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AN OVERVIEW of QA/QC REQUIREMENTS IN PRESENT NPP PROJECTS

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ABSTRACT

The paper analyses the Quality Assurance/Quality Control requirements imposed by various regulations concerning actual NPP projects and discusses the status of different codes in front of such provisions. Taking the example of several countries, the paper starts with a general view on regulations applicable to conventional pressure equipment, and covers in a second stage nuclear pressure equipment. It identifies for manufacturer and third parties, the right QA/QC questioning, before to begin any new nuclear pressure equipment project.

INTRODUCTION

Quality Control (QC) concerns the quality of the product itself, and Quality Assurance (QA) the organization and/or the systematic and repetitive actions which are implemented in the design, manufacture, and placing on the market of the product. QC/ QA will allow ensuring that the product will have the level of quality and safety which is expected. Generally QC requirements are fulfilled through the use of technical rules (regulatory provisions, standards, manufacturer specification or recognized Code). QA requirements apply to organization. The products covered by this paper are Pressure Equipment or assemblies of them, for conventional use in the first part, and for use in nuclear Pressurized Water Reactors in the second part.

NOMENCLATURE

NPP: Nuclear Power Plant
IAEA: International Atomic Energy Agency
QA/QC: Quality Assurance/Quality Control
RCC-M: Design and construction rules for mechanical components of Pressurized Water Reactor [1]
PED: European Pressure Equipment Directive n° 97/23/EC [2]
ESPN: Nuclear Pressure equipment in French language, as defined in reference [4].

1 CONVENTIONAL PRESSURE EQUIPMENT AND ASSEMBLIES

European Union (EU)

European Union imposes the Pressure Equipment Directive (PED n° 97/23/EC), and each country transposed it in its own regulation, notably France, Finland and United Kingdom.

QA of pressure equipment Manufacturers is taken in account through conformity assessment procedures (called “modules”):

- Modules D, D1: the manufacturer must operate an approved quality system for production, final inspection and testing and be subject to surveillance by Third Party,
- Modules E, E1: the manufacturer must operate an approved quality system for the final pressure equipment inspection and testing and be subject to surveillance by Third Party,
- Modules H, H1: the manufacturer must implement an approved quality system for design, manufacture, final inspection and testing and be subject to surveillance by Third Party.

The choice of the module by the manufacturer is based on the (pressure) hazards category of the equipment; this hazard is proportionate to the energy stored in the equipment, quantified by the product: [maximum allowable pressure]x[volume] for vessels. So category I is the lowest and IV the highest. Module H, H1 apply respectively for category III and IV.

The requirements of these modules were based on the requirements of former ISO 9001:1994 (H, H1), ISO 9002:1994 (D,D1) and ISO 9003:1994 (E,E1). Nevertheless, a principle of European New Approach is to avoid mentioning Standards as mandatory documents and the only requirements are given in annex 3 of PED.

Although ISO 9001 was revised in 2000 and 2008, PED didn't change. Quality assurance assessment has been maintained through the intervention of third parties (known as "Notified Bodies") which have assessed the conformance with requirements established in 1997 through the Process Approach of ISO 9001:2000, and now ISO 9001:2008.

QA modules are not mandatory, and a pressure equipment manufacturer can use other modules without consideration of QA assessed by third party:

- Module for design: B or B1, (Cat. II min),
- Modules for manufacturing: C1, F, (Cat. I min),
- Complete module, design and manufacturing: A (Cat. I), A1 (Cat. II), G (Cat. IV).

The modules will require QC trough the implementation by the manufacturer of essential safety requirements given in annex 1 of PED. These essential safety requirements will be fulfilled through the use of pressure equipment standards and codes.

Checks, reviews, and inspection performed by the third party (except for module A), when performing the assessment of conformity, will secure this QC.

The main principles of the European PED approach are the following:

- A Quality Assurance or quality management system is not mandatory for pressure equipment manufacturers in Europe,
- The Quality Control is monitored by third parties.

ASME (Sect.I or Sect VIII div.1).

Although the ASME code is not a regulation, it may be referred to in the regulation of several countries, or recognized, with variants:

- It is mandatory according to local Jurisdiction in USA, Canada, respectively with registration by US National Board or Canadian Province,
- It is mandatory with stamp (S stamp for Sect. I, U stamp for Sect. VIII div.1, e.g. marking of conformity) in some countries (Middle East, Asia, South America…),
- It is authorized with/without stamp in some other countries (Australia, China …),
- It is technically authorized without stamp but with adaptations (European Union, India, Republic of South Africa ...).

The stamp can only be affixed when an ASME Authorized Agency is completely involved with the ASME authorized manufacturer. In this case QA/QC is governed by meeting the code.

Outside US and Canada, local regulation may withdraw or add QA/QC requirements, mainly depending on the structure of the Authority: local/national law with or without national centralization, competence and availability of empowered Inspectors.

Examples of other approaches

The Indian Boiler Regulations, (1950, last amendment dated December 4th, 2008) defines in detail QC requirements, which will be assessed by local Agencies through Central Boiler Board requirements. No Management of Quality System is mandatory for the boiler manufacturer. Nevertheless, foreign Codes like ASME are authorized (Chapter I, 3, (3) Subs by G.S.R dated February, 7th 1994) as far as they are not in contradiction with I B R requirements. Issuance of compliance with I.B.R certificate is (Form II a) is mandatory. So, quality control system requirements (PG 105 4 of Sect. I) are not in the scope of I B R assessment.

Such practice is retained in several countries, where the regulation contains technical requirements and administrative requirements, and allows overlap with technical requirements of ASME, Sect. I, VIII, V, IX, … But do not retains a quality control system by the manufacturer as a basic and mandatory requirement.

2 NUCLEAR PRESSURE EQUIPMENT

The QA/QC requirements applicable to nuclear pressure equipment include specificities (see Table 1):

- General QA/QC requirements are derived from safety requirements; quite all countries consider AIEA Recommendations as a basis for nuclear safety. GS-R-3 or former 50-C-QA are basic documents [3];
- As a consequence, many National Laws impose QA to the Licensee (User), and not directly to the manufacturer; nevertheless QA/QC will be also implemented by the manufacturers, through Licensee Quality System Management.
- The European Union has no common Law, because PED excludes in article 1, point 3.8 "Items specifically designed for nuclear use, failure of which may cause an emission of radioactivity", but some PED principles are adapted to nuclear application.

In this paper, the examples of France, Finland and U.K in the European Union are developed. Some comparison is carried out with the ASME Sect. III approach in the USA.

The South African Republic nuclear regulation is a mix; India and China have their own approach.

European Union (EU)

The differences of approach on QA/QC in the 3 EU States which are now in the process of acceptance of new Nuclear Power Plants could be identified as follows:

<u>Scope of QA/QC</u>:

- The definition of "Nuclear Pressure Equipment (NPE)" is given by each country and classification and level is defined by guides: 3 levels in France and UK, 4 levels in Finland;

UK considers the leak from one equipment to another to classify equipment.

– France imposes direct QA/QC requirements to the pressure equipment manufacturer; Finland and UK always involve the Licensee (User of nuclear pressure equipment).

QA/QC system

France has issued a specific French Quality Order dated July 4, 1984, established before 50 CQ A, and a dedicated assessment, by an approved third party, of quality system for the design and production of nuclear pressure equipment is imposed to level 1 equipment. This demand of the ESPN Order [4] is completely in line with module H of PED. QC requirements for each equipment are in addition directly checked or inspected by the Inspectors of the Authority.

For level 2 and 3 equipment, a more direct reference is made to provisions applicable to non nuclear equipment, with limitations and upgrading. Of course some overlapping occurs between these requirements and those in the quality order of 1984, which should be revised.

Finland imposes in addition to Finnish Nuclear Guides 1.4 and 3.4 (YVL 1.4 and 3.4 cover respectively Quality assurance of a nuclear power plant and Approval of the manufacturer of nuclear pressure equipment) [5] on QA, a QC with technical requirements as implemented in codes (ASME Sect. III or equivalent), and a Construction Inspection by the Finnish Nuclear Authority (STUK or Inspection Organization) for all 4 safety classes of equipment.

In UK, the regulation requires that the Licensee has a quality system in Management of Safety (MS) n° 1, 2 & 3 of Safety Assessment Principles (SAP)[6], which is close to 50-C/SG-Q of IAEA. The Licensee will propose to the Authority an appropriate survey of QA/QC of manufacturers with an Independent Third Party Inspection Agency (ITPIA).

One of the main differences between Finland and France/UK is that the “PED new approach” has not been directly integrated in the Finnish Nuclear Guides (YVL) when the Olkiluoto 3 NPP construction project began. Even if nuclear equipment was out of the scope of the PED, the QA/QC approach of the European Directive is considered as being a great lever to take benefit of all improvement in the field of pressure equipment: certificates 3.1 or 3.2 according to EN 10204:2004, conformity assessment procedures (modules), role of third parties in the assessment, consideration of assemblies.

US/ASME Approach:

The US regulation is the Code of Federal Regulation, and Title 10 concerns Energy. The US Nuclear Regulatory Commission (NRC) is in charge of establishing standards and regulations relating to nuclear facilities and users of nuclear materials, and part 50 relates to Domestic licensing of Production and Utilization Facilities. Paragraph 50.55a provides applicable editions of Codes and Standards and ASME BVPC is the only recognized Code.

Appendix B of 10 CFR 50 establishes quality assurance requirements for the design, manufacture, construction, and operation of structures, systems, and components of nuclear facilities.

When applying editions and addenda issued later than the 1989 Edition of Section III, the requirements of NQA-1 "Quality Assurance Requirements for Nuclear Facilities" 1986 Edition through the 1992 Edition, appendix B can be satisfied for nuclear equipment. NQA-1 specified in NCA-4000 is used in conjunction with the administrative, quality, and technical provisions contained in the edition and addenda of Section III being used.

For materials, NCA 3800 is used to satisfied appendix B of 10 CFR 50.

NUREG reports are reports issued by NRC staff. The US NRC standard review plan (NUREG 0800 rev.2-July 1981) is used for review and assessment of quality assurance program for the design and construction phases in each application for a construction permit, a manufacturing license, or a standardized design approval.

It is important to note that Appendix B mentions in its introduction: "as used in this appendix, "quality assurance" comprises all those planned and systematic actions necessary to provide adequate confidence that a structure, system, or component will perform satisfactorily in service. Quality assurance includes quality control, which comprises those quality assurance actions related to the physical characteristics of a material, structure, component, or system which provide a means to control the quality of the material, structure, component, or system to predetermined requirements".

In conclusion, the US approach interlaces Regulation, ASME Code and QA/QC.

Republic of South Africa (RSA) regulation:

The RSA regulation is based on the new Pressure Equipment Regulation (PER) and SANS 347:2007: “Categorization and conformity assessment criteria for all pressure Equipment” is applicable [7]. It is reinforced for nuclear installations with RD 0034: “Quality and Safety Management Requirements for Nuclear Installations”.

It has to be noticed that RSA PER is quite the first one in the world which recognize the ASME assessment of conformity with Manufacturer Authorization (N, …) and ASME agency performance, but also Conformity Assessment Procedure (e.g. “modules”) as defined in European Directive (97/23/EC). Only one of those modules is new (E2), See Table 2 as an example for equipment in category IV.

PER recognizes different code, nuclear or non-nuclear (ASME, RCC-M, PD 5500,…), and different certification of third parties (Certification Body, US AIA or RSA AIA). NQA 1:2008 is a way of demonstration of QA/QC, but GS R 3 and ISO 9001 2000 are also compatible with RD 0034 (see Table 3 with ASME III as example).

Assessment with module H1 of PED (97/23/EC) for manufacturers of nuclear pressure equipment is mandatory whatever the code used (see Table 3, example with ASME III).

In conclusion, this approach allows different QA/QC systems; nevertheless it applies to each equipment, and without mixing of codes at the level of the equipment. Meanwhile this policy of openness allows the manufacturer of the nuclear facility to choose more easily the best adaptation of the suppliers.

Chinese and Indian regulations

The Chinese regulation put in force in January 2008 (HAF 601 and HAF 604) [8] or Indian regulation (AERB SC QA Code of Practice: October 2005) [9] do not refer to one specific Code. With general recommendations in HAF and more detailed requirements in AERB SC QA Code of Practice, the manufacturers may demonstrate each time to the Authority or their Representative the adequacy of their QA system and the QC of the product. It's up to the licensee to impose and to cascade a reasonable safety system, in which QA and QC choices will be sufficiently extended to accept various technical code, but sufficiently determined to have a complete chain of subcontractors on the same regime of audits.

CONCLUSIONS AND CONSEQUENCES

Quality Assurance and Quality Control for nuclear pressure equipment in present nuclear Projects, which are the first steps of the "Nuclear Renaissance", are quite all expressed under the umbrella of basic IAEA recommendation 50-CQ-A (1979), and for some cases, with its latest version GS-R-3 (2006). Nuclear equipment manufacturers consider that it is a good objective if Nuclear Authorities take the opportunity of new NPP orders to update their regulations using the latest IAEA recommendations.

Codes have to be consistent with these international provisions, but must also be adapted to local context through complementary provisions given in Equipment specifications. To this aim, in the particular case of the RCC-M code:

- A new chapter A 5000 of RCC-M is under preparation for integration in the 2009 addendum, complying with G-S-R 3,
- New non mandatory annexes (ZZ, ZY) have been developed to provide provisions adapted to PED and ESPN respectively [10], allowing to demonstrate conformity with these regulations. Other non mandatory annexes will be added for any local usage where the code can be implemented.

Suppliers of nuclear boilers, nuclear equipment, or conventional pressure equipment of Turbine Island, and also third parties involved (Inspection Companies), have to identify the Quality Control requirements they shall comply with:

- In US and Canada, the ASME code is fully applicable, in some cases with supplementary provisions,
- It is a bit more complicated in the European Union. Harmonized standards provide rules fulfilling the PED for non nuclear equipment, but they are not mandatory and where other industrial codes are used or where harmonized standards are not well adapted to nuclear needs, other codes such as RCC-M, ASME III (without stamp), or KTA, may be chosen on a case by case basis, and supplemented according to local regulation,
- An interesting mix with an opening to different Codes may be implemented in nuclear regulation; this is typically the case of RSA,
- Specific regulatory requirement for quality control, but with possibilities to take in account, and sometimes substitute, Codes requirements, have been identified in several regulations (Case of Finland, China, India).

Although differences have been identified in QA/QC approaches, actors involved express the need to work as far as possible on common Quality approaches to facilitate and secure the "Nuclear Renaissance". What Europe did with the PED should be enlarged and adapted at International level.

In the short term, basic technical provisions in codes have to be adapted to the national contexts, through guiding appendices integrated in the codes, or through contractors specifications.

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REFERENCES

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[2] Directive n° 97/23/EC of European Parliament and Council of 29th May 2007 on the approximation of the laws of the Member States concerning pressure equipment.

[3] IAEA Safety Standards; Management System for facilities and activities-Safety Requirements n° GS-R-3 of July 2006. «*§ 1.4 of Introduction : S-R Supersedes the Code on Quality Assurance (C-QA) for Safety in NPP.*. »

[4] French December 12, 2005 Order on nuclear pressure equipment.

[5] Regulatory Guides on nuclear safety of Finnish Nuclear and Radiation Authority www.stuk.fi/julkaisut_maaraykset/viranomaisohjeet/en_GB/yvl/

[6] Safety Assessment Principles for Nuclear Facilities, 2006.

[7] RSA-Pressure Equipment Regulation (PER); South African Standard: SANS 347:2007: RD 0034 Quality and Safety requirements for management for Nuclear Installation-September 2009.

[8] HAF 601-January 2008 Regulation on supervision and control of civil nuclear equipment.

[9] AERB SC QA Code of Practice :October 2005.

[10] J.M Grandemange “An Adaptation of RCC-M design and construction rule to the evolution of projects needs, regulatory evolutions and international exchanges” PVP 2009 Paper 78046.

TABLE 1. SAFETY REQUIREMENTS AND QA/QC

	FRANCE	**FINLAND**	**UK**	**USA**	**RSA**	**CHINA**	**INDIA**
Texts of reference of Quality System	Quality Order of August, 10th 1984; e.g 50 C Q A++	YVL 1.4 to Licensee, YVL 3.4 for pressure equipment manufacturers	Safety Assessment Principles 2006, MS1, MS2, MS3, e.g . 50 C Q A +	. 10CFR50 App B + 10CFR 21 ASME Sect III ; NQA 1	RD 0034 (Quality and Safety Management Requirements for Nuclear Installations)	HAF 601 - 604 : "Catalog of Civil Nuclear Safety Equipments" Specific HAF 604 for imported materials	AERB Code – SC/QA “Code of Practice on Quality Assurance for Safety in Nuclear Power Plants
Nuclear Authority	ASN/DEP	STUK	HSE/NII	NRC	NNR	NNSA	AERB
Requirement on Manufacturer quality System	Assessment according to module H for N1 equipment manufacturer ;	Assessment of management of quality system acc. To ISO 9001	SMQ requirements (50-C-SG-Q) + acceptance by Licensee	NQ A 1	RD 0034: Safety Management System as part of Integrated Management System (GS R 3 / NQA 1)	HAF 601/604: 2008: Regulation on supervision and control of civil nuclear equipment (46 provision in 6 chapters)	AERB-SG-QA-1 – Quality Assurance in, the design of Nuclear Power Plants
Specific Quality System for material manufacturers	requirements ISO + 50CQA + Technical qualification for level1	* YVL 3.9 for procurement (ISO+ Testing Organization)	EMC4/EMC 18: procedural control Inspection written scheme Vendor Quality Plan Audits ;eventual unannounced visit	"QSC" delivered by ASME or recognition by « N » authorized manufacturer,	Licensee must establish a supplier qualification process (…):	HAF 604: In China: according to HAF 601 : supplier approval before starting of operation by NNSA.	AERB-SG-QA-2/SG-QA-3 – Quality Assurance in the procurement of items/ In the manufacture of items
Who as by regulation enacted ?	DEP or Authorized representative	STUK for SC1 and 2 Inspection Organisation (YVL 1.3) for SC3 and 4.	ITPIA; user/owner choice	AIA	Surveillance by Licensee; NNR and Quality Organization	Surveillance by NNSA and Licensee (depending inside China our outside)	Independent organisational unit

Nomenclature:
ASN/DEP: (French) Nuclear Safety Authority/ Department of Pressure Equipment
STUK: (Finnish) Nuclear Authority, specifically in charge to issue Finnish Nuclear Guides “YVL”
SC: Safety Class
HSE/NII**: (**UK) Health and Safety Executive/ Nuclear Installations Inspectorate
EMC: Integrity of Metal Components and Structures
ITPIA**:** Independent Third Party Inspection Agency
NRC (US) Nuclear Regulatory Commission
NNR: Republic of South Africa (RSA) Nuclear Regulator
NNSA**:** (Chinese) Nuclear National Safety Administration
HAF: Departmental Regulation issued by NNSA under Internal Affair Committee in 1st of January 2008.
AERB**: (**Indian**)** Atomic Energy Regulatory Board

TABLE 2. ABSTRACT OF SANS 347 OF RSA

Table C.3 — Category IV module requirements —Modules G, B + F, H1 and B + E2

1	2	3	4	5
Requirements	**Module functions**			
	Modules			
	G	**B + F**	**H1**	**B + E2**
QA system	–	–	CB_c[a]	CB_c[a]
Type approval	–	AIA_v[b]	–	AIA_v[b]
Design	AIA_v[b]	–	AIA_v[b]	–
Procedures and qualifications				
Materials	AIA_v[b]	AIA_v[b]	CB_c[c]	CB_c[c]
Welding, forming and heat treatment				
NDE				
Inspection				
Personnel qualification				
Operations				
Manufacturing	AIA_v[b]	AIA_v[b]	CB_c[c]	CB_c[c]
Marking (AIA – ID)		AIA_{s+fi}[c]	AIA_v[b]	AIA_v[b]
Final inspection				

[a] Quality system, that is certified by the certification body, put in place for the manufacturer
[b] Verification function performed by the AIA
[c] Surveillance function by AIA and the certification body

Abbreviations :
AIA: approved inspection authority
AIA_{fi}: approved inspection authority for final inspection
AIA_s**:** approved inspection authority for surveillance
AIA_v**:** approved inspection authority for verification
CB_c**:** certification body for certification of quality systems (see SANS 17021)
CB_s**:** certification body for surveillance (see SANS 17021)

TABLE 3. ASME III DIV 1 VS RSA REGULATION

ASME III, Div. 1	US (R2)	South Africa (R1)
Manufacturer Certification (Management System)	"Joint Survey" by ASME and US-AIA acc. NCA-4000(NQA-1) + RD-0034 (draft) (*) *) verified by NNR	"Joint Survey" by NNR and SA-AIA/CB acc. NCA-4000(NQA-1) + RD-0034 (draft)
Manufacturer Assessment (e.g. Hold Points..)	Survey by US-AIA acc. to NCA-5000	Survey by SA-AIA acc. to SANS 347, Module "H1"