

MDEP VICWG-02 Technical Report

Related to: Vendor Inspection Cooperation Working Group Activities

Survey on quality assurance program requirements

1) Background:

The survey was prepared using the requirements of Appendix B to 10 CFR Part 50, "Quality Assurance Criteria for Nuclear Power Plants and Fuel Reprocessing Plants." These requirements form the basis upon which the U.S. NRC oversees the activities of vendors providing parts and services to the commercial U.S. nuclear power industry. As discussed and agreed to at the October 2008 Vendor Inspection Cooperation Working Group meeting in Dijon, France, the survey that follows was developed using these requirements. The survey is divided into the 18 basic criteria of Appendix B to 10 CFR Part 50. Within each criteria there are individual requirements that have been identified as separate and distinct elements that are covered during the inspection of vendor activities. In addition to the requirements of Appendix B to 10 CFR Part 50, the requirements of 10 CFR Part 21, "Reporting of Defects and Noncompliance," have been listed at the end of the survey as an example of "Other Requirements Related To Vendor Inspections," for the NRC.

2) Guidelines for completing the survey:

For each requirement enter:

- "Y" if your regulatory framework for quality assurance includes a similar requirement that is applicable to vendors and subject to direct inspection by the regulator or authorized body.
- "L" if your regulatory framework for quality assurance includes a similar requirement that is applicable to vendors and subject to indirect inspection by the regulator.
- "L*" if your regulatory framework (rules, guides, and regulatory practices) for quality assurance includes a similar requirement that is applicable indirectly to vendors (directly to licensees) and subject to indirect inspection by the regulator (through licensees)
- "N" if your regulatory framework for quality assurance does not include a similar requirement or that the requirement is not applicable to vendors. For example, there are requirements listed in the survey that for the NRC apply only to reactor or fuel reprocessing sites, not vendors. These requirements are marked with an "N" for the US because they do not apply to vendors.
- "N*" if your regulatory framework indicates indirect inspection of the vendors with the intention to migrate to the USNRC approach for vendors inspections as a requirement incorporated within a licence condition.
- "A" if your regulatory framework for quality assurance has an alternate requirement related to the specific requirement and is not consider to be similar to the stated requirement. Describe the alternate requirement in the space provided on the form. Please start the description of the alternate requirement with the heading "Alternate Requirement:" then proceed with the description.

For each criteria, if your regulatory framework includes a requirement that is not included within those identified in the survey, please describe the additional requirement in the space provided on the form. Please start the description of the additional requirement with the heading "Additional Requirement:" then proceed with the description.

Please consider that a requirement is similar if it is expected to achieve the same basic outcome or allows the same basic flexibilities to the vendor in achieving an outcome. Even if the specific wording is different, please focus on the outcome of the requirement rather than the specific wording of your requirement or the specific wording of the survey requirement.

At the end of the survey, please include other administrative or reporting related requirements that apply to vendors under your regulatory framework. Please do not include technical requirements related to the design, fabrication, or manufacturing processes, as these requirements are outside the scope of this survey.

The legend below provides the relationship between the country columns on the survey form and the associated country:

CA = Canada

CH = China
FI = Finland
FR = France
JP = Japan
RF = Russian Federation
SK = South Korea
SA = South Africa
UK = United Kingdom
US = United States

3) Explanatory notes

a. Japanese Explanatory Note

<General Explanation on the Japanese vendor inspection system >

1. The duty of the licensee and the involvement of the regulatory body relating to the inspection on the vendor QA activities
At the construction stage of a nuclear power plant, it is the duty of the licensee to perform the inspection on the vendor's QA activities. The regulatory body inspects the licensee's QA activities to confirm that the licensee is fulfilling his duties of performing the inspection on the vendor's QA system and on the components manufactured by the vendor. The regulatory body's actions include not only the review on the QA documents of the licensee's and vendor's activities but also the inspection on the licensee's and vendor's QA activities at vendor's shops when necessary.
2. The scope of the regulatory body's involvement in the vendor's QA inspection
The scope of the regulatory involvement in the vendor QA inspection is limited to the welding work of components which is the major process of component manufacturing.
The work in the other scope than welding is regulated in another method. For instance, as the regulatory body directly reviews the results of detail design of components, the regulatory requirement on the design QA is only the submittal of the fundamental QA policy document.
3. The fundamental concept of QA
In Japan, the QA policy is based on ISO 9000 Series and IAEA safety Standards.

b. Canadian Explanatory Note

Currently, the CNSC regulatory framework includes the Nuclear Safety and Control Act (NSCA), the regulations, in particular 'General Nuclear Safety and Control Regulations' and 'Class I Nuclear Facilities Regulations' (a nuclear power plant (NPP) is a Class I nuclear facility), various regulatory documents, and licence conditions included in the licences granted to licensees. Usually, these licence conditions impose specific and relatively detailed requirements on the licensees by referencing applicable standards issued by the Canadian Standards Association (CSA) and accepted by the CNSC as meeting its expectations.

In particular, regarding the QA requirements that specifically apply to pressure-retaining systems and components, there are two categories of CSA Standards that include QA requirements:

- (a) N285.0-06 'General requirements for pressure-retaining systems and components in CANDU NPPs' (Section 10 – General requirements for QA).
- (b) The CSA N286 series of QA Standards, containing general QA requirements and more specific ones for procurement, design, construction, commissioning, operation, and decommissioning.

N285.0-06, Section 10, refers to both the N286 series of QA standards and the ASME, Section III, Article NCA-4000.

During the last couple of years, some changes have been made in relation to the regulatory framework, and others are in preparation.

For example, the CNSC published in November 2008 the Regulatory Document RD-337 'Design of New NPPs'. This document sets out the expectations of the CNSC concerning the design of new water-cooled nuclear power plants (NPP). It indicates that "to the extent practicable, the guidance provided herein is technology-neutral with respect to water-cooled reactors. RD-337 represents the CNSC's adoption of the principles set forth by IAEA in NS-R-1, 'Safety of Nuclear Plants: Design', and the adaptation of those principles to align with Canadian expectations". Section 5.0 of this document, 'Safety Management during Design', includes sub-section 5.3 'Quality Assurance Program'.

Also, CSA published in February 2005 the CSA Standard N286-05 'Management system requirements for nuclear power plants'. It replaces CSA N286.0 'Overall Quality Assurance Program Requirements for NPPs', and the associated sub-tier CSA Standards N286.1 through N286.6. The intention was to combine all requirements into a single document. CNSC envisages referencing N286-05 in licence conditions for NPPs.

Therefore CNSC proposes a designation of N* to indicate indirect inspection of the vendors with the intention to migrate to the USNRC approach for vendors inspections as a requirement incorporated within a licence condition.

c. U.K. Explanatory Note

With regard to the QA criteria survey the UK has difficulties in responding as requested due mainly to our goal setting approach. The responsibility for safety rests with the licensee and we would expect current national and international quality standards to be applied throughout the supply chain with specific additional controls required by the contract. Any regulatory checking is done on a sample basis which would cover many of the criteria in the survey (based on 10-CFR-50 app B) but would not be intended to duplicate what the licensee or vendor should do. The NII concentrates on checking the controls applied by the licensee and if necessary vendors and contractors to ensure that these are adequate.

d. South African Explanatory Note

The National Nuclear Regulator (NNR) Regulatory Requirement Document RD-0034 defines quality and safety management requirements and must be complied with by all organisations involved in the life cycle of nuclear installations which includes the owner (applicant and holder of authorisations), designer, suppliers and sub suppliers which could have a direct or indirect influence on the nuclear or radiation safety of the plant. In this regard vendors of products categorized as important to nuclear and radiation safety have to comply with relevant requirements in RD-0034. The applicant/authorisation holder is responsible for nuclear and radiation safety and therefore has to ensure through various processes that the quality of components and parts are verified to be commensurate to their level of safety significance. The applicant/holder must have oversight over all activities that have the potential to impact nuclear safety and all organizations in the supply chain have to maintain intelligent customer capability. The applicant will have to ensure that all suppliers of products and services implement systems and processes ensuring compliance to the NNR requirements. The manufacturing of all components important to nuclear safety is subject to NNR authorization and compliance assurance processes and requirements.

Criteria	Requirements	CA	CH	FI	FR	JP	RF	SK	SA	UK@	US
1. Organization	a. The applicant [licensee, vendor, owner, etc.] is responsible for the establishment and execution of the quality assurance program.	N*	Y	Y	Y	L*	Y	Y	L		Y
	b. The applicant [licensee, vendor, owner, etc.] may delegate to others the work of establishing and executing the quality assurance program, or any part thereof, but shall retain responsibility for the quality assurance program.	N*	Y	N	Y	L*	Y	A	N		Y
	c. 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 [quality control functions] 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 safety-related functions have been correctly performed.	N*	Y	Y	A	L*	Y	Y	L		Y
	d. The persons and organizations performing quality assurance functions shall have sufficient authority and organizational freedom to:	N*	Y	Y	Y	L*	L	Y	L		Y
	1. identify quality problems	N*	Y	Y	Y	L*	L	Y	L		Y
	2. to initiate, recommend, or provide solutions	N*	Y	Y	Y	L*	L	Y	L		Y
	3. to verify implementation of solutions	N*	Y	Y	Y	L*	L	Y	L		Y
	e. 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 performed, shall have direct access to the levels of management necessary to perform this function.	N*	Y	Y	A	L*	L	Y	L		Y
Additional or Alternate Requirements	FINLAND: a) Quality assurance practices have developed such that today's quality assurance is part of the quality management system, which further is part of the organisation's management system										
	b) Consultant can be used for establishing the programme but it shall be executed through management-personnel co-ordination.										

Criteria	Requirements	CA	CH	FI	FR	JP	RF	SK	SA	UK@	US
	<p>C) A management system shall be planned and implemented to incorporate all the operations of an organization.</p> <p>FRANCE: a) and b) according to the french regulation , the 1a) requirements covers automatically the b)requirement . It depends of the english meaning of ‘‘delegate’’ c) the requirements is similar but limited to ‘‘ in regard to the quality of the design and to product quality’’ and not to ‘‘safety related functions’’ which enlarges the field of compliance;</p> <p>e) <u>the alternate requirements</u> are the following ones :</p> <p><i>Personnel performing work affecting product quality shall be competent on the basis of appropriate education, training, skills and experience. The organisation shall</i></p> <ul style="list-style-type: none"> - <i>determine the necessary competence for personnel performing work affecting product quality,</i> - <i>provide training or take other actions to satisfy these needs,</i> - <i>evaluate the effectiveness of the actions taken,</i> - <i>ensure that its personnel are aware of the relevance and importance of their activities and how they contribute to the achievement of the quality objectives, and</i> - <i>maintain appropriate records of education, training, skills and experience</i> <p><i>The organisation shall determine, provide and maintain the infrastructure needed to achieve conformity to product requirements. Infrastructure includes, as applicable</i></p> <ul style="list-style-type: none"> - <i>buildings, workspace and associated utilities,</i> - <i>process equipment (both hardware and software), and</i> - <i>supporting services (such as transport or communication).</i> 										
	SOUTH KOREA: NONE										
	<p>SOUTH AFRICA: ALTERNATIVE REQUIRMENT</p> <p>(b) RD-0034, req (1): <i>The licensee must ensure for its own organisation and for all suppliers of products important to nuclear safety that a QMS is implemented during all stages of the life cycle of the nuclear installation considering the respective requirements as specified in this RD</i></p>										

Criteria	Requirements	CA	CH	FI	FR	JP	RF	SK	SA	UK@	US
	RD-0034, req (4): <i>In case important to nuclear safety activities are outsourced by the licensee or suppliers to other suppliers / sub-suppliers, the delegating organisation must implement oversight measures for these activities to retain intelligent customer capabilities</i>										
	JAPAN: (Explanatory note) The regulatory QA inspection on vendors is carried out indirectly through on the work relating to welding which is the major process of component manufacturing.										
	CANADA: Explanatory Note										
	RUSSIAN FEDERATION: NONE										
	CHINA: Interface arrangement and interface activities among different organizations or organizational groups shall be controlled.										
2. Quality Assurance Program	a. The applicant [licensee, vendor, owner, etc.] 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 the established regulatory framework for such program [at NRC these are found in Appendix B to 10 CFR Part 50].	N*	Y	Y	Y	L*	Y	Y	A		Y
	b. The quality assurance program shall be documented by written policies, procedures, or instructions.	N*	Y	Y	Y	L*	Y	Y	L		Y
	c. The quality assurance program shall be carried out in accordance with the written policies, procedures, or instructions.	N*	Y	Y	Y	L*	Y	N	L		Y
	d. The applicant [licensee, vendor, owner, etc.] shall identify the structures, systems, and components to be covered by the quality assurance program and shall provide control over activities affecting the quality of the identified structures, systems, and components, to an extent consistent with their importance to safety.	N*	Y	A	A	L*	Y	Y	Y		Y
	e. The applicant [licensee, vendor, owner, etc.] shall identify the major organizations participating in the program, together with the designated functions of these organizations.	N*	Y	Y	N	L*	Y	Y	L		Y
	f. Activities affecting quality shall be accomplished under suitably controlled conditions. Controlled conditions include:	N*	Y	Y	Y	L*	L	Y	L		Y
	1. the use of appropriate equipment	N*	Y	Y	Y	L*	L	Y	L		Y
	2. suitable environmental conditions for accomplishing the activity, such as adequate cleanness	N*	Y	Y	A	L*	L	Y	A		Y

Criteria	Requirements	CA	CH	FI	FR	JP	RF	SK	SA	UK@	US
	3. assurance that all prerequisites for the given activity have been satisfied	N*	Y	Y	N	L*	L	Y	L		Y
	g. The program shall take into account the need for special controls, processes, test equipment, tools, and skills to attain the required quality, and the need for verification of quality by inspection and test.	N*	Y	Y	Y	L*	L	Y	L		Y
	h. 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.	N*	Y	Y	Y	L*	L	Y	L		Y
	i. The applicant [licensee, vendor, owner, etc.] shall regularly review the status and adequacy of the quality assurance program.	N*	Y	Y	Y	L*	L	Y	L		Y
	j. 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 executing.	N*	Y	Y	A	L*	L	Y	L		Y
Additional or Alternate Requirements	FINLAND: d and e) Advanced quality assurance programs (Management Systems) shall be employed in all activities which affect safety and relate to the design, construction and operation of a nuclear power plant.										
	FRANCE: d) <u>Alternate requirement</u> : <i>The licensee shall provide the manufacturer with a description of all the situations which may apply to the equipment, in accordance with the safety report of the installation for which it is intended, supplemented by the associated files, as well as all the loads to be taken into account for each situation. The manufacturer shall perform the risk analysis laid down in indent 3 of the preliminary comments of Annex 1 to the aforementioned Decree of 13 December 1999, taking account of the data provided by the user and the radioactive nature of the fluid that will be contained</i> f) 2) <u>Alternate requirement</u> : <i>The organization shall preserve the conformity of product during internal processing</i> j) <u>Alternate requirement</u> : <i>The organization shall manage the interfaces between different groups involved in design and development to ensure effective communication and clear assignment of responsibility ; Purchasing information shall describe the product to be purchased, including where appropriate :</i> <ul style="list-style-type: none"> - requirements for approval of product, procedures, processes and equipment, - requirements for qualification of personnel, and - quality management system requirements. <i>The organization shall ensure the adequacy of specified purchase requirements prior to their communication to the supplier.</i>										

Criteria	Requirements	CA	CH	FI	FR	JP	RF	SK	SA	UK@	US
	<p>SOUTH AFRICA:</p> <p>a) Alternate requirement: RD-0034, requirement (1) in conjunction with requirement (91): Req (1): <i>The licensee must ensure for its own organisation and for all suppliers of products important to nuclear safety that a QMS is implemented during all stages of the life cycle of the nuclear installation considering the respective requirements as specified in this RD</i> Req (91): <i>All suppliers of products important to nuclear safety involved in design, manufacturing, construction, operation and decommissioning must be registered in an up to date list (database) of approved suppliers, and their qualification / certification must be traceable. This list must include at least the following information:</i></p> <ul style="list-style-type: none"> • <i>Product to be delivered</i> • <i>Supplier of the product and sub-supplier of components</i> • <i>Safety and quality classification of the SSC</i> • <i>Selected codes and standards</i> • <i>Status of qualification / certification</i> <p><i>The list must be submitted to the NNR in accordance with agreed processes whenever changes involve suppliers of products of importance to nuclear safety and must be available in general for NNR inspection, review and audit</i></p> <p>f) (2): ISO 9001:2000 is considered as a basis for the QMS requirements specified in RD-0034. The licensee and all suppliers of products important to nuclear safety must therefore comply with all requirements specified in the standard Error! Reference source not found. or equivalent QM standards. The supplier qualification process by the licensee will verify the implementation thereof.</p>										
	SOUTH KOREA: NONE										
	JAPAN: (Explanatory note) The QA program is based on ISO 9000 Series and IAEA safety Standards.										
	CANADA: Explanatory Note										
	RUSSIAN FEDERATION: NONE										
	CHINA: The quality assurance program shall state the languages used for documentation. Translations of the documentation shall be reviewed by competent persons. Verification of conformance to the original is necessary.										

Criteria	Requirements	CA	CH	FI	FR	JP	RF	SK	SA	UK@	US
3. Design Control	a. Measures shall be established to assure that applicable regulatory requirements and the design basis for structures, systems, and components are correctly translated into specifications, drawings, procedures, and instructions.	N*	Y	Y	Y	A	Y	Y	A		Y
	b. 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.	N*	Y	Y	Y	A	Y	Y	L		Y
	c. Measures shall also be established for the selection and review for suitability of application of materials, parts, equipment, and processes that are essential to the safety-related functions of the structures, systems and components.	N*	Y	Y	A	A	Y	Y	L		Y
	d. Measures shall be established for the identification and control of design interfaces and for coordination among participating design organizations.	N*	Y	Y	Y	A	Y	Y	L		Y
	e. Design control measures shall include the establishment of procedures among participating design organizations for the:										
	1. review	N*	Y	Y	Y	A	L	Y	A		Y
	2. approval	N*	Y	Y	A	A	L	Y	A		Y
	3. release	N*	Y	Y	A	A	L	Y	A		Y
	4. distribution	N*	Y	Y	A	A	L	Y	A		Y
	5. revision of documents involving design interfaces	N*	Y	Y	A	A	L	Y	A		Y
	f. The design control measures shall provide for verifying or checking the adequacy of design, such as:	N*	Y	Y	Y	A	L	Y			Y
	1. by the performance of design reviews	N*	Y	Y	N	A	L	Y	Y		Y
	2. by the use of alternate or simplified calculational methods	N*	Y	Y	N	A	L	Y	Y		Y
	3. by the performance of a suitable testing program	N*	Y	Y	A	A	L	Y	Y		Y
	g. 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.	N*	Y	Y	L	A	L	Y	L		Y
h. 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.	N*	Y	Y	L	A	L	Y	Y		Y	
i. Design control measures shall be applied to items such as the following:											
1. reactor physics analyses	N*	Y	Y	N	A	L	Y	A		Y	

Criteria	Requirements	CA	CH	FI	FR	JP	RF	SK	SA	UK@	US
	2. stress analyses	N*	Y	Y	Y	A	L	Y	A		Y
	3. thermal analyses	N*	Y	Y	Y	A	L	Y	A		Y
	4. hydraulic analyses	N*	Y	Y	Y	A	L	Y	A		Y
	5. accident analyses	N*	Y	Y	N	A	L	Y	A		Y
	6. compatibility of materials	N*	Y	Y	Y	A	L	Y	L		Y
	7. accessibility for inservice inspection, maintenance, and repair	N*	Y	Y	Y	A	L	Y	L		Y
	9. delineation of acceptance criteria for inspections and tests	N*	Y	Y	Y	A	L	Y	L		
	j. Design changes, including field changes, shall be subject to design control measures commensurate with those applied to the original design.	N*	Y	Y	Y	A	L	Y	L		Y
	k. Design changes, including field changes, shall be approved by the organization that performed the original design unless the applicant designates another responsible organization.	N*	Y	Y	Y	A	L	Y	L		Y
Additional or Alternate Requirements	FINLAND: NONE										
	FRANCE: c) <u>Alternate requirement</u> (see also 2 d)) : <i>The manufacturer is under an obligation to analyse the hazards in order to identify those which apply to his equipment on account of pressure; he must then design and construct it taking account of his analysis</i> e) 2) 3) and 4) : <u>Alternate requirement</u> : there is probably a vocabulary issue for that requirements ; according to french regulatory framework we use verification and validation whose requirements are the following one : <ul style="list-style-type: none"> - <i>Verification shall be performed in accordance with planned arrangements to ensure that the design and development outputs have met the design and development input requirements. Records of the results of the verification and any necessary actions shall be maintained .</i> - <i>Design and development validation shall be performed in accordance with planned arrangements to ensure that the resulting product is capable of meeting the requirements for the specified application or intended use, where known. Wherever practicable, validation shall be completed prior to the delivery or implementation of the product. Records of the results of validation and any necessary actions shall be</i> 										

Criteria	Requirements	CA	CH	FI	FR	JP	RF	SK	SA	UK@	US
	<p><i>maintained</i></p> <p>e) 5) Alternate requirement : <i>The organization shall manage the interfaces between different groups involved in design and development to ensure effective communication and clear assignment of responsibility</i></p> <p>f)1 and 2) :Alternate requirement : the french regulation framework doesn't impose the way to check the design excepted for experimental design methods, then the requirements are the following one : <i>the design of the equipment may be validated, in all or in part, by an appropriate test programme carried out on a sample representative of the equipment or the category of equipment. Then detailed requirements are mentioned.</i></p> <p>g) this requirement is mentioned in another French regulation (ministerial order August 10th 1984 which is similar to 50 CQA IAEA standard) related to quality concerned activity which is addressed to the licensee. According to this regulation when a pressure equipment is considered as a safety class component then the design of such component has to be reviewed by other than those who performed the original design.</p> <p>i) 2)3)4)7)9) according to the french regulation, the manufacturer has to design its pressure equipment taking in account the requirements mentioned in article i) 2)3)4)6)7)9) ; so as part of "design control" the manufacturer has to control that the pressure equipment design complies with the previously requirements (<i>Verification shall be performed in accordance with planned arrangements to ensure that the design and development outputs have met the design and development input requirements</i>) . Article g) is covered by the requirement related to the operating instruction which have to describe the in service inspection program.</p> <p>SOUTH KOREA: NONE</p> <p>SOUTH AFRICA: (a) Alternate requirement: RD-0034, requirement (92) in conjunction with requirement (94): <i>(92) The requirements for the products must be clearly defined in procurement documents and design specifications for the suppliers. The documentation must specify the required codes and standards, materials, duties and capacities, operational and environmental parameters, loads, safety margins, settings, design limits, acceptable tolerances as well as QM requirements based on the classification of the SSC. These requirements must be compatible with the content of the Safety Case and the associated Safety Analysis Report</i></p>										

Criteria	Requirements	CA	CH	FI	FR	JP	RF	SK	SA	UK@	US
	<p><i>(SAR). Procurement documents or design specifications produced by suppliers on behalf of the licensee must be accepted by the licensee.</i></p> <p><i>(94) The licensee must ensure that the procurement documents for materials, items and equipment of the nuclear installations reflect the requirements established during the respective life cycle stage. Procurement documents must provide the following minimum information:</i></p> <ul style="list-style-type: none"> <i>• Intended application and operating conditions,</i> <i>• Quality characteristics and safety classifications,</i> <i>• Performance requirements and surveillance of in-process, final and functional tests and inspections,</i> <i>• Documentation and submission requirements for design and analyses, the manufacturing and assembly of parts, components and systems and the construction of civil structures, including the associated tests and inspections,</i> <i>• Requirements concerning handling, storage, conservation, transportation and packaging,</i> <i>• Identification coding for documents and for procured items, and</i> <i>• Product identification and traceability.</i> <p><i>(e) Alternate requirement: RD-0034, req (5):</i> <i>(5) Where there is collaboration between different organisations involved in the performance of design, manufacturing and/or construction tasks responsibilities and tasks must be defined and documented. The licensee must ensure that interfaces between these organisations are clearly specified and described</i></p> <p><i>(i) Alternative approach: RD-0034 has generic requirements on control measures to be</i></p>										

Criteria	Requirements	CA	CH	FI	FR	JP	RF	SK	SA	UK@	US
	<p>implemented to ensure quality and stipulate specific areas of concern. Eg. Req (18) states:</p> <p><i>Control measures must be established within the organisations to ensure that all documents are complete considering relevant requirements before release. All individuals involved in preparing, revising, reviewing or approving documents must be specifically assigned this work, must be competent to carry it out and must be given access to appropriate information on which to base their input or decisions</i></p> <p>JAPAN: (Explanatory note)</p> <ol style="list-style-type: none"> 1. The regulatory body does not carry out the detail inspection on the vendor's design QA system but performs the direct review on the results of detail design of components. <ol style="list-style-type: none"> (1) The construction of a nuclear power station cannot be started before the application of the construction permit, which was submitted by the constructor(licensee), has been reviewed and approved by regulatory body. (2) It is required that the documents to show the integrity of the component have to be included in this application. The constructor(licensee) prepares the drawings and the stress analysis documents based on the drawings and documents submitted to the constructor(licensee) by the vendors and submit them to the regulatory body. (3) The regulatory body reviews the drawings and documents submitted by the constructor(licensee) and if they are acceptable, the construction permit is issued. 2. The design QA manual of the vendor is reviewed by the constructor(licensee). <p>(Alternative Requirements or Alternative regulatory related actions)</p> <p>The QA requirements are confirmed during the process of the construction permit reviews as follows.</p> <ol style="list-style-type: none"> a. The quality level of components are indicated in the drawings for the construction permit and confirmed by the regulatory body. b. Ditto c. The construction permit review by the regulatory body corresponds to this process. d. The interface control is done by the vendor. e. The design control procedure is established by the vendor. f. The appropriateness of the design is conformed by the constructor(licensee) and regulatory body during the process of the construction review. g. The constructor(licensee)'s review can be considered to be the review by another party than the designer. 										

Criteria	Requirements	CA	CH	FI	FR	JP	RF	SK	SA	UK@	US
	<p>h. These matters are reviewed by the constructor(licensee) or the regulatory body during the process of the construction permit review.</p> <p>i. The reactor physics and the accident analysis are reviewed by the regulatory body in the establishment license phase the construction permit phase. The others are reviewed in the process of the construction permit.</p> <p>j. The same procedures are applied in the design change.</p> <p>k. ditto</p> <p>CANADA: Explanatory Note</p> <p>RUSSIAN FEDERATION: The following additional requirements have been established in Russia. In accordance with the Russian legislation and Government decree, an enterprise needs to obtain Regulator license for the right to design with the aim carry out activity on designing. According to the license conditions, supervision is exercised over design activity, it provides for a whole range of actions including supervision over development and implementation of QAPs at the stage of NPP design and equipment and items development, conduct of inspections. There are federal codes and standards in Russian in force, they establish requirements to QAPs for various nuclear facilities.</p> <p>CHINA: i. Design control measures shall be applied to items such as following: 10. radiation protection 11. human factors 12. fire protection</p>										
4. Procurement Document Control	<p>a. 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.</p> <p>b. To the extent necessary, procurement documents shall require contractors or subcontractors to provide a quality assurance program consistent with the pertinent provisions of the established regulatory framework for such programs [at NRC these are found in Appendix B to 10 CFR Part 50].</p>	N*	Y	Y	A/L	L*	L	Y	L		Y
		N*	Y	Y	A/L	L*	L	Y	L		Y

Criteria	Requirements	CA	CH	FI	FR	JP	RF	SK	SA	UK@	US	
Additional or Alternate Requirements	FINLAND: NONE							Y				
	FRANCE: 4 a) and b) <u>Alternate requirements</u> : <i>The organization shall ensure that purchased product conforms to specified purchase requirements.</i> <i>Purchasing information shall describe the product to be purchased, including where appropriate</i> - requirements for approval of product, procedures, processes and equipment, - requirements for qualification of personnel, and - quality management system requirements. <i>The organization shall ensure the adequacy of specified purchase requirements prior to their communication to the supplier.</i> <i>The type and extent of control applied to the supplier and the purchased product shall be dependent upon the effect of the purchased product on subsequent product realisation or the final product.</i> According to an another french regulation (ministerial order August 10 th ,1984), anyone involved in a quality concerned activity identified by the licensee has to implement a quality system in order to comply to the quality requirements specified by the licensee.											
	SOUTH KOREA: (Exemption to the requirement 4.b above) However, this requirement is exempted on condition that the Minister of Education, Science and Technology approves not to establish quality assurance program considering the characteristics of purchasing materials, components or services.											
	JAPAN: (Explanatory note) The regulatory QA inspection on vendors is carried out indirectly through on the work relating to welding which is the major process of component manufacturing.											
	CANADA: Explanatory Note											
	RUSSIAN FEDERATION: NONE											
	CHINA: NONE											
	5. Instructions, Procedures, and	a. Activities affecting quality shall be prescribed by documented instructions, procedures, or drawings, of a type appropriate to the circumstances.	N*	Y	Y	L	L*	L	Y	L		Y

Criteria	Requirements	CA	CH	FI	FR	JP	RF	SK	SA	UK@	US	
Drawings	b. Activities affecting quality shall be accomplished in accordance with the written instructions, procedures, or drawings.	N*	Y	Y	L	L*	L	Y	L		Y	
	c. Instructions, procedures, or drawings shall include appropriate quantitative or qualitative acceptance criteria for determining that important activities have been satisfactorily accomplished.	N*	Y	Y	Y	L*	L	Y	L		Y	
Additional or Alternate Requirements	FINLAND: NONE											
	FRANCE: 5 a) and b) According to the french ministerial order August 10 th, 1984, the licensee has to identify with its subcontractor (so with the pressure equipment manufacturer) the activities affecting the quality of its nuclear facility (mainly design, construction, maintenance, operating, facility modification , corrective actions) see also 4a)and 4b)											
	SOUTH KOREA: NONE											
	SOUTH AFRICA: None											
	JAPAN: (Explanatory note) The regulatory QA inspection on vendors is carried out indirectly through on the work relating to welding which is the major process of component manufacturing.											
	CANADA: Explanatory Note											
	RUSSIAN FEDERATION: NONE											
	CHINA: NONE											
6. Document Control	a. 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.	N*	Y	Y	A	L*	L	Y	L		Y	
	b. These measures shall assure that documents, including changes, are:											
	1. reviewed for adequacy and approved for release by authorized personnel	N*	Y	Y	A	L*	L	Y	L		Y	
	2. distributed to and used at the location where the prescribed activity is performed.	N*	Y	Y	A	L*	L	Y	L		Y	
c. 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.	N*	Y	Y	A	L*	L	Y	A			Y	
Additional or Alternate Requirements	FINLAND: NONE											
	FRANCE: a)b)c) <u>Alternate requirement</u> : <i>Documents required by the quality management system shall be controlled. Records are a special type of document</i>											

Criteria	Requirements	CA	CH	FI	FR	JP	RF	SK	SA	UK@	US
	<p><i>and shall be controlled according to the requirements given in 4.2.4. A documented procedure shall be established to define the controls needed</i></p> <p><i>a) to approve documents for adequacy prior to issue,</i></p> <p><i>b) to review and update as necessary and re-approve documents,</i></p> <p><i>c) to ensure that changes and the current revision status of documents are identified,</i></p> <p><i>d) to ensure that relevant versions of applicable documents are available at points of use,</i></p> <p><i>e) to ensure that documents remain legible and readily identifiable,</i></p> <p><i>f) to ensure that documents of external origin are identified and their distribution controlled, and</i></p> <p><i>g) to prevent the unintended use of obsolete documents, and to apply suitable identification to them if they are retained for any purpose.</i></p> <p>SOUTH KOREA: NONE</p> <p>SOUTH AFRICA</p> <p>(a) Alternative requirements: RD-0034 req (27)</p> <p>(27) The licensee must ensure that licensing documents, including changes, are independently reviewed by themselves and approved for release by authorised personnel. It must be ensured that these documents are available at the location where the relevant activity is carried out.</p> <p>JAPAN: (Explanatory note) The regulatory QA inspection on vendors is carried out indirectly through on the work relating to welding which is the major process of component manufacturing.</p> <p>CANADA: Explanatory Note</p> <p>RUSSIAN FEDERATION: NONE</p> <p>CHINA: NONE</p>										
7. Control of Purchased Material, Equipment, and Services	a. 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.	N*	Y	Y	Y	N	L	Y	L		Y
	b. These measures shall include provisions, as appropriate, for:										
	1. source evaluation and selection	N*	Y	Y	A	L*	L	Y	L		Y
	2. objective evidence of quality furnished by the contractor or subcontractor	N*	Y	Y	A	L*	L	Y	L		Y

Criteria	Requirements	CA	CH	FI	FR	JP	RF	SK	SA	UK@	US	
	3. inspection at the contractor or subcontractor source	N*	Y	Y	A	L*	L	Y	L		Y	
	4. examination of products upon delivery	N*	Y	Y	A	L*	L	Y	L		Y	
	c. Documentary evidence that material and equipment conform to the procurement requirements shall be available at the site prior to installation or use of such material and equipment.	N*	Y	Y	A	L*	L	Y	L		Y	
	d. This documentary evidence shall be retained at the site and shall be sufficient to identify the specific requirements, such as codes, standards, or specifications, met by the purchased material and equipment.	N*	Y	Y	A	L*	L	Y	L		Y	
	e. The effectiveness of the control of quality by contractors and subcontractors shall be assessed by the applicant or designee [licensee, vendor, owner, etc.] at intervals consistent with the importance, complexity, and quantity of the product or services.	N*	Y	Y	A	L*	L	Y	L		Y	
Additional or Alternate Requirements	FINLAND: b) Applied to Safety Classes 1 and 2.											
	FRANCE: 7 b) c) d) <u>Alternate requirements</u> : <i>The organisation shall establish and implement the inspection or other activities necessary for ensuring that purchased product meets specified purchase requirements.</i> <i>Where the organisation or its customer intends to perform verification at the supplier's premises, the organization shall state the intended verification arrangements and method of product release in the purchasing information.</i> <i>The documentation shall describe the means of monitoring the achievement of the required pressure equipment design and quality and the effective operation of the quality system</i>											
	SOUTH KOREA: NONE											
	JAPAN: (Explanatory note) 1 · The regulatory QA inspection on vendors is carried out indirectly through on the work relating to welding which is the major process of component manufacturing. 2 · Item b1. The activities relating to source evaluation and selection are in the responsibility of the vendor											
	CANADA: Explanatory Note											
	RUSSIAN FEDERATION: NONE											
	CHINA: NONE											
8. Identification and Control of	a. Measures shall be established for the identification and control of materials, parts, and components, including partially fabricated assemblies.	N*	Y	Y	Y	L*	L	Y	L		Y	

Criteria	Requirements	CA	CH	FI	FR	JP	RF	SK	SA	UK@	US
Materials, Parts, and Components	b. These measures shall assure that identification of the item is maintained by heat number, part number, serial number, or other appropriate means, either on the item or on records traceable to the item, as required throughout fabrication, erection, installation, and use of the item.	N*	Y	Y	A	L*	L	Y	L		Y
	c. These identification and control measures shall be designed to prevent the use of incorrect or defective material, parts, and components.	N*	Y	Y	Y	L*	L	Y	L		Y
Additional or Alternate Requirements	FINLAND: NONE										
	FRANCE: 8b) <u>Alternate requirement</u> : <i>Where appropriate, the organization shall identify the product by suitable means throughout product realization</i>										
	SOUTH KOREA: NONE										
	JAPAN: (Explanatory note) The regulatory QA inspection on vendors is carried out indirectly through on the work relating to welding which is the major process of component manufacturing.										
	CANADA: Explanatory Note										
	RUSSIAN FEDERATION: NONE										
	CHINA: NONE										
9. Control of Special Processes	a. Measures shall be established to assure that special processes, including welding, heat treating, and nondestructive testing, are controlled.	N*	Y	Y	Y	L*	L	Y	L		Y
	b. Special processes are accomplished by qualified personnel in accordance with applicable codes, standards, specifications, criteria, and other special requirements.	N*	Y	Y	A	L*	L	Y	L		Y
	c. Special processes are accomplished using qualified procedures in accordance with applicable codes, standards, specifications, criteria, and other special requirements.	N*	Y	Y	A	L*	L	Y	L		Y
Additional or Alternate Requirements	FINLAND: NONE										
	FRANCE: 9 b) c) <u>Alternate requirement</u> : <i>The organization shall</i> <ul style="list-style-type: none"> - determine the necessary competence for personnel performing work affecting product quality, - provide training or take other actions to satisfy these needs, - evaluate the effectiveness of the actions taken, - ensure that its personnel are aware of the relevance and importance of their activities and how they contribute to 										

Criteria	Requirements	CA	CH	FI	FR	JP	RF	SK	SA	UK@	US
	<p><i>the achievement of the quality objectives, and</i> <i>- maintain appropriate records of education, training, skills and experience</i> <i>This quality system documentation must permit a consistent interpretation of the procedural and quality measures</i> <i>such as reports concerning the qualifications or approvals of the personnel concerned, particularly those of the personnel undertaking the permanent joining of parts and the non-destructive tests.</i></p> <p>SOUTH KOREA: NONE</p> <p>JAPAN: (Explanatory note) The regulatory QA inspection on vendors is carried out indirectly through on the work relating to welding which is the major process of component manufacturing.</p> <p>CANADA: Explanatory Note</p> <p>RUSSIAN FEDERATION: NONE</p> <p>CHINA: NONE</p>										
10. Inspection	a. 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.	N*	Y	Y	A	L*	A	Y	L		Y
	b. Such inspection shall be performed by individuals other than those who performed the activity being inspected.	N*	Y	Y	A	L*	A	Y	L		Y
	c. Examinations, measurements, or tests of material or products processed shall be performed for each work operation where necessary to assure quality.	N*	Y	Y	Y	L*	A	Y	L		Y
	d. If inspection of processed material or products is impossible or disadvantageous, indirect control by monitoring processing methods, equipment, and personnel shall be provided.	N*	Y	Y	A	L*	A	Y	L		Y
	e. Both inspection and process monitoring shall be provided when control is inadequate without both.	N*	Y	Y	N	L*	A	Y	L		Y
	f. If mandatory inspection hold points are required, the specific hold points shall be indicated in appropriate documents. [hold points are steps in the activity that require witnessing or inspecting by a designated representative and beyond which work shall not proceed without the consent of a designated representative.]	N*	Y	Y	N	L*	A	Y	L		Y

Criteria	Requirements	CA	CH	FI	FR	JP	RF	SK	SA	UK@	US
Additional or Alternate Requirements	FINLAND: NONE										
	FRANCE: 10 a) b) <u>Alternate requirement</u> : <i>The organization shall conduct internal audits at planned intervals to determine whether the quality management system</i> <i>- conforms to the planned arrangements, to the requirements of the quality management system requirements established by the organization, and</i> <i>- is effectively implemented and maintained.</i> <i>An audit programme shall be planned, taking into consideration the status and importance of the processes and areas to be audited, as well as the results of previous audits. The audit criteria, scope, frequency and methods shall be defined. Selection of auditors and conduct of audits shall ensure objectivity and impartiality of the audit process.</i> <i>Auditors shall not audit their own work.</i> <i>The responsibilities and requirements for planning and conducting audits, and for reporting results and maintaining records shall be defined in a documented procedure.</i> 10 d) <u>Alternate requirement</u> : <i>The organisation shall validate any processes for production and service provision where the resulting output cannot be verified by subsequent monitoring or measurement. This includes any processes where deficiencies become apparent only after the product is in use or the service has been delivered.</i> <i>Validation shall demonstrate the ability of these processes to achieve planned results.</i> <i>The organisation shall establish arrangements for these processes including, as applicable</i> <i>- defined criteria for review and approval of the processes,</i> <i>- approval of equipment and qualification of personnel,</i> <i>- use of specific methods and procedures,</i>										

Criteria	Requirements	CA	CH	FI	FR	JP	RF	SK	SA	UK@	US
	<p>- requirements for records and</p> <p>- revalidation.</p>										
	SOUTH KOREA: NONE										
	JAPAN: (Explanatory note) The regulatory QA inspection on vendors is carried out indirectly through on the work relating to welding which is the major process of component manufacturing.										
	CANADA: Explanatory Note										
	RUSSIAN FEDERATION: Federal codes and rules NP-071-06 “Regulations for assessment of conformity of equipment, materials and semi finished products to be delivered to nuclear facilities. In accordance with the document, the following forms of conformity assessment should be used to evaluate the conformity of equipment, components, materials and semi finished products to be delivered to nuclear facilities: state control (supervision), testing, acceptance, confirmation of conformity. At the stage of manufacture assessment of conformity in the form of acceptance and testing is done by organizations authorized by regulatory body and state corporation Rosatom in accordance with requirements of NP-071-06 (as per quality plans).										
	CHINA: NONE										
11. Test Control	a. 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.	N*	Y	Y	N	Y	A	Y	L		Y

Criteria	Requirements	CA	CH	FI	FR	JP	RF	SK	SA	UK@	US
	b. The test program shall include, as appropriate:										
	1. proof tests prior to installation	N*	Y	Y	N	Y	A	Y	L		Y
	2. preoperational tests	N*	Y	Y	N	Y	A	Y	L		Y
	3. operational tests during operation of structures, systems, and components	N*	Y	Y	N	Y	A	N	L		N
	c. Test procedures shall include provisions for:										
	1. assuring that all prerequisites for the given test have been met	N*	Y	Y	N	Y	A	Y	L		Y
	2. assuring that adequate test instrumentation is available and used	N*	Y	Y	N	Y	A	Y	L		Y
	3. assuring that the test is performed under suitable environmental conditions	N*	Y	Y	N	Y	A	Y	L		Y
	4. documenting and evaluating testing results to assure that test requirements have been satisfied	N*	Y	Y	N	Y	A	Y	L		Y
Additional or Alternate Requirements	FINLAND: NONE										
	FRANCE: 11) Nowadays the different french regulation doesn't mention such requirements. Nevertheless it is the responsibility of the licensee to define the inservice performances of the pressure equipment to be achieved (for example flowrate and NPSH of a primary pump under normal operating condition and for a seismic load) and the responsibility of the manufacturer to take in account . The licensee has to describe in the safety analysis report, before operating the facility, the test program which will be implemented. A new ministerial order, (as a draft version for the moment) should mention such kind of requirements;										
	SOUTH KOREA: NONE										
	JAPAN: (Explanatory note) 1 After the manufacturing of components is completed, the regulatory test is carried out on the items as the commissioning test before the use of components is started. 2 Item b3. The operational tests of structure, system, and components during operation up to fuel loading is included in the commissioning test. After fuel loading, the operation is regarded as the plant operation.										
	CANADA: Explanatory Note										
	RUSSIAN FEDERATION: With account of additional requirements presented in item 10.										
	CHINA: NONE										
12. Control of	a. Measures shall be established to assure that tools, gages, instruments, and other measuring and	N*	Y	Y	Y	L*	L	Y	L		Y

Criteria	Requirements	CA	CH	FI	FR	JP	RF	SK	SA	UK@	US
Measuring and Test Equipment	testing devices used in activities affecting quality are properly controlled, calibrated, and adjusted at specified periods to maintain accuracy within necessary limits.										
Additional or Alternate Requirements	FINLAND: NONE										
	FRANCE: 12 a) <u>Additional requirements</u> : <i>- the organization shall assess and record the validity of the previous measuring results when the equipment is found not to conform to requirements. The organization shall take appropriate action on the equipment and any product affected</i> <i>- When used in the monitoring and measurement of specified requirements, the ability of computer software to satisfy the intended application shall be confirmed. This shall be undertaken prior to initial use and reconfirmed as necessary.</i> <i>-the metrological characteristics of measuring equipment shall be suitable for its intended use (that means for example the uncertainties of the measuring equipment have to be consistent with the dimensional tolerances of the product).</i>										
	SOUTH KOREA: NONE										
	JAPAN: (Explanatory note) After the manufacturing of component is completed, the regulatory test is carried out on the items except b3 as the commissioning test before the use of components are started.										
	CANADA: Explanatory Note										
	RUSSIAN FEDERATION: NONE										
	CHINA: NONE										
13. Handling, Storage and Shipping	a. Measures shall be established for material and equipment to control:										
	1. handling	N*	Y	Y	Y	L*	L	Y	L		Y
	2. storage	N*	Y	Y	Y	L*	L	Y	L		Y
	3. shipping	N*	Y	Y	Y	L*	L	Y	L		Y
	4. cleaning	N*	Y	Y	Y	L*	L	Y	L		Y
	5. preservation	N*	Y	Y	Y	L*	L	Y	L		Y
	b. These activities shall be done in accordance with work and inspection instructions to prevent damage or deterioration.	N*	Y	Y	Y	L*	L	Y	L		Y

Criteria	Requirements	CA	CH	FI	FR	JP	RF	SK	SA	UK@	US
	c. 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.	N*	Y	Y	Y	L*	L	Y	N		Y
Additional or Alternate Requirements	FINLAND: NONE										
	FRANCE: 13) the french requirement is considered to be similar : <i>The organisation shall preserve the conformity of product during internal processing and delivery to the intended destination. This preservation shall include identification, handling, packaging, storage and protection. Preservation shall also apply to the constituent parts of a product.</i>										
	SOUTH KOREA: NONE										
	JAPAN: (Explanatory note) The regulatory QA inspection on vendors is carried out indirectly through on the work relating to welding which is the major process of component manufacturing.										
	CANADA: Explanatory Note										
	RUSSIAN FEDERATION: NONE										
	CHINA: NONE										
14. Inspection, Test, and Operating Status	a. 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.	N*	Y	Y	A	L*	L	Y	L		Y
	b. 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.	N*	Y	Y	A	L*	L	Y	L		Y
	c. 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.	N*	Y	Y	N	Y	L	N	N		N
Additional or Alternate Requirements	FINLAND: NONE										
	FRANCE: 14 a) and b) <u>Alternate requirement</u> : <i>Where appropriate, the organization shall identify the product by suitable means throughout product realization. The organization shall identify the product status with respect to monitoring and measurement</i>										

Criteria	Requirements	CA	CH	FI	FR	JP	RF	SK	SA	UK@	US
	<i>requirements.</i> <i>Where traceability is a requirement, the organization shall control and record the unique identification of the product</i> SOUTH KOREA: NONE JAPAN: (Explanatory note) 1. The regulatory QA inspection on vendors is carried out indirectly through on the work relating to welding which is the major process of component manufacturing. 2. c. This is the matter for the plant operation. CANADA: Explanatory Note RUSSIAN FEDERATION:NONE CHINA: NONE										
15. Nonconforming Materials, Parts, or Components	a. 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:	N*	Y	Y	Y	L*	L	Y	L		Y
	1. identification of nonconforming materials, parts, or components	N*	Y	Y	Y	L*	L	Y	L		Y
	2. documentation of nonconforming materials, parts, or components	N*	Y	Y	Y	L*	L	Y	L		Y
	3. segregation of nonconforming materials, parts, or components	N*	Y	Y	Y	L*	L	Y	L		Y
	4. disposition of nonconforming materials, parts, or components	N*	Y	Y	Y	L*	L	Y	L		Y
	5. notification to affected organizations of nonconforming materials, parts, or components	N*	Y	Y	Y	L*	L	Y	L		Y
	b. Nonconforming items shall be:										
	1. reviewed and accepted in accordance with documented procedures	N*	Y	Y	Y	L*	L	Y	L		Y
	2. rejected in accordance with documented procedures	N*	Y	Y	Y	L*	L	Y	N		Y
3. repaired in accordance with documented procedures	N*	Y	Y	Y	L*	L	Y	L		Y	
4. reworked in accordance with documented procedures	N*	Y	Y	Y	L*	L	Y	L		Y	
Additional or Alternate Requirements	FINLAND: NONE										
	FRANCE: 15 a) <u>Additional requirement</u> : <i>When nonconforming product is detected after delivery or use has started, the organization shall take action appropriate to the effects, or potential effects, of the nonconformity.</i>										
	SOUTH KOREA: NONE										

Criteria	Requirements	CA	CH	FI	FR	JP	RF	SK	SA	UK@	US
	<p>JAPAN: (Explanatory note) The regulatory QA inspection on vendors is carried out indirectly through on the work relating to welding which is the major process of component manufacturing.</p> <p>CANADA: Explanatory Note</p> <p>RUSSIAN FEDERATION: NONE</p> <p>CHINA: When necessary, the nonconforming items shall be reported to the designated authority. [such as NNSA in China] Repaired or reworked items shall be reinspected according to applicable procedures.</p>										
16. Corrective Action	a. 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.	N*	Y	Y	Y	L*	L	Y	L		Y
	b. 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.	N*	Y	Y	Y	L*	L	Y	L		Y
	c. 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.	N*	Y	Y	Y	L*	L	Y	L		Y
Additional or Alternate Requirements	<p>FINLAND: NONE</p> <p>FRANCE: 16 a)b)c) according to the french regulation the objectives are the same : <i>The organisation shall take action to eliminate the cause of nonconformities in order to prevent recurrence.</i> <i>Corrective actions shall be appropriate to the effects of the nonconformities encountered.</i> <i>A documented procedure shall be established to define requirements for</i> <i>a) reviewing nonconformities (including customer complaints),</i> <i>b) determining the causes of nonconformities,</i> <i>c) evaluating the need for action to ensure that nonconformities do not recur,</i> <i>d) determining and implementing action needed,</i> <i>e) records of the results of action taken</i> <u>But there is an additional requirement</u> related to preventive actions : <i>The organisation shall determine action to eliminate the causes of potential nonconformities in order to prevent their occurrence. Preventive actions shall be appropriate to the effects of the potential problems.</i></p> <p>SOUTH KOREA: NONE</p>										

Criteria	Requirements	CA	CH	FI	FR	JP	RF	SK	SA	UK@	US
	SOUTH AFRICA: ADDITIONAL REQUIREMENTS RD-0034 specifies additional requirements relating to corrective actions: RD-0034, req (134): <i>Senior management of the licensee is responsible for ensuring that systems are in place to continuously improve organisational systems and processes. This must include implementing operating experience and lessons learned from internal and external sources, both within and outside the nuclear industry. A systematic event analysis and corrective action process, which addresses human, organisational factors and technical issues, must be established.</i>										
	JAPAN: (Explanatory note) The regulatory QA inspection on vendors is carried out indirectly through on the work relating to welding which is the major process of component manufacturing.										
	CANADA: Explanatory Note										
	RUSSIAN FEDERATION: NONE										
	CHINA: NONE										
17. Quality Assurance Records	a. Sufficient records shall be maintained to furnish evidence of activities affecting quality.	N*	Y	Y	Y	L*	L	Y	L		Y
	b. The records shall include at least the following:										
	1. Operating logs	N*	Y	A	Y	Y	L	N	A		N
	2. the results of reviews	N*	Y	Y	Y	L*	L	Y	A		Y
	3. the results of inspections	N*	Y	Y	Y	L*	L	Y	A		Y
	4. the results of tests	N*	Y	Y	N	L*	L	Y	A		Y
	5. the results of audits	N*	Y	Y	Y	L*	L	Y	A		Y
	6. the results of monitoring of work performance	N*	Y	Y	Y	L*	L	Y	A		Y
	7. the results of materials analyses	N*	Y	Y	Y	L*	L	Y	A		Y
	c. The records shall also include closely-related data such as:										
	1. qualifications of personnel	N*	Y	Y	Y	L*	L	Y	N		Y
	2. qualifications of procedures	N*	Y	Y	Y	L*	L	Y	N		Y
	3. qualifications of equipment	N*	Y	Y	Y	L*	Y	Y	N		Y
	d. Inspection and test records as a minimum shall:										
	1. identify the inspector or data recorder	N*	Y	Y	N	L*	L	Y	N		Y
2. the type of observation	N*	Y	Y	N	L*	L	Y	N		Y	
3. the results	N*	Y	Y	Y	L*	L	Y	N		Y	
4. the acceptability	N*	Y	Y	Y	L*	Y	Y	N		Y	
5. the action taken in connection with any deficiencies noted.	N*	Y	Y	Y	L*	L	Y	N		Y	

Criteria	Requirements	CA	CH	FI	FR	JP	RF	SK	SA	UK@	US
	e. Records shall be identifiable and retrievable.	N*	Y	Y	Y	L*	L	Y	L		Y
	f. Consistent with applicable regulatory requirements, the applicant shall establish requirements concerning record retention, such as duration, location, and assigned responsibility.	N*	Y	Y	Y	L*	L	Y	A		Y
Additional or Alternate Requirements	FINLAND: b1) No specific requirements for operating logs (meaning to be clarified)										
	FRANCE: NONE										
	SOUTH KOREA: NONE										
	SOUTH AFRICA: ALTERNATIVE REQUIREMENT (b) and (f) RD-0034 contains generic requirements on records and does not specify types of records: RD-0034 req (22): <i>The organisations must ensure that records are retained to furnish evidence of activities affecting quality and safety. These records must be readable, complete, identifiable, classified, stored and easily retrievable. Retention times of records must be defined</i>										
	Additional Requirements: RD-0034, req (125): <i>Rework and repair actions must be described in documents equivalent to those on which manufacturing of the respective parts was based. These documents must be reviewed and maintained as records in the same manner as the original documents</i>										
	RD-0034, req (127): <i>The licensee must ensure that the sources of any data used are traceable and must be validated for the specific application. Documented records must be maintained of the source from which the data is taken and the measures introduced for its validation and verification. Data input must be part of the controlled process defined for QM and SM</i>										
	JAPAN: (Explanatory note) 1. The regulatory QA inspection on vendors is carried out indirectly through on the work relating to welding which is the major process of component manufacturing. 2. b1, The operational record up to fuel loading is included in the commissioning test of the component.										
CANADA: Explanatory Note											
RUSSIAN FEDERATION: NONE											

Criteria	Requirements	CA	CH	FI	FR	JP	RF	SK	SA	UK@	US
	CHINA: NONE										
18. Audits	a. 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.	N*	Y	Y	Y	L*	L	Y	L		Y
	b. 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.	N*	Y	Y	Y	L*	L	Y	L		Y
	c. Audit results shall be documented and reviewed by management having responsibility in the area audited.	N*	Y	Y	Y	L*	L	Y	L		Y
	d. Followup action, including reaudit of deficient areas, shall be taken where indicated.	N*	Y	Y	Y	L*	L	Y	L		Y
Additional or Alternate Requirements	FINLAND: NONE										
	FRANCE: NONE										
	SOUTH KOREA: NONE										
	JAPAN: (Explanatory note) The regulatory QA inspection on vendors is carried out indirectly through on the work relating to welding which is the major process of component manufacturing.										
	CANADA: Explanatory Note										
	RUSSIAN FEDERATION: NONE										
	CHINA: NONE										
OTHER REQUIREMENTS RELATED TO VENDOR INSPECTIONS											
19. Reporting of Defects and noncompliances	a. 10 CFR Part 21 of NRC's regulations requires any individual director or responsible officer of a firm constructing, owning, operating, or supplying the components of any facility or activity which is licensed or otherwise regulated by the NRC, who obtains information reasonably indicating: (a) That the facility, activity or basic component supplied to such facility or activity fails to comply with the Atomic Energy Act of 1954, as amended, or any applicable rule, regulation, order, or license of the Commission relating to substantial safety hazards or (b) that the facility, activity, or basic component supplied to such facility or activity contains defects, which could create a substantial safety hazard, to immediately notify the Commission of such failure to comply or such defect, unless he has actual knowledge that the Commission has been adequately informed of such defect or failure to comply	N*		A	N	Y	L	N	A		
Additional or Alternate Requirements	FINLAND: YVL 3.0 requires that a person responsible for manufacturing of pressure equipment for Finnish projects must be nominated and accepted by STUK. The nominated person has to give a written certificate for the conformity of the component including acceptance of all										

Criteria	Requirements	CA	CH	FI	FR	JP	RF	SK	SA	UK@	US
	<p>nonconformities.</p> <p>FRANCE: In one hand according to the ministerial order August 10th, 1984, the non-conformances which are significant for the nuclear safety have to be notified by the licensee to ASN.</p> <p>In the other hand, according to the ministerial order Dec 12th, 2005, the conformity assessment of the nuclear pressure equipment design and manufacturing is carried out by ASN or by an agreed body. Then, ASN or an agreed body is automatically informed of a non-conformance, which impacts the quality of the considered nuclear pressure equipment.</p> <p>KOREA: NONE</p> <p>SOUTH AFRICA: ALTERNATIVE REQUIREMENT RD-0034, req (126): <i>The NNR must be informed of non conforming products based on the safety classification as soon as such non conformances are recognized by the licensee. The licensee must implement the respective processes which must adequately reflect the NNR involvement</i></p> <p>JAPAN: (Explanatory note) The same kind of the requirement is delineated in the Japanese rules, as It can be interpreted in the following rules that "<u>the information needed for preserving the conditions of procured items and using procured services (only relating to maintenance)</u>" includes "<u>the information on defects, which could create a substantial safety hazard</u>"</p> <ol style="list-style-type: none"> In case of procuring items and services from outside vendors, the QA implementation plan has to define the requirements necessary for implementing the purchasing activities (including the means to obtain and to share with other licensees <u>the information needed for preserving the conditions of procured items and using procured services (only relating to maintenance)</u> and the method to ensure the fulfillment of those requirements. For improvement of maintenance activities, it is required that the findings which have been obtained not only by implementing the maintenance activities at the own nuclear facilities but also from the other facilities shall be reflected in the implementation of preventive measures. <p>CANADA: Explanatory Note</p> <p>RUSSIAN FEDERATION: NONE</p> <p>CHINA: NONE</p>										
20. Deliberate misconduct	10 CFR 50.5 requires: (a) Any licensee, applicant for a license, employee of a licensee or applicant; or any contractor (including a supplier or consultant), subcontractor, employee of a	N*		A	N	Y	N	N	A		

Criteria	Requirements	CA	CH	FI	FR	JP	RF	SK	SA	UK@	US
	<p>contractor or subcontractor of any licensee or applicant for a license, who knowingly provides to any licensee, applicant, contractor, or subcontractor, any components, equipment, materials, or other goods or services that relate to a licensee's or applicant's activities in this part, may not:</p> <p>(1) Engage in deliberate misconduct that causes or would have caused, if not detected, a licensee or applicant to be in violation of any rule, regulation, or order; or any term, condition, or limitation of any license issued by the Commission; or</p> <p>(2) Deliberately submit to the NRC, a licensee, an applicant, or a licensee's or applicant's contractor or subcontractor, information that the person submitting the information knows to be incomplete or inaccurate in some respect material to the NRC.</p> <p>(b) A person who violates paragraph (a)(1) or (a)(2) of this section may be subject to enforcement action in accordance with the procedures in 10 CFR part 2, subpart B.</p> <p>(c) For the purposes of paragraph (a)(1) of this section, deliberate misconduct by a person means an intentional act or omission that the person knows: (1) Would cause a licensee or applicant to be in violation of any rule, regulation, or order; or any term, condition, or limitation, of any license issued by the Commission; or (2) Constitutes a violation of a requirement, procedure, instruction, contract, purchase order, or policy of a licensee, applicant, contractor, or subcontractor.</p>										
Additional or Alternate Requirements	<p>FINLAND: Enforcement requirements are given in Finnish Nuclear Energy Act and in other relevant legislation such as penal code.</p>										
	<p>FRANCE: In one hand according to the ministerial order August 10th, 1984, the non-conformances which are significant for the nuclear safety have to be notified by the licensee to ASN.</p> <p>In the other hand, according to the ministerial order Dec 12th, 2005, the conformity assessment of the nuclear pressure equipment design and manufacturing is carried out by ASN or by an agreed body. Then, ASN or an agreed body is automatically informed of a non-conformance, which impacts the quality of the considered nuclear pressure equipment.</p>										
	<p>SOUTH KOREA: (Alternative Requirements)</p> <p>Atomic Energy Act / Article 104-4 "Protection of Employees" requires:</p> <p>Any atomic energy-related enterpriser or persons engaged shall not disadvantage their employees for actions that fall within any of the following Subparagraphs: <Amended by Dec.</p>										

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	<p>30, 1996, Feb. 8, 1999></p> <ol style="list-style-type: none"> Act for complying with the operational technical specifications as prescribed in Article 21 (2) or the provisions of Article 33 (2), the safety administration rules as prescribed in Articles 43(3), 57(2) or 65(5) or the provisions of Article 76(2), or the quality assurance plan regarding readings as prescribed in the provisions of Article 90-4(3); Acts informing the Minister of Science and Technology, or the head of the agency to which the Minister of Science and Technology delegates or entrusts his authority, relating to violations or possible violation of the operational technical specifications, the safety administration rules or quality assurance plan regarding readings as provided for in Paragraph (1) by an atomic energy-related enterpriser or person engaged in readings. <p>Act of giving testimony or producing evidence in order to comply with any inspection or investigation pursuant to Articles 16 (including application <i>mutatis mutandis</i> from Article 36), 23-2 (including application <i>mutatis mutandis</i> from Article 36), 45, 59, 67, 73, 78, 90-3 and 90-6 or the provisions of Article 103.</p>										
	<p>SOUTH AFRICA: EXPLANATORY NOTE</p> <p>Section 52 of the National Nuclear Regulator Act provides for “Offences and penalties”.</p>										
	<p>JAPAN: (Explanatory note)</p> <p>The same kind of the requirement is delineated in the Japanese rules, as It can be interpreted in the following rules that <u>“the information needed for preserving the conditions of procured items and using procured services (only relating to maintenance)”</u> includes <u>“the information on defects, which could create a substantial safety hazard”</u></p> <ol style="list-style-type: none"> In case of procuring items and services from outside vendors, the QA implementation plan has to define the requirements necessary for implementing the purchasing activities (including the means to obtain and to share with other licensees <u>the information needed for preserving the conditions of procured items and using procured services (only relating to maintenance)</u> and the method to ensure the fulfillment of those requirements. For improvement of maintenance activities, it is required that the findings which have been obtained not only by implementing the maintenance activities at the own nuclear facilities but also from the other facilities shall be reflected in the implementation of preventive 										

Criteria	Requirements	CA	CH	FI	FR	JP	RF	SK	SA	UK@	US
	measures.										
	CANADA: Explanatory Note										
	RUSSIAN FEDERATION: NONE										
	CHINA: NONE										