

MDEP

Common Position

CP-VICWG-01

Related to: Vendor Inspection Cooperation Working Group

Common Position:

**Establishment of Common QA/QM Criteria for the
 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 common position	All
Regulators with no objection:	N/A
Regulators which disagree:	N/A
Compatible with existing IAEA related documents:	Yes

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I . INTRODUCTION

This document provides a set of common positions for harmonizing inspection criteria called “Common QA/QM Criteria” which will be used in Multinational Vendor Inspections.

This document was prepared by the Vendor Inspection Co-operation Working Group (VICWG) of the Multinational Design Evaluation Programme (MDEP).

The “Common QA/QM Criteria” provides the basic areas for consideration when performing Vendor Inspections. The criteria have been developed in conformity with International Codes and Standards such as IAEA, ISO, etc. that MDEP member countries have 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.

At the initiation of the working group, the VICWG performed a survey to understand and to identify areas of commonality and differences between the regulatory practices of member countries in the area of vendor inspection by using the US 10CFR50 Appendix B as a template. (The survey was later updated as membership of the group grew.) The results of the survey result is documented in Technical Report TR-VICWG-02 “Survey on quality assurance program requirements” [Ref. 1].

Subsequently, observations of regulatory vendor inspections amongst the MDEP member countries (Witness and Joint Inspection) were also performed. The protocol for these inspections is documented in Technical Report TR-VICWG-01, Version 1 “Witnessed, Joint, and Multinational Vendor Inspection Protocol” [Ref. 2].

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 outcome of this comparison activity is documented in MDEP Technical Report TR-VICWG-03 “Common QA/QM criteria for the multinational vendor inspection” [Ref. 3]

Basic Consideration

Purpose: To provide Common QA/QM Criteria for use in Multinational Vendor Inspections

Concept: Corresponds to the International Codes and Guides whilst additionally applying the Major Requirements. “Common QA/QM Criteria for Multinational Vendor Inspection” are composed of “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”

III COMMON POSITION ON THE ESTABLISHMENT OF COMMON QA/QM CRITERIA

The VICWG identified the following common positions for the establishment the common QA/QM criteria for the multinational vendor inspection:

1. The multinational vendor inspection should be conducted based on the common QA/QM criteria.
2. There are many standards related to the QA/QM for nuclear facilities such as IAEA safety standards and ISO standards. However when performing vendor inspection, the criteria should be more detailed in scope of design, manufacturing and engineering.
3. The experience of MDEP countries should be used to further develop the criteria.
4. The common QA/QM criteria should be considered the criteria of each MDEP country since it is based on the survey result which in turn is based on the US 10CFR50 Appendix B.
5. The common QA/QM criteria should reflect the latest knowledge and experience. Therefore, "Safety culture," as addressed by the new safety standards of the IAEA, should be incorporated.
6. Before performing the multinational vendor inspection, the application of the common QA/QM criteria and each country's own criteria should be determined.

The first VICWG multinational inspection was conducted at Valinox Nuclear in Montbard, France to assess compliance with the quality assurance/quality control (QA/QM) criteria described in Ref. 3, VICWG Technical Report TR-VICWG-03 “Common QA/QM Criteria for Multinational Vendor Inspection.” The result of the inspection is documented in VICWG Technical Report TR-VICWG-03, “Multinational Vendor Inspection Assessment,” [Ref. 4].

IV HIERARCHY STRUCTURE OF COMMON QA/QM CRITERIA

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

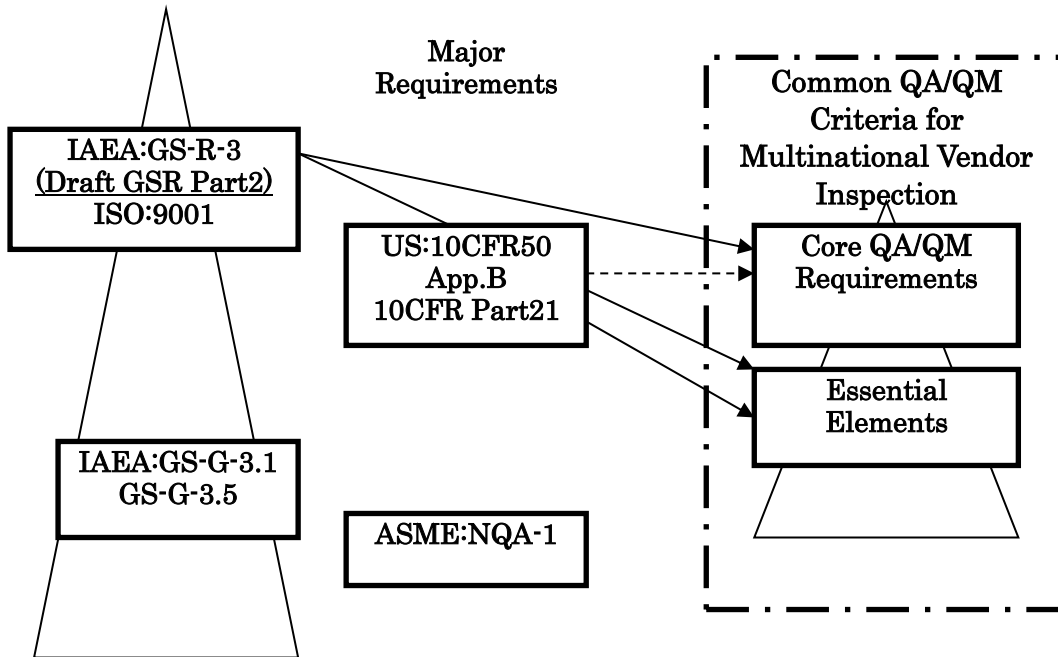


Fig.1 Hierarchy Structure of Common QA/QM Criteria for Multinational Vendor Inspection

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. These are described in Ref. 3 of “Technical Report: Common QA/QM Requirement for the multinational vendor inspection” TR-VICWG-03.

- 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.

V REFERENCES

1. Multinational Design Evaluation Program, “Technical Report: Survey on quality assurance program requirements” TR-VICWG-02, 9December 2011, OECD Nuclear Energy Agency, Paris, France.
2. Multinational Design Evaluation Program, “Technical Report: Witnessed, Joint, and Multinational Vendor Inspection Protocol” TR-VICWG-01, Version 1, 20 march 2014, OECD Nuclear Energy Agency, Paris, France.
3. Multinational Design Evaluation Program, “Technical Report: Common QA/QM criteria for the multinational vendor inspection” TR-VICWG-03, 30 January 2014 OECD Nuclear Energy Agency, Paris, France.
4. Multinational Design Evaluation Program, “Technical Report: Multinational Vendor Inspection Assessment,” TR-VICWG-04, 16 September 2015, OECD Nuclear Energy Agency, Paris, France.