



JEUMONT
ELECTRIC

Quality Department

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**INSTRUCTIONS
TO SUPPLIERS FOR ALL
ASSEMBLIES OR
COMPONENTS
IMPORTANT TO NUCLEAR
SAFETY**

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D	12/13	B. Jakubowski	A. Cailleux	B. Jakubowski	Modification following SGAQ changes Added list of AIPs
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1 PURPOSE AND FIELD OF APPLICATION

This procedure sets out the additional rules to be followed by suppliers. For safety-classified components, it covers product quality, from documentation and technical monitoring to product manufacture up to its Quality system.

It applies to equipment and services relating to ITNS equipment intended for installation in a nuclear power plant, in France or another country. It sets out the additional requirements to those of PQE 201 (similar to those of ISO 9001 in terms of quality systems).

2 REFERENCES

2.1 Documents external to Jeumont Electric

- ISO 19443 - 2018 Quality management systems - Specific requirements for the application of ISO 9001: 2015 by organizations in the supply chain of the nuclear energy sector providing products and services important to nuclear safety (ITNS)
- 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
- ASME NQA-1: Quality Assurance Program Requirements for Nuclear Facilities
- RCCE: Regulation Pertaining to the Design and Construction of Electrical and Mechanical Equipment
- EPRI - NP 5652: Nuclear Dedication
- Reg guides 89.2 & 91.5
- D3095518038669 ind C: SGAQ Contracts for reactors in operation and for EPR2-type new build projects in France 2021 Edition (appendix 1)
- DPNT-DIPNN common policy for the protection of interests ind 0 of 03/032021

2.2 Jeumont Electric internal documents

- Procedure PQE 201 - "General requirements for suppliers"

3 GENERAL

3.1 Component "Important to Nuclear Safety" ITNS

A component (or service) classified as an ITNS has critical characteristics the failure of which could lead to undue exposure to radiation of people and the environment.

Following a graduated approach implemented by the designer of the nuclear installation, Jeumont Electric is notified of the ITNS status of certain equipment or services that it supplies.

In that context, the products supplied by Jeumont Electric require certain components to meet ITNS requirements. They include the requirements of section 2.1 adapted to the extent necessary for its components.

For practical reasons, Jeumont has translated these requirements into instructions for its suppliers.

IMPORTANT: If the supplier does not know how to produce the products, ITNS items, a "Commercial grade Dedication" as defined below, may be carried out.

3.2 Activity Important for Protection (AIP) according to the SGAQ

Activities the failure of which may result in the Product not complying with the requirements notified by the customer for those activities contributing to the prevention or limitation of the risks and inconveniences that the Basic Nuclear Installation (BNI) presents for the protected interests.

3.3 Commercial-grade items (CGI)

An item or activity which has an impact on nuclear safety and which has not been designed, manufactured or produced in accordance with specific nuclear requirements

Given their nature, some products that are Important To Nuclear Safety may originally have been designed and produced for industrial use, without being the result of a safety-related Quality approach. They are considered "commercial grade items". A specific Commercial Grade Dedication approach is then used to assess the use of those products as safety-rated components.

The processing of that type of component is covered in section 6.

3.4 Reporting procedure

This "reporting" concerns parts or equipment covered by 10CFR21, governed by the US Atomic Energy Act of 1954, i.e. those meeting the following conditions:

- they are installed in the United States of America,
- they provide a function directly related to safety.

Those conditions are determined by Jeumont Electric and the application of 10CFR21 is notified with the purchase order.

10 CFR 21 is a law that requires the competent authorities to be notified of any problem with a component related to the safety of facilities.

The application of this reporting procedure is covered in section 6.

Note: some states outside the USA can notify the application of 10CFR21

4 ADDITIONAL REQUIREMENTS TO THE QUALITY MANAGEMENT SYSTEM

4.1 Quality Management System

All players in the nuclear energy supply chain providing products or services important to nuclear safety (ITNS) comply with the requirements of the ISO 19443 standard 2018 edition.

4.2 Activities Important for Protection

In application of the SGAQ cited in section 2.1, suppliers must identify and manage AIPs

4.2.1 AIP performance and control

Suppliers must draw up a list identifying which activities are important (for safety or protection), according to their production process.

Every one of them must be defined:

- Who is in charge of carrying out the activity
- How the conduct of the activity is recorded
- Who is in charge of checking the activity
- How audits are provided for (systematic, sampling) and what they cover (type of checks carried out)
- How the checks on the activity are documented.

An example is provided in **Appendix 1**

4.2.2 - Effectiveness assessment

Suppliers assess the effectiveness of the measures they have taken to guarantee control of the AIPs.

The persons or bodies carrying out the assessment are different from the persons in charge of carrying out or monitoring the activities.

This assessment is based on:

- the quality audits referred to in § 8.2.2 of the ISO 9001 standard
- where necessary, scheduled checks or checks based on sampling during the process.

The schedule and results of the checks and verifications carried out during the process are recorded.

5 GENERAL REQUIREMENTS

5.1 Nuclear Safety culture

Suppliers must be the guarantors of an appropriate Nuclear Safety Culture that takes into account:

- a. The leadership and commitment of senior management and line managers at all levels to Nuclear Safety, by raising the awareness of all staff to nuclear safety and encouraging them to adopt a questioning attitude;
- b. A balanced, rigorous and prudent approach to decisions in terms of quality, costs, deadlines and safety so that Nuclear Safety is not compromised;
- c. Transparent communication;
- d. The use of adequately documented information;
- e. The reporting of problems relating to human, technical and organisational factors;
- f. Feedback;
- g. Questioning risk generating acts, behaviours and conditions.

5.2 CFS Items

In addition to the requirements set out in section 8.4 of PQE 201.

Suppliers must implement all the necessary measures to prevent, detect and combat any fraud, suspicious practice or counterfeiting relating to the subject of the purchase order and, more generally, in the context of their activities or those of their subcontractors

In particular, Suppliers will implement the following measures:

- Raise CFS awareness among all staff;
- A procedure guaranteeing the independence of the staff in charge of Quality Assurance from the rest of the operational organisations;
- The introduction of tools to detect this type of practice in the inspection methods;
- A procedure making it possible for every employee to report any discrepancy or anomaly regarding compliance with the Purchase order specifications and/or likely to jeopardise the safety of the subject of the Purchase Order, while remaining anonymous ("whistleblower system").

When Jeumont Electric becomes aware of fraud, suspicious practices or counterfeiting within a company, Jeumont Electric may ask the Supplier whether it uses, or has used, that company as a subcontractor for its orders, and must provide the list of part references as well as the orders concerned within 24 hours..

When fraud, suspicious practices or counterfeiting are detected in their own activities or in their chain of subcontractors, Suppliers must:

- Inform Jeumont Electric, and if required, the safety authority, immediately upon detection;
- Analyse the scope impacted by the CFS practices (period, volume, etc.), carry out a cause analysis, and take all necessary steps to prevent any further occurrences;
- Inform Jeumont Electric without delay of the scope concerned, the impacted products, components and services, and the corrective actions taken;
- Submit all the corresponding non-conformity records to Jeumont Electric for processing and decision;
- Repair or replace the products delivered to Jeumont Electric when necessary

5.3 Nuclear safety and quality management requirements

5.3.1 Standards and classification

Suppliers must draw up and document a Nuclear Safety and Quality Management System having a graduated approach depending on the levels and standards made applicable in Jeumont Electric's requests for proposals and purchase orders:

Classification	Standard
Items and/or services with standard quality impacts	ISO 9001*
Items and/or services with an impact on nuclear safety or quality	ISO 19443*
	10CFR50 App B + 10CFR21 Explained using ASME NQA1

(*) For Supplier certifications, the scope of the certificate must cover all the requested activities, Items and/or Services.

Suppliers must also update the Nuclear Safety Management System in accordance with the regulatory standards made applicable in Jeumont Electric's requests for proposals and Purchase orders.

5.3.2. Application of the 10 CFR 21 REPORTING PROCEDURE

Under US regulations (when applicable to the order through 10 CFR21), all subcontractor personnel are required to report all incidents that may impact equipment or a service that has already been delivered, to a designated person.

As a result, any Jeumont Electric supplier who is aware or has heard of a defect or detected non-conformity (discrepancies that could significantly impact the safety of the nuclear power plant):

- during manufacture
- after delivery of the product and/or provision of the associated services

must forward this information immediately (within 48 hours) to JEUMONT Electric's Quality Department, bearing the statement "application of 10 CFR 21 and 10CFR 50 app.B".

JEUMONT Electric remains in charge of assessing and reporting discrepancies that could impact the safe operation of nuclear power plants to the NRC.

IMPORTANT: It is compulsory for Suppliers to fill in the "Supplier Commitment" form (IQE 68 in the appendix)

They should request it from the buyer if it was not received when the order was placed.

5.3.3. JEUMONT ELECTRIC ASSESSMENT AND APPROVAL

Suppliers may request Jeumont Electric's support if they need to clarify the requirements applicable to their Nuclear Safety and Quality Management System, with a view to responding to Jeumont Electric's requests for proposals and Purchase orders

Suppliers must make sure their Nuclear Safety and Quality Management System remains compliant with the conditions of its approval as set out in the Jeumont Electric Requests for Proposals and Purchase Orders.

Jeumont Electric is notified of any major changes to their Nuclear Safety and Quality Management System

5.4 Right of access in the subcontracting chain

In addition to the requirements set out in section 8.4 of PQE 201.

Suppliers and their entire subcontractor chain must provide all facilities to the persons designated by Jeumont Electric, the Customer, the Safety Bodies and Authorities, the ANI (Authorized Nuclear Inspector), as well as their designated representatives, to allow them to fully carry out their mission.

Suppliers must allow Jeumont Electric inspectors access to their industrial facilities, workshops and to the quality documentation associated with the Purchase Order:

- According to the notification to attend items defined in the Purchase order, or
- Unannounced without notice, or at very short notice.

Suppliers will authorise Jeumont Electric to carry out cross-checks on the Goods and/or Services that are the subject of the Purchase order, or on the documentation, by comparing the certificates issued by the Supplier with the original reports issued by the subcontractors or laboratories used by the Supplier.

In this respect, they authorise Jeumont Electric to request the original reports from their subcontractors, and accept that the subcontractors forward them directly to Jeumont Electric.

Suppliers must make the results of their own Subcontractor activity monitoring available to Jeumont Electric.

For all Purchase orders requiring compliance with the requirements of the ISO 19443 standard, suppliers must provide Jeumont Electric with a list of its subcontractors and the complete material supply chain.

5.5 Checks, tests and analyses

5.5.1. Check

Suppliers must have the checking procedures drawn up and checked by personnel certified to the appropriate level of competence in accordance with the standards applicable to the purchase order.

Suppliers must make the files and lists of qualified personnel available to Jeumont Electric and the relevant Stakeholders.

Suppliers must check that the qualifications of the personnel carrying out these operations (including the interpretation of the results) are valid on the date of the operation.

Suppliers must arrange to record the results obtained in a test report featuring the information required by Jeumont Electric.

5.5.2. Tests and analyses

Suppliers must define the following characteristics adapted for each type of test and analysis, and then verify them (using validation methods):

- The description of the materials used in the initial state;
- The identification and traceability from sampling to specimen preparation;
- The identification and traceability of the test specimen during and after the test;
- The test procedure in accordance with recognised standards or validated test methods;
- The qualification and authorisation of personnel concerning the test method;
- The calibration and traceability of checking, measurement and testing equipment to national or international standards, certified reference materials or any other means when such standards do not exist;
- The carrying out of the tests in accordance with the test method;
- The traceability between the test specimens and the test results obtained;

5.6 Acceptance certificates

For the supply of products important to nuclear safety ("ITNS" as defined in the ISO 19443 standard), suppliers must check all the information contained in the material certificates used:

- either by demonstrating the similarity with the original certificate issued by the producer (cross-checking with the original version or authentication by the issuer),
- or by carrying out contradictory tests or analyses on representative materials.

Suppliers must make sure the entire supply chain complies with the EN 10204 standard. Indeed, Suppliers must only send either an original or a copy of the inspection documents supplied by the producer without any modification.

This documentation must be accompanied by appropriate means of product identification to guarantee traceability between the product and the documentation.

A copy of the original document is permitted provided that traceability procedures are applied and that the original document is available on request. When producing copies, the information relating to the initial delivered quantity may be replaced by the partial quantity actually delivered.

6 COMMERCIAL GRADE ITEMS (CGI)

Jeumont Electric works together with suppliers to study:

- Whether or not the ordered component is a Commercial Grade Item
- What dedication method will be used.

A CGI identification record is drawn up.

Depending on the selected dedication method, Jeumont Electric will define the additional practices to be implemented together with the supplier, such as:

- Specific identification or segregation of supplied and/or manufactured batches
- Additional checks to be carried out (physical and/or documentary checks)
- Sampling plan
- Control of changes to the definition or manufacture of components after dedication of the first supplied components

and any other measures appropriate to the nature of the product or the manufacturing process

By accepting the product and authorising its use, Jeumont Electric reclassifies the CGI as an ITNS component

7. REFERENCE FILE

Jeumont Electric has set up a procedure for monitoring modifications to certain equipment qualified for accident conditions (MQCA) to guarantee compliance with standard or qualified equipment.

This is done through a Reference file (RF)

When Suppliers are in charge of producing the components for such equipment, they are required to check the conformity of the equipment and any changes to it and thus participate in the management of the RF.

A specific procedure will then be notified to the supplier.



APPENDIX 1 Example of an AIP list

COMPONENTS:	Type of activity	Execution	Carried out by	Documented by
Component name <i>Example:</i> Shaft Mechanically welded assembly Bearing Electronic board regulator	Activity recognised as AIP or IPS. <i>Example:</i> Forging Brazing Tests Component supply	Implemented instructions: <i>Forging programme, heat treatment instructions, test programme, list of components</i>	Operator carrying out the operation. <i>Workshop operator, Furnace, press operator</i>	Type of task traceability: <i>Signature on the document, tracking system records, etc.</i>

COMPONENTS:	Type of activity	Technical inspection	Carried out by	Documented by
Component name <i>Example:</i> Shaft Mechanically welded assembly Bearing Electronic board regulator	Activity recognised as AIP or IPS. <i>Example:</i> Forging Brazing Tests Component supply	Type of inspection: <i>systematic or by sampling</i> Points checked. <i>Compliance with manufacturing requirements</i> <i>Compliance with welding, treatment or tightening, etc. parameters</i> <i>Compliance with assembly parts lists</i>	Person carrying out the check: <i>Workshop supervisors, operator other than the one who carried out the operation, Inspection or Quality department</i>	Type of verification traceability: <i>Signature on the document, tracking system records, etc.</i>

This list is the supplier's responsibility, depending on the equipment produced, the manufacturing and inspection processes, and the internal organisation

This list is not specific to any one contract or type of equipment. It may be generic. It is kept at the disposal of JE's representatives, unless formally requested in the contract.

The important activities are then identified in the quality plan (or tracking document) if required by the contract.

This document is subject to JE approval.



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Appendix 2 IQE 68 Form



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Service Qualité Sécurité Environnement et
Contrôle

Quality, Safety, Environment and inspection
Department

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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**

*Within 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 :

APPENDIX 3 Generic Letters 89 02 and 91 05 from the NRC

March 21, 1989

TO ALL HOLDERS OF OPERATING LICENCES AND BUILDING PERMITS FOR NUCLEAR REACTORS.

SUBJECT: ACTIONS INTENDED TO IMPROVE THE DETECTION OF COUNTERFEIT AND FRAUDULENTLY TRADED PRODUCTS (LETTER OF PRINCIPLE 89-02).

Recent examples of counterfeiting and fraudulent marketing of products having an effect on our suppliers' products have prompted the NRC to raise concerns about the capacity of licensees to guarantee the quality of purchased products and to reduce the likelihood of counterfeit or fraudulent products being used in nuclear power plants. During its recent inspections of licensees and suppliers, the NRC found a wide variety of practices and programmes concerning procurement, acceptance checking, testing and the dedication of equipment and materials to safety-related applications. The purpose of this generic letter is to share some of the elements of programmes that appear to be effective in providing the means to detect counterfeit or fraudulently marketed products with all licensees, and to guarantee the quality of products from suppliers. The staff is aware of the efforts made by the industry working group to define guidelines in these areas, and encourages it in this endeavour.

Three characteristics of effective procurement and dedication programs were identified during these NRC inspections. They are: (1) the involvement of the engineering team in the product procurement and acceptance process; (2) effective checks at source, acceptance checks and testing programs; and (3) extensive engineering-based programs for the inspection, testing and dedication of commercial-grade products, to make sure those products are suitable for use in safety-related applications. The NRC found that programs that included all three of the above elements were generally effective in providing improved means of detecting counterfeit or fraudulently traded products, and in guaranteeing the quality of procured products, both in safety-related and other industrial systems.

Licensees are required to examine the applicability of these requirements to their programs in order to reduce the risk of counterfeit or fraudulent products being brought into their factories, and to guarantee the quality of the products procured from suppliers.

It should be noted that the NRC team conditionally endorses the guidelines contained in document EPRI NP-5652 "Guidelines for the use of commercial-grade items in safety-related nuclear applications -NCIG-07)", which was published by EPRI in June 1988 for use in safety-related applications.

Context:

Over the past 2 years, the NRC has identified many examples of the nuclear industry receiving, accepting and installing equipment that was not of the quality claimed by the manufacturer or supplier, due to apparently false claims. Significant failures were also detected in the commercial-grade dedication programs intended for use in safety-related applications.

The use of counterfeit or fraudulently marketed products in nuclear facilities increases the likelihood of certain plant equipment performing below expectations. (See attached list of Information Notes and Bulletins published by the NRC)

Discussion:

The Quality Assurance (QA) checks on purchases to make sure products are used in safety-related applications are defined in Appendix B of 10 CFR Part 50 and in Regulatory Directives 1.28, 1.33 and 1.123. It is agreed that Appendix B provides criteria applicable to QA programs, and does not specifically address fraudulent activity; nevertheless, a QA programme effectively implemented by a licensee would increase the likelihood of detecting fraudulently marketed supplier products. Even though a properly implemented QA program may detect sub-standard products more easily than a commercial-grade component improvement process, the commercial-grade dedication process implemented by a licensee as described in section C will significantly increase the effectiveness of current improvement practices. The actions described in sections A and B have also proved useful in detecting substandard, counterfeit or fraudulently marketed products intended for use in systems required for the safe operation of the installation.

A. Engineering commitment to the Procurement Process

Appropriate involvement of the engineering departments is guaranteed during the procurement and acceptance processes, including testing, for products used in nuclear power plants. Insufficient commitment from engineering departments has frequently been a weak point in licensees' procurement programmes, especially when procuring commercial-grade products. For a licensee, engaging engineering department management in an effective procurement process would normally involve (1) developing specifications for purchasing products for use in the plant, (2) determining the critical characteristics of the selected products that need to be checked during the product acceptance phase, (3) determining the specific test requirements applicable to the selected products, and (4) assessment of the test results. The extent of the required engineering department commitment depends on the nature and use of the products in question.

B. Product acceptance programs

Experience shows that checking part numbers and certification documentation is not sufficient to guarantee the quality of purchased products. Licensees who apply effective product acceptance programs have included acceptance/source checks and appropriate testing criteria in their programs, as well as effective supplier audits, special testing and installation and post-installation testing. They apply the inspection and test criteria to the products procured for use in safety-related systems, and for all commercial-grade products assessed for their suitability for use in safety-related systems. The inspection and test criteria also required the identification and verification of the critical product characteristics. By selecting the critical characteristics to be verified, we are able to take into account the importance of safety, its complexity and the application of various products. For suppliers with acceptable QA programs - as confirmed by the verifications at these licensees' premises - sampling plans are often used to carry out the required checks and tests. In addition to those reception/source inspections and tests, effective licensee programmes normally verify the traceability of purchased materials, equipment and components back to the original manufacturers in cases where the original manufacturers' certifications are part of the safety-related or commercial-grade procurement program elements.

Effective audits have included consideration of the approach taken to the verification, its extent, and the composition of the verification team, and have involved competent representatives from the engineering/technical departments. Global audit teams working with multiple licensees have also proved effective.

C. Dedication programs

Each licensee is responsible for reasonably guaranteeing that non-compliant products do not enter its factories. Dedication programs that certify the suitability of critical product parameters used in safety-related applications can also help to identify counterfeit or fraudulently marketed supplier products.

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

Properly implemented, the EPRI guidelines as modified below create methods that comply with the current requirements of Appendix B to Section 10 CFR, as they apply to the process of dedicating commercial-grade items.

1. Acceptance Method 2, "Supplier commercial-grade product audit" should not be used as a basis for accepting items from suppliers with undocumented commercial-grade product inspection programs, or programs that do not actually implement the essential checks that they themselves apply. Nor should Method 2 be used as a basis for accepting items from distributors, unless the audit also covers the parts manufacturer(s), and confirms that the parts distributor and manufacturer(s) have all carried out appropriate checks.
2. Acceptance Method 4 "Supplier Archive/Acceptable Item Performance" should not be used separately unless:
 - a. The created history record is based on industry-wide operational data directly applicable to the critical characteristics of the item and the safety-related application, and:



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- b. The measures adopted by the manufacturer to verify changes in design, process and materials have been adequately implemented, as confirmed by an audit (audit teams at multiple licensees are acceptable).

The NRC staff considers that if licensee procurement programs effectively implement the elements outlined in sections A, B and C, they will reduce the likelihood of counterfeit or fraudulent products entering their factories.

Although this letter does not require a response, please get in touch with the technical contact below if you have any questions.

Yours sincerely

Steven A. Varga
Interim Associate Director in charge of Projects
Nuclear Reactor Regulation Office

09/04/1991

TO ALL HOLDERS OF OPERATING LICENCES AND BUILDING PERMITS FOR NUCLEAR POWER REACTORS.

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

The purpose of this generic letter is to notify 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 US *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 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 the decrease in the number of 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* (CFR 10). 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 processes 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's 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 1 January 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 supplier adequacy 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, further sampling of the previously procured commercial-grade items may be warranted.

In NRC Generic Letter 89-02, "Actions to Improve the Detection of Counterfeit and Fraudulently Marketed Products," the staff described its perspectives 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 inspections, 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 characteristic" is not contained in Appendix B and has no specific regulatory significance beyond its use and definition in various industry guides and standards. The NRC first used the term critical characteristics in its Generic Letter 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 the 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 Generic Letter 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 Materials, 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 of 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 the 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 generic letter 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

APPENDIX 4: EDF Group ethics and compliance alert system

DISPOSITIF D'ALERTE ETHIQUE ET CONFORMITE DU GROUPE EDF

« La présente prestation concerne un produit (équipement ou partie d'équipement), ou un service important pour la protection des intérêts protégés (que sont la sécurité publique, la santé et la salubrité publiques et la protection de la nature et de l'environnement) à destination finale d'une installation nucléaire d'EDF SA.

A ce titre, la compréhension des enjeux de sûreté en lien avec la conception, la fabrication, la construction, le montage et les essais est fondamentale.

Chaque Prestataire Externe intervenant dans la chaîne de réalisation doit appréhender l'importance de se conformer aux spécifications (elles doivent être conformes aux exigences techniques du Marché EDF SA qui déclinent les exigences définies) et doit comprendre le rôle qu'il joue pour permettre la conformité du produit ou service à ces exigences et donc in fine le lien avec la sûreté nucléaire des installations.

En ce qui concerne les opérations d'étude, d'approvisionnement, de fabrication, de montage et de maintenance des produits, le risque de fraudes et de contrefaçons doit être pris en compte afin de définir les dispositions de contrôles internes et de surveillance des Prestataires Externes.

APPENDIX 5 Common DPNT-DIPNN policy for the protection of interests



Dans un contexte environnemental, industriel et réglementaire en évolution, notre enjeu en cohérence avec la raison d'être d'EDF SA est de conserver la confiance du public en assurant une production d'électricité sûre et en veillant à la santé et la sécurité du public, en maîtrisant l'usage des ressources naturelles et les impacts sur l'environnement, tout en pérennisant et renouvelant l'outil industriel. En tant qu'exploitant d'INB responsable et maître d'œuvre intégrateur de la filière nucléaire, **nous nous engageons à assurer la protection des intérêts** que sont la santé, la sécurité et la salubrité publiques ainsi que la protection de la nature et de l'environnement **par la prévention des risques et inconvénients générés par nos installations et activités et à lui accorder la priorité sur tout avantage économique ou industriel procurés par nos activités en nous appuyant sur une sûreté nucléaire irréprochable.**

Dans une démarche permanente d'amélioration continue, chacun, notamment toute personne contribuant aux Activités Importantes pour la Protection de ces Intérêts (AIP) et tout manager, à son niveau, connaît, met en œuvre, respecte et fait respecter cette politique, qui repose sur 5 principes communs au cœur de notre engagement :

1- Identifier, prévenir et maîtriser les risques ou inconvénients de nos activités sur les intérêts protégés

Nous identifions, prévenons et maîtrisons les impacts potentiels de nos activités et de nos décisions sur la santé, la sécurité et la salubrité publiques, la protection de la nature et de l'environnement.

2- Connaître et appliquer les référentiels en vigueur

Nous identifions et déclinons dans nos organisations, les dispositions réglementaires et les référentiels internes (en particulier la politique sûreté nucléaire du Groupe EDF) afin de s'y conformer.

Nous les mettons en œuvre, nous nous assurons de leur appropriation et de leur application. Nous capitalisons les remontées du terrain pour les rendre simples et accessibles.

3- Etre formés et responsables dans nos métiers

Nous connaissons notre rôle, nos responsabilités et nous maîtrisons les gestes professionnels liés à notre activité grâce :

- à la performance humaine des acteurs (salariés EDF et intervenants extérieurs) intègres et disposant des moyens de développement des compétences individuelles et collectives nécessaires à la maîtrise des activités,
- au développement d'une culture de sûreté des acteurs libres de soulever toute question et rapportant de façon rapide et transparente les problématiques à traiter,

- à l'efficacité de nos organisations au moyen d'un système de management clair, responsabilisant les acteurs et qui s'appuie sur un dispositif de contrôle robuste,
- à une surveillance responsable sur les activités que les prestataires réalisent pour nous.

4- Améliorer nos performances par les différentes boucles de progrès

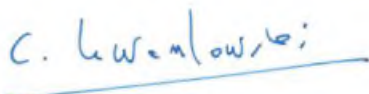
Nous identifions, analysons et traitons nos écarts dans des délais adaptés aux risques et aux enjeux.

Nous promouvons l'amélioration continue de nos organisations et de nos pratiques par un regard critique sur nos modes de fonctionnement, le partage de l'information et l'analyse du retour d'expérience de conception, d'exploitation et provenant d'autres industriels pour améliorer nos performances et faire face aux nouveaux enjeux.

5- Dialoguer et renforcer la confiance avec nos parties intéressées

Nous recherchons en toutes circonstances le dialogue et la transparence avec les parties intéressées dans un esprit d'écoute et de respect mutuel : nos salariés et leurs représentants, nos prestataires et nos fournisseurs, les instances de contrôle, les collectivités locales, les CLI, le public, les ONG...

Le climat de confiance ainsi généré stimule la prévention des risques et l'atteinte d'objectifs partagés.



Cédric LEWANDOWSKI
Directeur de la DPNT



Xavier URSAT
Directeur de la DIPNN

L'engagement des directeurs de la DPNT et de la DIPNN

« Nous nous engageons à faire réaliser les activités conformément à cette politique et à garantir les ressources humaines et financières nécessaires à l'exploitation de nos installations nucléaires.

Nous chargeons les équipes de Direction des entités de contrôler l'application et la conformité des décisions prises, l'efficacité de l'organisation mise en place et de rendre compte périodiquement des résultats.

C'est notre engagement, notre responsabilité d'exploitant nucléaire pour assurer la protection des intérêts relatifs à, la sécurité la santé et la salubrité publiques, la protection de la nature et de l'environnement. »