AUDIT REPORT

Client:	Data Systems & Solutions, LLC Reston, Virginia
Date:	February 3, 2009
Facility Audited:	Data Systems & Solutions, SAS 23 Chemin du Vieux Chene F-38246, Meylan Cedex France
Audit Date:	January 19 – 23, 2009
Products/Scope:	Design and Manufacture of safety Instrumentation and Controls Systems
QA Program:	PQM/Quality Management Plan Data Systems & Solutions SAS, Revision N, June 2008.

Main Standards used by the company:

ISO **International Organization for Standardization**
ISO9001: Quality Management System – Requirements.
The company QMS is certified in compliance with ISO9001:2000 since July 2001.

IEC **International Electrotechnical Commission**
IEC 60880: Software for Computers in the Safety Systems of nuclear power station.

IAEA **International Atomic Energy Agency**
50-C/SG-Q series: Quality Assurance for Nuclear Power Plant Safety and Codes of good practices (Formerly 50-C-QA).

EDF **SGAQ: DE-EPN/96-09: Quality Assurance General specification.**

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AFCEN	**Association Fracaise pour les regles de Conception et de Construction des materiels des Chaudieres Electro-Nucleaires.** RCC-E: Design and Manufacturing rules for electric equipments in Nuclear Plants. Chapter A5000: Quality Assurance Chapter C5000: Software Systems.
CEFRI	**Comite francais de Certification des Enterprises puor formation et le Suivi du Personnel traivaillant sous Rayonnements losinants.** Radiation protection requirements,
TickIT	**Applications guide for ISO9001-2000 requirements for software**. Joint certification with ISO9001.
10CFR part 50 Appendix B	**Quality Assurance Criteria for Nuclear Power Plants and Fuel Reprocessing Plants.**
10CFR part 21	**Reporting of Defects and non-compliances.**
ANSI/ASME NQA-1	**Quality Assurance Requirements for Nuclear Facilities.**

Audit Team: Leopoldino (Leo) Masiero Audit Team Leader
(GQA)

Personnel Contacted:

Jacky Sert	Head of Industrial Development	(1 & 4)
Laurent Ponthieu	General Manager	(2)
Jean Michel Paleric	Technical Director	(1 & 4)
Alan Morgan	Finance Director	(2)
Philippe Paillat	QA Manager	(1 & 4)
Robert Sonnocal	Customer Business Director	(2)
Daniel Stella	Financial Comptroller	(2 & 4)
Francoise Baillon Nartos	Customer Service Manager	(2)
Marie-Pierre Durand	Project Quality Engineer	(1 & 4)
Sylvain Bazinette	Project Manager	(3 & 4)
Lionel Heitz	Deputy GN Operations	(4)
Michel Belnand	Harware Design & Control Mgr.	(3 & 4)
Jean-Pierre Burel	System Design Manager	(3 & 4)

(1) Attended Pre and Post Audit Conferences.
(2) Attended Pre Audit Conference only.

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(3) Attended Post Audit Conference only.
(4) Contacted During the Audit Performance.

1.0 Introduction

Data Systems & Solutions SAS Meylan originated from the start of the French nuclear program, in the 60's. They were selected to develop the nuclear flux instrumentation and then the safety and non safety class reactor controls. At that time, the Company was part of Merlin Gerin, an established electrical engineering company in Grenoble, which later became Schneider Electric.

In January 2003 Schneider Electric was subsequently acquired by Data Systems & Solutions LLC, headquartered in Reston, Virginia. As of March 2006, Data Systems & Solutions LLC is a fully-owned subsidiary of Rolls-Royce and became part of Rolls-Royce on January 1st 2009.

Through the years, Data Systems & Solutions SAS has delivered to Electricité de France (EDF) the most important part of its Nuclear Island Controls as follows: Nuclear Instrumentation, Reactor Protection, Safety Breakers, Rod Controls and Measurements. Data Systems & Solutions SAS stands number one in terms of mission-critical I&C Assets with EDF. Data Systems & Solutions designs and manufactures Safety Instrumentation and Control systems. Their products include:

- I&C Systems
- Automation and Industrial control

DS&S is the exclusive supplier for Safety I&C French 58 NPP's nuclear market and a world leader in digital protection systems. This market Includes China (second largest customer), Korea, South Africa, Belgium, Bulgaria, Armenia, over 100 reactors have been fitted with DS&S safety I&C.

The DS&S facility is maintained in a 9300 sq. meters area and employs 300 personnel including 30 employees residing at various sites.

2.0 Audit Scope and Summary of Findings

2.1 AUDIT SCOPE

The scope of this audit was to determine the effectiveness of the Data Systems & Solutions, SAS, Quality Management Plan, Revision N, dated June 2008 as it relates to the requirements of 10CFR50 Appendix B.

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2.2 IDENTIFIED FINDINGS and OBSERVATION

The result of the audit was presented to DS&S personnel at the Post Audit Conference held on January 23, 2009. Two findings and three Observations were identified during the audit. The findings and observations are summarized below:

Summary of Findings

Finding AFR No. 1: "Section XII Control of Measuring and Test Equipment". During a tour of the facilities Crimper ID: PO 110 was found without a calibration label. Additionally procedure 924 374K RIS/Detecteur requires specific flow rates during soldering, as well as specific temperature for ovens. Gages used to monitor gas flow and ovens temperatures were not calibrated.

Finding AFR No. 2: "Section XIII Handling, Storage and Shipping".
During a tour in the production area, it was noted that Carbon Steel pliers were used to pull SS wire through SS tubing during a brazing operation. Additionally the file and sandpaper used during the same process were not confirmed by personnel involved in the process as being made of compatible material. Also the jaws of a carbon steel vise located in the same area did not exhibit a buffer.

Summary of Observations

- The status of Armoire (cabinet) CP0503, Belleville 2, was not indicated on the sign. Personnel were well aware of the status and upon request were able to provide evidence.
- Use of Whiteout was observed in some of the documents reviewed as well as changes made without initials and dates.
- The methods used for QA Records storage in the mezzanine do not provide protection from natural disasters (i.e. fire).

Recommendations

- Provide prominence to specific Appendix B requirements, by addressing them in as high a tier document as practical (i.e. separation between personnel performing original design and personnel performing design verification is identified in level II procedures, but not stated in the Quality Plan. Likewise the requirement for "right of access" is mentioned in 8 307 139, Rev. B sub-paragraph 4.5.2, but not in the Quality Plan. Special Processes: Brazing, Soldering and Welding are not identified as SP in the Quality Plan).
- Provide an expiration date on printed documents (i.e. those used in production) to improve document control.
- Ensure that all 10CFR 50 Appendix B sections are referenced in QMP Cross reference Matrix Appendix A.1 (i.e. section V, and XIV).

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- Establish Equivalency between French/European documents (Standards, Specifications, etc.) to US documents (i.e. COFRAC and NIST; 10CFR50 Appendix B and French Regulation for Nuclear Safety [Quality Order of August 10, 1984]).
- Perform a gap-analysis between the existing quality system and the requirements of NQA-1 1994.

3.0 Audit Approach

The audit investigation was conducted using the Audit Checklist: Appendix B to Part 50 supplied by DS&S, Reston, Virginia, USA. No Technical Specialist was used for this audit. The audit was performance based to the extent possible.

4.0 Investigation of Industry Notice/Previous Audit Findings

No previous NRC Inspection Findings/violations, 10CFR Part 21, or any follow up for previous audit findings identified by the client.

5.0 Order Entry and Shipping Point

Customers purchase order requirements are translated by engineering into three main categories: 1. System Specifications (CCS); 2. Equipment Specifications (CCE) and 3. Software Specifications (CCL). This input is followed by a series of actions, a "V" approach, where on one side of the "V" occur design activities, each matched on the other side of the "V" with design documents initiated by engineering for assuring that items and components will be properly fabricated and assembled. The last step, located at the apex of the "V", is Industrial Implementation where Shop Travelers are generated. Shop Travelers provide information relative to hold/witness points (DS&S and Customers), inspections, tests and shipping instructions, work scope, special codes and standards required, and reference to applicable drawings. An evaluation of items is performed for determining safety and seismic class, quality requirements, design methods and design scope. Design documents are evaluated, reviewed and approved by Project Engineering. This final review is performed by an engineer independent of the group performing the design. Upon completion of the review, the independent engineer will indicate acceptance by signing the design document and will indicate the method used for verification. Seismic evaluations are processed in accordance with DS&S Procedures. The Quality Assurance department reviews all safety purchase orders. Exceptions to PO requirements will be communicated to the customer and resolved prior to processing the PO. Shipping occurs after satisfactory performance of final tests.

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6.0 Summary

The Quality Assurance Manager maintains sufficient independence to assure that quality problems are promptly identified and corrected. He reports directly to the DS&S Group Quality Director for relevant matters and issues. Additionally QA tasks and resources are budgeted separately. The effectiveness of quality assurance program is reviewed annually during management review.

DS&S Quality Management Plan Revision N, dated June 2008, is structured to meet the requirements of ISO 9001-2000, with inclusion of additional requirements aimed to meet the intent of 10CFR50 Appendix B. 10CFR Part 21 is stated in the QMP, but the responsibility for compliance will be retained by DS&S Chattanooga, TN (QA Department) according to DS&S management and is supplemented by Quality Procedures. These documents identify specific requirements of codes and standards for providing items/components and parts to the nuclear industry of France, China (second largest customer), Korea, South Africa, Belgium, Bulgaria, Armenia. Procedures and quality records are approved by authorized personnel; controlled; and distributed to the applicable work stations. Required documents are properly identified and indicate applicable acceptance criteria and status.

The Quality Assurance Manual and Quality Procedures identify indoctrination and training needs. Indoctrination and training is provided to all personnel performing activities effecting quality. The implementing procedures describe the requirements for indoctrinating and training of personnel as well as the requirements for qualifying and certifying Auditors, Inspection Personnel and NDE Personnel.

Customers purchase order requirements are translated, by engineering, into three main categories: 1. System Specifications; 2. Equipment Specifications and 3. Software Specifications. This input is followed by a series of actions, a “V” approach, where on one side of the “V” occur design activities, each matched on the other side of the “V by a verification/validation activity. The final output, at the apex of the “V”, is the “Industrial Production” stage. Evaluations performed include determining safety and seismic class, quality requirements, design methods and design scope. Design documents are evaluated, reviewed and approved by Project Engineering. Design reviews are performed by an engineer independent of the group performing the design.

Design changes are processed using Gestion des Evolutions (GEVOL) which is similar to a Design Change Authorization. Changes are subject to the same process as the original design, which include independent verification/validation.

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The procurement process starts with the issuance of a requisition that includes the technical and quality requirements. Procurement sources are reviewed and a vendor is selected using the DS&S Approved Suppliers List. These suppliers are capable of supplying Graded Safety & Quality Related Activities (GSQRA). GSQRA's requirements must be imposed to sub-contractors as needed. When a tier 1 supplier can not comply with GSQRA, it is incumbent on that supplier to demonstrate compliance of those requirements by its subcontractor(s). A PO is prepared utilizing the information received for the item, part, component or services to be procured and according to Class. The PO contains attachments that further define necessary technical and quality requirements. Engineering and QA reviews purchase orders prior to release. Changes to purchase orders are processed in the same manner as the original purchase order.

DS&S ensures that external audits (Quality and Technical), commercial grade surveys, and source verifications are planned and performed periodically. DS&S performs suppliers audits according to 8 307 302, "Rapport audit Systeme". Results of audits are reviewed and evaluated by Quality and once a year collectively by Top Management and the ASL is revised accordingly.

Items and components received from approved suppliers are properly stored and marked/identified in accordance with the requirements established by the applicable procedure(s). Items returned from customers are properly identified with a nonconforming tag and stored in the QC Inspection area. DS&S uses common carriers that normally provide a covered vehicle for shipping items to customers. DS&S ships items using either the client or customer purchase order requirements or standard industry shipping practices. No shipping was in process during the audit for observing.

DS&S generates a Suivi Operation Usine (SOU = a Shop Traveler) which references Quality requirements for processing the received items into fabricated/assembled items and components. The Shop Traveler references design and specification requirements, design changes, SP, tests requirements, and inspection reports. The steps listed on the SOU Quality inspection reports are verified by qualified personnel who initial and date the acceptable steps listed on these documents. SOU's, Quality documents and Material Traceability Reports are generated for maintaining traceability of items, parts and components. Items considered acceptable are identified with an identification tag attached to the items or marked with a paint stick. Traceability Code numbers are cross-referenced on documents and is the controlling identifier for traceability purposes and remains with the item/component throughout the entire fabricating/assembly processes. This was observed during the audit. In-process

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and completed safety job packages were reviewed for program and costumer purchase order compliance.

Special Process controls are adequately identified, performed under controlled conditions, include documented procedures, require brazing/soldering and welding personnel to be qualified and utilize qualified equipment. The welder qualification date, positions qualified, welding codes and procedures qualified to are listed on each Qualification Record.

Inspections are performed in accordance with documented procedures utilizing Quality Instructions and Inspection Reports. Receiving Inspections are performed on items received and the results of inspections are documented on Receiving Reports (RR). Receiving Inspections are performed to verify compliance to PO requirements, identified critical characteristics and acceptance criteria listed on the Commercial Grade Item Package. Receiving, in-process and final test and inspections are performed by qualified personnel using applicable and controlled documents that include acceptance or rejection criteria. Rejected items are processed using the DS&S Nonconformance and Corrective Action system. Measuring and test equipment used in performing test and inspections are maintained in a computer database that includes the calibration date, as-found/as-left condition and the calibration due date. The calibration of the majority of the DS&S measuring and test equipment is calibrated by approved outside calibration agencies. Calibration of measuring and test equipment by DS&S is performed in an adequately controlled environment utilizing standards that are traceable to COFRAC (French Committee of Accreditation equivalent to A2LA). One crimper was found without a calibration label. Additionally the brazing/soldering procedure observed during the audit, requires specific flow rates during soldering, as well as specific temperature for ovens. Gages used to monitor gas flow and ovens temperature were not calibrated (refer to finding AFR No. 1).

Parts and components are stored in a manner that precludes deterioration and contamination. SS tubing and other SS material is prevented from contacting CS by the use of buffer material (i.e. plywood). However during a tour in the production area, it was noted that Carbon Steel pliers were used to pull SS wire through SS tubing during a brazing operation. Additionally the file and sandpaper used during the same process were not confirmed by personnel involved in the process as being made of compatible material. Also the jaws of a carbon steel vise, located in the same area, did not exhibit a buffer (refer to AFR No. 2).

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Quality Procedure 8 303 194 K, “Maitrise du Prodiut Achete`”, defines established requirements for qualifying commercial grade items and services for use as part of or as a basic component in nuclear safety applications. The methods of dedication include Special Test (method 1); Commercial Grade Survey (method 2); and Source Inspection (method 3).

Dedication of Commercial Grade Items is processed using a Dedication Plan that includes the critical characteristics, quality standards, documentation requirements, and inspection activities. No Commercial Grade Dedication processes were being conducted for observing during the audit.

Statistical Sampling are developed in accordance with 8 303 405 H and established the size, formulation, sample plans decisions, and describes the type of sampling plan to be used. Sampling Plans are used to indicate the lot and sample size to be verified using the normal method for nondestructive and destructive testing inspections.

Quality Assurance records are maintained in accordance with the established program and procedure requirements. Records reviewed were verified to be completed, legible, identifiable and retrievable.

7.0 Technical Specialist Summary

A technical specialist was not part of this audit team.

8.0 Effectiveness

Based on the procedures, instructions, drawings reviewed, and personnel interviewed the DS&S Grenoble, France, QA Program was deemed effectively implemented (with the exception of findings # 1 and # 2).

Prepared by: Date: February 14, 2009

Leopoldino Masiero
GQA - Audit Team Leader

Attachments

1. Findings/Observation
2. Checklist

11602 LAKE UNDERHILL RD., SUITE 106 * ORLANDO, FL 32825
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AUDIT FINDING REPORT

Page 1 of 1

AUDIT NO. PO 4400000737 **AFR NO 1**

AUDITED ORGANIZATION: Data Systems & Solutions, SAS

AUDIT LOCATION: 23 Chemin du Vieux Chene, F-38246, Meylan Cedex, France

10 CFR PART 21 EVALUATION REQUIRED: [ ] YES [X] NO

REQUIREMENT/CRITERIA: 10CFR50 Appendix B, Sec XII states: "…Measures shall be established to assure that tools, gages, instruments, and other measuring and testing devices used in activities affecting quality are properly controlled, calibrated, and adjusted at specified periods to maintain accuracy within necessary limits…"

CONTINUED [ ]

FINDING/DISCUSSION: Contrary to the above requirements: Crimper ID: PO 110 was found without a calibration label.

Additionally procedure 924 374K RIS/Detecteur requires specific flow rates during soldering, and oven temperatures.

Gages used to monitor gas flow and oven temperatures were not calibrated.

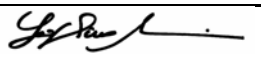
CONTINUED [ ]

RECOMMENDATIONS:
Affix a calibration label to Crimper ID PO 110. Calibrate gages monitoring flow rates and temperatures.

CONTINUED [ ]

IMMEDIATE ACTION TAKEN/IMPACT:
Potential for improper crimping and soldering.

CONTINUED [ ]



ATL: **DATE: Feb. 16, 2009**

CUSTOMER REPLY (INCLUDE CAUSE, CORRECTIVE/PREVENTATIVE ACTION)

CONTINUED [ ]

CUSTOMER QA REPRESENTATIVE: **DATE:**

EVALUATION OF REPLY:

CONTINUED [ ]

ATL: **DATE:**

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AUDIT FINDING REPORT

AUDIT NO. PO 4400000737 **AFR NO 2.**

AUDITED ORGANIZATION: Data Systems & Solutions, SAS

AUDIT LOCATION: 23 Chemin du Vieux Chene, F-38246, Meylan Cedex, France

10 CFR PART 21 EVALUATION REQUIRED: [ ] YES [X] NO

REQUIREMENT/CRITERIA: 10CFR50 Appendix B, Sec XIII states: "… Measures shall be established to control the handling, storage, shipping, cleaning and preservation of material and equipment in accordance with work and inspection instructions to prevent damage or deterioration. When necessary for particular products, special protective environments, such as inert gas atmosphere, specific moisture content levels, and temperature levels, shall be specified and provided…"

CONTINUED [ ]

FINDING/DISCUSSION: Carbon Steel pliers were used to pull SS wire through SS tubing during a brazing operation. Additionally the file and sandpaper used during the same process were not confirmed by personnel involved in the process as being made of compatible material. Also jaws of a carbon steel vise located in the same area did not exhibit a buffer.

CONTINUED [ ]

RECOMMENDATIONS:
Use SS pliers and compatible file and sandpaper. Install buffers on the vise jaws.

CONTINUED [ ]

IMMEDIATE ACTION TAKEN/IMPACT:
No immediate action taken.
Potential for ferritic contamination.

CONTINUED [ ]

ATL:	**DATE: Feb. 16, 2009**

CUSTOMER REPLY (INCLUDE CAUSE, CORRECTIVE/PREVENTATIVE ACTION)

CONTINUED [ ]

CUSTOMER QA REPRESENTATIVE:	**DATE:**

EVALUATION OF REPLY:

CONTINUED [ ]

ATL:	**DATE:**

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AUDIT FINDING REPORT

AUDIT NO. PO 4400000737 **AFR NO 1**

AUDITED ORGANIZATION: Data Systems & Solutions, SAS

AUDIT LOCATION: 23 Chemin du Vieux Chene, F-38246, Meylan Cedex, France

10 CFR PART 21 EVALUATION REQUIRED: [ ] YES [X] NO

REQUIREMENT/CRITERIA: 10CFR50 Appendix B, Sec XII states: "…Measures shall be established to assure that measuring and testing devices used in activities affecting quality are properly controlled, calibrated, and adjusted at sp within necessary limits…"

FINDING/DISCUSSION: Contrary to the above requirements: Crimper ID: PO 110 was found without a calibration label.

Additionally procedure 924 374K RIS/Detecteur requires specific flow rates during soldering, and oven temperatures. Gages used to monitor gas flow and oven temperatures were not calibrated. **CONTINUED [ ]**

RECOMMENDATIONS:
Affix a calibration label to Crimper ID PO 110. Calibrate gages monitoring flow rates and temperatures. **CONTINUED [ ]**

IMMEDIATE ACTION TAKEN/IMPACT:
Potential for improper crimping and soldering.

ATL: **DATE: Feb. 16, 2009**

CUSTOMER REPLY (INCLUDE CAUSE, CORRECTIVE/PREVENTATIVE ACTION)

1) Crimpers

Cause: Periodic pulling tests are performed and we thought it was sufficient to verify the crimpers.

Corrective Action: Crimpers P0110 and P0111 are now verified and identified with a label. They are managed in the Hasting database. An annual verification is scheduled and performed by internal people using a "Go No-Go" tool (CAGE 11851 – G125 ID: T090101). This tool is verified by France Quality company which is COFRAC certified. Furthermore, a corrective action is opened to study where to describe this kind of crimping process: in an existing special process document or a new one.

2) Flow meters and oven temperatures

Cause: No precise measurement is required in the process. The value range defined in the instruction is an indicative one.

Corrective Action: Nevertheless, in order to avoid potential non controlled drifts, flow meters and ovens will be monitored.

The two flow meters will be verified once a year by a certified company. They will be identified with a label and managed in the Hasting database.

Regarding oven temperature, a thermocouple or another calibrated mean will be used to compare the temperature inside the oven and the displayed value. A margin will be defined to identify non-conforming ovens. This verification will be performed every year. They will be identified with a label and managed in the Hasting database.

CUSTOMER QA REPRESENTATIVE: MP. Durand **DATE: March 24, 2009**

EVALUATION OF REPLY: Response is acceptable. The objective evidence submitted is sufficient to ensure that the stated corrective action has been established and implemented. The effectiveness of the corrective actions taken will be reviewed at the next audit.

CONTINUED [ ]

ATL: **DATE: April 30, 2009**

AUDIT FINDING REPORT

AUDIT NO. PO 4400000737 **AFR NO 2.**

AUDITED ORGANIZATION: Data Systems & Solutions, SAS

AUDIT LOCATION: 23 Chemin du Vieux Chene, F-38246, Meylan Cedex, France

10 CFR PART 21 EVALUATION REQUIRED: [ ] YES [X] NO

REQUIREMENT/CRITERIA: 10CFR50 Appendix B, Sec XIII states: "… Measures shall be established to control the handling, storage, shipping, cleaning and preservation of material and equipment in accordance with work and inspection instructions to prevent damage or deterioration. When necessary for particular products, special protective environments, such as inert gas atmosphere, specific moisture content levels, and temperature levels, shall be specified and provided…"

CONTINUED [ ]

FINDING/DISCUSSION: Carbon Steel pliers were used to pull SS wire through SS tubing during a brazing operation. Additionally the file and sandpaper used during the same process were not confirmed by personnel involved in the process as being made of compatible material. Also jaws of a carbon steel vise located in the same area did not exhibit a buffer.

CONTINUED [ ]

RECOMMENDATIONS:
Use SS pliers and compatible file and sandpaper. Install buffers on the vise jaws.

CONTINUED [ ]

IMMEDIATE ACTION TAKEN/IMPACT:
No immediate action taken.
Potential for ferritic contamination.

CONTINUED [ ]

ATL: **DATE: Feb. 16, 2009**

CUSTOMER REPLY (INCLUDE CAUSE, CORRECTIVE/PREVENTATIVE ACTION)

Cause: problem was already identified but the corrective action was not opened.

Corrective action: The improvement action AA-09-741 has been created.
According this action we have planed to

1) Identify the tools and operations with potential risk (End of May)
2) Analyze each case and propose solution (June-July 09)
3) Implement the solutions; replace the tools that have to be replaced (until the end of the year).

CUSTOMER QA REPRESENTATIVE: MP. Durand **DATE: April 20, 2009**

EVALUATION OF REPLY: Response is acceptable. The objective evidence submitted is sufficient to ensure that the stated corrective action has been established and implemented. The effectiveness of the corrective actions taken will be reviewed at the next audit.

CONTINUED [ ]

ATL: **DATE: April 30, 2009**

Appendix B to Part 50 -- Quality Assurance Criteria for Nuclear Power Plants and Fuel Reprocessing Plants

Section #	10CFR50 App B Requirement	Compliance of the DS&S QA Program (I&C US)	Finding #'s
		Automatically filled in from the individual criteria tabs	Insert Finding # from Final Audit Report
I	Organization	*Comply*	
II	Quality Assurance Program	*Comply*	
III	Design Control	*Comply*	
IV	Procurement Document Control	*Comply*	
V	Instructions, Procedures, and Drawings	*Comply*	
VI	Document Control	*Comply*	
VII	Control of Purchased Material, Equipment, and Services	*Comply*	
VIII	Identificaiton and Control of Materials, Parts and Components	*Comply*	
IX	Control of Special Processes	*Comply*	
X	Inspection	*Comply*	
XI	Test Control	*Comply*	
XII	Control of Measuring and Test Equipment	*Comply*	AFR No.1
XIII	Handling, Storage and Shipping	*Comply*	AFR No.2
XIV	Inspection, Test, and Operating Status	*Comply*	
XV	Nonconforming Materials, Parts, or Components	*Comply*	
XVI	Corrective Action	*Comply*	
XVII	Quality Assurance Records	*Comply*	
XVIII	Audits	*Comply*	

Appendix B to Part 50 -- Quality Assurance Criteria for Nuclear Power Plants and Fuel Reprocessing Plants				
Criteria	**10CFR50 App B Requirement**	**Compliance of I&C France**	**Supporting Documents**	**Findings Necessary to ensure Compliance, responsible party**

Choose from the pulldown list the correct summary statement for the compliance of this criteria. Click on the box below and use the arrow on the right side.

Comply

I - Organization				
I - Organization	The applicant (1) shall be responsible for the establishment and execution of the quality assurance program. The applicant may delegate to others, such as contractors, agents, or consultants, the work of establishing and executing the quality assurance program, or any part thereof, but shall retain responsibility for the quality assurance program. The authority and duties of persons and organizations performing activities affecting the safety-related functions of structures, systems, and components shall be clearly established and delineated in writing. These activities include both the performing functions of attaining quality objectives and the quality assurance functions. The quality assurance functions are those of (1) assuring that an appropriate quality assurance program is established and effectively executed; and (2) verifying, such as by checking, auditing, and inspecting, that activities affecting the safetyrelated functions have been correctly performed. The persons and organizations performing quality assurance functions shall have sufficient authority and organizational freedom to identify quality problems; to initiate, recommend, The persons and organizations performing quality assurance functions shall report to a management level so that the required authority and organizational freedom, including sufficient independence from cost and schedule when opposed to safety considerations, are provided. Because of the many variables involved, such as the number of personnel, the type of activity being performed, and the location or locations where activities are performed, the organizational structure for executing the quality assurance program may take various forms, provided that the persons and organizations assigned the quality assurance functions have the required authority and organizational freedom. Irrespective of the organizational structure, the individual(s) assigned the responsibility for assuring effective execution of any portion of the quality assurance program at any location where activities subject to this appendix are being	*[expected in this box are the high level polocies and manuals that govern how this criteria is exhibited]* ***8 303 701*** *Organization*	*[expected in this box are the support secondary policies, work instructions, workflow diagrams and other guidance documents utilized by staff to exhibit complaint to this criteria. This could be corporate policies and records as well.]* **ICQ-004** Quality Organization Diagram **ICQ-005** Quality Oversight Board **CPP00/001** Company Overview and Organization	*[expected in this box are any associated Findings related to this specific criteria]* CMA #1) Development of ICQ-004 & ICQ-005 - LW CMA #2) Review of organization structures between the three entities to ensure continuity - LW, PP, TS

Appendix B to Part 50 -- Quality Assurance Criteria for Nuclear Power Plants and Fuel Reprocessing Plants				
Criteria	**10CFR50 App B Requirement**	**Compliance of I&C France**	**Supporting Documents**	**Findings Necessary to ensure Compliance, responsible party**
Comply				
I - Organization				
I - Organization	The applicant (1) shall be responsible for the establishment and execution of the quality assurance program. The applicant may delegate to others, such as contractors, agents, or consultants, the work of establishing and executing the quality assurance program, or any part thereof, but shall retain responsibility for the quality assurance program. The authority and duties of persons and organizations performing activities affecting the safety-related functions of structures, systems, and components shall be clearly established and delineated in writing. These activities include both the performing functions of attaining quality objectives and the quality assurance functions. The quality assurance functions are those of (1) assuring that an appropriate quality assurance program is established and effectively executed; and (2) verifying, such as by checking, auditing, and inspecting, that activities affecting the safetyrelated functions have been correctly performed. The persons and organizations performing quality assurance functions shall have sufficient authority and organizational freedom to The persons and organizations performing quality assurance functions shall report to a management level so that the required authority and organizational freedom, including sufficient independence from cost and schedule when opposed to safety considerations, are provided. Because of the many variables involved, such as the number of personnel, the type of activity being performed, and the location or locations where activities are performed, the organizational structure for executing the quality assurance program may take various forms, provided that the persons and organizations assigned the quality assurance functions have the required authority and organizational freedom. Irrespective of the organizational structure, the individual(s) assigned the responsibility for assuring effective execution of any portion of the quality assurance program at any location where activities subject to this appendix are being	Quality Management Plan Rev. N Dated 06/2008, Paragraph 1.3 "Organization" andParagraph 4.1 " Corporate Structure and company's main processes" SMQ's 8 303 701 "Presentation and Organization", and 8 303 242 Rev. L "Quality Management System". The requirements, reviewed during the audit, are existing requirements. As of January 1st 2009, DS&S is no longer a subsidiary of Rolls Royce, but part of it.	Personnel Interviewed: Jacky Sert Head of Industrial Development; Laurent Ponthieu General Manager; Jean Michel Paleric Technical Director; Alan Morgan Finance Director; Philippe Paillat QA Manager; Robert Sonnocal Customer Business Director; Daniel Stella Financial Comptroller; Francoise Baillon Nartos Customer Service Manager; and Marie-Pierre Durand Project Quality Engineer SMQ 8 303 701 provides additional information regarding the Organization. The Org. chart shown in this document does not present the same level of Quality Dpt. independence shown in the QMP, where the QA Manager reports directly to the DS&S Quality Director (via dotted line). However this independence is re-instated within the body of SMQ 8 303 701. The Organizational structure is well documented, and reflects functional responsibilities, level of authority, and communications lines for activities affecting quality. Independence (not only organizational but also financial, in that the QA Department has its own budget), authority and access to management of personnel performing quality verifications a	**Comment:** Paragraph 4.1 does not indicate that when the organization chooses to outsource any product that affects product conformity with requirements, the organization ensures control over such processes and retains responsibility. Reference ISO 9001-2000 Paragraph 4.1

Appendix B to Part 50 -- Quality Assurance Criteria for Nuclear Power Plants and Fuel Reprocessing Plants				
Criteria	**10CFR50 App B Requirement**	**Compliance of I&C France**	**Supporting Documents**	**Findings Necessary to ensure Compliance, responsible party**
Comply				
II - Qualtiy Assurance Program				
II - Quality Assurance Program	The applicant shall establish at the earliest practicable time, consistent with the schedule for accomplishing the activities, a quality assurance program which complies with the requirements of this appendix. This program shall be documented by written policies, procedures, or instructions and shall be carried out throughout plant life in accordance with those policies, procedures, or The applicant shall identify the structures, systems, and components to be covered by the quality assurance program and the major organizations participating in the program, together with the designated functions of these organizations. The quality assurance program shall provide control over activities affecting the quality of the identified structures, systems, and components, to an extent consistent with their importance to safety. Activities affecting quality shall be accomplished under suitably controlled conditions. Controlled conditions include the use of appropriate equipment; suitable environmental conditions for accomplishing the activity, such as adequate cleanness; and assurance that all prerequisites for the given activity have been satisfied. The program shall take into account the need for special controls, processes, test equipment, tools, and skills to attain the required The program shall provide for indoctrination and training of personnel performing activities affecting quality as necessary to assure that suitable proficiency is achieved and maintained. The applicant shall regularly review the status and adequacy of the quality assurance program. Management of other organizations participating in the quality assurance program shall regularly review the status and adequacy of that part of the quality assurance program which they are	Personnel Interviewed: P. Paillat Quality Manager; MP Durant Quality Engineer QMP Paragraph 4, and SMQ 8 303 242 "Quality Management System" Rev. L; QMP Paragraph 6, and SMQ 8 303 696 "Resource Management Process" Rev. E; QMP Paragraph 6.2, SMQ 8 307 053 "Humane Resources Process" Rev. B, SMQ 8 303 321 "Training of Personnel" Rev. J, and SMQ 8 303 386 "Training of Personnel for On-site Activities" Rev. J	The organization satisfactorily defines the planning, implementation, and maintenance of its quality program which includes appropriate links to safety, and, where necessary, requirements for controlled conditions. Requirements for proficiency achievement and retraining of personnel performing quality affecting activities, or for personnel performing special processes (i.e. soldering, brazing and NDE) are defined (please see comment on the next column).	**Comment** Requirements for proficiency achievement and retraining of personnel performing quality affecting activities, or for personnel performing special processes (i.e. soldering, brazing and NDE) are defined, but not to the degree of specificity stated, for instance, in the applicable ANSI N45.2 daughters standard nor are there specific references to NQA-1 Supplements. The QMP in Paragraph 2 "Normative References" simply lists NQA-1 (but not revision date), and 10CFR Part 21. Methods for implementation of these two documents were not notably stated in the QMP, or any of the other top tier documents reviewed during the audit.

Appendix B to Part 50 -- Quality Assurance Criteria for Nuclear Power Plants and Fuel Reprocessing Plants				
Criteria	**10CFR50 App B Requirement**	**Compliance of I&C France**	**Supporting Documents**	**Findings Necessary to ensure Compliance, responsible party**
		Comply		
		III - Design Control		
III - Design Control	Measures shall be established to assure that applicable regulatory requirements and the design basis, as defined in § 50.2 and as specified in the license application, for those structures, systems, and components to which this appendix applies are correctly translated into specifications, drawings, procedures, and instructions. These measures shall include provisions to assure that appropriate quality standards are specified and included in design documents and that deviations from such standards are controlled. Measures shall also be established for the selection and review for suitability of application of materials, parts, Measures shall be established for the identification and control of design interfaces and for coordination among participating design organizations. These measures shall include the establishment of procedures among participating design organizations for the review, approval, release, distribution, and revision of documents involving design interfaces. The design control measures shall provide for verifying or checking the adequacy of design, such as by the performance of design reviews, by the use of alternate or simplified calculational methods, or by the performance of a suitable testing program. The verifying or checking process shall be performed by individuals or groups other than those who performed the original design, but who may be from the same organization. Where a test program is used to verify the adequacy of a specific design feature in lieu of other verifying or checking processes, it shall include suitable qualifications testing of a prototype unit under the most adverse design conditions. Design control measures shall be applied to items such as the following: reactor physics, stress, thermal, hydraulic, and accident analyses; compatibility of materials; accessibility for inservice inspection, maintenance, and repair; Design changes, including field changes, shall be subject to design control measures commensurate with those applied to the original design and be approved by the organization that performed the original design unless the applicant designates another responsible	Personnel Interviewed: JM Palaric, JP Burel, G Favier, Daviau, H Tabouret, MP Durand, P Lin. QMP Paragraph 7, and SMQ 8 303 693 "Product Development Process" Rev. E; QMP Paragraph 7.3, SMQ 8 303 8 303 349 "Electronic Design Process" Rev. J, SMQ 8 303 714 "Control of EMC Constraints", SMQ 8 303 352 "Control of Subassemblies Long Term Maintenance" Rev. F, SMQ 8 303 334 "System Design (Safety Systems)" Rev. F, SMQ 8 307 170 "System Design (Non Safety Systems)" Rev. A, SMQ 8 307 032 "Principles for control of Design Safety Systems" Rev. C, SMQ 8 307 032 "Principles for control of Design Non Safety Systems" Rev. A, and SMQ 8 303 603 "Equipment Design Process" Rev. F.	The review of the design activities included a presentation of a project from members of the Design Team, Sylvain Bazinette (Project Manager), Pascale Baranek (System Engineer), Hélène Tabouret (Software QA), Pierre Bechetoile (Software Engineer). This presentation, and the documentation provided, indicated that the design process is governed by a number of procedures each providing directions on the implementation of different facets and for coordination among participants in the overall design process. The "V" chart, and the records reviewed, clearly indicate separation by System Design and System Integration-Validation.	**N/A**

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Criteria	**10CFR50 App B Requirement**	**Compliance of I&C France**	**Supporting Documents**	**Findings Necessary to ensure Compliance, responsible party**
Comply				
IV - Procurement Document Control				
IV - Procurement Document Control	Measures shall be established to assure that applicable regulatory requirements, design bases, and other requirements which are necessary to assure adequate quality are suitably included or referenced in the documents for procurement of material, equipment, and services, whether purchased by the applicant or by its contractors or subcontractors. To the extent necessary, procurement documents shall require contractors or subcontractors to provide a quality assurance program consistent with the pertinent provisions of this appendix.	Personnel Interviewed: B Ferrier, D Mathieu. QMP Paragraph 7.4, SMQ 8 303 698 "Purchasing Process" Rev. D; SMQ 8 303 398 "Purchasing Order Processing Procedure" Rev. L; SMQ 8 307 139 "Project Development Process" Rev. J; and SMQ 8 303 194 "Commercial Grade Items" Rev. K; QMP Paragraph 7, SMQ 8 303 314 Rev. J; and SMQ 8 303 699 "Project Control" Rev. C; QMP Paragraph 7.2, SMQ 8 303 700 "Launch Review" Rev. B.	Personnel interviewed, and sample of PO's (for safety related procurement) reviewed provided evidence of appropriate reference to scope of work, QA requirements, technical requirements (referenced or stated, including requirements for inspection and test and acceptance criteria), requirements for reporting of nonconformances, and requirements for control of sub-suppliers. Right of Access and Spare and Replacements Parts were also indicated.	**N/A**

Appendix B to Part 50 -- Quality Assurance Criteria for Nuclear Power Plants and Fuel Reprocessing Plants				
Criteria	**10CFR50 App B Requirement**	**Compliance of I&C France**	**Supporting Documents**	**Findings Necessary to ensure Compliance, responsible party**
Comply				
V - Instructions, Procedures and Drawings				
V - Instructions, Procedures and Drawi	Activities affecting quality shall be prescribed by documented instructions, procedures, or drawings, of a type appropriate to the circumstances and shall be accomplished in accordance with these intructions, procedures, or drawings. Instructions, procedures, or drawings shall include appropriate quantitative or qualitative acceptance criteria for determining that important activities have been satisfactorily accomplished.	Personnel Interviewed: C. Dessaigne, MP Durand. QMP paragraph 4.2.3, SMQ 8 303 719 "Control of Documents".	Documents range from Quality Management Plan, a top tier document describing the Quality System and its interaction among all departments, to a "Suivi Operation Usine" (SOU, comparable to a "Traveller") describing the step-by step operations including reference to inspection/test requirements, instructions, drawings, and Hold or Witness points. SOU's provide also accept or reject status, reference to nonconformity (when applicable) and a record of the person performing the activities, which in turn provides evidence of inspecting personnel independence. Inspection Instructions are approved by QA, Work Instructions are approved by Engineering.	**N/A**

Appendix B to Part 50 -- Quality Assurance Criteria for Nuclear Power Plants and Fuel Reprocessing Plants				
Criteria	**10CFR50 App B Requirement**	**Compliance of I&C France**	**Supporting Documents**	**Findings Necessary to ensure Compliance, responsible party**
Comply				
VI - Document Control				
VI - Document Control	Measures shall be established to control the issuance of documents, such as instructions, procedures, and drawings, including changes thereto, which prescribe all activities affecting quality. These measures shall assure that documents, including changes, are reviewed for adequacy and approved for release by authorized personnel and are distributed to and used at the location where the prescribed activity is performed. Changes to documents shall be reviewed and approved by the same organizations that performed the original review and approval unless the applicant designates another responsible organization.	Personnel Interviewed: C Dessaigne, MP Durand. QMP Paragraph 4.2, and SMQ 8 303 719 "Control of Documents" Rev. E; QMP Paragraph 7.3, SMQ 8 307 198 "Control of Engineering Documents" Rev. P,	Documents are generated by qualified and authorized personnel, and reviewed by a "…qualified person, other than the author, having at least the same skills level than the writer…" are uniquely identified, distributed under controlled conditions. The correct document is typically cross-referenced in implementing instructions and drawings. Documents reviewed during the audit provided evidence of compliance with the above requirements.	**Observation**: Use of Whiteout was observed in some of the documents reviewed, as well as changes made without initials and dates.

Appendix B to Part 50 -- Quality Assurance Criteria for Nuclear Power Plants and Fuel Reprocessing Plants				
Criteria	**10CFR50 App B Requirement**	**Compliance of I&C France**	**Supporting Documents**	**Findings Necessary to ensure Compliance, responsible party**
		Comply		
		VII - Control of Purchased Materials, Equipment and Services		
VII - Control of Purchased Materials, Equipment and Services	Measures shall be established to assure that purchased material, equipment, and services, whether purchased directly or through contractors and subcontractors, conform to the procurement documents. These measures shall include provisions, as appropriate, for source evaluation and selection, objective evidence of quality furnished by the contractor or subcontractor, inspection at the contractor or subcontractor source, and examination of products upon delivery.	Personnel Interviewed:B Ferrier, D Mathieu, P Paillat. QMP Paragraph 7.4, and SMQ 8 303 404 "Procurement Inspection (quantity)" Rev. K; SMQ 8 303 405 "Procurement Inspection (quality)" Rev. H; QMP Paragraph 7.3, QPM 7.5 SMQ 8 303 715 "Monitoring of subassemblies Suppliers" Rev. G.	According to personnel interviewed and records provided, the Organization presently deals with 30-35 suppliers whose performance is evaluated, on a point system, quarterly and yearly. New suppliers are selected (according to 8, prior to award of contract, on the basis of Quality, Technical Expertise, and Finances. Suppliers are evaluated on a yearly basis (reports are sent to Receiving Inspection) and they are listed in four categories ranging from A to D. Category "A" for Safety related suppliers. "Category B" are suppliers of product impacting the quality of the final product. Category "C" are suppliers are based on Availability, and category "D" on the specific impact on the product being manufactured. Key suppliers (i.e. suppliers of safety related items) are audited by the organization.	**N/A**
	Documentary evidence that material and equipment conform to the procurement requirements shall be available at the nuclear powerplant or fuel reprocessing plant site prior to installation or use of such material and equipment. This documentary evidence shall be retained at the nuclear powerplant or fuel reprocessing plant site and shall be sufficient to identify the specific requirements, such as codes, standards, or specifications, met by the purchased material and equipment.		Incoming product, as witnessed during a visit to the receiving area, is checked and inspected for in-transit damage and correct quantity. Product is then forwarded to the RI department, where receiving inspection is performed by qualified and certified personnel. The type of inspection or test is identified on a traveller which references applicable accept/reject criteria, certificates required from the supplier, or, when necessary, reference to applicable instructions. The items reviewed during the audit included: Supplier: ERMA, PO 0A08-01292, PN 0923333, provided both quantity/quality acceptance records of and traceability via lot number. Supplier: Tech. Power Electronics 4/11/2008 Test Procedure 147507 Rev. B "Specification d' Approvinionament" provides a sampling plan, Table II-A. Records provide required test results as well as traceability.	
	The effectiveness of the control of quality by contractors and subcontractors shall be assessed by the applicant or designee at intervals consistent with the importance, complexity, and quantity of the product or services.			

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Criteria	**10CFR50 App B Requirement**	**Compliance of I&C France**	**Supporting Documents**	**Findings Necessary to ensure Compliance, responsible party**
Comply				
VIII - Identification and Control of Materials, Parts and Components				
VIII - Identification and Control of Materi	Measures shall be established for the identification and control of materials, parts and componenets, including partially fabricated assemblies. These measures shall assure that identification of the item is maintained by heat number, part number, serial number, or other appropirate means, either on the item or on records traceable to the item, as required throughout fabrication, erection, installation, and use of the item. These identification and control measures shall be designed to prevent the use of incorrect or defective material, parts and components.	Personnel Interviewed: M Bainard, MP Durand. QMP Paragraph 7.5, and SMQ 8 303 221 "Product Identification and Traceability" Rev. G	SMQ 8 303 221 "Product Identification and Traceability" Rev. G, provides requirements relative to identification, maintenance of identification, and methods for traceability. Identification is obtained by the use of tags, labels and signs. Traceability is maintained through serial numbers, or lot number assigned by the Organization, procured parts and components are traceable to suppliers' part or lot number. During production all product observed in the warehouse and production areas, was identified, and traceability obtainable through paper-trail. Identification (including status of Inspection and test) and Traceability in production is maintained on the SOU (traveller).	**N/A**

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Criteria	**10CFR50 App B Requirement**	**Compliance of I&C France**	**Supporting Documents**	**Findings Necessary to ensure Compliance, responsible party**
Comply				
IX - Control of Special Processes				
IX - Control of Special Processes	Measures shall be established to assure that special processes, including welding, heat treating, and nondestructive testing, are controlled and accomplished by qualified personnel using qualified procedures in accordance with applicable codes, standards, specifications, criteria, and other special requirements	Personnel interviewed: M Belnand, H Boumedien, A Stourm, MP Durand, P Paillat. QMP Paragraph 7.5, SMQ 8 303 222 "Manufacturing Process" Rev. G; SMQ 8 303 380 "Control of on-site used Processes" Rev. H.	According to top management representatives interviewed, personnel responsible for Brazing, Soldering and Welding are trained at an outside consulting firm. It is unclear if the training given complies with a French/European standards, and if so, how they compare to US standards (i.e.: ASME IX). Nevertheless, after formal training, personnel is further trained by DS&S and required to perform a hands-on test (coupon) to verify their ability to meet requirements. These coupons, however, are not kept. Records of training is maintained, and was verified for Mr. Sebastian Dermedreu.	**N/A**

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Criteria	**10CFR50 App B Requirement**	**Compliance of I&C France**	**Supporting Documents**	**Findings Necessary to ensure Compliance, responsible party**
Comply				
X - Inspection				
X - Inspection	A program for inspection of activities affecting quality shall be established and executed by or for the organization performing the activity to verify conformance with the documented instructions, procedures, and drawings for accomplishing the activity. Such inspection shall be performed by individuals other than those who performed the activity being inspected. Examinations, measurements, or tests of material or products processed shall be performed for If inspection of processed material or products is impossible or disadvantageous, indirect control by monitoring processing methods, equipment, and personnel shall be provided. Both inspection and process monitoring shall be provided when control is inadequate without both. If mandatory inspection hold points, which require witnessing or inspecting by the applicant's designated representative and beyond which work shall not proceed without the consent of its designated representative are required, the specific hold points shall be indicated in appropriate documents.	Personnel interviewed: M Belnand, D Mathieu, MP Durand. QMP Paragraph 8.2.4, SMQ 8 303 223 "In-process Inspection and Test" Rev. M; QMP 7.5 SMQ 8 303 662 "Inspection and Test for Product Repair" Rev. G.	Inspection requirements (Receiving, In-process, and Final Inspections) are approved by the QA Department, and are performed by qualified personnel other than those performing the task being inspected. A tour of the facility, warehouse and production areas indicated that SOU's state the inspections to be performed, as well as Witness or Hold points. They also provide a record on the status of those inspections any nonconformity identified, and the need for Repair, Rework or Replacement, in which case re-inspection is required.	**N/A**

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Criteria	**10CFR50 App B Requirement**	**Compliance of I&C France**	**Supporting Documents**	**Findings Necessary to ensure Compliance, responsible party**
Comply				
XI - Test Control				
XI - Test Control	A test program shall be established to assure that all testing required to demonstrate that structures, systems, and components will perform satisfactorily in service is identified and performed in accordance with written test procedures which incorporate the requirements and acceptance limits contained in applicable design documents. The test program shall include, as appropriate, proof tests prior to installation, preoperational tests, and operational tests during nuclear power plant or fuel reprocessing plant operation, of structures, systems, and components. Test procedures shall include provisions for assuring that all prerequisites for the given test have been met, that adequate test instrumentation is available and used, and that the test is performed under suitable environmental conditions. Test results shall be documented and evaluated to assure that test requirements have been satisfied.	Personnel interviewed: M Belnand, H Boumedien, A Stourm, MP Durand. QMP Paragraph 8.2.4, SMQ 8 303 223 "In-process Inspection and Test" Rev. M; QMP 7.5 SMQ 8 303 662 "Inspection and Test for Product Repair" Rev. G; SMQ 8 303 382 "On-site Maintenance Preparation, Follow-up" Rev. K.	Test requirements (to verify product, including software, conformance to requirements) are defined during design and approved by Engineering. They are performed by qualified personnel other than those performing the task being inspected. A tour of the facility, warehouse and production areas indicated that SOU's state the inspections to be performed, as well as Witness or Hold points. Final acceptance Test (FAT) results are archived and were easily retrievable for IDMS 5 100 436-750 Rev. L, (the binder contained Drawings, Test Procedures, Parts-List, Wiring Diagrams). They also provide a record on the status of those tests and any nonconformity identified.	**N/A**

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Criteria	**10CFR50 App B Requirement**	**Compliance of I&C France**	**Supporting Documents**	**Findings Necessary to ensure Compliance, responsible party**
Comply				
XII - Control of Measuring and Test Equipment				
XII - Control of Measuring and Test Equipment	Measures shall be established to assure that tools, gages, instruments, and other measuring and testing devices used in activities affecting quality are properly controlled, calibrated, and adjusted at specified periods to maintain accuracy within necessary limits.	Personnel interviewed: M Belnand, H Boumedien, A Stourm, MP Durand. QMP Paragraph 7.6, and SMQ 8 303 224 Rev. K	Paragraph 7.6 requires for all measuring and test instruments to be checked in approved laboratories. Metrotetech S.A, located in Vendome, has been accredited by COFRAC (Comite` Francais d' Accreditation), whose certification is based on ISO 17025. COFRAC is a signatory of an MLA (multilateral Agreement) set up by ILAC (International Laboratory Accreditation Cooperation) among others, which establishes a MRA (Mutual Recognition Arrangement) which includes for testing and Calibration: A2LA; NVLAP; IAS; ACLASS and L-A-B. For testing only: PJLA. Irrespective of the above, the organization's top documents do not appear to require traceability to a NIST equivalent Body. Notwithstanding the comment stated above, governing documents provide detail description and reference to all M&TE (i.e: tools gages, instruments, etc.). Methods and frequency of calibration are established, as well as records. Also provision exist for the ID, segregation and disposition for M&TE found nonconforming, or consistently out of calibration. Notwithstanding the comment stated above, governing documents provide detail description and reference to all M&TE (i.e: tools, gages, instruments, etc.). Methods and frequency of calibration are established, as well as records. Also provision exist for the ID, segregation and disposition for M&TE found nonconforming, or consistently out of calibration. The Following M&TE were selected, and the label's information verified against the applicable records: **ID Description Cal Date Cal Due** 022E Calipers 12/16/07 04/2009 C33585 Megohmmetre 04/09/08 09/2009 PO110 Crimper No label (please see Finding on the next column).	**Finding AFR No.1:** During a tour of the facilities Crimper ID: PO 110, was found without a calibration label. Additionally procedure 924 374K RIS/Detecteur requires specific flow rates during soldering, as well as specific temperature for ovens. Gages used to monitor gas flow, and ovens temperature were not calibrated.

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Criteria	**10CFR50 App B Requirement**	**Compliance of I&C France**	**Supporting Documents**	**Findings Necessary to ensure Compliance, responsible party**
Comply				
XIII - Handling, Storage and Shipping				
XIII - Handling, Storage and Shipping	Measures shall be established to control the handling, storage, shipping, cleaning and preservation of material and equipment in accordance with work and inspection instructions to prevent damage or deterioration. When necessary for particular products, special protective environments, such as inert gas atmosphere, specific moisture content levels, and temperature levels, shall be specified and provided.	Personnel interviewed: D Mathieu, E Picard, F Geffroy, MP Durand. QMP Paragraph 7.5, and SMQ 8 303 226 "Shipping" Rev. J.	Interview of responsible personnel, and tour of the facility, revealed (with the exception of the comments on the nest column) a good system for handling, storage, preservation, and shipping of material and equipment. Work Instructions provide direction for each of these processes (i.e.: 8 303 077 Rev. B, requires shelf life for electronics to be verified every three months). Parts and components, both in the warehouse and on the production floor, were stored in a manner to prevent damage or deterioration. Wooden or plastic buffers are located between CS and SS to prevent ferritic contamination. ESD straps, mats and bags are provided in the production areas. Subdivided items have marking transferred to each item (i.e.: SS tubing).	**AFR 2**: Carbon Steel pliers were used to pull SS wire through SS tubing during a brazing operation, Additionally the file and sandpaper used during the same process were not confirmed by personnel involved in the process as being made of compatible material. Also jaws of a carbon steel vise located in the same area did not exhibit a buffer.

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Criteria	**10CFR50 App B Requirement**		**Supporting Documents**	**Findings Necessary to ensure Compliance, responsible party**
Comply				
XIV - Inspections, Test and Operating Status				
XIV - Inspections, Test and Operating Status	Measures shall be established to indicate, by the use of markings such as stamps, tags, labels, routing cards, or other suitable means, the status of inspections and tests performed upon individual items of the nuclear power plant or fuel reprocessing plant. These measures shall provide for the identification of items which have satisfactorily passed required inspections and tests, where necessary to preclude inadvertent bypassing of such inspections and tests. Measures shall also be established for indicating the operating status of structures, systems, and components of the nuclear power plant or fuel reprocessing plant, such as by tagging valves and switches, to prevent inadvertent operation.	Personnel interviewed: M Belnand, H Bomedien, C Caillet, MP Durand.	While a specific section for these requirements has not been dedicated in top tier documents, these requirements may be found in QMP Paragraph 7 and SMQ 8 303 221: "Processus Realisation Affaires" which, in paragraph 6.3 references the Suivi Operation Usine (SOU's, equivalent to shop travelers). SOU's provide information, or reference documents containing information, relative to the status of inspection and test activities: inspection, test, witness/hold points, and the results of these activities including reference to any nonconformance and relative disposition(s). Tags, labels, signs and marking are also used to maintain status and traceability. It was noticed during the audit that product, sub-assemblies, and final assemblies were well identified by tags, and accompanied by SOU's, with one minor exception, please see comments in the next column.	**Observation:** The status of Armoire (cabinet) CP0503, Belleville 2, was not indicated on the sign. Personnel were well aware of the status, and, upon request, were able to provide evidence.

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Criteria	**10CFR50 App B Requirement**	**Compliance of I&C France**	**Supporting Documents**	**Findings Necessary to ensure Compliance, responsible party**
Comply				
XV - Nonconforming Materials, Parts of Components				
XV - Nonconforming Materials, Parts of Components	Measures shall be established to control materials, parts, or components which do not conform to requirements in order to prevent their inadvertent use or installation. These measures shall include, as appropriate, procedures for identification, documentation, segregation, disposition, and notification to affected organizations. Nonconforming items shall be reviewed and accepted, rejected, repaired or reworked in accordance with documented procedures.	Personnel interviewed: M Belnand, H Boumedien, JP Gonnetand, MP Durand. QMP Paragraph 8.3, SMQ 8 303 647 "On site nonconformities" Rev. G; SMQ 8 303 202 "Nonconformities" Rev. L, SMQ 8 307 152 "Classified Nonconformities" Rev. A; QMP 7, SMQ 8 303 697 "Product Repair Process" Rev. F.	A nonconformance report is issued for any product that does not comply with stated product characteristics, requirements, drawings or specifications. All nonconformities (major quality issues are brought to the attention of top management) are handled by personnel with competency in the specific area(s) being evaluated, a disposition to control further processing, delivery, use or installation will be provided and records generated. During a tour of the facilities, it was noticed that Nonconforming items are well identified and segregated in hold areas (i.e.: a designated area in the warehouse) or in other areas when transportation is impractical due to size or other constraints. Nonconforming product is identified with tags and on Suivi Operation Usine (SOU's) while in production. The procedures employed seem well suited to preclude inadvertent use of nonconforming items. Records of Nonconformities include: item nomenclature, traceability information, nature of the nonconformity, and disposition.	**Observation:** QMP paragraph 7, does not address specific requirements relative to "use-as-is" dispositions.

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Criteria	**10CFR50 App B Requirement**	**Compliance of I&C France**	**Supporting Documents**	**Findings Necessary to ensure Compliance, responsible party**
Comply				
XVI - Corrective Action				
XVI - Corrective Action	Measures shall be established to assure that conditions adverse to quality, such as failures, malfunctions, deficiencies, deviations, defective material and equipment, and nonconformances are promptly identified and corrected. In the case of significant conditions adverse to quality, the measures shall assure that the cause of the condition is determined and corrective action taken to preclude repetition. The identification of the significant condition adverse to quality, the cause of the condition, and the corrective action taken shall be documented and reported to appropriate levels of management.	Personnel interviewed: P Paillat, MP Durand. QMP 8.5, SMQ 8 303 238 "Corrective and Preventive Actions" Rev. H.	Conditions adverse to quality be identified promptly and corrected as soon as practicable. The records of corrective actions reviewed: AA-08-604, Dated 6-21-08 (open), and AA-08-596, Dated 5/21/08 (closed end verified) provide evidence of compliance with procedure's requirements. Corrective actions are reviewed during management review, that allows management to evaluate the effectiveness of the CA program.	**Observation:** QMP 8.3 addresses "…major quality issues that must be escalated to the upper level of management…", QMP paragraph 8.5.2, does not adequately address"significant conditions adverse to quality" .

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Criteria	**10CFR50 App B Requirement**	**Compliance of I&C France**	**Supporting Documents**	**Findings Necessary to ensure Compliance, responsible party**
Comply				
XVII - Quality Assurance Records				
XVII - Quality Assurance Records	Sufficient records shall be maintained to furnish evidence of activities affecting quality. The records shall include at least the following: Operating logs and the results of reviews, inspections, tests, audits, monitoring of work performance, and materials analyses. The records shall also include closely-related data such as qualifications of personnel, procedures, and equipment. Inspection and test records shall, as a minimum, identify the inspector or data recorder, the type of observation, the results, the acceptability, and the action taken in connection with any deficiencies noted. Records shall be identifiable and retrievable. Consistent with applicable regulatory requirements, the applicant shall establish requirements concerning record retention, such as duration, location, and assigned responsibility.	Personnel interviewed: C Dessaigne, MP Durand. QMP 4.2.4, SMQ 8 303 320 "Control of Records" Rev. L.	With the exception of the Observation stated in the next column, the QA program, QMP and SMQ provide for control, identification, storage, protection, retrieval, retention time and disposition of quality records. Quality records review during the tour of warehouse and production areas were available. Archived records were also made available in short notice.	**Observation:** The methods used for QA Records storage in the mezzanine visited during the audit, do not provide protection from natural disasters (i.e.: fire,)

Appendix B to Part 50 -- Quality Assurance Criteria for Nuclear Power Plants and Fuel Reprocessing Plants				
Criteria	**10CFR50 App B Requirement**	**Compliance of I&C France**	**Supporting Documents**	**Findings Necessary to ensure Compliance, responsible party**
Comply				
XVIII - Audits				
XVIII - Audits	A comprehensive system of planned and periodic audits shall be carried out to verify compliance with all aspects of the quality assurance program and to determine the effectiveness of the program. The audits shall be performed in accordance with the written procedures or check lists by appropriately trained personnel not having direct responsibilities in the areas being audited. Audit results shall be documented and reviewed by management having responsibility in the area audited. Followup action, including reaudit of deficient areas, shall be taken where indicated.	Personnel interviewed: C Dessaigne, MP Durand. QMP 8.2.2, SMQ 8 303 239 "Audits" Rev. M.	The entire system is audited once every two years, in accordance to procedure, and by qualified/certified personnel not directly responsible for the activities audited. The schedule is adjusted according to the status and importance of the activities to be audited. According to the 2008 internal and suppliers' audit schedule reviewed, all scheduled audits were performed (with the exception of one supplier's audit, as the supplier had gone out of business). The records reviewed for Audit No. DES/08.4261, contained scope, requirements, activities to be audited, as well as checklist and reference to the applicable governing documents.	**N/A**