communicated to the customer without delay.

For products to be delivered to US customers or when required by customers, the requirements of 10 CFR 21 "Reporting of Defects and Noncompliance," are fulfilled in the affected LUs. A similar reporting procedure is implemented for other contracts as required by the customer.

Discrepant shipping containers are removed from service and either refurbished/repaired to comply with license requirements or the license is amended (if justified) to accommodate the new configuration(s).

#### 5.4. Analysis of Data

The FS and its LUs collect and analyze appropriate data to determine suitability and effectiveness of the QM System and identify improvement potential (performance indicators). This includes data generated by measuring and monitoring activities and other relevant sources.

Analysis of data and performance indicators identify areas of improvement for the QM System. The results of the analysis are internally communicated to all organizational units to facilitate improvement initiatives.

These data are analyzed to provide information on:

- Customer satisfaction, customer complaints
- Conformity to product requirements
- Characteristics of processes, products and their trends
- Suppliers' performance

Results of data analysis by the LUs are transmitted to the FS QM Manager in order to determine suitability and effectiveness of the FS QM System.

#### 5.5 Improvement

##### 5.5.1. Continual Improvement

FS continually improves the effectiveness of the QM System through the use of the following instruments:

- Quality policy (see sect. 2.1)

- Quality objectives (see sect. 2.3.1)
- Management Review (see sect. 2.5)
- Customer satisfaction (see sect. 5.2.1)
- Audits (see sect. 5.2.2)
- Monitoring and measurement of processes (see sect. 5.2.3)
- Control of nonconformance product (see sect. 5.3)
- Analysis of data (see sect. 5.4)
- Corrective action (see sect. 5.5.2)
- Preventive action (see sect. 5.5.3)

### **5.5.2. Corrective Action**

Actions are taken to eliminate the cause of nonconformances or customer complaints in order to prevent recurrence. Such corrective actions are appropriate to the effects of the encountered problems and are also used to drive process improvement.

Nonconforming conditions, internal and customer or authority audits, inspection or surveillance of products, customer complaints or other events which can adversely affect product or shipping container quality constitute the main sources of corrective actions. Such situations are analyzed for root causes and reported to appropriate levels of management for review and decision.

Depending on the effect of the nonconformance, corrective actions are defined. A follow-up system is implemented. Evidence of implementation and verification of efficiency is recorded.

Lists of actions in progress are periodically issued or filed in databases and communicated to involved people in charge of the actions, management and the project Manager (customer complaints).

Corrective actions can also be imposed to the suppliers following surveillance and/or audit activities.

The corrective action process is described in an FS procedure FQP 04.

### **5.5.3. Preventive Action**

Actions are taken to eliminate the causes of potential nonconformances in order to prevent their occurrence. Such preventive actions are appropriate to the effects of the potential problems.

The procedure for planning and implementing preventive actions consists of the following:

- Evaluating and using suitable sources of information concerning product Quality
- Applying analysis methods where useful
- Defining actions which may result in a safer and more reliable product
- Implementing and documenting preventive actions
- Monitoring and reviewing effectiveness of implemented actions

Analysis of Quality data, audits and other actions such as process reviews are the main source of preventive actions.

The corrective action process is described in FS procedure FQP 04.



## Appendix I

Correlation of 10 CFR 50, Appendix B Criteria and  
10 CFR 71, Subpart H Requirements with ISO 9001 Requirements

| 10 CFR 50, Appendix B<br>QA Criteria |  | Corresponding ISO 9001<br>Requirements                                | Section Which<br>Imposes<br>Criteria/Requirement | 10 CFR 71,<br>Subpart H<br>Requirements | Revisions<br>Permissible<br>at<br>FRA-ANP's<br>Discretion |
|--------------------------------------|--|---|--|---|---|
| I                                    | Organization   | Management<br>Responsibility  | 2.4  | 71.103                                  |   |
| II                                   | QA Program   | QA System and<br>Management<br>Responsibility, Training               | 1.0, 2.0, & 3.0                                  | 71.101 &<br>71.105                      |   |
| III                                  | Design Control                                       | Design Control  | 4.3  | 71.107                                  |   |
| IV                                   | Procurement Document<br>Control                      | Purchasing  | 4.4  | 71.109                                  |   |
| V                                    | Instructions, Procedures,<br>and Drawings            | Not Applicable  | 4.5  | 71.111                                  |   |
| VI                                   | Document Control                                     | Document Control  | 1.3  | 71.113                                  |   |
| VII                                  | Control of Purchased<br>Material                     | Purchasing, Purchaser<br>Supplied Product,<br>Quality Audits          | 4.4, 4.5.4, & 5.2.2                              | 71.115                                  |   |
| VIII                                 | Identification and Control<br>of Materials and Parts | Product Identification<br>and Traceability,<br>Inspection and Testing | 4.5.3 & 5.2.3                                    | 71.117                                  |   |
| IX                                   | Control of Special<br>Processes                      | Process Control   | 4.5.2  | 71.119                                  |   |
| X                                    | Inspection   | Inspection and Testing  | 5.2.3  | 71.121                                  |   |
| XI                                   | Test Control   | Not Applicable  | 4.5.3  | 71.123                                  |   |
| XII                                  | Calibration of Equipment                             | Inspection, Measuring,<br>and Test Equipment                          | 4.6  | 71.125                                  |   |
| XIII                                 | Handling, Storage, and<br>Shipping                   | Handling, Storage,<br>Packaging, and Delivery                         | 4.5.5  | 71.127                                  |   |
| XIV                                  | Inspection, Testing, and<br>Operating Status         | Inspection and Test<br>Status   | 4.5.3  | 71.129                                  |   |
| XV                                   | Nonconforming Material                               | Control of<br>Nonconforming Product                                   | 5.3  | 71.131                                  |   |
| XVI                                  | Corrective Action                                    | Corrective Action   | 5.5  | 71.133                                  |   |
| XVII                                 | QA Records   | Quality Records   | 1.4  | 71.135                                  |   |
| XVIII                                | Audits   | Quality Audits  | 5.2.2  | 71.137                                  |   |
| N/A                                  | N/A  | Contract Review   | 4.2  | N/A                                     | X   |
| N/A                                  | N/A  | Servicing   | 4.5.5  | N/A                                     | X   |
| N/A                                  | N/A  | Statistical Techniques  | 5.4  | N/A                                     | X   |

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**Appendix II**

**Applicability of ANSI Standards and Regulatory Guides**

The FRA-ANP Quality Assurance Program satisfies the requirements of Appendix B to 10 CFR 50, "Quality Assurance Criteria for Nuclear Power Plants"; USNRC Regulatory Guide 1.28, "Quality Assurance Program Requirements"; ANSI N45.2 (1977), "Quality Assurance Program for Nuclear Fuel Power Plants"; 10 CFR 71, Subpart H, "Quality Assurance Requirements for Packaging and Transportation of Radioactive Material"; and ANSI N14.1 (1995), "Uranium Hexafluoride Packaging for Transport."

Since the Quality Assurance requirements and guidelines of the Regulatory Guides and ANSI Standards were initiated to apply to nuclear power plants, interpretation is required to determine their applicability to services, and the design and manufacture of a plant component such as nuclear fuel. The FRA-ANP Quality Assurance Program follows the guidelines set forth in Section 17.1 of the USNRC Standard Review Plan insofar as it applies to fuel design and fabrication activities performed by FRA-ANP. The extent to which the ANSI Standards and Regulatory Guides referenced in the Standard Review Plan are deemed to be applicable to FRA-ANP activities is summarized in the table which follows. The listed ANSI Standards apply only to nuclear safety-related activities. Specific exceptions to the documents are included with appropriate justification. Standards or Guides referenced by the Standard Review Plan which are deemed not applicable to fuel design and fabrication have been omitted.



| APPLICABILITY OF ANSI STANDARDS AND REGULATORY GUIDES |  |   |
|---|--|---|
| ITEM NO.  | DOCUMENT NUMBER & DATE                 | SUBJECT AND APPLICABILITY   |
| 1.  | Reg. Guide 1.28<br>(Rev. 3, Aug. 1985) | Quality Assurance Program Requirements<br>(Design Construction)   |
|   | ANSI N45.2, 1977                       | Quality Assurance Program Requirements for Nuclear Power Plants<br><br>Applicability: Fully applicable.   |
|   | ANSI/ASME NQA-1                        | Quality Assurance Requirements for Nuclear Facilities<br><br>Applicability: Applicable with same comments as described below for corresponding Supplements.   |
| 2.  | Reg. Guide 1.38<br>(Rev. 2, May 1977)  | Quality Assurance Requirements for Packaging, Shipping, Receiving, Storage, and Handling of Items for Water-Cooled Nuclear Power Plants   |
|   | ANSI N45.2.2 - 1972                    | Packaging, Shipping, Receiving, Storage, and Handling of Items for Nuclear Power Plants<br><br>Applicability: ANSI N45.2.2, Section 2.7.1 (3), defines nuclear fuel as a Level A item. As such, ANSI N45.2.2, Section 3.2.1, Items 1-9, apply with the following exceptions:<br><br>1) ANSI N45.2.2, Section 3.2.1, Item 1 is amended to eliminate the need for temperature and humidity controls.<br><br>2) The serial number of the fuel assembly constitutes adequate item identification as required by Section 3.2.1, Item 9 of ANSI N45.2.2. Shipping container marking shall comply with the requirements of applicable state and federal regulations governing nuclear fuel shipments.<br><br>Additionally, the following sections of ANSI N45.2.2 are deemed to apply: 4.6, 5.1, 5.2.1 (5), 5.2.2. (7), 5.2.2 (8), 5.2.2 second paragraph (2) and (4), 5.3, 5.4, 5.5, 5.7, 6.1 (at fuel fabrication site only, and with exception of temperature and humidity controls). Storage in shipping containers may satisfy the requirements of Section 6.1 of ANSI N45.2.2, and 7.1 |



| APPLICABILITY OF ANSI STANDARDS AND REGULATORY GUIDES |   |   |
|---|---|---|
| ITEM NO.  | DOCUMENT NUMBER & DATE                  | SUBJECT AND APPLICABILITY   |
| 3.  | Reg. Guide 1.58<br>(Rev. 1, Sept. 1980) | Qualification of Nuclear Power Plant Inspection, Examination, and Testing Personnel   |
|   | ANSI N45.2.6, 1978                      | <p>Qualification of Inspection, Examination, and Testing Personnel for the Construction Phase of Nuclear Power Plants</p> <p>Applicability: Applicable with the following clarifications:</p> <ol style="list-style-type: none"> <li>1) Levels of capability and associated certifications, as specified by Sections 2.0, 3.1 and 4 of ANSI N45.2.6, are applicable only to special processes, as defined by ASNT-TC-1A.</li> <li>2) Formal levels of qualification are not assigned for nuclear fuel ultrasonic test and helium leak check equipment operating personnel. However, formal training programs for all inspectors are conducted and documented in accordance with ASNT-TC-1A recommended practice. The degree of evaluating acceptability of test results is limited by procedure, to comparing chart or dial readings of product tests versus acceptance limits established using approved standards.</li> <li>3) Practical experience and on-the-job training times may vary from the ASNT-TC-1A classifications. Other inspections and testing qualifications, while formalized, are not deemed to require designation of levels of capability or certification. In addition, physical examinations after initial training are verified biennially in lieu of annually per Section 2.5, since this is company policy.</li> <li>4) A special category, "Level II Rod Film Reader Only," is defined at the Richland facility to evaluate acceptability of fuel rod weld radiographs only. This classification requires less extensive general training and experience than "Level II," and limits qualification to an in-depth ability to read and interpret film only. Special training with demonstration of ability to consistently detect defects is required and is documented in training files.</li> <li>5) Liquid penetrant inspectors are trained and certified under a FRA-ANP developed training program. This program is based upon ASNT-TC-1A.</li> </ol> |



| APPLICABILITY OF ANSI STANDARDS AND REGULATORY GUIDES |  |  |
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| ITEM NO.  | DOCUMENT NUMBER & DATE                 | SUBJECT AND APPLICABILITY  |
| 4.  | Reg. Guide 1.64<br>(Rev. 2, June 1976) | Quality Assurance Requirements for the Design of Nuclear Fuel Power Plants   |
|   | ANSI N45.2.11 - 1974                   | <p>(Same title of Reg. Guide 1.64)</p> <p>Applicability: Applicable with the following clarifications and exceptions which make the standard more consistent with Nuclear Fuel Design: (1) Paragraph 3.2 of ANSI N45.2.11 is changed to read as follows: "The design shall be such as to be capable of accommodating the following where applicable:</p> <ol style="list-style-type: none"> <li>1) Basic functions of each structure and component.</li> <li>2) Performance requirements.</li> <li>3) Codes, standards, and regulatory requirements including the applicable issue and/or addenda.</li> <li>4) Design conditions such as pressure and temperature.</li> <li>5) Loads such as seismic, thermal, and dynamic where required.</li> <li>6) Environmental conditions anticipated during fabrication, storage, and operation, such as pressure, temperature, humidity, corrosiveness, and nuclear radiation.</li> <li>7) Interface requirements, including definition of the functional and physical interfaces involving structures and components.</li> <li>8) Material requirements, including such items as compatibility and corrosion resistance.</li> <li>9) Mechanical requirements, such as vibration, etc.</li> <li>10) (Not applicable)</li> <li>11) Hydraulic requirements such as allowable pressure drops and fluid velocities.</li> <li>12) (Not applicable)</li> <li>13) (Not applicable)</li> <li>14) Layout and arrangement requirements.</li> <li>15) Operational requirements under various conditions, such as plant startup, normal plant operation, plant shutdown, plant emergency operation, special or infrequent operation and system abnormal or emergency operation.</li> <li>16) Provision for accommodating installation of necessary instrumentation.</li> </ol> |



| APPLICABILITY OF ANSI STANDARDS AND REGULATORY GUIDES |                        |  |
|---|------------------------|--|
| ITEM NO.  | DOCUMENT NUMBER & DATE | SUBJECT AND APPLICABILITY  |
|   |                        | <p>17) (Not applicable)</p> <p>18) (Not applicable)</p> <p>19) Failure effects requirements of structures, and components, including a definition of those events and accidents which they must be designed to withstand.</p> <p>20) Test requirements including in-plant tests and conditions under which they will be performed.</p> <p>21) Accessibility, maintenance, repair and in-service inspection requirements for the fuel, including the conditions under which these will be performed.</p> <p>22) Personnel requirements and limitations, including qualification and number of personnel available for testing and inspection and permissible personnel radiation exposures for specified areas and conditions.</p> <p>23) Transportability requirements such as size and shipping weight, limitations, and DOT regulations.</p> <p>24) (Not applicable)</p> <p>25) Handling, storage, and shipping requirements.</p> <p>26) Other requirements to prevent undue risk to the health and safety of the public.</p> <p>27) Materials, processes, parts, and equipment suitable for application.</p> <p>28) Safety requirements for preventing personnel injury, including such items as radiation hazards, and restricting the use of dangerous material."</p> |
|   |                        | <p>(2) If, in an exceptional circumstance, the designer's immediate supervisor is the only technically qualified individual available, this review can be conducted by the supervisor, provided that:</p> <p>a) The provisions of the Regulatory Guide are satisfied.</p> <p>b) The supervisor did not prescribe or limit the techniques or inputs used in the design document. The use of supervisors as reviewers is approved in each instance by the cognizant manager.</p> <p>c) Quality Assurance audits will cover the frequency and efficiency of the use of immediate supervisors as design verifiers to guard against abuse.</p>  |
|   |                        | <p>(3) The requirements of Section 6.3.3 for incorporation of design test acceptance limits into test procedures is not deemed applicable if the purpose of the test is to produce data for design inputs. Additionally, not all qualification tests are conducted under the worst conceivable design conditions.</p>  |



| APPLICABILITY OF ANSI STANDARDS AND REGULATORY GUIDES |   |   |
|---|---|---|
| ITEM NO.  | DOCUMENT NUMBER & DATE  | SUBJECT AND APPLICABILITY   |
| 5.  | Reg. Guide 1.74 (Feb. 1974)<br>ANSI N45.2.10-1973               | Quality Assurance Terms and Definitions<br>(Same title as Reg. Guide 1.74)<br><br>Applicability: Fully applicable.  |
| 6.  | Reg. Guide 1.88<br>(Rev. 2, Oct. 1976)<br><br>ANSI N45.2.9-1974 | Collection, Storage, and Maintenance of Nuclear Power Plant Quality Assurance Records<br><br>Requirements for Collection, Storage, and Maintenance of Quality Assurance Records for Nuclear Power Plants<br><br>Applicability: Applicable with the following exceptions:<br><br>1) The FRA-ANP vault at Richland has no provision for drainage, as recommended by Section 5.6 (6); however, there is no credible mechanism (e.g., sprinkler system) for entry of water into the vault. Lynchburg maintains duplicate storage of lifetime QA Records in remote locations.<br><br>2) Calibration records are maintained in the calibration laboratory as these are not subject to vault storage until reasonable time after fuel shipment.<br><br>3) Quality Control records and procurement records need not be transferred to vault storage.<br><br>4) Radiographs of fuel assembly components are not retained as QA Records. Results of the review are recorded on Inspection Report and/or routing cards and these are saved as lifetime QA Records.<br><br>5) The requirements of Section 5 do not apply to nonpermanent QA Records. Retention times are established for these records and they are maintained by designated organizations. |



| APPLICABILITY OF ANSI STANDARDS AND REGULATORY GUIDES |   |   |
|---|---|---|
| ITEM NO.  | DOCUMENT NUMBER & DATE  | SUBJECT AND APPLICABILITY   |
| 7.  | Reg. Guide 1.144<br>(Rev. 1, Sept. 1980)<br><br>ANSI N45.2.12-1977  | <p>Auditing of Quality Assurance Programs for Nuclear Power Plants</p> <p>Applicability: Applicable with the following exceptions:</p> <p>1) With respect to the annual audit frequency requirements of Paragraph 3.5.2, the term "Applicable elements..." is interpreted within the following context. FRA-ANP conducts comprehensive internal QA Audits of important quality functional areas. Each functional area audit may address implementation of one or more of the QA Program criteria (elements) applicable to the area. Each QA Program criterion is audited at least once every three years during the performance of functional area audits. The basis for this frequency is the considerable QA involvement in support of customer program audits which occur numerous times yearly. In determining the audit scope and frequency, an evaluation of the area being audited is performed. The evaluation may include some or all of the following: prior quality assurance program audits, results of audits from other sources, assessment by FRA-ANP lead auditors during their support for utility oversight activities, nature and frequency of identified discrepancies, significant changes in the organization or quality assurance program, and the corrective actions taken to correct discrepancies.</p> <p>External (Supplier) audits are regularly scheduled on the basis of supplier performance and importance to safety of the activities being performed. Audit frequency of suppliers, normally between one and three years, may be altered (increased or decreased) based on an annual evaluation of the supplier's quality assurance program, history of performance, and implementation of that program. This evaluation considers the complexity of the system or component concerned and the degree of quality and process control required by the manufacturing effort.</p> <p>As an exception to the foregoing, audits of suppliers are not necessarily performed for procurement actions where acceptance of the product is in accordance with Section 10.3.2 of ANSI N45.2.13 - 1976.</p> <p>In the case of both internal and external audits, audit frequency is adjusted, as necessary, from these requirements depending on the importance and status of the organization/area being audited.</p> <p>2) Concerning Paragraph 4.5.2.1, a written reply to the audit report is obtained only if required by the audit report or the audit report transmittal. Written responses to individual adverse findings (Corrective Action Requests) are obtained in accordance with Paragraph 4.5.1.</p> |
| 8.  | Reg. Guide 1.123<br>(Rev. 1, July 1977)<br><br>ANSI N45.2.13 - 1976 | <p>Quality Assurance Requirements for Control of Procurement Items and Services for Nuclear Power Plants</p> <p>(Same title as Reg. Guide 1.123.)</p> <p>Applicability: Fully applicable.</p>   |



| APPLICABILITY OF ANSI STANDARDS AND REGULATORY GUIDES |   |   |
|---|---|---|
| ITEM NO.  | DOCUMENT NUMBER & DATE                                    | SUBJECT AND APPLICABILITY   |
| 9.  | Reg. Guide 1.146<br>Aug. 1980<br><br>ANSI N45.2.23 - 1978 | Qualification of Quality Assurance Program Audit Personnel for Nuclear Power Plants<br><br>(Same title as Reg. Guide 1.146.)<br><br>Applicability: Applicable with the following exception:<br><br>Calibration and lab services supplier audits may be performed by QC auditors, rather than QA auditors, due to the specialized and limited scope of these audits. QC auditors are appropriately trained and qualified in accordance with approved procedures, but are not required to be formally designated Lead Auditors, as defined by ANSI N45.2.23.            |
| 10.   | ANSI N14.1 (1995)   | Uranium Hexafluoride Packaging for Transport<br><br>Applicability: Fully applicable.  |
| 11.   | ASME Section VIII   | Applicability: Repairs or rework that require welding and inspection of 30B cylinders shall be performed in accordance with National Board Inspection Bureau (NBIB) "R" stamp requirements. Weld operators shall be certified in accordance with AWS D1.1 requirements and be employed by a NBIB "R" certificate holder. The FRA-ANP designated welding engineer shall review weld procedures, procedure qualification records, welding operator qualifications, and rework travelers prior to weld operations. Weld inspectors shall be National Board Commissioned. |

**Appendix III**

**Matrix Chart of FRA-ANP QA Program and  
 QA Procedures Related to QA Criteria**

| 10 CFR 50, APPENDIX B / 10 CFR 71<br>QA CRITERIA |   | FRA-ANP                    |
|--|---|----------------------------|
|  |   | QA PROCEDURES<br>By Number |
| I / 71.103                                       | Organization                                      | QAP #1                     |
| II / 71.101<br>& 105                             | QA Program  | All Listed QA Procedures   |
| III / 71.107                                     | Design Control                                    | QAP #4                     |
| IV / 71.109                                      | Procurement Document Control                      | QAP #6                     |
| V / 71.111                                       | Instructions, Procedures, and Drawings            | All Listed QA Procedures   |
| VI / 71.113                                      | Document Control                                  | QAP #5                     |
| VII / 71.115                                     | Control of Purchased Material                     | QAP #6<br>QAP #7           |
| VIII / 71.117                                    | Identification and Control of Materials and Parts | QAP #8                     |
| IX / 71.119                                      | Control of Special Processes                      | QAP #9                     |
| X / 71.121                                       | Inspection  | QAP #10                    |
| XI / 71.123                                      | Test Control                                      | QAP #10                    |
| XII / 71.125                                     | Calibration of Equipment                          | QAP #11                    |
| XIII / 71.127                                    | Handling, Storage, and Shipping                   | QAP #15                    |
| XIV / 71.129                                     | Inspection, Testing, and Operating Status         | QAP #12                    |
| XV / 71.131                                      | Nonconforming Material                            | QAP #13                    |
| XVI / 71.133                                     | Corrective Action                                 | QAP #14                    |
| XVII / 71.135                                    | QA Records  | QAP #16                    |
| XVIII / 71.137                                   | Audits  | QAP #17                    |