

ENCLOSURE 1

TOPICAL REPORT

FRA - QP/85 0782 NP

FRAMATOME QUALITY ASSURANCE PROGRAM

(FOR UNITED STATES APPLICATIONS)

8510020278 850916
PDR TOPRP EMVFRAMA
C PDR

ENCLOSURE 1

TOPICAL REPORT

FRA - QP/85 0782 NP

FRAMATOME QUALITY ASSURANCE PROGRAM

(FOR UNITED STATES APPLICATIONS)

A B S T R A C T

This Topical Report, submitted by FRAMATOME et Cie, Paris, France, describes that Company's Quality Assurance Program as it will be applied to products and services provided in the United States. The report, which is similar in scope and content to equivalent reports by U.S. NSSS vendors, includes a discussion of the FRAMATOME QA program organization, a point-by-point discussion of compliance with the 18 criteria of 10 CFR Part 50, Appendix B, and a comparison of the program with applicable Regulatory Guides. There are no significant exceptions or deviations from NRC regulations or associated guidance.

TABLE OF CONTENTS

<u>Section</u>	<u>Page</u>
FOREWORD	2
1. ORGANIZATION	3
2. QUALITY ASSURANCE PROGRAM	5
3. DESIGN CONTROL	6
4. PROCUREMENT DOCUMENT CONTROL	7
5. INSTRUCTIONS, PROCEDURES, AND DRAWINGS	8
6. DOCUMENT CONTROL	8
7. CONTROL OF PURCHASED MATERIAL, EQUIPMENT, AND SERVICES	9
8. IDENTIFICATION AND CONTROL OF MATERIALS, PARTS, AND COMPONENTS . .	10
9. CONTROL OF SPECIAL PROCESSES	10
10. INSPECTION	10
11. TEST CONTROL	11
12. CONTROL OF MEASURING AND TEST EQUIPMENT	12
13. HANDLING, STORAGE, AND SHIPPING	12
14. INSPECTION, TEST, AND OPERATING STATUS	13
15. NON-CONFORMING MATERIALS, PARTS, OR COMPONENTS	13
16. CORRECTIVE ACTION	13
17. QUALITY ASSURANCE RECORDS	14
18. AUDITS	14
TABLE 1 - FRAMATOME POSITIONS ON REGULATORY GUIDES AND INDUSTRY STANDARDS	
FIGURE 1 - FRAMATOME ORGANIZATION FOR UNITED STATES APPLICATIONS	
FIGURE 2 - TYPICAL MANUFACTURING FACILITY ORGANIZATION	

TOPICAL REPORT
FRAMATOME QUALITY ASSURANCE PROGRAM
(FOR UNITED STATES APPLICATIONS)

FOREWORD

This Topical Report describes the Quality Assurance (QA) program of FRAMATOME applicable to design, construction and maintenance activities affecting the quality of all quality related products and services* provided directly by FRAMATOME to users in the United States. The program described in this Topical Report will be implemented by FRAMATOME for these products and services and it will be the policy of FRAMATOME to comply with the requirements of 10 CFR 50, Appendix B when supplying such products or associated services. The purpose of this Topical Report is to establish that FRAMATOME has a quality assurance program capable of producing and delivering products and services which comply with U.S. regulations, as such products and services are required by U.S. customers.

All orders for quality related products and services will be processed through the FRAMATOME order entry channels. Items supplied by any FRAMATOME organizational element will be controlled through the procurement control systems described in this Topical Report. These procurement control systems provide mechanisms to impose appropriate quality requirements upon the supplying organization(s).

Changes to the commitments contained in this Topical Report will be submitted to the NRC for approval. Changes that may reduce the commitments contained herein will be submitted for approval prior to implementation, other changes will be submitted for approval within 90 days of the change.

* Any products or services for U.S. supply which are "Q" listed by the user and duly identified as such, or for which fully equivalent QA requirements are mandated by contract. Although FRAMATOME may or may not apply the same QA program for individual non-U.S. products or services, all products or services for U.S. application will be separately identified and will be manufactured or performed, and will be quality assured, by personnel certified in U.S. requirements. All required QA records (per ANSI/ASME NQA - 1) will be in English.

1. ORGANIZATION

Within FRAMATOME, Nuclear Operations is responsible for carrying out all U.S. nuclear orders received.

The authority and responsibility of each organizational element shown in Figures 1 and 2 are established by the President of FRAMATOME.

The Quality Committee is a special group within the Corporate Quality organization, which is responsible for annually assessing that the quality policy established by the President is implemented properly by all organizational elements.

Nuclear Operations is responsible for the design, procurement, surveillance, testing and maintenance of quality related products and services and for control of technical interfaces between the user, its agents and FRAMATOME suppliers.

International Operations is the FRAMATOME Commercial Organization and coordinates all calls for bids or contracts received from a U.S. customer. Management of these bids and contracts is performed either by the International Operations or by an Operating Division (i.e. Maintenance, Manufacturing). The organization in charge is responsible for interfaces between FRAMATOME and its customers. Manufacturing facilities of FRAMATOME, which report to Industrial Operations are responsible for manufacturing components ordered by Nuclear Operations, which controls them through the procurement control system.

The Nuclear Operations Executive Vice-President and the Managers of manufacturing facilities are responsible for establishing and implementing a quality assurance program that meets the requirements of this Topical Report.

Although organizationally within Nuclear Operations, the Quality Division also has jurisdiction over International Operations and Industrial Operations for quality matters. The President has assigned to the Director of the Quality Division, the authority for enforcement of this program within International Operations.

Within Nuclear Operations and within each manufacturing facility, responsibility for documenting the QA program is assigned to the Quality Manager who is sufficiently free from direct pressures for cost and schedule and has the authority to stop unsatisfactory work or otherwise control further processing, delivery or installation of non-conforming materials.

The Quality Manager has access, as necessary, to higher management levels to assure the ability to identify quality problems, to initiate, recommend or provide solutions through designated channels, and to verify implementation of solutions.

This QA management position has the following characteristics:

- a) It has direct access to the highest level Manager in the organizational element or facility involved on all quality related issues.
- b) It has effective communication channels with other senior management positions.
- c) It has responsibility for approval of Quality Assurance Manual(s).
- d) It has no other responsibilities unrelated to quality assurance that would divert the Quality Manager's attention from quality assurance matters.

The minimum qualification requirements for the Quality Manager are:

- a) Graduation equivalent to bachelor's degree in a technical field.
- b) At least ten (10) years experience in engineering or manufacturing with at least one of these years in a quality assurance organization (or equivalent).
- c) At least five (5) years management experience through assignment in responsible positions commensurate with this position.
- d) Knowledge of applicable quality-related codes, standards, and regulatory and statutory requirements.
- e) Demonstrated ability to prescribe, apply, and assess compliance with applicable requirements.

Figures 1 and 2 provide the general organizational commitments of FRAMATOME for the supply of quality related products and services. FRAMATOME will keep the NRC informed of changes that impact these organizational commitments.

Functional organizations within FRAMATOME are also responsible for performing activities that assure the quality of quality related products and services.

Functional organizations typically have responsibilities as follows.

- a) Engineering groups are responsible for performing the various technical functions associated with the design and specification of quality related products and services and for technical follow-up of the remainder of the design cycle at item suppliers.
- b) Engineering groups are also responsible for providing applicable safety analyses. The control of design interfaces among the various engineering groups is described in Section 3.

- c) Project groups are responsible for the coordination of items supplied to the user. These groups serve as the prime interface between FRAMATOME and the user.
- d) Manufacturing groups are responsible for the manufacture, construction, testing and/or servicing of quality related products and services. This responsibility includes material control, generation and control of manufacturing data, product planning and control, manufacturing functions, process qualification, and control and qualification of personnel.
- e) QA groups are responsible for performing verification of implementation of the QA program and reporting the degree of compliance to management in order to provide necessary information to assure that the QA program is established and effective.
- f) QA activities in each area (those covered by the Engineering, Manufacturing Facility, or Maintenance QA Manual) include review of documents, service surveillance, audit of suppliers, performance of inspections and examinations, recording of results, preparation of documentation associated with the release of products, schedule of and participation in internal audits, and the development and maintenance of specific QA program documents.

2. QUALITY ASSURANCE PROGRAM

The program described herein is applied to activities affecting quality related products and services and other items when required by the customer.

This Topical Report describes the commitments of FRAMATOME to all quality assurance related Regulatory Guides with those variations as shown in Table 1.

FRAMATOME Nuclear Operations and the Le Creusot and Saint Marcel Manufacturing Facilities comply with the requirements of 10 CFR 50.55a. As applicable, ASME Code requirements are supplemented with the guidance of the Regulatory Guides as per Table 1. FRAMATOME also is committed to compliance with 10 CFR 50.55(e) by reporting, as necessary, to NRC Licensees which it either has provided or is providing products or services.

FRAMATOME Nuclear Operations and each Manufacturing Facility involved in supplying quality related products and services have QA programs and procedures which describe their compliance with the commitments of this Topical Report and provide for special equipment, environmental conditions and processes as necessary.

These programs and procedures are documented and controlled as described in Section 6. They are reviewed by the QA organization and are made mandatory by the President.

FRAMATOME management is responsible for the review of the status and adequacy of the QA programs within Nuclear Operations and at the Manufacturing Facilities and for compliance with the commitments of this Topical Report and the requirements of 10 CFR 50, Appendix B. Reviews performed by the Quality Committee are documented in a report that describes the Committee activities and meetings and the performance and results of an annual assessment of the QA programs, including corrective action identification and follow-up.

Personnel performing inspection, testing, examination and audit activities are qualified and the qualification is documented. Personnel qualification includes documentation of capability either through the use of formal written tests or through physical demonstration of skills. Maintenance of proficiency is based on continuing satisfactory performance or retraining. Qualification requirements include specific provisions for education and/or experience. Documentation in the form of certificates of qualification or other similar records include the activities the individual is qualified to perform and the basis used for certification.

All personnel performing and verifying quality affecting activities are trained. This training includes indoctrination to the requirements of the applicable QA programs and provides for training required for the performance of special activities. This training is documented.

3. DESIGN CONTROL

FRAMATOME has established measures to correctly translate applicable regulatory requirements and design bases into design, procurement and procedural documents. This design control program is applied to design activities for quality related products and services. All design documents include appropriate quality standards.

As described in Section 1, engineering groups within Nuclear Operations and Manufacturing Facilities are responsible for the preparation, review, approval and verification of design documentation. Identified errors in approved design documents are documented and corrected.

Design interface controls are established in procedures, instructions and formal agreements. These controls include a description of the responsibilities of the affected parties for the review, approval, release, distribution, and revision of design documents that involve multiple design organizations, including the user or its agent.

Technical drawings and specifications are used to specify technical and quality requirements for equipment. They are reviewed to verify their accuracy and completeness. These specifications are also reviewed by Quality Assurance representatives to assure that they include proper quality, inspection, test, and documentation requirements.

Design verification is performed using one or more of the following verification methods: design review, alternate calculation and/or qualification testing. The design verification method is selected based on the complexity of the design and on the type of design document. It is performed by individuals or groups other than those who performed the original design. When the designer's supervisor is the only available technically qualified person, the supervisor will perform the design verification. In those cases, the justification is documented and approved in advance by the supervisor's management. Design verification (other than qualification testing) may be deferred provided the justification is documented and the status of affected design documents is clearly identified.

Qualification tests may be used to verify portions of a design together with other verification methods. They are performed under conditions that simulate the most adverse design conditions.

Procedures identify the verifier's responsibilities, areas and pertinent considerations to be verified, and the required documentation.

Computer codes used in design are verified and their use is controlled. Procedures prescribe requirements for computer code development, verification, determination of applicability to the problem, certification for use, configuration control, and documentation.

Written procedures control design changes, including field changes and identified design deficiencies. The design change controls assure that the level of control and organizational involvement is commensurate with that for the original design.

4. PROCUREMENT DOCUMENT CONTROL

Technical and quality requirements applicable to the procurement of quality related products and services are specified in procurement documents. The quality requirements include supplier QA program requirements, requirements for access to the supplier's facility, requirements for documentation, and requirements for non-conformance control. Generally, technical and/or quality requirements are specified by reference to technical specifications and/or other documents. These documents are controlled as described in Sections 3, 5 and 6. Procurement documents are developed based on input from requisitioners and are reviewed and approved by the involved engineering and quality assurance groups. This includes review to assure that quality requirements are correctly specified, including adequate acceptance and rejection criteria, and that the procurement documents have been prepared, reviewed and approved in accordance with quality assurance procedures. Spare or replacement parts are procured in accordance with requirements equal to or better than the original requirements.

Procurement is from approved suppliers. Suppliers are approved as described in Section 7.

5. INSTRUCTIONS, PROCEDURES, AND DRAWINGS

Activities affecting quality of quality related products and services are performed in accordance with documented instructions, procedures or drawings which include appropriate quantitative and qualitative means of verifying quality. Required actions and responsibilities for preparation, review, approval and control of these documents are established in procedures or instructions.

6. DOCUMENT CONTROL

Measures for the review, approval and issuance of documents covering quality related products and services and changes thereto are established internally to assure technical adequacy and inclusion of appropriate quality requirements prior to implementation. These measures include responsibilities for required independent reviews by qualified individuals for quality provisions. In addition, these procedures provide a means to assure that:

- a) The proper document revisions are used.
- b) Obsolete or superseded documents are controlled to prevent inadvertent use.
- c) Controls are performed for document changes.
- d) Individuals or groups responsible for reviewing, approving, and issuing documents and revisions thereto are identified.
- e) Review and approval of changes are performed by organizations which originally reviewed/approved the document or by a designated alternate organization.
- f) Approved changes are included in instructions, procedures, drawings, and other documents prior to implementation of the change.
- g) Documents are available at the location where the activity will be performed prior to commencing the work.

Document control activities also include provisions for the use and availability of master lists and/or tables of contents to identify the current revisions of documents.

Document control is applied to design, procurement and non-conformance documents including as-built documents and documents related to computer codes, as well as to instructions and procedures. Topical Reports and other required regulatory documents are controlled as described in this section.

7. CONTROL OF PURCHASED MATERIAL, EQUIPMENT, AND SERVICES

When specified in its procurement documents (see Section 4), FRAMATOME provides for QA surveillance of suppliers during fabrication, inspection, testing and release of quality related products and services.

For complex items, established quality standards provide planned guidance for surveillance activities. Where no pre-established quality standards exist for a specific supplier, the specific technical requirements of the procurement documents are used as the basis for surveillance. The degree of surveillance varies with the degree of importance of equipment, supplier performance and complexity of items.

Prior to placing an order with a new supplier, a survey or evaluation is conducted by quality assurance engineers and, as appropriate, engineering and/or purchasing. The results of these surveys or evaluations, including identified deficiencies, are documented and reported to management. These surveys or evaluations verify that the supplier is capable of complying with the quality requirements of the procurement documents. Deficiencies are resolved with the supplier prior to start of fabrication. Periodically, suppliers are reaudited to verify continued acceptable compliance with procurement document requirements.

In some cases a FRAMATOME organization may procure a product or service from another FRAMATOME organizations. Review of these FRAMATOME organizations' QA programs is performed by members of the Quality Committee and results are used as the basis for approval by the procuring organization.

For items shipped to a FRAMATOME manufacturing facility, receiving or source inspection is performed to verify that the item and specified documentation comply with the procurement requirements. The status is identified on or traceable to the item.

For items shipped to a site, quality assurance personnel issue a quality release. The quality release is a document which includes specific information identifying the item and the applicable procurement documents, and which certifies that the item meets all procurement requirements, including documentation requirements. The quality release includes identification of any approved deviations from the procurement requirements and is signed by an authorized person. Procedures identify the actions necessary to initiate, authorize, issue, distribute and revise quality releases. These procedures include provisions for review and acceptance of supplier furnished documentation (e.g. Certificates of Conformance, Certified Material Test Reports, Non-destructive Examination Reports) and for identifying and following-up contingent conditions that require additional action after delivery to the power plant site. Contingent conditions are monitored and their closing-out is documented.

8. IDENTIFICATION AND CONTROL OF MATERIALS, PARTS, AND COMPONENTS

Identification requirements are established in QA programs and are specified in the procurement documents for quality related products and services.

These requirements take into consideration the location and the method of identification so that the fit, function, or quality of the item being identified is not adversely affected.

Identification and control procedures assure that identification is maintained on the item or on records traceable to the item to preclude use of incorrect or defective items. Identification of items can be traced to appropriate documentation such as design documents, procurement documents and/or inspection records. Identification of items is verified and documented prior to release of the item for further use.

9. CONTROL OF SPECIAL PROCESSES

FRAMATOME has established procedures to maintain control over special processes for quality related products and services. This control includes the qualification of processes and personnel for welding and inspection in accordance with ASME requirements, non-destructive examination per SNT-TC-1A, and other processes which may be necessary for adequate control. Qualification records are maintained and are reviewed periodically for currency.

Special processes, such as welding, casting, heat treating, non-destructive examination, electro-mechanical machining, explosive forming, cleaning, and painting are prescribed by means of documented procedures. The special process procedures and certificates of qualified personnel are maintained under document control and record keeping systems. Special processes are performed by qualified personnel and accomplished in accordance with prescribed procedural controls. Recorded evidence of verification is maintained.

10. INSPECTION

FRAMATOME has established procedures that control fabrication activities of quality related products and services. These procedures control the selection and identification of required inspections, including mandatory hold points, and tests at significant points during manufacture, and provide for quality assurance personnel involvement in the selection process. Inspections for product acceptance are performed by personnel who are not responsible for the work being inspected. Inspection personnel are qualified. Their qualification is certified as described in Section 2.

Inspection procedures, instructions, and/or checklists and identified drawings and specifications include identification of characteristics and activities to be inspected, identification of the organizations (or individuals) responsible for the performance of the inspection, acceptance and rejection criteria, description of inspection methods, including special inspection equipment and accuracy requirements, and recording the inspector or the data recorder and the results of the inspection operation.

11. TEST CONTROL

FRAMATOME has established measures to control testing of quality related products and services. These measures include identification of required testing, development of procedures, a means of assessing the adequacy of tested items, and designation of responsibility for performing the various phases of testing activities.

Test procedures and/or associated instructions include:

- a) Methods and instructions for performing the test.
- b) Test prerequisites, such as calibrated instrumentation; adequate and appropriate equipment; trained, qualified, and licensed and/or certified personnel; preparation, condition, and completeness of the item to be tested; and suitable and, if required, controlled environmental conditions.
- c) Requirements and acceptance/rejection limits, by incorporation or reference.
- d) Mandatory inspection hold points for witness by owner, contractor, or inspector.
- e) Requirements for documenting test data and results.

These procedures and/or associated instructions may be provided in various controlled forms, such as test procedures, test specifications, drawings, process routing sheets, and test instructions.

Test results are documented, evaluated, and their acceptability determined by a qualified, responsible individual or group. Modifications, repairs, and replacements are tested in accordance with the original test requirements or appropriate alternatives.

12. CONTROL OF MEASURING AND TEST EQUIPMENT

FRAMATOME maintains means of controlling measuring and test equipment used on quality related products and services. The Manufacturing Facilities and the Maintenance Division have developed their own programs considering such attributes as inherent stability, purpose of use, desired accuracy, and degree of usage. Measuring and test equipment used for the acceptance and verification of quality of quality related products and services is maintained under control systems which identify the status of all measuring and test items. Typical of this equipment are micrometers, plug gages, hardness testers, etc. Documents detail the requirements for the calibration (including frequency and maintenance) of measuring and test equipment and the use of appropriately traceable measurement standards, and describe organizational responsibilities for establishing, implementing, and assuring effectiveness of the calibration program. When calibrating measuring and test equipment, typical transfer ratios of four to one are used. Exceptions may be necessary because of limitations in the state-of-the-art. Measuring and test equipment are identified and traceable to the calibration test data and for other required documentation. The complete status of all items under the calibration system, including personal acceptance gages, is recorded, maintained, and controlled. This calibration status is indicated on or traceable to the measuring and test equipment.

Procedures assure accuracies within established standards and include disposition and/or corrective measures when discrepancies are noted. Damaged or inaccurate measuring and test equipment is removed from use until repaired, recalibrated or replaced. Measures are taken and documented to determine the validity of previous inspections performed when measuring and test equipment is found to be out of calibration.

13. HANDLING, STORAGE, AND SHIPPING

FRAMATOME has established procedures to control cleaning, packaging, shipping, storage, and handling activities for quality related products and services. Where required, these activities are accomplished by appropriately trained individuals.

These procedures include control of cleaning, handling, storage, packaging, shipping, and preservation of materials, components, and systems in accordance with design specification requirements to preclude unacceptable damage, loss, or deterioration by environmental conditions. The identified controls include considerations for identification of inspection, use, personnel training and qualification, auditing, non-conformances, and other appropriate requirements. These procedures may be in various formats, such as manufacturing procedures, shipping instructions, drawings, manufacturing routing sheets, cleaning process specifications, and procedural training booklets.

14. INSPECTION, TEST, AND OPERATING STATUS

FRAMATOME has established procedures to indicate inspection, test and operating status of quality related products and services during fabrication, installation and testing. These procedures control the application and removal of status indicators through the use of inspection control cards, shop travelers or other documents. Those procedures also control sequence changes and the identification of non-conforming items (see Section 15).

15. NON-CONFORMING MATERIALS, PARTS, OR COMPONENTS

FRAMATOME has established procedures to control the identification, documentation, segregation, review and disposition of non-conforming quality related products and services. They include notification to affected organizations if disposition is other than scrap. These procedures identify individuals or groups who are authorized to disposition and approve non-conformances and describe the segregation and/or control of non-conforming items to prevent inadvertent use.

Documentation identifies the non-conforming items, describes the non-conformance, the disposition of the non-conformance, including re-inspection requirements, and includes documented approval of this disposition. When non-conforming items are repaired or otherwise made suitable for their designed use, they are inspected and tested in accordance with the original inspection and test requirements or acceptable alternatives.

16. CORRECTIVE ACTION

FRAMATOME has established procedures that provide for corrective actions for quality related products and services. These procedures include the initiation and documentation of corrective actions to preclude recurrence of significant conditions adverse to quality. Implementation of corrective action is verified by responsible individuals or organizations, and verification is documented to close out the corrective actions. In the case of corrective actions resulting from non-conformance reports and audit reports (or similar reports such as NRC inspection reports or customer audit reports) the quality assurance organization participates in verifying that appropriate corrective actions are implemented.

For significant conditions adverse to quality, the cause and corrective actions taken are documented and reported to management, including upper management, for review. Non-conformance reports are generated as described in Section 15. These non-conformance reports are reviewed to determine the need for corrective action and are analyzed for trends. The results of these trend analyses are provided to upper management.

17. QUALITY ASSURANCE RECORDS

FRAMATOME, as appropriate, has established procedures to provide for the generation, maintenance, retention, and use of quality assurance records related to quality related products and services. Records procedures control those design, fabrication and inspection records essential to demonstrate product quality. They indicate responsibility for indexing, distribution, identification, classification, retrieval, and retention of quality assurance records. Long term retention of quality assurance records is accomplished by single copy records at the FRAMATOME Records Center.

When required by contract, records are forwarded to the user for retention.

18. AUDITS

FRAMATOME has established procedures that provide a comprehensive system of quality assurance program audits of activities affecting the quality of quality related products and services. Audits are performed by qualified audit personnel using written procedures or checklists designed to provide an objective evaluation of the quality assurance program and its effective implementation. Auditors are independent of the group or function being audited. A written report that documents the audit results and required corrective action is prepared and distributed to management. Verification of corrective action (including re-audit of deficient areas, where appropriate) is performed and documented.

Audits are regularly scheduled and include the full scope of quality-related activities within each organization having a QA Manual conforming to the requirements of this Topical Report. For internal audits, the audit schedule provides for audits of quality-related activities at least once a year or once within the life of the activity, whichever is shorter. For vendor audit scheduling, see Section 7.

TABLE 1

FRAMATOME POSITIONS ON REGULATORY GUIDES AND INDUSTRY STANDARDS

+++++

Regulatory Guide 1.8, Rev. 1-R and ANSI N3.1-1978
Personnel Selection and Training

FRAMATOME follows the NRC Regulatory Position for personnel involved.

+++++

Regulatory Guide 1.26, Rev. 3
Quality Group Classifications and Standards for Water-Steam-and
Radioactive-Waste-Containing Components of Nuclear Power Plants

As an alternative FRAMATOME follows the provisions of ANSI N18.2 - 1973 and addendum N18.2-a-1975 for the quality classification for nuclear power plant components.

+++++

Regulatory Guide 1.28, Rev. 2 and ANSI/ASME N4⁵.2 -1977
Quality Assurance Program Requirements (Design and Construction)

FRAMATOME follows the NRC Regulatory Position.

+++++

Regulatory Guide 1.29, Rev.3
Seismic Design Classification

FRAMATOME follows the NRC Regulatory Position.

+++++

Regulatory Guide 1.30, Rev. 0 and ANSI N45.2.4-1972
Quality Assurance Requirements for the Installation, Inspection
and Testing of Instrumentation and Electric Equipment

FRAMATOME follows the NRC Regulatory Position.

+++++

Regulatory Guide 1.33, Rev. 2 and ANSI N18.7 - 1976/ANS-3.2
Quality Assurance Program Requirements (Operation)

FRAMATOME follows the NRC Regulatory Position.

+++++

Regulatory Guide 1.37, Rev. 0 and ANSI N45.2.1-1973
Quality Assurance Requirements for Cleaning of Fluid Systems
and Associated Components of Water-Cooled Nuclear Power Plants

FRAMATOME follows the NRC Regulatory Position for site activities.

+++++

Regulatory Guide 1.38, Rev. 2 and ANSI N45.2.2-1972
Quality Assurance Requirements for Packaging, Shipping, Receiving,
Storage and Handling of Items for Water-Cooled Nuclear Power Plants

FRAMATOME follows the Regulatory Position with the following clarifications and alternative.

REG. GUIDE/ANSI STD. PARAGRAPH

FRAMATOME POSITION

1. Qualification of Personnel

(Section 2.4)

"Those personnel who perform inspection, examination or testing activities at the job site shall be qualified in accordance with N45.2.6"

Clarification

These requirements apply to FRAMATOME personnel performing inspection, examination or testing activities on site.

When these activities are subcontracted FRAMATOME identifies requirements to suppliers in its procurement documents.

REG. GUIDE/ANSI STD. PARAGRAPH

FRAMATOME POSITION

Requirements of ANSI N45.2.6 apply to personnel performing complicated functions such as the assembly/disassembly of equipment, acceptance testing, non-destructive examination, etc. However, these personnel qualification requirements need not be applied to personnel performing simple functions such as warehousing, visual inspections, etc.

REG. GUIDE/ANSI STD. PARAGRAPH

FRAMATOME POSITION

2. Receiving (Section 5)
Requirements for receiving
contained in Section 5.

Clarification

FRAMATOME follows this section for
those portions of site activities
within its scope of supply.

3. Storage (Section 6)
Requirements for storage
contained in Section 6.

Clarification

FRAMATOME follows this section for
those portions of site activities
within its scope of supply.

4. Handling (Section 7)
Requirements for handling
contained in Section 7.

Alternative

FRAMATOME and its suppliers use
conservative practices for
controlling the lifting and
moving of completed components
during packaging and shipping
operations.

+++++
Regulatory Guide 1.39, Rev. 2 and ANSI N45.2.3-1973

Housekeeping Requirements for Water-Cooled Nuclear Power Plants

FRAMATOME follows the NRC Regulatory Position with the following alternative.

Whenever FRAMATOME is involved in on-site activities, such as a major maintenance operation, FRAMATOME will conform to its usual rigorous housekeeping practices in the area of its activity, and will conform to the housekeeping requirements established for that activity by the U.S. customer; however, FRAMATOME will not be responsible for adherence to the Regulatory Position with respect to general site or general plant requirements not directly related to the limited area involved in performing its contracted specific activity.

+++++

Regulatory Guide 1.58, Rev. 1 and ANSI/ASME N45.2.6-1978
Qualification of Nuclear Power Plant Inspection,
Examination, and Testing Personnel

FRAMATOME follows the NRC Regulatory Position with the following clarification and alternative.

REG. GUIDE/ANSI STD. PARAGRAPH

FRAMATOME POSITION

1. Levels of Capability

(Regulatory Position C.6)

"6. Section 3.5, "Education and Experience-Recommendations", of ANSI N45.2.6-1978 states that the education and experience specified are recommendations and that other factors may provide reasonable assurance that a person can competently perform a particular task. The set of recommendations has been reviewed by the NRC staff and found to be acceptable with one exception. In addition to the recommendations listed under Section 3.5 for Level I, II and III personnel, the candidate should be a high school graduate or have earned the General Education Development equivalent of a high school diploma. Since only one set of recommendations is provided for the education and experience of personnel, a commitment to comply

Alternative

Within FRAMATOME the specific level designations for personnel involved in inspection, examination, and testing activities may not be used. A combination of position descriptions and pre-determined qualification requirements for a position define the level of capability required to perform the function. These methods are used to identify levels of capability that include the comparable requirements of the levels identified in this standard.

The French education system is the reference base for evaluating the general education level required.

REG. GUIDE/ANSI STD. PARAGRAPH

FRAMATOME POSITION

with the regulatory positions of this guide in lieu of providing an alternative to the recommendations of the standard means that the specified education and experience recommendations of the standard will be followed".

2. Document Objective Evidence

(Regulatory Position C.10)

"10. Section 2.2, "Determination of Initial Capability", and Section 2.3, "Evaluation of Performance", of ANSI N45.2.6-1978 dealt with the use of evaluation of job performance and determination of initial capability to perform the job. Use of the measures outlined in these sections to establish that an individual has the required qualifications in lieu of required education and experience should result in documented objective evidence (i.e., procedures and record of written test) demonstrating that the individual indeed does have "comparable" or "equivalent" competence to that which would be gained from having the required education and experience".

Clarification

Each record or certificate of qualification includes, in definitive terms, the activities the individual is qualified to perform and the basis used for certification. Personnel are formally qualified for the tasks they are assigned to perform. FRAMATOME evaluates the adequacy of the personnel qualification programs through its audit and/or surveillance activities.

+++++

Regulatory Guide 1.64, Rev. 2 and ANSI N45.2.11-1974
Quality Assurance Requirements for the Design of Nuclear
Power Plants

FRAMATOME follows the NRC Regulatory Position with the following clarifications, alternative, and exception.

REG. GUIDE/ANSI STD. PARAGRAPH

FRAMATOME POSITION

1. Supervisory Design Verification

(Regulatory Position C2)

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

Alternative

Within FRAMATOME, the designer's immediate supervisor may perform design verification in exceptional cases when the supervisor is the only qualified individual available. In each case when the designer's immediate supervisor performs the design verification, justification is documented and approved in advance by the supervisor's management. Additionally, the other provisions of this Regulatory Guide are satisfied, and during quality assurance audits, the frequency and effectiveness of the use of supervisors as design verifiers is reviewed to avoid abuse.



REG. GUIDE/ANSI STD. PARAGRAPH

FRAMATOME POSITION

2. Delegation of Responsibilities (Section 1.3)

"It is the responsibility of the plant owner and other organizations invoking this standard to identify the structures, systems, and components, and to specify the extent to which the provisions of this standard apply to such structures, systems, and components".

Clarification

FRAMATOME defines the extent to which suppliers are responsible for satisfying the requirements of ANSI N45.2.11. Additional specific quality assurance requirements are issued by FRAMATOME to the supplier for the definition and translation of design requirements, control of design interfaces, verification of designs, control of changes and deviations from the original design, and documentation of the design.

3. Transmittal of Information among External Design Interfaces (Section 5.1.3)

"Documents shall identify the positions and titles of key personnel in the communication channels and their responsibilities for decision-making, for resolution of problems, and for taking other action within the scope of this standard".

Clarification

The titles, responsibilities and authority of persons involved in the design process are defined in FRAMATOME by organization charts and internal procedures. These documents are available for audit but are not transmitted to external organizations. Various interface agreements are established among the FRAMATOME design departments and suppliers or customers to ensure the proper flow and control of design information among the participants, and are documented by corresponding procedures, memorandums of understanding or contract documents.

REG. GUIDE/ANSI STD. PARAGRAPH

FRAMATOME POSITION

4. Documentation of Design Verification (Section 6.1, Paragraph 3)
"The results of design verification efforts shall be clearly documented, with the identification of the verifier clearly indicated thereon, and filed".

Clarification

For design verification activities performed within FRAMATOME the signature of a responsible reviewer may be used to document and substantiate the performance of the verification activity when authorized by the quality assurance program.

5. Auditing of Design Verification (Section 6.1, Paragraph 3)
"Documentation of results shall be auditable against the verification methods identified by the responsible design organization".

Clarification

Design verification requirements and methods within FRAMATOME are identified in internal procedures. The design verification process is audited against internal procedures and regulatory requirements to assure that appropriate design verification methods are used. These methods of verification, however, are not necessarily specified in advance, since different methods can be used for individual applications.

6. Editorial Changes to Design Documents (Section 7.2)
"However, minor changes to design documents, such as inconsequential editorial corrections or changes to commercial terms and conditions, may not require that the revised document receive the same review and approval as the original documents. To avoid a possible omission of a required review, the type of

Exception

When an editorial or commercial change is made in a design document, the change is approved by designated responsible authorized personnel. These types of changes do not require any additional review. However, revised approved documents are distributed to the appropriate quality assurance personnel who may verify that their review was not required.



REG. GUIDE/ANSI STD. PARAGRAPH

FRAMATOME POSITION

minor changes which do not require such a review and approval and the persons who can authorize such a decision shall be clearly delineated in the document control procedures."

+++++

Regulatory Guide 1.74, Rev. 0 and ANSI/ASME N45.2.10-1973
Quality Assurance Terms and Definitions

FRAMATOME follows the NRC Regulatory Position.

+++++

Regulatory Guide 1.88, Rev. 2 and ANSI N45.2.9-1974
Collection, Storage and Maintenance of Nuclear Power
Plant Quality Assurance Records

FRAMATOME follows the NRC Regulatory Position with the following clarifications and alternatives.

REG. GUIDE/ANSI STD. PARAGRAPH

FRAMATOME POSITION

1. Definition of a Quality Assurance Record (Section 1.4)
"Quality Assurance Records - Those records which furnish documentary evidence of the quality of items and of activities affecting quality. For the purposes of this standard a document is considered a quality assurance record when the document has been completed."

Alternative

A manufacturing document is considered a quality assurance record, and thus requires protection, at the time of product shipment. During the period from receipt or generation of the record until it is incorporated in the long-term protection system, these documents are afforded protection by normal office procedures, and

REG. GUIDE/ANSI STD. PARAGRAPHFRAMATOME POSITION

duplicate copies of completed records (signed and issued for use) are maintained in different locations in the same building. Records lost during this period will be reconstructed.

2. Completion of Quality Assurance Records (Section 3.2.1)

"All such quality records shall be legible, completely filled out and adequately identified to the item involved".

Alternative

Procedures identify requirements and provide guidance for completing quality assurance records. These procedures require that applicable portions of these records be completed. It should be recognized that in all cases it is not appropriate to "completely fill out" all records, particularly for those records completed on pre-printed forms.

3. Indexing of Quality Assurance Records (Section 3.2.2)

"The quality assurance records shall be listed in an index".

Clarification

More than one index for quality assurance records to provide necessary access and retrievability may be maintained. This practice is utilized as an alternative to a single index for all quality assurance records.

4. Permanent Storage Facility (Section 5.6)

"Where a single records storage facility is maintained, at least the following features should be contained in its construction:

Clarification

All records except supplier drawings are kept in a FRAMATOME storage facility which meets ANSI requirements. Supplier drawings are stored in an external facility belonging to a National Organization responsible for storage of French Industrial documents. This facility has been audited and approved by FRAMATOME.

REG. GUIDE/ANSI STD. PARAGRAPHFRAMATOME POSITION

Concrete floor and roof with sufficient slope for drainage; if a floor drain is provided a check valve (or equal) shall be provided.

Alternative (For supplier drawings)
Floor and roof drains are not necessary. The rooms used for FRAMATOME document storage are located at the first (uppermost) basement level; the building has five basement levels and only the fifth, or lowest one, is near the water table, and a pumping system, for which emergency power is provided from a special diesel group, is used to eliminate any water that may possibly collect at that level.

Adequate fire protection systemClarification

A series of smoke detectors is located throughout the storage facility and would alert the security team. In addition, the alarm system, which will reverse the ventilation system, is tied into a central fire alarm board at the guard station. Fire extinguishers are located throughout the storage areas. Doors, frames and hardware are made of non-flammable materials.

REG. GUIDE/ANSI STD. PARAGRAPH

FRAMATOME POSITION

No pipes other than those providing fire protection to the storage facility are to be located within the facility."

Alternative (For supplier drawings)
One small pipe for evacuating used water is located in the ceiling, at the periphery of the room. Periodic tours are performed inside the room once a week to detect any leakage. Furthermore, the boxes containing the drawings are placed on metallic shelves, the lowest being 5 inches above the floor. Conservative analysis has shown that the periodicity of the surveillance tours will detect leakage water before it reaches the level of the boxes.

+++++

Regulatory Guide 1.94, Rev. 1 and ANSI N45.2.5-1974

- Quality Assurance Requirements for Installation, Inspection,
and Testing of Structural Concrete and Structural Steel
During the Construction Phase of Nuclear Power Plants

This Regulatory Guide is not applicable to the FRAMATOME scope of supply.

+++++

Regulatory Guide 1.116, Rev. 0-R and ANSI N45.2.8-1975
Quality Assurance Requirements for Installation, Inspection
and Testing of Mechanical Equipment and Systems

FRAMATOME follows the NRC Regulatory Position.

+++++

Regulatory Guide 1.123, Rev. 1 and ANSI N45.2.13-1976
Quality Assurance Requirements for Control of Procurement
of Items and Services for Nuclear Power Plants

FRAMATOME follows the NRC Regulatory Position with the following clarification and alternatives.

REG. GUIDE/ANSI STD. PARAGRAPH

FRAMATOME POSITION

1. Purchaser/Notification Points

(Regulatory Position C.6.b)

"Section 6.2 - The guideline concerning purchaser notification points as part of pre- and post-award activities".

Alternative

FRAMATOME identifies notification points in supplier documents when applicable. Such points are not always identified in pre- and post-award meetings. However, the required notification/hold points are specified on the quality plan required from the supplier before authorizing the supplier to start manufacturing activities.

REG. GUIDE/ANSI STD. PARAGRAPH

FRAMATOME POSITION

2. Technical Requirements in Procurement Documents (Section 3.2.2)

"Technical requirements shall be specified in the procurement drawings, specifications, codes, regulations, procedures or instructions including revisions thereto that describe the items or services to be furnished".

Alternative

Technical requirements may be clarified or amended in a change notice "Notification with Acknowledgement of Receipt" and are not always specified "by reference" to other documents. This practice is used to specify unique or changing requirements which have not been routinely incorporated in the documents referenced in the purchase order.

REG. GUIDE/ANSI STD. PARAGRAPHFRAMATOME POSITION

3. Vendor Quality Assurance Program

Requirements (Section 3.2.3)

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

Clarification

Within FRAMATOME, standard hardware and catalog items and materials are procured to standard commercial terms and conditions. To assure that these items are of requisite quality, a certificate of compliance, source inspection, or receiving inspection may be required depending upon the use of these items in the manufacturing process. Additionally, the integrity of these types of items is verified through testing of the completed component.

This requirement for a documented quality assurance program is applicable to all other safety-related equipment.

4. QA Review of Procurement Documents

(Section 3.3)

"Bid Solicitation

"A review of the procurement documents shall be made to assure that documents transmitted to the prospective suppliers for bid... purposes include appropriate provisions to assure items or services meet the specified requirement".

Alternative

Within FRAMATOME, the process of soliciting bids and awarding a purchase order are separate tasks. The bid solicitation process is primarily considered a commercial function and, as such, is not subject to regulatory requirements in the same manner as a purchase order award. The FRAMATOME alternative for implementing the requirements of this section of ANSI N45.2.13 is described below for bid (request for quotation) activities.

REG. GUIDE/ANSI STD. PARAGRAPH

FRAMATOME POSITION

Bid Solicitation - A request for quotation is initiated by engineering personnel and prepared by purchasing personnel, reviewed and approved by the responsible approval authority, and transmitted for solicitation of quotations. This request for quotation contains sufficient technical and quality assurance information to allow the supplier to bid. The technical and quality assurance specifications used in soliciting the bid have either been previously reviewed by quality engineers or will be reviewed before the time of purchase order. These processes, which are identified in internal procedures, assure that appropriate information is transmitted to the supplier.

+++++

Regulatory Guide 1.143, Rév. 1

Design Guidance for Radioactive Waste Management Systems, Structures, and Components Installed in Light-Water-Cooled Nuclear Power Plants

FRAMATOME follows the NRC Regulatory Position when it is applicable to its scope of work.

+++++

Regulatory Guide 1.144, Rev. 1 and ANSI/ASME Standard N45.2.12-1977
Auditing of Quality Assurance Program for Nuclear Power Plants

FRAMATOME follows the NRC Regulatory Position with the following alternatives.

REG. GUIDE/ANSI STD. PARAGRAPH

FRAMATOME POSITION

1. Annual Audits (Section 3.5.2)

"Audits shall be regularly scheduled on the basis of the status and importance of the activities to assure the adequacy of, and conformance with, the program".

Alternative

In lieu of conducting annual audits of suppliers, FRAMATOME has implemented an alternative evaluation program which assures that suppliers have established and are maintaining an acceptable quality assurance program. Suppliers are audited initially to determine the acceptability of their quality assurance programs. If acceptable, the suppliers are placed on the approved supplier list. In lieu of routinely conducting an annual reaudit, a formal evaluation of suppliers is performed each year to determine if reaudits are required during the upcoming year. This evaluation includes a review of some or all of the following: prior quality program audits, supplier surveillance activities, nature and frequency of hardware discrepancies, results of audits from other sources (customers, ASME, etc.) when available, significant changes in the supplier's

REG. GUIDE/ANSI STD. PARAGRAPHFRAMATOME POSITION

quality assurance program, and the supplier's responsiveness and cooperation in resolving quality questions or problems. As a result of this evaluation, suppliers requiring a complete quality assurance program reaudit are identified. The results of this evaluation are documented and approved by responsible management. Regardless of the results of the evaluation, suppliers are reaudited every three years.

At facilities holding the appropriate ASME certificates of authorization, suppliers are categorized as ASME Code and non-ASME Code suppliers. For ASME Code suppliers, as defined in the ASME Code, the purchasing organizations follow the rules of the latest addenda of the ASME Code for approving and auditing suppliers. For non-ASME Code suppliers, the position as described herein is applicable.

REG. GUIDE/ANSI STD. PARAGRAPH

FRAMATOME POSITION

2. Performance of Audit Follow-up

(Section 4.5.2)

"Follow-up action shall be performed by the audit team leader or management of the auditing organization..."

Alternative

Within FRAMATOME, audit follow-up actions may be delegated to an auditor other than the lead auditor or to the individual qualified for performing surveillance of the supplier. For example, audit follow-up for a supplier audit may be routinely performed by a quality engineer (other than the audit team leader) during product surveillance activities.

The auditor or surveillance individual receives a check list prepared by the auditing organization, which clearly delineate the checks to be made. Results are evaluated within the auditing organization by the quality engineer responsible for evaluation of the supplier involved.

+++++

Regulatory Guide 1.146, Revision 0 and ANSI/ASME N45.2.23-1978
Qualification of Quality Assurance Program Audit Personnel
for Nuclear Power Plants

FRAMATOME follows the NRC Regulatory Position with the following clarification:

The general education level of personnel is determined by reference to the French education system instead of the American education system.

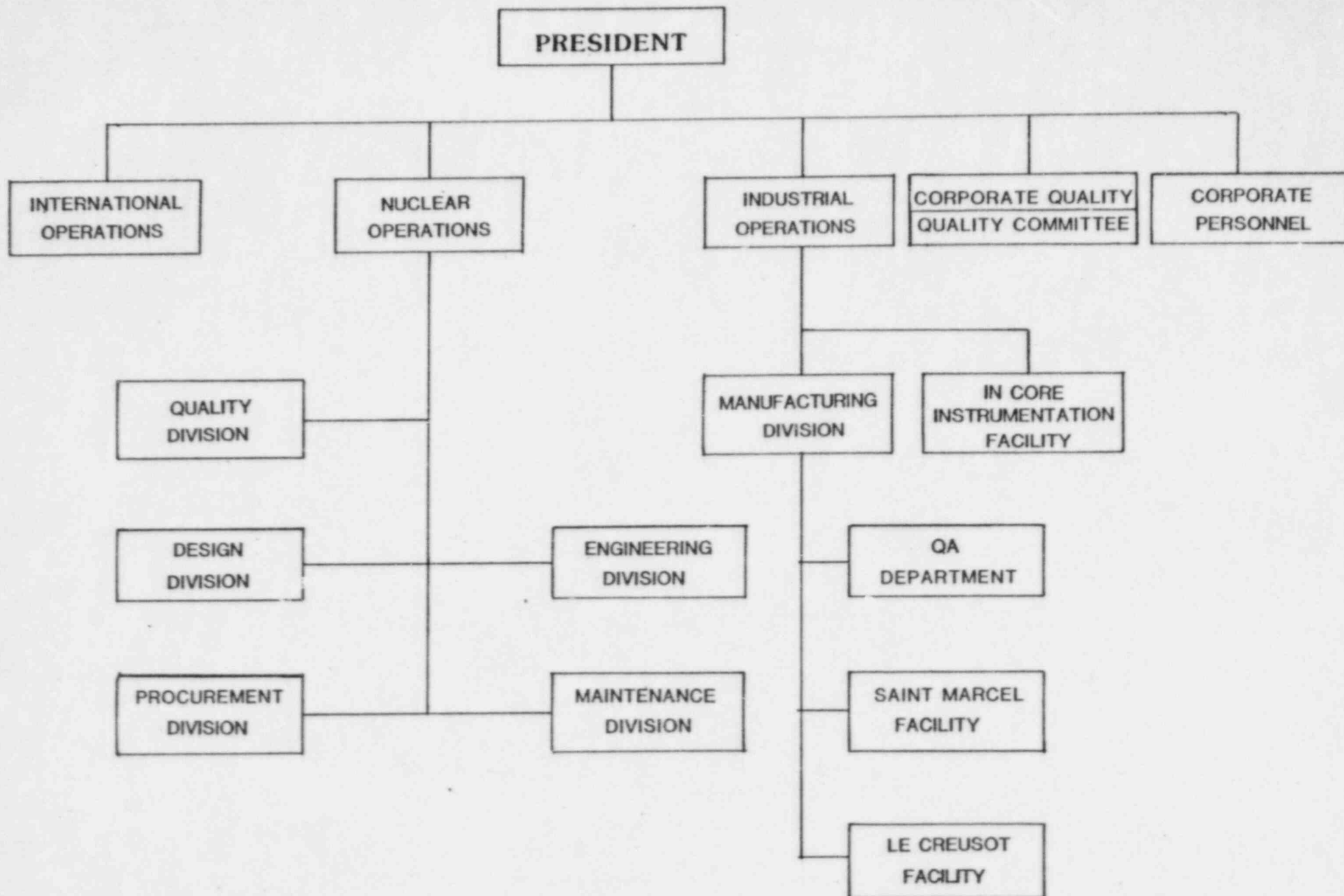


FIGURE 1 FRAMATOME ORGANIZATION FOR UNITED STATES APPLICATIONS

FIGURE 2

TYPICAL MANUFACTURING FACILITY ORGANIZATION

