PRESCRIPTIONS FOR SUPPLIERS REGARDING SAFETY OR PROTECTION-RELATED ASSEMBLIES OR COMPONENTS

Rev	Date	Rédacteur/ *Written by* Name and Signature:	Reviewed by/ *Checked by* Name and Signature:	Emetteur/ *Issued by* Name and Signature:	DOCUMENT CHANGES
D	12/13	B. Jakubowski	A. Cailleux	B. Jakubowski	Updated further to changes in SGAQ. List of AIP added
PO:	11/09	B. Jakubowski	C. Jeuland	B. Jakubowski	Complete rewrite
B	06/07	B. Jakubowski	JM. Plançon	JM. Plançon	Generic letters added
A	03/01/2007	E. Monjean	B. Jakubowski	JM. Plançon	First issue

The original document is signed and stored in EQ. An electronic version is distributed on the Quality site

CONTENTS

1 SCOPE AND PURPOSE

This procedure sets out the additional rules to be followed by suppliers. With regard to safety-related components, it concerns the Quality of the product, documentation and technical surveillance, from product manufacture to the supplier's Quality system.

It is applicable for equipment and services concerning safety-related equipment to be installed in a nuclear power plant, in France or abroad. It sets out the additional requirements to those of PQE 201 (which are close to those of ISO 9001 as regards Quality systems).

2 REFERENCES

2.1 Documents external to Jeumont Electric

- 10 CFR 50 Appendix B: Quality Assurance Criteria for Nuclear Power Plant and Fuel Reprocessing Plants
- 10 CFR 21: Reporting of defects and non compliance
- 50-C/SG-Q of the IAEA: Code on the safety of Nuclear Plants: Quality Assurance
- ASME NQA-1: Quality Assurance Program Requirements for Nuclear Facilities
- RCCE – RCCM: Design and Construction Rules for Electrical and Mechanical Materials
- EPRI - NP 5652: Nuclear Dedication
- Reg guides 89.2 & 91.5
- EDMSN 130127 ed A SGAQ Edition 2013 (AIP domaine)

2.2 Internal Jeumont Electric documents

- Proceédure PQE 201 "Prescriptions générales aux fournisseurs" – General Prescriptions for Suppliers

3 GENERAL

3.1 Safety Related or "Important pour la sûreté" (IPS) components

- All items fulfilling the following functions are classified as SAFETY-RELATED ITEMS:
  - The integrity of the pressure vessel
  - The capacity to avoid or reduce the consequences of accidents that could entail exposure to radiation (or contamination) outside the site.

The classification of a component as safety-related will generally be specified by the operator.
In this context, the products supplied by Jeumont Electric require that the components purchased by it meet the requirements defined herein. They englobe the requirements of §2.1, insofar as they are applicable to the supplier's components.
For practical reasons, Jeumont has set these requirements out in the form of instructions for its suppliers.

IMPORTANT: Should the supplier be unable to meet the requirements for Safety-related items, its products may be dedicated as commercial grade products according to the definition below.

3.2 Activities related to the protection of interests or "Important pour la Protection" activities (AIP)

Activities whose failure could generate Product non-compliance to requirements set down by the Customer for those contributing to the prevention or limitation of the risks and inconveniences presented by the BNI for protected interests.

3.3 Commercial Grade Item, Dedication

Certain products that are important for safety may, on account of their nature, have been originally designed and produced for industrial use and are not the result of a safety-related Quality approach. These are considered "Commercial grade items". A special "dedication" process (Commercial Grade Dedication) is therefore implemented in order to assess the possibility of using these products as safety-related items.
The handling of this type of component is dealt with in paragraph 5.

3.4 Reporting procedure

This reporting procedure concerns parts or equipment that are compliant with 10CFR21 and governed by the Atomic Energy law of 1954, and which therefore meet the following conditions:

- Are installed in the United States of America
- Provide a function that is directly safety-related.

These conditions are determined by Jeumont Electric who will state in the purchase order if 10CFR21 is applicable.

10CFR21 is a law which makes it obligatory to report any problems arising with a safety-related component of a plant to the competent authorities.

Implementation of this reporting procedure is dealt with in paragraph 6.

4 ADDITIONAL REQUIREMENTS TO THE QUALITY MANAGEMENT SYSTEM

Each player in the supply chain in charge of a protection-related activity shall comply with the requirements of standard ISO 9001 - 2008 issue, with in addition the following requirements.

Each player in the supply chain shall apply the policy for the protection of interests (or the safety of equipment) and ensure that the various players have understood the risks and the importance of the activities they are in charge of.
Each player in the supply chain in charge of an activity deemed important for the protection of interests (or important for safety) by its Customer shall be responsible for identifying its own activities (safety or protection-related) that are important for realizing the product under consideration.

In addition to the requirements of ISO 9001, the following is stipulated: The paragraph titles are those of ISO 9001

4.1 Quality Management System (§ 4.1 4.2.3 and 4.2.4 of ISO 9001)

The supplier must implement a Quality Management System that is compliant with the requirements of this document, in particular for safety-related products or those products whose operation will impact a safety-related function or protected interests (items classed as safety-related or protection-related).

The supplier must inform each of its own suppliers of the applicable Quality Management System requirements.

4.2 Management Responsibility (§ 5.5 of ISO 9001)

The independence of personnel with "Quality Assurance" functions shall be demonstrated.

4.3 Resources Management (§ 6.2 of ISO 9001)

Employees must be sensitized to the requirements related to the application of this document and to the importance of the tasks they perform with regard to safety or protected interests.

4.4. 4.4 Verification of design (§7.3.5 of the standard)

Design activities are verified by different individuals to those who performed them.

4.5. Document control (§4.2.3 of the standard)

Before being distributed, all documents and data are reviewed by a different person to the person who prepared them.

4.6 Purchasing (§ 7.4 of the standard)

a) Each player in the supply chain shall take the necessary measures with regard to its purchasing data, to ensure that the requirements relating to the purchase are met by its suppliers.
b) At all levels of the supply chain, each Customer shall ask its suppliers to identify the protection-related activities necessary for realizing the product ordered. This identification is only necessary if the Customer itself has identified the realization of the project subject of the contract to be protection-related.
c) Each Customer, irrespective of its position in the supply chain, shall take the necessary provisions to ensure that its contractual requirements are correctly fulfilled by its suppliers.
In particular, they will check that all protection related activities are controlled and realized in accordance with contractual requirements.
All controls and verifications shall be documented.

4.7 Identification and traceability (§ 7.5.3 of the standard)

Documents required contractually, or kept at the disposal of the Customer, are identified and clearly linked to the products concerned.

4.8. 4.7 Process Control (§ 7.5.1 and 7.5.2 of the standard)

4.8.1 Performance and inspection of protection-related activities

The supplier must draw up a list, according to its realization process, identifying which of its activities are safety or protection related.

Against each of these activities, it must be indicated:
- Who is in charge of performing this activity
- How the performance of the activity is recorded
- Who is in charge of verifying this activity
- How verification is conducted (systematically or by spot checks) and what the verification concerns (nature of the controls made)
- How the verification of the activity is documented.

4.8.2 Evaluation of effectiveness

The supplier evaluates the effectiveness of the measures it has taken to ensure that protection-related activities are controlled.

The individuals or organizations conducting this evaluation shall be independent from those in charge of peforming or inspecting these activities.

The evaluation shall be based on:

- quality audits according to paragraph 8.2.2 of standard ISO 9001
- where necessary, on scheduled spot checks in the course of the process.

Scheduling and the results of the inspections and verifications performed in process shall be recorded.

For example:

COMPONENTS:	Nature of the activity	Performance	Performed by	Documented by	Technical Control	Performed by	Documented by
Designation of the component *e.g.:* *Shaft* *Fabricated assembly* *Bearing* *PCB* *Regulator*	Recognized Protection or Safety-related activity *e.g.:* *Forging* *Brazing* *Tests* *Procurement of components*	Instructions followed: *Forging program, heat treatment instruction, test program, list of components*	Operator performing the operation. *Workshop operator, Furnace operator, press operator*	Type of record of performance: *Signature on document, completed tracking system, etc.*	Type of inspection: *systematic or spot check* Items checked. *Compliance with manufacturing requirements* *Compliance with welding, heat treatment or tightening etc. parameters.* *Compliance with assembly nomenclature*	Person conducting the check: *Different workshop supervisor to the one who performed the operation, Inspection or Quality department*	Type of record of verification: *Signature on document, completed tracking system, etc.*

This list is the supplier's resonsibility, according to the equipment produced, the manufacturing and inspection process and the internal organization.

This list is not specific to a contract or type of equipment. It may be of a generic nature. It is kept available for consultation by the representatives of JE, unless formally requested in the contract.

Safety or protection-related activities are then identified in the quality plan (or tracking document) if so requested in the contract.

This document is subject to JE's agreement.

4.8. Product Surveillance and Measurement (§ 8.2.4 of the standard)

All protection or safety-related activities involved in the manufacture of a product are the subject of the appropriate inspections, in addition to possible operator control actions.

This control shall be performed by individuals other than those having performed the activity. The control conditions (frequency, type, etc.) are described and justified in the aforementioned list.

4.10. Control of non-conforming product (§ 8.3 of the standard)

All players in the supply chain in charge of a protection-related activity (AIP) shall keep at the disposal of JE, all records of handling these non-conformances to contractual requirements and to its own requirements.

Where particular provisions are provided for in the contract documents, the requirements of this paragraph will be added to and clarified by the corresponding articles of these documents.

4.11. Control of records (§4.2.4 of the standard)

Records concerning protection-related activities and not handed over under the contract shall be kept available for 5 years from the date of delivery of the product(s) concerned.

5 COMMERCIAL GRADE DEDICATION

Jeumont Electric will consider with the supplier:
- Whether the component ordered is a commercial grade item or not
- Which dedication method will be used.

A CGI identification sheet will be issued.

According to the dedication method used, JE will define the additional measures to be put in place with the supplier, such as:
- specific identification or segregation of the lots procured and/or manufactured
- Additional inspections (physical and/or documentary)
- Sampling Plan
- Control of changes to the definition or manufacture of the components after dedication of the first components supplied

and any other provision in keeping with the nature of the product or manufacturing process

By accepting the product and authorizing its utilization, Jeumont Electric reclassifies the CGI as a SAFETY-RELATED ITEM.

6 10 "CFR 21" REPORTING PROCEDURE

All suppliers to Jeumont Electric who are aware that a defect or non-conformity (deviation that could significantly affect the safety of the nuclear power plant) has been detected:
- during manufacture,
-after delivery of the product and/or provision of related services
must immediately (within 48 hours maximum) report this information to the Quality Department of Jeumont Electric, stating the words "application of 10 CFR 21 and 10 CFR 50 app B".
Jeumont Electric shall retain all responsibility for the evaluation and reporting to NRC of all deviations that could affect the safe operation of nuclear power plants.

IMPORTANT: It is compulsory for the supplier to complete the form "Supplier's Undertaking" (IQE 68 attached herewith)
If not received with the purchase order, it must be requested from the buyer.

JEUMONT Electric

Service Qualité Sécurité Environnement et Contrôle

Quality, Safety, Environment and Inspection Department

SERVICE EMETTEUR / ISSUED BY : EQ

N° DOCUMENT / DOCUMENT No IQE 68

REVISION: B PAGE : 1 / 1

Date :

ENGAGEMENT DU FOURNISSEUR / SUPPLIER'S COMMITMENT

DANS LE CADRE DE L'ENGAGEMENT DE JEUMONT ELECTRIC A RESPECTER LES EXIGENCES DE LA REGLEMENTATION NUCLEAIRE DES USA PRECISEES DANS LE

Whithin the framework of the commitment of JEUMONT ELECTRIC to comply with the requirements of the USA Nuclear Regulatory Commission specified in the :

10 CFR PART 21 et/and 10 CFR PART 50 app B

- **IL EST DEMANDE A TOUTE PERSONNE, AYANT CONNAISSANCE OU AYANT ENTENDU PARLER DE DEFAUT OU NON-CONFORMITE, DETECTE LORS DE LA CONSTRUCTION DE TOUT PRODUIT ET DE LA FOURNITURE DES SERVICES ASSOCIES, DE TRANSMETTRE IMMEDIATEMENT CETTE INFORMATION A SON SUPERIEUR HIERARCHIQUE. LE FOURNISSEUR S'ENGAGE A EN INFORMER JEUMONT ELECTRIC, MEME APRES LA LIVRAISON DU PRODUIT OU LA FOURNITURE DES SERVICES CONCERNES.**

  Any employee having, during any product construction or associated services supply, knowledge or hearing of a detected defect or non-conformance, is required to immediately report such information to his supervisor. The supplier commits to inform JEUMONT ELECTRIC even after the delivery of the product or of the concerned services.

- **LA REGLEMENTATION NUCLEAIRE DES ETATS-UNIS ET LES PROCEDURES PEUVENT ETRE OBTENUES AUPRES DU SERVICE QUALITE SECURITE ENVIRONNEMENT ET CONTRÔLE (EQ).**

  The United States Nuclear Regulatory and procedures can be obtained from Quality Safety, Environment and Inspection Department (EQ)

Par / By :

Titre / Title :

Document mis à l'affichage et joint aux ordres de fabrication /
Document for public notice and joined to fabrication orders

APPENDIX 2 Generic Letters 89 02 and 91 05 of the NRC

March 21, 1989

To: ALL HOLDERS OF OPERATING LICENSES AND CONSTRUCTION PERMITS FOR NUCLEAR POWER REACTORS

SUBJECT: ACTIONS TO IMPROVE THE DETECTION OF COUNTERFEIT AND FRAUDULENTLY MARKETED PRODUCTS (GENERIC LETTER 89-02).

Recent instances of counterfeit and fraudulently marketed vendor products have heightened the NRC's concerns for licensees' capability to assure the quality of procured products and to reduce the likelihood of the use of counterfeit or fraudulent products in nuclear power plants. During recent NRC inspections of licensees and vendors, the NRC has observed a wide variety of practices and programs for procurement, receipt inspection, testing and dedication of equipment and material for safety-related applications. The purpose of this generic letter is to share with all licensees some of the elements of programs that appear to be effective in providing the capability to detect counterfeit or fraudulently marketed products and in assuring the quality of vendor products. The staff is aware of and encourages the industry working group efforts to develop guidance in these areas.

Three characteristics of effective procurement and dedication programs have been identified during these NRC inspections These characteristics are: (1) the involvement of engineering staff in the procurement and product acceptance process; (2) effective source inspection, receipt inspection, and testing programs; and (3) thorough, engineering based, programs for review, testing, and dedication of commercial-grade products for suitability for use in safety-related applications. NRC has found that programs that embodied the above three elements were generally effective in providing enhanced capability to detect counterfeit or fraudulently marketed products and in assuring the quality of procured products, both in safety-related and other plant systems.

Licensees may want to consider the applicability of these characteristics to their programs to reduce the likelihood of the introduction of counterfeit or fraudulent products into their plants and to assure the quality of procured vendor products.

It should be noted that the NRC staff conditionally endorses the guidelines contained in EPRI NP-5652, "Guideline for the Utilization of Commercial-Grade Items in Nuclear Safety-Related Applications (NCIG-07)," that was issued by EPRI in June 1988 for evaluating commercial-grade products for suitability for use in safety-related applications.

Background:

Numerous instances have been identified by the NRC during the past 2 years in which the nuclear industry received, accepted, and installed items of hardware that were not of the quality purported by the manufacturer or supplier due to apparent misrepresentation. Significant deficiencies have also been identified in the programs for dedicating commercial-grade products for use in safety-related applications.

The use in nuclear facilities of products which are counterfeit or fraudulently marketed increases the likelihood that some plant equipment may not perform as expected. (See the enclosed list of NRC Information Notices and Bulletins regarding this matter.)

Discussion:

Procurement quality assurance (QA) controls for products to be used in safety-related applications are established in Appendix B to 10 CFR Part 50, and in Regulatory Guides 1.28, 1.33, and 1.123. It is recognized that Appendix B provides criteria for QA programs and does not specifically address fraudulent activities; however, an effectively implemented licensee QA program would increase the likelihood of detecting fraudulently marketed vendor products. Although a properly implemented QA program may more readily detect substandard products than will the commercial-grade component upgrade process, a licensee's commercial-grade dedication process, as described in paragraph C., will greatly enhance the effectiveness of current upgrade practices. The actions described in paragraphs A. and B. have also proved useful in detecting substandard, counterfeit or fraudulently marketed products intended for use in systems needed for the safe operation of the facility.

A. Engineering Involvement in the Procurement Process

Appropriate engineering involvement is warranted during the procurement and product acceptance processes, including testing, for products used in nuclear power plants. Inadequate engineering involvement has been a common weakness in licensees' procurement programs, particularly when commercial-grade procurements were involved. Involvement of a licensee's engineering staff in an effective procurement process would normally include (1) development of specifications to be used for the procurement of products to be used in the plant, (2) determination of the critical characteristics of the selected products that are to be verified during product acceptance, (3) determination of specific testing requirements applicable to the selected products, and (4) evaluation of test results. The extent of necessary engineering involvement is dependent on the nature and use of the products involved.

B. Product Acceptance Programs

Experience indicates that reliance on part number verification and certification documentation is insufficient to ensure the quality of procured products. Licensees with effective product acceptance programs have included receipt/source inspection and appropriate testing criteria, effective vendor audits, special tests and inspections and post-installation tests in their programs. These licensees have applied the inspection and testing criteria to products procured for use in safety-related systems and for all commercial-grade products being evaluated for suitability for use in safety-related systems. The inspection and testing criteria also have required identification and verification of the products' critical characteristics. In selecting the critical characteristics to be verified, consideration may be given to the safety significance, complexity, and application of the various products. For suppliers with acceptable QA programs, as confirmed by licensee audits, sampling plans are often utilized to perform the required inspections and tests. In addition to these receipt/source inspections and tests, effective licensee programs normally verify the traceability to the original manufacturers of procured materials, equipment, and components in those cases where original manufacturer's certifications are elements of the safety-related procurement or commercial-grade dedication program.

Effective audits have included consideration of audit approach, depth of audit, and audit team composition and have included appropriate engineering/technical representatives. Comprehensive multi-licensee audit teams have also been found to be effective.

C. Dedication Programs

It is each licensee's responsibility to provide reasonable assurance that nonconforming products are not introduced into their plants. Dedication programs that ensure the adequacy of critical parameters of products used in safety-related applications can also contribute to the identification of counterfeit or fraudulently marketed vendor products.

The NRC staff believes that licensees who use methods similar to those described in EPRI NP-5652 "Guideline for the Utilization of Commercial Grade Items in Nuclear Safety-Related Applications (NCIG-07)," to verify the critical characteristics of commercial-grade items intended for safety-related applications have the basis for effective dedication programs.

Properly implemented, the EPRI guidelines, as modified below, establish methods which satisfy existing requirements of Appendix B to 10 CFR Part 50 as they apply to the dedication process of commercial-grade items.

1. Acceptance Method 2, "Commercial-Grade Survey of Supplier," should not be employed as the basis for accepting items from suppliers with undocumented commercial quality control programs or with programs that do not effectively implement their own necessary controls. Likewise, Method 2 should not be employed as the basis for accepting items from distributors unless the survey includes the part manufacturer(s) and the survey confirms adequate controls by both the distributor and the part manufacturer(s).

2. Acceptance Method 4, "Acceptable Supplier/Item Performance Record," should not be employed alone unless:

a. a. The established historical record is based on industry-wide performance data that is directly applicable to the item's critical characteristics and the intended safety-related application; and
b. b. The manufacturer's measures for the control of design, process, and material changes have been adequately implemented as verified by audit (multi-licensee team audits are acceptable).

The NRC staff believes that if licensees' procurement programs effectively implement the elements discussed in paragraphs, A., B., and C., they will reduce the likelihood of the introduction of counterfeit or fraudulent products into their plants.

Although no response to this letter is required, if you have any questions regarding this matter, please contact the technical contact listed below.

Sincerely,

Steven A. Varga
Acting Associate Director for Projects
Office of Nuclear Reactor Regulation

09 April 1991

To: ALL HOLDERS OF OPERATING LICENSES AND CONSTRUCTION PERMITS FOR NUCLEAR POWER REACTORS

SUBJECT: LICENSEE COMMERCIAL-GRADE PROCUREMENT AND DEDICATION PROGRAMS(GENERIC LETTER 91-05)

This generic letter notifies the industry of the staff's pause in conducting certain procurement inspection and enforcement activities and identifies a number of failures in licensees' commercial-grade dedication programs identified during recent team inspections performed by the U.S. Nuclear Regulatory Commission (NRC). The pause, which began in March of 1990, will end in late summer of 1991. The purpose of the pause is to allow licensees sufficient time to fully understand and implement guidance developed by industry to improve procurement and commercial-grade dedication programs.
This generic letter expresses staff positions regarding certain aspects of licensee commercial-grade procurement and dedication programs which would provide acceptable methods to meet regulatory requirements.

During the period from 1986 to 1989, the NRC conducted 13 team inspections of the licensees' procurement and commercial-grade dedication programs.
During these inspections, the NRC staff identified a common, programmatic deficiency in the licensees' control of the procurement and dedication process of commercial-grade items for safety-related applications. In a number of cases, the staff found that licensees had failed to adequately maintain programs as required by 10 CFR Part 50, Appendix B, to assure the suitability of commercially procured and dedicated equipment for its intended safety-related applications. In addition, the staff identified equipment of indeterminate quality installed in the licensees' facilities.

Because of a decrease in the number of qualified nuclear-grade vendors, the NRC staff is aware that there has been a change in the industry's procurement practices. Ten years ago, licensees procured major assemblies from approved vendors who maintained quality assurance programs pursuant to Appendix B of Part 50 of Title 10 of the Code of Federal Regulations (10 CFR). Currently, due to the reduction in the number of qualified nuclear-grade vendors, licensees are increasing the numbers of commercial-grade replacement parts that they procure and dedicate for use in safety-related applications. This is a substantial change from the environment in which 10 CFR Part 50, Appendix B was promulgated. This has necessitated an increased emphasis by licensees and the NRC staff to maintain procurement and dedication programs that adhere to the requirements of 10 CFR Part 50, Appendix B, and thus assure the quality of items purchased and installed in safety-related applications. Therefore, dedication processes for commercial-grade parts have increased in importance and NRC inspections have determined that a number of licensees have not satisfactorily performed this procurement and dedication process.

The industry has been made fully aware of the NRC's concerns in this program area. In the past, escalated enforcement cases have provided notice to the affected licensees and to the industry of NRC's findings, concerns, and expectations in the implementation of procurement and dedication programs.

Further, the NRC staff continues to participate in numerous industry meetings and conferences at which the NRC's positions in this area have been presented.
The Nuclear Utility Management and Resources Council (NUMARC) Board of Directors recently approved a comprehensive procurement initiative as described in NUMARC 90-13, "Nuclear Procurement Program Improvements," which commits licensees to assess their procurement programs and take specific action to enhance or upgrade the program if they are determined to be inadequate. The initiative on the dedication of commercial-grade items, which is part of NUMARC 90-13, was to be implemented by January 1, 1990. The staff is monitoring implementation of licensee program improvements by conducting assessments of their procurement and commercial-grade dedication programs and maintaining close interaction with the nuclear industry through participation in conferences, panels, and meetings.

The staff will continue to perform reactive inspections relating to plant specific operational events or to defective equipment and, as required, will continue to initiate resultant enforcement actions. In addition, the staff will continue to perform inspections of vendors. The staff expects to resume procurement and dedication inspection activities in the late summer of 1991. These resumed inspections will be conducted using 10 CFR Part 50, Appendix B (not the NUMARC initiatives) as the applicable regulatory requirement. Licensee programs must assure the suitability of commercially procured and dedicated equipment for its intended safety-related application.

The staff position is that the staff will not initiate enforcement action in cases of past programmatic violations that have been adequately corrected. In addition, the staff does not expect licensees to review all past procurements. However, if during current procurement activities, licensees identify shortcomings in the form, fit, or function of specific vendor products, or if failure experience or current information on supplieradequacy indicates that a component may not be suitable for service, corrective actions are required for all such installed and stored items in accordance with Criterion XVI of 10 CFR Part 50, Appendix B.

Also in accordance with Criterion XVI, licensees must determine programmatic causes when actual deficiencies in several products from different vendors are identified during current procurement activities and these deficiencies lead to the replacement of installed items as part of the corrective action. In such cases, a further sampling of previously procured commercial-grade items may be warranted.

In NRC Generic Letter (GL) 89-02, "Actions to Improve the Detection of Counterfeit and Fraudulently Marketed Products," the staff described its perspective on good practices in procurement and dedication and provided the NRC's conditional endorsement of an industry standard (EPRI NP-5652) on methods of commercial-grade procurement and dedication. A number of recent inspection findings, as discussed in Enclosure 1, indicate that licensees have failed to include certain key activities, as appropriate, in the implementation of the dedication process. The NRC staff's positions on the successful implementation of licensees' programs for commercial-grade dedication with respect to critical characteristics and like-for-like replacements are as follows. (These are also included in Enclosure 1.)

The term "critical characteristics" is not contained in Appendix B and has no special regulatory significance beyond its use and definition in various industry guides and standards. The NRC first used the term critical characteristics in GL 89-02 as constituting those characteristics which need to be identified and verified during product acceptance as part of the procurement process. The NRC has not taken the position that all design requirements must be considered to be critical characteristics as defined and used in EPRI NP-5652. Rather, as stated in Appendix B, Criterion III, licensees must assure the suitability of all parts, materials, and services for their intended safety-related applications (i.e., there needs to be assurance that the item will perform its intended safety function when required). The licensee is responsible for identifying the important design, material, and performance characteristics for each part, material, and service intended for safety-related applications, establishing acceptance criteria, and providing reasonable assurance of the conformance of items to these criteria.

A like-for-like replacement is defined as the replacement of an item with an item that is identical. For example, the replacement item would be identical if it was purchased at the same time from the same vendor as the item it is replacing, or if the user can verify that there have been no changes in the design, materials, or manufacturing process since procurement of the item being replaced. If differences from the original item are identified in the replacement item, then the item is not identical, but similar to the item being replaced, and an evaluation is necessary to determine if any changes in design, material, or the manufacturing process could impact the functional characteristics and ultimately the component's ability to perform its required safety function. If the licensee can demonstrate that the replacement item is identical, then the licensee need not identify the safety function or review and verify the design requirements and critical characteristics. Engineering involvement is necessary in the above activities. Reliance on part number verification and certification documentation is insufficient to ensure the quality of commercially procured products.

The other matters discussed in Enclosure 1 do not constitute NRC staff positions, but provide information on inspection findings and clarify the characterization of effective procurement and dedication programs previously described in GL 89-02.

BACKFIT DISCUSSION:

Based on past inspection findings and the resulting enforcement actions, the NRC staff has determined that licensee commercial-grade procurement and dedication programs needed to be improved to comply with the existing NRC requirements as described in 10 CFR Part 50, Appendix B, Criterion III (Design Control), IV (Procurement Document Control), VII (Control of Purchased Material, Equipment and Services), and XVIII (Audits). Specifically, licensees have failed to adequately maintain programs to assure the suitability of commercially procured and dedicated equipment for its intended safety-related application.
Since the generic letter presents staff positions regarding implementation of existing regulatory requirements, as contained in Appendix B to 10 CFR Part 50, the staff has concluded, that this is a compliance backfit and has prepared the generic letter in accordance with 10 CFR 50.109 (a)(4)(i).
In light of the inadequacies identified in the procurement and dedication programs of a large number of licensees, the issuance of this generic letter is necessary to express the staff's position on the key element that licensees must include as part of the dedication process, specifically that commercial-grade procurement and dedication programs must assure the suitability of equipment for its intended safety-related application.
This generic letter is also intended to clarify the elements of effective procurement and commercial-grade dedication programs that were previously provided to licensees in GL 89-02. Since licensees' procurement and dedication programs may contain programmatic deficiencies, the staff has included in the generic letter the necessary licensee corrective action to address shortcomings identified in specific vendor products or components that directly lead to the component not being suitable for safety-related service.

Although no response to this letter is required, if you have any questions regarding this matter, please contact the persons listed below.

Sincerely,

James G. Partlow
Associate Director for Projects
Office of Nuclear Reactor Regulation