Multinational Design Evaluation Programme
Technical Report
TR-VICWG-03

Date: 30 January 2014
Validity: **until next update or archiving**
Version : 1

MDEP

Technical Report

TR-VICWG-03

Related to: Vendor Inspection Cooperation Working Group

Technical Report

Common QA/QM Criteria for Multinational Vendor Inspection

Participation

Regulators involved in the MDEP working group discussions:	Canada, China, Finland, France, India, Japan, Republic of Korea, Russian Federation, South Africa, Sweden, the U.A.E., the U.K., and the U.S.
Regulators that support the Technical Report	All
Regulators with no objection:	N/A
Regulators which disagree: N/A	N/A
Compatible with existing IAEA related documents	Yes

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Ⅰ. INTRODUCTION

This VICWG document provides the “Common QA/QM Criteria” which will be used in Multinational Vendor Inspection. The “Common QA/QM Criteria” provides the basic consideration when performing the Vendor Inspection. These criteria has been developed in conformity with International Codes and Standards such as IAEA, ISO and so on that MDEP member countries adopted.

Ⅱ. BACKGROUND

The purpose of the VICWG is to establish areas of co-operation in the Vendor Inspection practices among MDEP member countries as described in the MDEP issue-specific Terms of Reference（ToR）. The ToR states:

> *[The VICWG] should identify areas of commonality and differences between regulatory practices of member countries in the area of vendor inspection programmes, should identify best practices, and should develop an overall framework and timeline for the conduct of inspections of vendors and a protocol for sharing results among national regulatory bodies. The results of all MDEP-related vendor inspections should be incorporated into the MDEP library.*

As part of this, from the beginning, a survey was performed to understand and to identify areas of commonality and differences between regulatory practices of member countries in the area of vendor inspection. The VICWG also collaborated by performing Witnessed Inspections and Joint Inspections.

Through these activities, it was recognized that member countries commonly apply the IAEA safety standard (GS-R-3) to the vendor inspection criteria, and almost all European member countries apply the ISO standard (ISO9001). In the US, the NRC regulatory requirement in 10 CFR, Part 50, Appendix B is used. South Korea uses the same criteria as in the US.

As a result of the information obtained, a comparison table between codes and standards (IAEA GS-R-3, ISO 9001:2008.10CFR50 Appendix B and ASME NQA-1) has been developed in order to inform the development of “Common QA/QM Criteria.” The result is documented in Table 1, “MDEP CORE QA/QM Requirement and Comparison between Codes and Standards. In addition, each country’s criteria were compared with the US 10CFR50 Appendix B as a template. Table2 shows VICWG Survey on Quality Assurance Program Requirements.

Through these activities above, we considered that the core requirements should be consistent with both IAEA safety standard and ISO standard, and considered that the common requirements in the US 10CFR50 Appendix B used to the survey program should be as a guideline of essential elements.

Basic Consideration

Purpose: To provide Common QA/QM Criteria for use I Multinational Vendor Inspection.

Concept: Corresponding to the International Codes and Guides and additionally applying the Major Requirements. "Common QA/QM Criteria for Multinational Vendor Inspection" are composed "Core QA/QM Requirements" and "Essential Elements".

Use of Survey Results: Proposal of "Common QA/QM Criteria"was considered by using "The comparison table between Codes and Standards" (Table 1) and "VICWG Survey on Quality Assurance Program Requirements" (Table 2).

Ⅲ. HIERARCHY STRUCTURE OF COMMON QA/QM CRITERIA

A hierarchy structure of “Common QA/QM Criteria” was considered shown in Fig. 1 below.

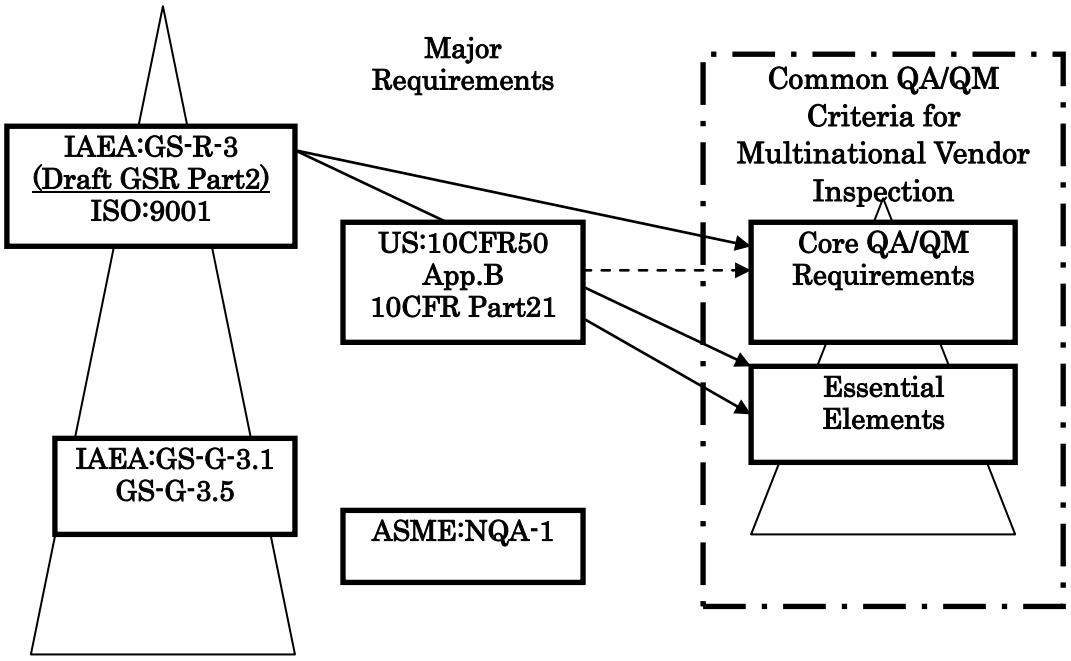

Fig.1 Hierarchy Structure of Common QA/QM Criteria for Multinational Vendor Inspection

The “Common QA/QM Criteria” shown in the right side of Fig. 1 is made up of the “Core QA/QM Requirements” and the “Essential Elements”.

The “Core QA/QM Requirements” is intended to indicate the basic requirements of inspection, and also intended to cover comprehensively each item of IAEA GS-R-3 of the standards and international standards shown on the left side of Figure 1, it is also related to the requirements of ISO9001.

The “Essential Elements” shows in detail the items to be considered. It is intended to cover a common area that satisfies the basic requirements of the country for US 10CFR50 Appendix B. In this case, we are referring to the part of the ASME NQA-1 standard.

The process by which the “Core QA/QM Requirements” will be used in carrying out the Multinational Vendor Inspection, is that after selecting the item to be inspected according to each item in the “Core QA/QM Requirements,” inspection will be performed to evaluate and verify the requirements set forth herein are satisfied (through verification of documents, and/or direct inspection). The specific aspect of this case will be evaluated against each item of the “Essential Elements.”

Core QA/QM Requirements

- Basic requirements of each PDCA activity in an overall description.
- For the most part corresponding to IAEA GS-R-3 (and Draft GSR Part2) and vary depending on the ISO9001.
- These requirements are mandatory.

Essential Elements

The “Essential Elements” shows the basic consideration items when performing the Vendor Inspection.

- Essential Elements are composed of Core Quality Management Requirements.
- Using the result of “VICWG Survey on Quality Assurance Program Requirements”
- Using the Comparison Table between Codes and Standards.
- Corresponding to the IAEA GS-G-3.1 and 3.5.
- These elements are used as reference items.

Ⅳ. "COMMON QA/QM CRITERIA" FOR MULTINATIONAL VENDOR INSPECTION (CORE QA/QM REQUIRMENTS AND ESSENTIAL ELEMENT)

The proposal of "Common QM Criteria for Multinational Vendor Inspection" ("Core QM Requirements" and "Essential Elements") are as follows

(1. Quality management system)

〔Core QA/QM Requirements〕

1.1〔2.1〕[1] IAEA &〔4.1〕[1] ISO A quality management system shall be established, implemented, assessed and continually improved of its effectiveness. (IAEA & ISO)

〔Essential Elements〕

1.1〔2.1〕[1] IAEA The main aim of the quality management system should be to achieve and enhance safety by:

—Bringing together in a coherent manner all the quality requirements for managing the organization;

—Ensuring that quality requirements are not considered separately from safety requirements, to help preclude their possible negative impact on safety. (IAEA)

1.2〔1c〕[1] App.B The authority and duties of persons and organizations performing activities affecting the safety-related functions of structures, systems, and components should be clearly established and delineated in writing.

These activities include both the performing functions of attaining quality objectives and the quality management functions.

The quality management functions are those of

(a) assuring that an appropriate quality management program is established and effectively executed; and

(b) verifying, such as by checking, auditing, and inspecting, that activities affecting the safety related functions have been correctly performed. (Organization of 10CFR50 App.B)

(2. Grading)

〔Core QA/QM Requirements〕

2.1〔2.6〕[1] IAEA The implementation of quality management system shall be graded so as

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[1] The number in parenthesis is a reference to the section number in IAEA Safety Standards Series, "The Management System for Facilities and Activities" No.GS-R-3 (2006) from which the Core QA Requirement was reproduced consideration with the ISO "Quality management system – Requirements" No. ISO 9001:2008, and is a reference to the section number in VICWG Survey o Quality Assurance Program (10CFR50 Appendix B) Requirements.

to deploy appropriate resources.(IAEA)

〔Essential Elements〕

2.1〔2d〕[1 App.B] The organization should provide control over activities affecting the quality of the identified structures, systems, and components, to an extent consistent with their importance to safety. (Quality Assurance Program of App.B)

2.2〔2.6〕[1 IAEA] The grading should be considered by:

—The significance and complexity of each product or activity;

—The hazards and the magnitude of the potential impact (risks) associated with the safety, health, environmental, security, quality and economic elements of each product or activity;

—The possible consequences if a product fails or an activity is carried out incorrectly. (IAEA)

2.3〔2.7〕[1 IAEA] Grading of the application of management system requirements should be applied to the products and activities of each process. (IAEA)

2.4〔7e〕[1 App.B] The effectiveness of the control of quality by contractors and subcontractors should be assessed by the applicant or designee at intervals consistent with the importance, complexity, and quantity of the product or services. (Control of Purchased Material, Equipment, and Service of App.B)

(3. Documentation of the quality management system)

〔Core QA/QM Requirements〕

3.1〔2.8〕[1 IAEA] &〔4.2〕[1 ISO] The documentation of the quality management system shall include a measure of planning, responsibility, resource management, implementation, measurement, analysis, improvement and review. (IAEA & ISO)

〔Essential Elements〕

3.1〔2a〕[1 App.B] The applicant [licensee, vendor, owner, etc.] should establish at the earliest practicable time, consistent with the schedule for accomplishing the activities, a quality management program which complies with the requirements of the established regulatory framework for such program. (Quality Assurance Program of App.B)

3.2〔2b〕[1 App.B] The quality management program should be documented by written policies, procedures, or instructions. (Quality Assurance Program of App.B)

3.3〔2d〕[1 App.B] The applicant [licensee, vendor, owner, etc.] should identify the structures, systems, and components to be covered by the quality management program. (Quality Assurance Program of App.B)

3.4〔2f〕[1 App.B] Activities affecting quality should be accomplished under suitably controlled conditions. Controlled conditions include:

1. the use of appropriate equipment
2. suitable environmental conditions for accomplishing the activity, such as adequate

cleanness

–(Quality Assurance Program of App.B)

3.5〔2g〕[1 App.B] The program should 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. (Quality Assurance Program of App.B)

3.6〔2i〕[1 App.B] The applicant [licensee, vendor, owner, etc.] should regularly review the status and adequacy of the quality management program. (Quality Assurance Program of App.B)

3.7〔2j〕[1 App.B] Management of other organizations participating in the quality management program should regularly review the status and adequacy of that part of the quality management program which they are executing. (Quality Assurance Program of App.B)

(4. Control of documents and records)

〔Core QA/QM Requirements〕

4.1〔5.12〕[1 IAEA] &〔4.2.3 & 4.2.4〕[1 ISO] Documents and records required by the quality management system shall be controlled. (IAEA & ISO)

〔Essential Elements〕

4.1〔6a〕[1 App.B] Measures should be established to control the issuance of documents, such as instructions, procedures, and drawings, including changes thereto, which prescribe all activities affecting quality. (Document Control of App.B)

4.2〔6b〕[1 App.B] These measures should assure that documents, including changes, are:

1. reviewed for adequacy and approved for release by authorized personnel
2. distributed to and used at the location where the prescribed activity is performed. (Document Control of App.B)

4.3〔6c〕[1 App.B] Changes to documents should be reviewed and approved by the same organizations that performed the original review and approval unless the applicant designates another responsible organization. (Document Control of App.B)

4.4〔17a〕[1 App.B] Sufficient records should be maintained to furnish evidence of activities affecting quality. (Quality Assurance Records of App.B)

4.5〔17b〕[1 App.B] The records should include at least the following:

1. the results of reviews
2. the results of inspections
3. the results of audits
4. the results of monitoring of work performance
5. the results of materials analyses(Quality Assurance Records of App.B)

4.6〔17c〕[1 App.B] The records should also include closely-related data such as:

1. qualifications of personnel
2. qualifications of procedures
3. qualifications of equipment(Quality Assurance Records of App.B)

4.7〔17d〕[1 App.B] Inspection and test records as a minimum should:

1. the type of observation
2. the results
3. the acceptability
4. the action taken in connection with any deficiencies noted. (Quality Assurance Records of App.B)

4.8〔17e〕[1 App.B] Records should be identifiable and retrievable. (Quality Assurance Records of App.B)

4.9〔17f〕[1 App.B] Consistent with applicable regulatory requirements, the applicant should establish requirements concerning record retention, such as duration, location, and assigned responsibility. (Quality Assurance Records of App.B)

(5. Responsibility and Leadership)

〔Core QA/QM Requirements〕

5.1〔3.12〕[1 IAEA] &〔5.5.1〕[1 ISO] Top or senior management shall be ultimately responsible for the quality management system and shall ensure that it is established, implemented, assessed and continually improved. (IAEA & ISO)

5.2〔Req. 2〕[1 IAEA] Effective Leadership for safety shall be demonstrated at all levels in the organization.(IAEA Draft GSR Part2)

〔Essential Elements〕

5.1〔1a〕[1 App.B] The organization shall be responsible for the establishment and execution of the quality management system. (Organization of App.B)

5.2〔1d〕[1 App.B] The persons and organizations performing quality management functions should have sufficient authority and organizational freedom to identify quality problems; to initiate, recommend, or provide solutions; and to verify implementation of solutions. (Organization of App.B)

5.3〔1e〕[1 App.B] The persons and organizations performing quality management functions should 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 management program may take various forms, provided that the persons and organizations assigned the quality management 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 management program at any location where activities subject to this appendix are being performed, should have direct access to the levels of management necessary

to perform this function. (Organization of App.B)

(6. Human resources)

〔Core QA/QM Requirements〕

6.1〔4.3〕[1 IAEA] &〔6.2.1〕[1 ISO] Personnel performing work affecting quality shall be competent on the basis of appropriate education, training, skills and experience. (IAEA & ISO)

〔Essential Elements〕

6.1〔2h〕[1 App.B] The program should provide for indoctrination and training of personnel performing activities affecting quality as necessary to assure that suitable proficiency is achieved and maintained. (Quality Assurance Program of App.B)

(7. Process Implementation)

〔Core QA/QM Requirements〕

7.1〔5.1〕[1 IAEA] &〔7.1〕[ISO] The process of the quality management system that are needed to achieve the goals, provide the means to meet all requirements and deliver the products of the organization shall be identified, and their development shall be planned, implemented, assessed and continually improved. (IAEA & ISO)

〔Essential Elements〕

7.1〔5a〕[1 App.B] Activities affecting quality should be prescribed by documented instructions, procedures, or drawings, of a type appropriate to the circumstances. (Instructions, Procedures, and Drawings of App.B)

7.2〔5b〕[1 App.B] Activities affecting quality should be accomplished in accordance with the written instructions, procedures, or drawings. (Instructions, Procedures, and Drawings of App.B)

7.3〔5c〕[1 App.B] Instructions, procedures, or drawings should include appropriate quantitative or qualitative acceptance criteria for determining that important activities have been satisfactorily accomplished. (Instructions, Procedures, and Drawings of App.B)

7.4〔3a〕[1 App.B] Measures should 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. (Design Control of App.B)

7.5〔3b〕[1 App.B] These measures should include provisions to assure that appropriate quality standards are specified and included in design documents and that deviations from such standards are controlled. (Design Control of App.B)

7.6〔3c〕[1 App.B] Measures should 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. (Design Control of App.B)

7.7〔3d〕[1 App.B] Measures should be established for the identification and control of design interfaces and for coordination among participating design organizations. (Design Control of App.B)

7.8〔3e〕[1 App.B] Design control measures should include the establishment of procedures among participating design organizations for the:

1. review
2. approval
3. release
4. distribution
5. revision of documents involving design interfaces(Design Control of App.B)

7.9〔3f〕[1 App.B] The design control measures should provide for verifying or checking the adequacy of design, such as:

by the performance of a suitable testing program(Design Control of App.B)

7.10〔3g〕[1 App.B] The verifying or checking process should be performed by individuals or groups other than those who performed the original design, but who may be from the same organization. (Design Control of App.B)

7.11〔3h〕[1 App.B] Where a test program is used to verify the adequacy of a specific design feature in lieu of other verifying or checking processes, it should include suitable qualifications testing of a prototype unit under the most adverse design conditions. (Design Control of App.B)

7.12〔3i〕[1 App.B] Design control measures should be applied to items such as the following:

1. stress analyses
2. thermal analyses
3. hydraulic analyses
4. compatibility of materials
5. accessibility for inservice inspection, maintenance, and repair
6. delineation of acceptance criteria for inspections and tests(Design Control of App.B)

7.13〔3j〕[1 App.B] Design changes, including field changes, should be subject to design control measures commensurate with those applied to the original design. (Design Control of App.B)

7.14〔3k〕[1 App.B] Design changes, including field changes, should be approved by the organization that performed the original design unless the applicant designates another responsible organization. (Design Control of App.B)

(8. Control of planning and implementation changes)

〔Core QA/QM Requirements〕

8.1 〔5.6〕[1 IAEA] &〔7.3.7〕[1 ISO] Planning and implementation changes shall be identified and records maintained. (IAEA & ISO)

〔**Essential Elements**〕

8.1〔3j〕[1 App.B] Design changes, including field changes, should be subject to design control measures commensurate with those applied to the original design. (Design Control of App.B)

8.2〔3k〕[1 App.B] Design changes, including field changes, should be approved by the organization that performed the original design unless the applicant designates another responsible organization. (Design Control of App.B)

(9. Purchasing)

〔**Core QA/QM Requirements**〕

9.1 〔5.23-25〕[1 IAEA] &〔7.4.1〕[1 ISO] Purchasing items and services shall be controlled by appropriate manner. (IAEA & ISO)

〔**Essential Elements**〕

9.1〔4a〕[1 App.B] Measures should 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. (Procurement Document Control of App.B)

9.2〔4b〕[1 App.B] To the extent necessary, procurement documents should require contractors or subcontractors to provide a quality management program consistent with the pertinent provisions of the established regulatory framework for such programs. (Procurement Document Control of App.B)

9.3〔7a〕[1 App.B] Measures should be established to assure that purchased material, equipment, and services, whether purchased directly or through contractors and subcontractors, conform to the procurement documents. (Control of Purchased Material, Equipment, and Services of App.B)

9.4〔7b〕[1 App.B] These measures should include provisions, as appropriate, for:

1. source evaluation and selection
2. objective evidence of quality furnished by the contractor or subcontractor
3. inspection at the contractor or subcontractor source
4. examination of products upon delivery

(Control of Purchased Material, Equipment, and Services of App.B)

9.5〔7c〕[1 App.B] Documentary evidence that material and equipment conform to the procurement requirements should be available at the site prior to installation or use of such material and equipment. (Control of Purchased Material, Equipment, and Services of App.B)

9.6〔7d〕[1 App.B] This documentary evidence should 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. (Control of Purchased Material, Equipment, and Services of App.B)

9.7〔7e〕[1 App.B] The effectiveness of the control of quality by contractors and subcontractors should 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. (Control of Purchased Material, Equipment, and Services of App.B)

(10. Control of implementation)

〔Core QA/QM Requirements〕

(10.1 Control of implementation)

10. 1〔5.6〕[1 IAEA] &〔7.5.1〕[1 ISO] The organization shall plan and carry out implementation under controlled conditions. (IAEA & ISO)

〔Essential Elements〕

10.1.1〔5.6〕[1 IAEA] For each process a designated individual should be given the authority and responsibility for:

1. Developing and documenting the process and maintaining the necessary supporting documentation;
2. Ensuring that there is effective interaction between interfacing processes;
3. Ensuring that process documentation is consistent with any existing documents;
4. Ensuring that the records required to demonstrate that the process results have been achieved are specified in the process documentation;
5. Monitoring and reporting on the performance of the process;
6. Promoting improvement in the process;
7. Ensuring that the process, including any subsequent changes to it, is aligned with the goals, strategies, plans and objectives of the organization. (IAEA)

10.1.2〔5.9〕[1 IAEA] The work performed in each process should be carried out under controlled conditions, by using approved current procedures, instructions, drawings or other appropriate means that are periodically reviewed to ensure their adequacy and effectiveness. Results should be compared with expected values. (IAEA)

10.1.3〔13a〕[1 App.B] Measures should be established for material and equipment to control the handling, storage, shipping, cleaning and preservation. (Handling, Storage and Shipping of App.B)

10.1.4〔13b〕[1 App.B] These activities should be done in accordance with work and inspection instructions to prevent damage or deterioration. (Handling, Storage and Shipping of App.B)

10.1.5〔13c〕[1 App.B] When necessary for particular products, special protective environments,

such as inert gas atmosphere, specific moisture content levels, and temperature levels, should be specified and provided. (Handling, Storage and Shipping of App.B)

(10.2 Identification and control of items)

〔Core QA/QM Requirements〕

10.2.1〔Req.8〕App.B & NQA-1 Control shall be established to assure that only correct and accepted items are used or installed.(Identification and Control of Items of NQA1＝Same consideration of IAEA, ISO, App.B)

10.2.2〔Req.8〕App.B & NQA-1 Identification shall be maintained on the items or in documents traceable to the items, or in a manner that assures that identification is established and maintained. (Identification and Control of Items of NQA1＝Same consideration of IAEA, ISO, App.B)

〔Essential Elements〕

10.2.1〔8a〕1 App.B Measures should be established for the identification and control of materials, parts, and components, including partially fabricated assemblies. (Identification and Control of Materials, Parts, and Components of App.B)

10.2.2〔8b〕1 App.B These measures should 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. (Identification and Control of Materials, Parts, and Components of App.B)

〔8b〕1 App.B *Where appropriate, the organization should identify the product by suitable means throughout product realization. (Alternate by FR to* Identification and Control of Materials, Parts, and Components of App.B*)*

10.2.3〔14a〕1 App.B Measures should 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. (Inspection, Test, and Operating Status of App.B)

10.2.4〔14b〕1 App.B These measures should 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. (Inspection, Test, and Operating Status of App.B)

(10.3 Control of special process)

〔Core QA/QM Requirements〕

10.3〔Req.9〕App.B & NQA-1 Special process that control or verify quality, such as those used in welding, heat treatment, and nondestructive examination, shall be performed by

qualified personnel using qualified procedures in accordance with specified requirements. (Control of Special Process of NQA1＝Same consideration of ISO, App.B)

〔Essential Elements〕

10.3.1〔9a〕[1 App.B] Measures should be established to assure that special processes, including welding, heat treating, and nondestructive testing, are controlled. (Control of Special Processes of App.B)

10.3.2〔9b〕[1 App.B] Special processes are accomplished by qualified personnel in accordance with applicable codes, standards, specifications, criteria, and other special requirements. (Control of Special Processes of App.B)

10.3.3〔9c〕[1 App.B] Special processes are accomplished using qualified procedures in accordance with applicable codes, standards, specifications, criteria, and other special requirements. (Control of Special Processes of App.B)

(11.Monitoring and measurement of product and service)

〔Core QA/QM Requirements〕

11.1 〔5.16-18〕[1 IAEA] &〔8.2.4 & 7.4.3〕[1 ISO] The organization shall monitor and measure the characteristics of the product and service to verify those requirements have been met. (IAEA & ISO)

〔Essential Elements〕

11.1〔12a〕[1 App.B] Measures should be established to assure that tools, gages, instruments, and other measuring and testing devices used in activities affecting quality are properly controlled, calibrated, and adjusted at specified periods to maintain accuracy within necessary limits. (Control of Measuring and Test Equipment of App.B)

11.2〔10a〕[1 App.B] A program for inspection of activities affecting quality should 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. (Inspection of App.B)

11.3〔10b〕[1 App.B] Such inspection should be performed by individuals other than those who performed the activity being inspected. (Inspection of App.B)

11.4〔10c〕[1 App.B] Examinations, measurements, or tests of material or products processed should be performed for each work operation where necessary to assure quality. (Inspection of App.B)

11.5〔10d〕[1 App.B] If inspection of processed material or products is impossible or disadvantageous, indirect control by monitoring processing methods, equipment, and personnel should be provided. (Inspection of App.B)

11.6〔11a〕[1 App.B] A test program should 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. (Test Control of App.B) (Not applied by some countries)

11.7〔11b〕[1 App.B] The test program should include, as appropriate:

1. proof tests prior to installation
2. preoperational tests
3. operational tests during operation of structures, systems, and components(Test Control of App.B) (Not applied by some countries)

11.8〔11c〕[1 App.B] Test procedures should include provisions for:

1. assuring that all prerequisites for the given test have been met
2. assuring that adequate test instrumentation is available and used
3. assuring that the test is performed under suitable environmental conditions
4. documenting and evaluating testing results to assure that test requirements have been satisfied(Test Control of App.B) (Not applied by some countries)

(12. Assessment)

〔Core QA/QM Requirements〕

12.1〔6.2-3〕[1 IAEA] &〔8.2.2〕[1 ISO] The organization shall conduct assessments at planned intervals to confirm the effectiveness of quality management system. (IAEA & ISO)

〔Essential Elements〕

12.1〔18a〕[1 App.B] A comprehensive system of planned and periodic assessments should be carried out to verify compliance with all aspects of the quality management program and to determine the effectiveness of the program. (Audits of App.B)

12.2〔18b〕[1 App.B] The assessments should be performed in accordance with the written procedures or check lists by appropriately trained personnel not having direct responsibilities in the areas being assessed. (Audits of App.B)

12.3〔18c〕[1 App.B] Assessment results should be documented and reviewed by management having responsibility in the area assessed. (Audits of App.B)

12.4〔18d〕[1 App.B] Followup action, including reassessments of deficient areas, should be taken where indicated. (Audits of App.B)

(13. Non-conformances)

〔Core QA/QM Requirements〕

13.1〔6.11〕[1 IAEA] &〔8.3〕[1 ISO] The case of non-conformances shall be determined and remedial actions shall be taken to prevent their recurrence. (IAEA & ISO)

〔Essential Elements〕

13.1〔15a〕[1 App.B] Measures should 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 should include, as appropriate, procedures for:

1. identification of nonconforming materials, parts, or components
2. documentation of nonconforming materials, parts, or components
3. segregation of nonconforming materials, parts, or components
4. disposition of nonconforming materials, parts, or components
5. notification to affected organizations of nonconforming materials, parts, or components

(Nonconforming Materials, Parts, or components of App.B)

13.2〔15b〕[1 App.B] Nonconforming items should be:

1. reviewed and accepted in accordance with documented procedures
2. rejected in accordance with documented procedures
3. repaired in accordance with documented procedures
4. reworked in accordance with documented procedures

(Nonconforming Materials, Parts, or components of App.B)

(14. Corrective and preventive actions)

〔Core QA/QM Requirements〕

14.1〔6.14〕[1 IAEA] &〔8.5.2〕[1 ISO] Corrective actions for eliminating non-conformances shall be determined implemented. (IAEA & ISO)

14.2〔6.14〕[1 IAEA] &〔8.5.3〕[ISO] Preventive actions to eliminate the cases of potential non-conformances shall be determined and taken.(IAEA & ISO)

〔Essential Elements〕

14.1〔16a〕[1 App.B] Measures should be established to assure that conditions adverse to quality, such as failures, malfunctions, deficiencies, deviations, defective material and equipment, and non-conformances are promptly identified and corrected. (Corrective Action of App.B)

14.2〔16b〕[1 App.B] In the case of significant conditions adverse to quality, the measures should assure that the cause of the condition is determined and corrective action taken to preclude repetition. (Corrective Action of App.B)

14.3〔16c〕[1 App.B] The identification of the significant condition adverse to quality, the cause of the condition, and the corrective action taken should be documented and reported to appropriate levels of management. (Corrective Action of App.B)

(15.Safety culture)

〔Core QA/QM Requirements〕

15.1〔Req.12 & 13〕[1 IAEA] All individuals in the organization from the senior management down, shall promote safety and to continuous improvement of safety culture supported

by the management system.

Senior management shall periodically commission independent and self-assessment of safety culture and leadership for safety. (IAEA Draft GSR Part2)

〔Essential Elements〕

15.1〔Req.12, 5.1〕[1 IAEA] Desired and expected attitudes and behaviours that result in a strong safety culture should be developed and integrated in the management system. (IAEA Draft GSR Part2)

15.2〔Req.12, 5.2〕[1 IAEA] All individuals in the organization, from the senior management down, should contribute to promoting and fostering a strong safety culture by implementing and reinforcing:

a. Individual and collective commitment to safety;
b. Ownership of safety;
c. An open culture that encourages trust, collaboration, free communication, ensures good working conditions and that values the reporting of human and organizational problems;
d. The reporting of deficiencies of structures, systems and components to avoid degradation of safety;
e. Prompt acknowledgement and feedback for identified problems and suggestions for improvement;
f. Means by which the organization continually seeks to develop and improve safety and the safety culture;
g. Responsibility and accountability of organizations and of individuals at all levels for safety;
h. Measures to encourage a questioning and learning attitude and to discourage complacency at all levels in the organization with regard to safety;
i. A common understanding of the key aspects of safety and safety culture within the organization;
j. Awareness of the risks and hazards related to their work and work environment, and an understanding of potential consequences;
k. Safety driven conservative decision making in all activities.

(IAEA Draft GSR Part2)

15.3〔Req.12, 5.3〕[1 IAEA] The management system should make provision to ensure the involvement and visibility in field activities of all levels of management in the organization, from senior management down to supervisors. (IAEA Draft GSR Part2)

15.4〔Req.12. 5.4〕[1 I AEA] The management system should make provision to support individuals and teams in carrying out their tasks safely and successfully with regard to

safety, taking into account the interactions between individuals, technology and organizations. (IAEA Draft GSR Part2)

15.5〔Req.13, 5.7〕[1 IAEA] The results of such assessments should be communicated, in an open and transparent manner, to all levels in the organization and be acted up to ensure improvements to promote a learning organization. (IAEA Draft GSR Part2)

Ⅴ. APPLY METHOD

Following methods will be considered when perform the Multinational Vendor Inspection (MVI) by using Common QA/QM Criteria (CQMC).

【 Case 1 】

- The MVI will be performed only by using CQMC.
- Additional Vendor Inspection will be able to conducted by one or plural countries by applying their own Unique QA/QM Criteria (UQMC) following to the MVI or separately other timing.

【 Case 2 】

- The MVI will be performed by Multinational Inspectors by using CQMC and will be conducted by applied countries Inspectors by using UQMC with parallel manner.

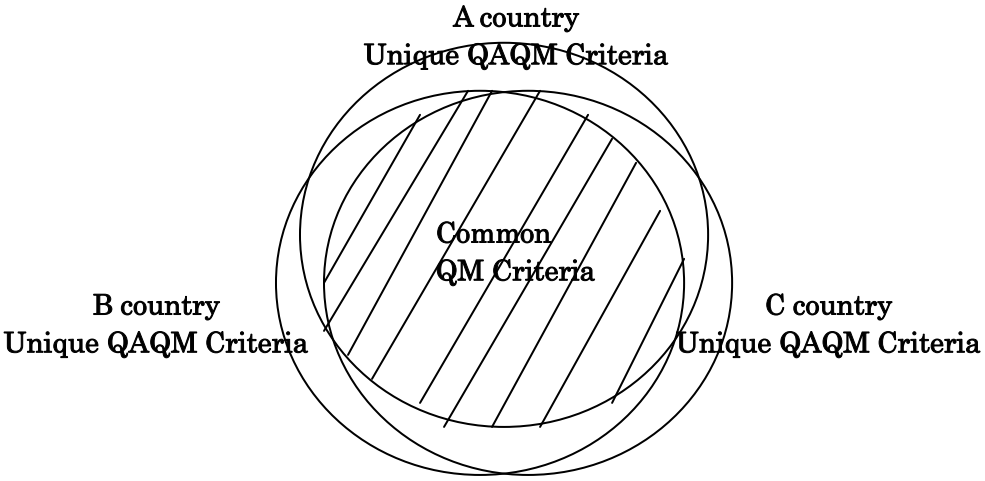

Fig.2 Structure of Common and Unique QA/QM Criteria

Table 1: Proposal of MDEP CORE QA/QM Requirement and Comparison between Codes and Standards (Extract)

MDEP CORE QA/QM Requirements to be included in Common QA/QM Criteria	IAEA GS-R-3	ISO9001-2008	10CFR50 App. B	ASME NQA-1-2008
(Quality management system) A management system shall be established, implemented, assessed and continually improved of its effectiveness.	**2. Management System** **General Requirement** 2.1. A management system shall be established, implemented, assessed and continually improved. It shall be aligned with the goals of the organization and shall contribute to their achievement. The main aim of the management system shall be to achieve and enhance safety by: —Bringing together in a coherent manner all the requirements for managing the organization; —Describing the planned and systematic actions necessary to provide adequate confidence that all these requirements are satisfied; —Ensuring that health, environmental, security, quality and economic requirements are not considered separately from safety requirements, to help preclude their possible negative impact on safety. (Re) **5. Process**	**4.Quality management system** **4.1 General requirements** The organization shall establish, document, implement and maintain a quality management system and continually improve its effectiveness in accordance with the requirements of this International Standard. The organization shall a) determine the processes needed for the quality management system and their application throughout the organization (see 1.2), b) determine the sequence and interaction of these processes, c) determine criteria and methods needed to ensure that both the operation and control of these processes are effective, d) ensure the availability of resources and information necessary to support the operation and monitoring of these processes,	(Re Part) **I. Organization** The applicant shall be responsible for the establishment and execution of the quality assurance program. The applicant may delegate to others, such as contractors, agents, or consultants, the work of establishing and executing the quality assurance program, or any part thereof, but shall retain responsibility for the quality assurance program. The authority and duties of persons and organizations performing activities affecting the safety-related functions of structures, systems, and components shall be clearly established and delineated in writing. These activities include both the performing functions of attaining quality objectives and the quality assurance functions. The quality assurance functions are those of (a) assuring that an appropriate quality assurance program is	**Requirement 1** **Organization** **100 BASIC** Responsibilities for the establishment and implementation of the quality assurance program shall be defined. The organizational structure, functional responsibilities, levels of authority, and lines of communications for activities affecting quality shall be documented. **Requirement 2** **Quality Assurance Program** **100 BASIC** (a) A documented quality assurance program shall be planned, implemented, and maintained in accordance with this Part (Part I), or portions thereof. The program shall identify the activities and items to which it applies. The program shall provide control over activities affecting quality to an extent consistent with their importance. The program shall include monitoring activities against acceptance criteria in a manner sufficient to provide assurance that the activities affecting quality are performed satisfactorily. The program shall be established at the earliest time consistent with the schedule for accomplishing the activities. The program shall provide for the planning and accomplishment of activities affecting quality under suitably controlled conditions. Controlled conditions include the use of appropriate equipment suitable environmental conditions for accomplishing the activity, and

MDEP CORE QA/QM Requirements to be included in Common QA/QM Criteria	IAEA GS-R-3	ISO9001-2008	10CFR50 App. B	ASME NQA-1-2008
	Implementation **Developing Processes** **5.1.** The processes of the management system that are needed to achieve the goals, provide the means to meet all requirements and deliver the products of the organization shall be identified, and their development shall be planned, implemented, assessed and continually improved. **5.2.** The sequence and interactions of the processes shall be determined. **5.3.** The methods necessary to ensure the effectiveness of both the implementation and the control of the processes shall be determined and implemented. **5.4.** The development of each process shall ensure that the following are achieved: (Re) **Process Management** **5.6.** For each process a designated individual shall be given the authority and responsibility for:	e) monitor, measure where applicable, and analyse these processes, and f) implement actions necessary to achieve planned results and continual improvement of these processes. These processes shall be managed by the organization in accordance with the requirements of this International Standard.	established and effectively executed; and (b) verifying, such as by checking, auditing, and inspecting, that activities affecting the safetyrelated functions have been correctly performed.	assurance that prerequisites for the given activity have been satisfied. The program shall provide for any special controls, processes, test equipment, tools, and skills to attain the required quality of activities and items and for verification of that quality. The organization shall establish and implement processes to detect and correct quality problems. (b) The program shall provide for indoctrination, training, and qualification as necessary of personnel performing or managing activities affecting quality to ensure that suitable proficiency is achieved and main-tained. (c) Management shall regularly assess the adequacy and effective implementation of the quality assurance program.

MDEP CORE QA/QM Requirements to be included in Common QA/QM Criteria	IAEA GS-R-3	ISO9001-2008	10CFR50 App. B	ASME NQA-1-2008
(Grading) The implementation of management system shall be graded so as to deploy appropriate resources. ←	**Grading the Application of Management System Requirements** 2.6. The application of management system requirements shall be graded so as to deploy appropriate resources, on the basis of the consideration of: —The significance and complexity of each product or activity; —The hazards and the magnitude of the potential impact (risks) associated with the safety, health, environmental, security, quality and economic elements of each product or activity; —The possible consequences if a product fails or an activity is carried out incorrectly. 2.7. Grading of the application of management system requirements shall be applied to the products and activities of each process.		(Re Part) **II. Quality Assurance Program** The quality assurance program shall provide control over activities affecting the quality of the identified structures, systems, and components, to an extent consistent with their importance to safety. (Re Part) **VII. Control of Purchased Material, Equipment, and Services** The effectiveness of the control of quality by contractors and subcontractors shall be assessed by the applicant or designee at intervals consistent with the importance, complexity, and quantity of the product or services.	

MDEP CORE QA Requirements to be included in Common QA Criteria	IAEA GS-R-3	ISO9001-2008	10CFR50 App. B	ASME NQA-1-2008
(Control of implementation) The organization shall plan and carry out implementation under controlled conditions. **(Identification and control of items)** Control shall be established to assure that only correct and accepted items are used or installed. Identification shall be maintained on the items or in documents traceable to the items, or in a manner that assures that identification is established and maintained. *	**Process Management** **5.6.** For each process a designated individual shall be given the authority and responsibility for: —Developing and documenting the process and maintaining the necessary supporting documentation; —Ensuring that there is effective interaction between interfacing processes; —Ensuring that process documentation is consistent with any existing documents; —Ensuring that the records required to demonstrate that the process results have been achieved are specified in the process documentation; —Monitoring and reporting on the performance of the process; —Promoting improvement in the process; —Ensuring that the process, including any subsequent changes to it, is	**7.5 Production and service provision** **7.5.1 Control of production and service provision** The organization shall plan and carry out production and service provision under controlled conditions. Controlled conditions shall include, as applicable, a) the availability of information that describes the characteristics of the product, b) the availability of work instructions, as necessary, c) the use of suitable equipment, d) the availability and use of monitoring and measuring equipment, e) the implementation of monitoring and measurement, and f) the implementation of product release, delivery and post-delivery activities. **7.5.3 Identification and traceability** Where appropriate, the	(Re) **V. Instructions, Procedures, and Drawings** Activities affecting quality shall be prescribed by documented instructions, procedures, or drawings, of a type appropriate to the circumstances and shall be with these instructions, procedures, or drawings. Instructions, procedures, or drawings shall include appropriate quantitative or qualitative acceptance criteria for determining that important activities have been satisfactorily accomplished. **VIII. Identification and Control of Materials, Parts, and Components** Measures shall be established for the identification and control of materials, parts, and components, including partially fabricated assemblies. These measures shall assure that identification of the item is	**Requirement 8** **Identification and Control of Items** **100 BASIC** Control shall be established to assure that only correct and accepted items are used or installed. Identification shall be maintained on the items or in documents traceable to the items, or in a manner that assures that identification is established and maintained. **200 IDENTIFICATION METHODS** **201 Item Identification** Items of production (batch, lot component, part) shall be identified from the initial receipt and fabrication of items up to and including installation and use. This identification shall relate an item to an applicable design or other pertinent specifying document. **202 Physical Identification** Physical identification shall be used to the maximum extent possible. Where physical identification on the item is either impractical or insufficient physical separation, procedural control, or other appropriate means shall be employed. Identification markings shall be applied using materials and methods that provide a clear and legible identification and do not degrade the function or service life of the item. Markings shall be transferred to each part of an identified item when subdivided and shall not be obliterated or hidden by surface treatment or coating unless other means of

Just using the sentence of NQA-1

MDEP CORE QA Requirements to be included in Common QA Criteria	IAEA GS-R-3	ISO9001-2008	10CFR50 App. B	ASME NQA-1-2008
*	aligned with the goals, strategies, plans and objectives of the organization. **5.9**. The work performed in each process shall be carried out under controlled conditions, by using approved current procedures, instructions, drawings or other appropriate means that are periodically reviewed to ensure their adequacy and effectiveness. Results shall be compared with expected values. **Control of products** **5.19**. Products shall be identified to ensure their proper use. Where traceability is a requirement, the organization shall control and record the unique identification of the product.	organization shall identify the product by suitable means throughout product realization. The organization shall identify the product status with respect to monitoring and measurement requirements throughout product realization. Where traceability is a requirement, the organization shall control the unique identification of the product and maintain records (see 4.2.4).	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. These identification and control measures shall be designed to prevent the use of incorrect or defective material, parts, and components.	identification are substituted. **300 SPECIFIC REQUIREMENTS** **301 Identification and Traceability of Items** When codes, standards, or specifications include specific identification or traceability requirements (such as identification or traceability of the item to applicable specification and grade of material; heat batch, lot part, or serial number; or specified inspection, test or other records), the program shall provide such identification and traceability control. **302 Limited Life Items** Items having limited calendar or operating life or cycles shall be identified and controlled to preclude use of items whose shelf life or operating life has expired. **303 Maintaining** Identification of Stored Items Provisions shall be made for the control of item identification consistent with the planned duration and conditions of storage, such as (a) provisions for maintenance or replacement of markings and identification records due to damage during handling or aging (b) protection of identifications on items subject to excessive deterioration due to environmental exposure (c) provisions for updating existing plant records

Table2. VICWG Survey on Quality Assurance Program 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			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	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			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			Y
	1. identify quality problems	N*	Y	Y	Y	L*	L	Y			Y
	2. to initiate, recommend, or provide solutions	N*	Y	Y	Y	L*	L	Y			Y
	3. to verify implementation of solutions	N*	Y	Y	Y	L*	L	Y			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			Y

Table2. VICWG Survey on Quality Assurance Program Requirements

Criteria	Requirements	CA	CH	FI	FR	JP	RF	SK	SA	UK	US
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. C) A management system shall be planned and implemented to incorporate all the operations of an organization.										
	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*;* *e)* the alternate requirements are the following ones : *Personnel performing work affecting product quality shall be competent on the basis of appropriate education,* *training, skills and experience. The organisation shall* - *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 the achievement of the quality objectives, and* - *maintain appropriate records of education, training, skills and experience* *The organisation shall determine, provide and maintain the infrastructure needed to achieve conformity to product* *requirements. Infrastructure includes, as applicable* - *buildings, workspace and associated utilities,* - *process equipment (both hardware and software), and* - *supporting services (such as transport or communication).*										
	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.										

Table2. VICWG Survey on Quality Assurance Program Requirements

Criteria	Requirements	CA	CH	FI	FR	JP	RF	SK	SA	UK	US
	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			Y
	b. The quality assurance program shall be documented by written policies, procedures, or instructions.	N*	Y	Y	Y	L*	Y	Y			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			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
	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			Y
	f. Activities affecting quality shall be accomplished under suitably controlled conditions. Controlled conditions include:	N*	Y	Y	Y	L*	L	Y			Y
	1. the use of appropriate equipment	N*	Y	Y	Y	L*	L	Y			Y
	2. suitable environmental conditions for accomplishing the activity, such as adequate cleanness	N*	Y	Y	A	L*	L	Y			Y
	3. assurance that all prerequisites for the given activity have been satisfied	N*	Y	Y	N	L*	L	Y			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			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			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			Y

Table2. VICWG Survey on Quality Assurance Program Requirements

Criteria	Requirements	CA	CH	FI	FR	JP	RF	SK	SA	UK	US
	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			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> *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* f) 2) <u>Alternate requirement</u> : *The organization shall preserve the conformity of product during internal processing* j) <u>Alternate requirement :</u> *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 :* *- requirements for approval of product, procedures, processes and equipment,* *- requirements for qualification of personnel, and* *- quality management system requirements.* *The organization shall ensure the adequacy of specified purchase requirements prior to their communication to the supplier.*										
	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										

Table2. VICWG Survey on Quality Assurance Program Requirements

Criteria	Requirements	CA	CH	FI	FR	JP	RF	SK	SA	UK	US
	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.										
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			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			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			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			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			Y
	2. approval	N*	Y	Y	A	A	L	Y			Y
	3. release	N*	Y	Y	A	A	L	Y			Y
	4. distribution	N*	Y	Y	A	A	L	Y			Y
	5. revision of documents involving design interfaces	N*	Y	Y	A	A	L	Y			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
	2. by the use of alternate or simplified calculational methods	N*	Y	Y	N	A	L	Y			Y
	3. by the performance of a suitable testing program	N*	Y	Y	A	A	L	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			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
	i. Design control measures shall be applied to items such as the following:										
	1. reactor physics analyses	N*	Y	Y	N	A	L	Y			Y

Table2. VICWG Survey on Quality Assurance Program Requirements

Criteria	Requirements	CA	CH	FI	FR	JP	RF	SK	SA	UK	US
	2. stress analyses	N*	Y	Y	Y	A	L	Y			Y
	3. thermal analyses	N*	Y	Y	Y	A	L	Y			Y
	4. hydraulic analyses	N*	Y	Y	Y	A	L	Y			Y
	5. accident analyses	N*	Y	Y	N	A	L	Y			Y
	6. compatibility of materials	N*	Y	Y	Y	A	L	Y			Y
	7. accessibility for inservice inspection, maintenance, and repair	N*	Y	Y	Y	A	L	Y			Y
	9. delineation of acceptance criteria for inspections and tests	N*	Y	Y	Y	A	L	Y			
	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			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			Y
Additional or	FINLAND: NONE										

Table2. VICWG Survey on Quality Assurance Program Requirements

Criteria	Requirements	CA	CH	FI	FR	JP	RF	SK	SA	UK	US
Alternate Requirements	FRANCE: c) Alternate requirement (see also 2 d)) : T*he 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* e) 2) 3) and 4) : Alternate requirement : 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 : - *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 .* - *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 maintained* e) 5) Alternate requirement *:* *The organization shall manage the interfaces between different groups involved in design and development to ensure effective communication and clear assignment of responsibility* 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 : *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. 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. 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 (*Verification shall be performed in accordance with planned arrangements to ensure that the design and development outputs have met the design and development input*										

Table2. VICWG Survey on Quality Assurance Program Requirements

Criteria	Requirements	CA	CH	FI	FR	JP	RF	SK	SA	UK	US
	SOUTH KOREA: NONE										

Table2. VICWG Survey on Quality Assurance Program Requirements

Criteria	Requirements	CA	CH	FI	FR	JP	RF	SK	SA	UK	US
	JAPAN: (Explanatory note) 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. (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). (Alternative Requirements or Alternative regulatory related actions) The QA requirements are confirmed during the process of the construction permit reviews as follows. 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. h. These matters are reviewed by the constructor(licensee) or the regulatory body during the process of the construction permit review. 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. j. The same procedures are applied in the design change. ditto										

Table2. VICWG Survey on Quality Assurance Program Requirements

Criteria	Requirements	CA	CH	FI	FR	JP	RF	SK	SA	UK	US
	CANADA: Explanatory Note										
	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.										
	CHINA: i. Design control measures shall be applied to items such as following: 10. radiation protection 11. human factors 12. fire protection										
4. Procurement Document Control	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.	N*	Y	Y	A/L	L*	L	Y			Y
	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].	N*	Y	Y	A/L	L*	L	Y			Y
Additional or	FINLAND: NONE							Y			

Table2. VICWG Survey on Quality Assurance Program Requirements

Criteria	Requirements	CA	CH	FI	FR	JP	RF	SK	SA	UK	US
Alternate Requirements	FRANCE: 4 a) and b) <u>Alternate requirements :</u> *The organization shall ensure that purchased product conforms to specified purchase requirements.* *Purchasing information shall describe the product to be purchased, including where appropriate* *- requirements for approval of product, procedures, processes and equipment,* *- requirements for qualification of personnel, and* *- quality management system requirements.* *The organization shall ensure the adequacy of specified purchase requirements prior to their communication to the supplier.* *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.* According to an another french regulation (ministerial order August 10th,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 Drawings	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			Y
	b. Activities affecting quality shall be accomplished in accordance with the written instructions, procedures, or drawings.	N*	Y	Y	L	L*	L	Y			Y

Table2. VICWG Survey on Quality Assurance Program Requirements

Criteria	Requirements	CA	CH	FI	FR	JP	RF	SK	SA	UK	US
	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			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										
	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			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			Y
	2. distributed to and used at the location where the prescribed activity is performed.	N*	Y	Y	A	L*	L	Y			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			Y
Additional or	FINLAND: NONE										

Table2. VICWG Survey on Quality Assurance Program Requirements

Criteria	Requirements	CA	CH	FI	FR	JP	RF	SK	SA	UK	US
Alternate Requirements	FRANCE: a)b)c) Alternate requirement : *Documents required by the quality management system shall be controlled. Records are a special type of document* *and shall be controlled according to the requirements given in 4.2.4. A documented procedure shall be established to define the controls needed* *a) to approve documents for adequacy prior to issue,* *b) to review and update as necessary and re-approve documents,* *c) to ensure that changes and the current revision status of documents are identified,* *d) to ensure that relevant versions of applicable documents are available at points of use,* *e) to ensure that documents remain legible and readily identifiable,* *f) to ensure that documents of external origin are identified and their distribution controlled, and* *g) to prevent the unintended use of obsolete documents, and to apply suitable identification to them if they are* *retained for any purpose.*										
	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										
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			Y
	b. These measures shall include provisions, as appropriate, for:										
	1. source evaluation and selection	N*	Y	Y	A	L*	L	Y			Y
	2. objective evidence of quality furnished by the contractor or subcontractor	N*	Y	Y	A	L*	L	Y			Y
	3. inspection at the contractor or subcontractor source	N*	Y	Y	A	L*	L	Y			Y
	4. examination of products upon delivery	N*	Y	Y	A	L*	L	Y			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			Y

Table2. VICWG Survey on Quality Assurance Program Requirements

Criteria	Requirements	CA	CH	FI	FR	JP	RF	SK	SA	UK	US
	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			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			Y
Additional or Alternate Requirements	FINLAND: b) Applied to Safety Classes 1 and 2.										
	FRANCE: *7 b) c) d)* Alternate requirements *: The organisation shall establish and implement the inspection or other activities necessary for ensuring that purchased product meets specified purchase requirements.* *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.* *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*										
	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 Materials, Parts, and Components	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			Y
	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			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			Y

Table2. VICWG Survey on Quality Assurance Program Requirements

Criteria	Requirements	CA	CH	FI	FR	JP	RF	SK	SA	UK	US
Additional or Alternate Requirements	FINLAND: NONE										
	FRANCE: 8b) Alternate requirement : *Where appropriate, the organization shall identify the product by suitable means throughout product realization*										
	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			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			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			Y
Additional or Alternate Requirements	FINLAND: NONE										
	FRANCE: 9 b) c) Alternate requirement : *The organization shall* *- 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* *the achievement of the quality objectives, and* *- maintain appropriate records of education, training, skills and experience* **This quality system documentation must permit a consistent interpretation of the procedural and quality measures** *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.*										

Table2. VICWG Survey on Quality Assurance Program Requirements

Criteria	Requirements	CA	CH	FI	FR	JP	RF	SK	SA	UK	US
	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										
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			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			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			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			Y
	e. Both inspection and process monitoring shall be provided when control is inadequate without both.	N*	Y	Y	N	L*	A	Y			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			Y
Additional or	FINLAND: NONE										

Table2. VICWG Survey on Quality Assurance Program Requirements

Criteria	Requirements	CA	CH	FI	FR	JP	RF	SK	SA	UK	US
Alternate Requirements	FRANCE: 10 a) b) Alternate requirement : *The organization shall conduct internal audits at planned intervals to determine whether the quality management system* *- conforms to the planned arrangements, to the requirements of the quality management system requirements established by the organization, and* *- is effectively implemented and maintained.* *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.* *Auditors shall not audit their own work.* **The responsibilities and requirements for planning and conducting audits, and for reporting results and maintaining** *records shall be defined in a documented procedure.* *10 d)* Alternate requirement : *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.* *Validation shall demonstrate the ability of these processes to achieve planned results.* *The organisation shall establish arrangements for these processes including, as applicable* *- defined criteria for review and approval of the processes,* *- approval of equipment and qualification of personnel,* *- use of specific methods and procedures,* *- requirements for records and* *- revalidation.*										
	SOUTH KOREA: NONE										

Table2. VICWG Survey on Quality Assurance Program Requirements

Criteria	Requirements	CA	CH	FI	FR	JP	RF	SK	SA	UK	US
	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			Y
	b. The test program shall include, as appropriate:										
	1. proof tests prior to installation	N*	Y	Y	N	Y	A	Y			Y
	2. preoperational tests	N*	Y	Y	N	Y	A	Y			Y
	3. operational tests during operation of structures, systems, and components	N*	Y	Y	N	Y	A	N			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			Y
	2. assuring that adequate test instrumentation is available and used	N*	Y	Y	N	Y	A	Y			Y
	3. assuring that the test is performed under suitable environmental conditions	N*	Y	Y	N	Y	A	Y			Y
	4. documenting and evaluating testing results to assure that test requirements have been satisfied	N*	Y	Y	N	Y	A	Y			Y
Additional or	FINLAND: NONE										

Table2. VICWG Survey on Quality Assurance Program Requirements

Criteria	Requirements	CA	CH	FI	FR	JP	RF	SK	SA	UK	US
Alternate Requirements	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 Measuring and Test Equipment	a. Measures shall be established to assure that tools, gages, instruments, and other measuring and testing devices used in activities affecting quality are properly controlled, calibrated, and adjusted at specified periods to maintain accuracy within necessary limits.	N*	Y	Y	Y	L*	L	Y			Y
Additional or Alternate	FINLAND: NONE										

Table2. VICWG Survey on Quality Assurance Program Requirements

Criteria	Requirements	CA	CH	FI	FR	JP	RF	SK	SA	UK	US
Requirements	FRANCE: 12 a) Additional requirements : *- 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* *- 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.* *-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).										
	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			Y
	2. storage	N*	Y	Y	Y	L*	L	Y			Y
	3. shipping	N*	Y	Y	Y	L*	L	Y			Y
	4. cleaning	N*	Y	Y	Y	L*	L	Y			Y
	5. preservation	N*	Y	Y	Y	L*	L	Y			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			Y
	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			Y
Additional or	FINLAND: NONE										

Table2. VICWG Survey on Quality Assurance Program Requirements

Criteria	Requirements	CA	CH	FI	FR	JP	RF	SK	SA	UK	US
Alternate Requirements	FRANCE: 13) the french requirement is considered to be similar : *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.*										
	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			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			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
Additional or Alternate Requirements	FINLAND: NONE										
	FRANCE: 14 a) and b) Alternate requirement : *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 requirements. Where traceability is a requirement, the organization shall control and record the unique identification of the product*										
	SOUTH KOREA: NONE										

Table2. VICWG Survey on Quality Assurance Program Requirements

Criteria	Requirements	CA	CH	FI	FR	JP	RF	SK	SA	UK	US
	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. 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			Y
	1. identification of nonconforming materials, parts, or components	N*	Y	Y	Y	L*	L	Y			Y
	2. documentation of nonconforming materials, parts, or components	N*	Y	Y	Y	L*	L	Y			Y
	3. segregation of nonconforming materials, parts, or components	N*	Y	Y	Y	L*	L	Y			Y
	4. disposition of nonconforming materials, parts, or components	N*	Y	Y	Y	L*	L	Y			Y
	5. notification to affected organizations of nonconforming materials, parts, or components	N*	Y	Y	Y	L*	L	Y			Y
	b. Nonconforming items shall be:										
	1. reviewed and accepted in accordance with documented procedures	N*	Y	Y	Y	L*	L	Y			Y
	2. rejected in accordance with documented procedures	N*	Y	Y	Y	L*	L	Y			Y
	3. repaired in accordance with documented procedures	N*	Y	Y	Y	L*	L	Y			Y
	4. reworked in accordance with documented procedures	N*	Y	Y	Y	L*	L	Y			Y
Additional or Alternate Requirements	FINLAND: NONE										
	FRANCE: 15 a) Additional requirement : *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.*										
	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										

Table2. VICWG Survey on Quality Assurance Program Requirements

Criteria	Requirements	CA	CH	FI	FR	JP	RF	SK	SA	UK	US
	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.										
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			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			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			Y
Additional or Alternate Requirements	FINLAND: NONE										
	FRANCE: 16 a)b)c) according to the french regulation the objectives are the same : *The organisation shall take action to eliminate the cause of nonconformities in order to prevent recurrence.* *Corrective actions shall be appropriate to the effects of the nonconformities encountered.* *A documented procedure shall be established to define requirements for* *a) reviewing nonconformities (including customer complaints),* *b) determining the causes of nonconformities,* *c) evaluating the need for action to ensure that nonconformities do not recur,* *d) determining and implementing action needed,* *e) records of the results of action taken* <u>But there is an additional requirement</u> related to preventive actions : *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.*										
	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										

Table2. VICWG Survey on Quality Assurance Program Requirements

Criteria	Requirements	CA	CH	FI	FR	JP	RF	SK	SA	UK	US
	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			Y
	b. The records shall include at least the following:										
	1. Operating logs	N*	Y	A	Y	Y	L	N			N
	2. the results of reviews	N*	Y	Y	Y	L*	L	Y			Y
	3. the results of inspections	N*	Y	Y	Y	L*	L	Y			Y
	4. the results of tests	N*	Y	Y	N	L*	L	Y			Y
	5. the results of audits	N*	Y	Y	Y	L*	L	Y			Y
	6. the results of monitoring of work performance	N*	Y	Y	Y	L*	L	Y			Y
	7. the results of materials analyses	N*	Y	Y	Y	L*	L	Y			Y
	c. The records shall also include closely-related data such as:										
	1. qualifications of personnel	N*	Y	Y	Y	L*	L	Y			Y
	2. qualifications of procedures	N*	Y	Y	Y	L*	L	Y			Y
	3. qualifications of equipment	N*	Y	Y	Y	L*	Y	Y			Y
	d. Inspection and test records as a minimum shall:										
	1. identify the inspector or data recorder	N*	Y	Y	N	L*	L	Y			Y
	2. the type of observation	N*	Y	Y	N	L*	L	Y			Y
	3. the results	N*	Y	Y	Y	L*	L	Y			Y
	4. the acceptability	N*	Y	Y	Y	L*	Y	Y			Y
	5. the action taken in connection with any deficiencies noted.	N*	Y	Y	Y	L*	L	Y			Y
	e. Records shall be identifiable and retrievable.	N*	Y	Y	Y	L*	L	Y			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			Y
Additional or Alternate Requirements	FINLAND: b1) No specific requirements for operating logs (meaning to be clarified)										
	FRANCE: NONE										
	SOUTH KOREA: NONE										

Table2. VICWG Survey on Quality Assurance Program Requirements

Criteria	Requirements	CA	CH	FI	FR	JP	RF	SK	SA	UK	US
	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										
	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			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			Y
	c. Audit results shall be documented and reviewed by management having responsibility in the area audited.	N*	Y	Y	Y	L*	L	Y			Y
	d. Followup action, including reaudit of deficient areas, shall be taken where indicated.	N*	Y	Y	Y	L*	L	Y			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	N*		A	N	Y	L	N			Y

Table2. VICWG Survey on Quality Assurance Program Requirements

Criteria	Requirements	CA	CH	FI	FR	JP	RF	SK	SA	UK	US
	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										
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 nonconformities.										
	FRANCE: In one hand according to the ministerial order August 10 th, 1984, the non-conformances which are significant for the nuclear safety have to be notified by the licensee to ASN. 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.										
	KOREA: NONE										

Table2. VICWG Survey on Quality Assurance Program Requirements

Criteria	Requirements	CA	CH	FI	FR	JP	RF	SK	SA	UK	US
	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 "the information needed for preserving the conditions of procured items and using procured services (only relating to maintenance)" includes "the information on defects, which could create a substantial safety hazard" 1. 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 the information needed for preserving the conditions of procured items and using procured services (only relating to maintenance) 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.										
	CANADA: Explanatory Note										
	RUSSIAN FEDERATION: NONE										
	CHINA: NONE										
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 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: (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 (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. (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. (c) For the purposes of paragraph (a)(1) of this section, deliberate misconduct by a	N*		A	N	Y	N	N			Y

Table2. VICWG Survey on Quality Assurance Program Requirements

Criteria	Requirements	CA	CH	FI	FR	JP	RF	SK	SA	UK	US
	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.										
Additional or Alternate Requirements	FINLAND: Enforcement requirements are given in Finnish Nuclear Energy Act and in other relevant legislation such as penal code.										
	FRANCE: In one hand according to the ministerial order August 10 th, 1984, the non-conformances which are significant for the nuclear safety have to be notified by the licensee to ASN. 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.										

Table2. VICWG Survey on Quality Assurance Program Requirements

Criteria	Requirements	CA	CH	FI	FR	JP	RF	SK	SA	UK	US
	SOUTH KOREA: (Alternative Requirements) Atomic Energy Act / Article 104-4 "Protection of Employees" requires: 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. 30, 1996, Feb. 8, 1999> 1. 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); 2. 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. Act of giving testimony or producing evidence in order to comply with any inspection or investigation pursuant to Articles 16 (including application *mutatis mutandis* from Article 36), 23-2 (including application *mutatis mutandis* from Article 36), 45, 59, 67, 73, 78, 90-3 and 90-6 or the provisions of Article 103.										

Table2. VICWG Survey on Quality Assurance Program Requirements

Criteria	Requirements	CA	CH	FI	FR	JP	RF	SK	SA	UK	US
	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 "the information needed for preserving the conditions of procured items and using procured services (only relating to maintenance)" includes "the information on defects, which could create a substantial safety hazard" 1. 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 the information needed for preserving the conditions of procured items and using procured services (only relating to maintenance) 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.										
	CANADA: Explanatory Note										
	RUSSIAN FEDERATION: NONE										
	CHINA: NONE										

(Note 1)

"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.

(Note 2)

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