# Quality Assurance System compliance with 10CFR50 appendix B requirements

- Context
- Gap analysis & actions
- Next steps

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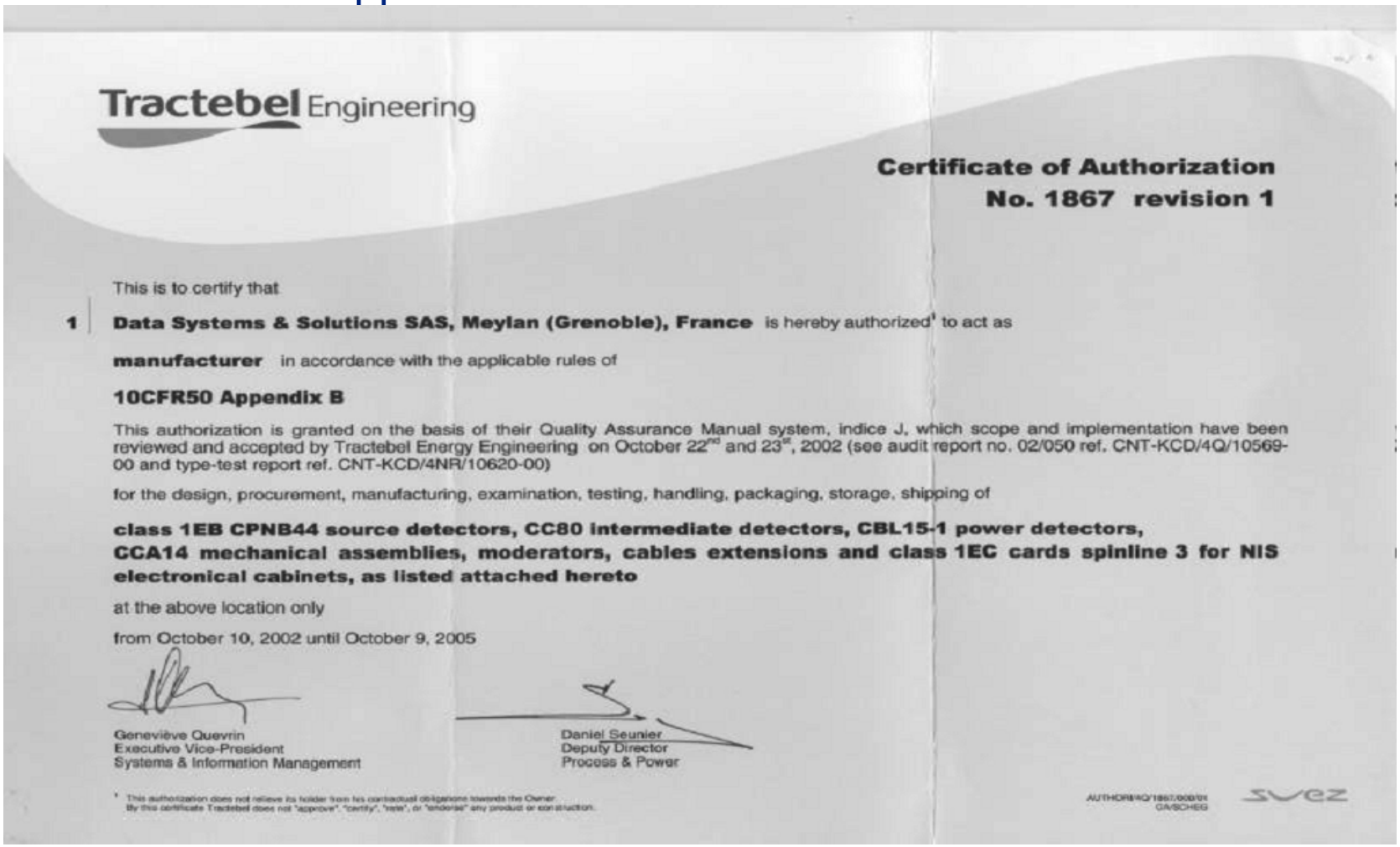
# Introduction

- DSS has already been in the past authorized to work in accordance with 10 CFR 50 App B



Tractebel Engineering

**Certificate of Authorization**
**No. 1867 revision 1**

This is to certify that

1 **Data Systems & Solutions SAS, Meylan (Grenoble), France** is hereby authorized* to act as

**manufacturer** in accordance with the applicable rules of

**10CFR50 Appendix B**

This authorization is granted on the basis of their Quality Assurance Manual system, indice J, which scope and implementation have been reviewed and accepted by Tractebel Energy Engineering on October 22nd and 23rd, 2002 (see audit report no. 02/050 ref. CNT-KCD/4Q/10569-00 and type-test report ref. CNT-KCD/4NR/10620-00)

for the design, procurement, manufacturing, examination, testing, handling, packaging, storage, shipping of

**class 1EB CPNB44 source detectors, CC80 intermediate detectors, CBL15-1 power detectors, CCA14 mechanical assemblies, moderators, cables extensions and class 1EC cards spinline 3 for NIS electronical cabinets, as listed attached hereto**

at the above location only

from October 10, 2002 until October 9, 2005

Geneviève Quevrin
Executive Vice-President
Systems & Information Management

Daniel Seunier
Deputy Director
Process & Power

* This authorization does not relieve its holder from his contractuall obligations towards the Owner.
By this certificate Tractebel does not "approve", "certify", "rate", or "endorse" any product or construction.

AUTHOR/4Q/1867/000/01
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# Context

- Data Systems & Solutions SAS QA system was initiated in 1976, based on the IAEA 50-C-QA requirements.
- Until now, he meets the ISO9001 revision 2000 requirements (certification renewed in june 2006), and is strenghtened with the additional IAEA 50-C/SG-Q code.
- Assessment of the system against 10CFR50 appB + NQA-1 and 1a (revision 1983) was carried out by MPR associates, based on the QA manual and root procedures.The result shows the system meets the root requirements of appB, but some improvements shall be made in the QA system, to bring expected clarifications on criteria compliance. Also, some of our practices are deemed not enough documented ; we'll made the appropriate written upgrades on procedures and records that bring the expected evidences of compliance.
- Next part details the gap analysis by appB criteria, our position and committments, and most probable completion date.

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# Gap Analysis

| MPR Findings based on Quality Managt Plan | DS&S Position and Actions | End |
|---|---|---|
| **Criteria 1 : ORGANIZATION**<br>**No clear statements that :**<br>**- Quality is independent of budget and planning**,<br>- **persons responsible for quality assurance must also follow qms procedures/instructions**<br>**- qc inspectors has direct access to qa/management** | (A1, A3) : Though effective in practice, those statements will be added in the QMP 8303186 rev N and in the Procedure Presentation & organization 8303701, relevant sections, and in the relevant job descriptions.<br>A2 : the QMS is mandatory for all the DS&S SAS Staff, including QA personnel, and functional QA reports such as controllers and inspectors. | Dec 2006 |
| **Criteria 2 : QUALITY ASSURANCE PROGRAM**<br>**7.4.1 describes classified procurements – no distinction is made in the program for identification of items with safety related requirements**<br>**The term "importance to safety" is not specifically stated.**<br><br>**Sections 6.3 and 6.4 cover infrastructure and work environment – but the text in these sections does not directly relate the required controlled conditions to those that affect quality.** | A4 : new revision of the 8 303 334 E will precise the practice : no distinction is made since an item reference cannot be linked to more than one type of requirements.<br>A5 : this term will be added in 8303701 in the appropriate parts.<br>A6 : Infrastructures affecting quality are identified in a maintained list. Existing instructions on pre-requisites will be addressed by a procedure linked to the Resources management process (8303695). Specific pre-requisites, if any, are included in the project QA plan. | Dec 2006 |

# Gap Analysis

| MPR Findings based on Quality Managt Plan | DS&S Position and Actions | End |
|---|---|---|
| **Criteria III : DESIGN CONTROL**<br>**Except with regard to purchasing, where per 7.4.1 describes classified procurements – no distinction is made in the program for identification of items with safety related requirements.** | A7 : 1E subassemblies gets supplementary qualification for environmental conditions.<br>1E software are designed with specific rules, compliant with IEC60880.<br>Safety related functions are determined in the technical specification, based on the safety analysis.<br>If a cabinet contains safety related functions, the whole endorses the safety qualification.<br>Relevant QA procedure will clarify this practice. | Feb 2007 |
| **8303198 covers verification of engineering documents that represent the design – However, text does not clearly state independence of all individuals involved in the verification of the design - need to clarify scope of reviews performed as part of verification (when performed in addition to checking) and need to demonstrate independence of "review team".** | A8 : design documents are submitted for approval to the customer engineering team.<br>The equipment design is verified by type tests performed by test team, independent of design.<br>PCBs test plans and type tests performed by designer ; plans and results are submitted to a review team whose members are not involved in the tasks execution.<br>For 1E classified software, independent V&V team is initiated with budget different of the development resources.<br>Those principles will be clarified in the QMP. | |

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|---|---|---|
| **Criteria IV : PROCUREMENT DOC CTROL. For this approach, DS&S will need to demonstrate all sub-contractors are indoctrinated accordingly into the DS&S appendix b compliant qa program.** | A9 : A contractual procedure is forwarded to the subcontractors concerned, describing all the requirements related to nuclear QA .<br>DS&S will take the responsibility of appB application to the subs, and will formally establish a direct path form the subs to DS&S QA, in application of 10CFR21 requirements.<br>The contractual procedure will be upgraded. | Jan 2007 |
| **Criteria V : INSTRUCTIONS PROCEDURES & DRAWINGS** | No findings | |
| **Criteria VI : DOCUMENT CONTROL<br>The qa manual text does not explicitly state the check is done by someone other than preparer .<br>Terminology for changes control may need clarification, i.e., "same organizations"** | A10 : This QA manual section addresses the procedure 8303 198 which states explicitly this rule. Will also be added in QMP 8 303 186 N<br>A11 : the terminology issue is due to the translation into english. Will be fixed in next english version. | Dec 2006 |
| **Criteria VII : CONTROL OF PURCHASE MATERIAL, EQUIPMENT & SERVICES** | No findings. | |

# Gap Analysis

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|---|---|---|
| **Criteria VIII : IDENTIFICATION AND CONTROL OF MATERIALS, PARTS AND COMPONENTS.**<br><br>**Traceability of batch/lot parts not consistent with NQA-1 requirements** | A12 : We consider our identification and traceability rules as consistent with NQA-1, 8S-1.<br>All subassemblies have clear ID reference + revision and serial numbers.<br>Parts also have ID as appropriate : in all the case, the reference number, and when appropriate, a serial number.<br>We keep the records of all components accepted .<br>Traceability for sensitive parts (classified procurement), is ensured by a serial or unique control number. Records are joined to the end of manufacturing reports (CRU) and links the part ID with the delivered equipment. This pratice is described in the procedure 8303228 (end of manufacturing reports) but may be clarified. | Jan 2007 |
| **Criteria IX : CONTROL OF SPECIAL PROCESSES** | No finding identified. | |
| **Criteria X : INSPECTION**<br>**Independence of the test & control group should be better clarified in writing**<br><br>**Ds&s should clearly specifies how hold points are setup.** | A13 : Independence of the controllers is established since manufacturing operations are subcontracted. Evidence is provided through the filled follow-up form, with marks of the personnel concerned. Procedure will be upgraded<br>A14 : clarifications will be added in the procedure : 8 303 217 “establishment of manufacturing and tests documents”. | Dec 2006 |

# Gap Analysis

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| **Criteria XI : TEST CONTROL**<br>**Section 7.5.3 clarify "final inspection" and "final testing".**<br>**Acceptance criteria are mentioned in the templates. However, the procedures for applying and developing the test plans (with templates) does not clearly require that acceptance criteria, prerequisites and environmental conditions be included.** | A15 : We'll precise in the section mentioned that final test are completed before the final inspection.<br>A16 : Though clearly defined in the relevant templates, sections 3.2 and 3.3 of the procedure 8303217 "establishment of manufacturing and test documents" will be amended to fix that.<br>Unless contractual environmental conditions specified, the conditions applied are those defined in the Afcen RCC-E document. | Dec 2006 |
| **Criteria XII : CONTROL of MEASURING Eqt,** | No finding identified. | |
| **Criteria XIII : HANDLING STORAGE & SHIPPING**<br>**Not clear that statement of "defining specific conditions" for storage addresses protective environments**.<br>**Instructions specifically mentioned in QM for handling but <u>not</u> for storage, package, and shipping.** | A17 : refers to NQA-1 supplement 13-S1 section 3. The finding refers to a specific requirement (NQA-1 says : "when required for particular items").<br>A 2005 QA instruction, ref : 921 628 describes precisely the methods and criteria for packaging, handling ,storage, and shipping. The protective environments criteria are determined.<br>These methods will be more clearly addressed form the relevant root procedure | Dec 2006 |
| **Criteria XIV : INSPECTION & TEST STATUS** | No Issues identified. | |

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# Gap Analysis

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|---|---|---|
| **Criteria XV : NON CONFORMANCES**<br>**8303202 states nc procedure is applicable by all the personnel in factory and on site.**<br>**However, section 8.3 of qm does not identify that non-conformances can be initiated by employees.** | A18 : QMP 8303 186 N will mention that Non conformities can be initiated by all employees working on quality related tasks.<br>However, the current revision 8303 202 K (since october 2005) clearly identifies the scope of application. This will be reviewed to include 10CFR21 requirements. | Jan 2007 |
| **Criteria XVI : CORRECTIVE ACTION**<br><br>**Precise the conditions where non conformance generates improvement actions**<br><br>**the QM and procedure text did not explicitly state that actions are required to determine the cause of the adverse conditions.**<br>**Examples/description of what constitutes a non_conformance is not given in 8303202.**<br><br>**The text in the applicable QMS procedures do not explicitly state the requirement to report the cause and corrective actions to appropriate levels of management** | A19 : current practice is compliant but procedure 8 303 238 will be upgraded for clarification.<br><br>A20 : the 8303 238 procedure, section 1, synopsis clearly indicates that root cause determination is a part of the corrective action itself. This will be written in litteral in next revision.<br><br>A21: Definition of what constitutes a non conformance will be added in 8303 202 next revision.<br>A new form of NC report, including the relevant report levels, will also be created to be consistent with the 10CFR21 requirements implementation. | Dec 2006<br><br>Dec 2006<br><br>Jan 2007 |

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# Gap Analysis

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| **Criteria XVII : QA RECORDS**<br>**Contract and purchase order documents not specifically listed. As permanent records – ds&s needs to confirm record retentions consistent with n45.2.**<br><br>**8303320 did not specifically state the retention period for personnel/training qualification records. Also, no statements in text requiring that all records are legible and traceable as required per nqa-1.** | A22 : NQA-1 supplement 17 S-1 doesn't mention contract or PO as permanent records. PO are only mentioned in the non mandatory guidance appendix 17 A-1. No action.<br>The current revision of our procedure 8303320 now precise this.<br>Qualification and training records will become permanent (no limit for retention). Legibility, traceability and access to the records will be also precised in next revision. | Dec 2006 |
| **Criteria XVIII : Audits**<br>**This procedure does not directly state the requirement to re-audit deficient areas; however, some credit may be taken in practice that this is done as part of the annual process review when they determine what audits are needed.**<br><br>**However, based on the QM and procedure 8303194, the process for performing external audits for qualifying suppliers or subcontractors is not described.** | A23 : procedure 8303239 will be upgraded accordingly. Our practice is to open a corrective action for each finding and assign it to the auditee. After the finding resolution, the closeout includes a verification made by the auditor, with assessment of effectiveness. Criteria to determine an area as globally deficient will also be added.<br>A24 : The audit procedure 8303239 will describe the external audit for supplier qualification, and procedure 8303194 "procurement control" will be upgraded accordingly. | Dec 2006 |

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# Gap Analysis

| **MPR ADDITIONAL OBSERVATIONS & RECOMMENDATIONS** | DS&S Position and Actions | End |
|---|---|---|
| Add a top level document presenting the DS&S QA program vs AppB criteria | A25/ A26 : we'll issue an appendix in the QMP 8303 186, dedicated to 10CFR50 appB requirements, which facilitates the mapping of our QMS with the appB criteria. | Feb 2007 |
| Compliance with 10CFR21 | A27 : compliance with 10CFR21 will be implemented. Relevant documents & information will be posted at appropriate places in the office to ensure a direct accessibility. | Jan 2007 |
| Commercial grade dedication program. | A28 : This issue was clarified with MPR. Our current practices themselves are correct but a global explanation is recommended, so we'll issue a root procedure explaining the different ways by which we ensure the control of commercial grades and their conformity to the qualified reference. This future QMS document will address the existing procedures & instructions. | Jan 2007 |

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# Next steps

- Most of the actions on the QA program will be completed by January 2007.
- A training of personnel on the main changes will be performed during the 2007 first quarter.
- The QA system will be in place for third party QA audits against NQA-1 1983 in march 2007.
- A project QA plan will be issued when the DS&S activities starts. It will address the QA system relevant procedures. If not all actions of the gap analysis are completed, the necessary arrangements for appendix B compliance will be taken and described in this QA plan.