*Transactions of the Korean Nuclear Society Spring Meeting*
*Chuncheon, Korea, May 25-26 2006*

# The Recent Trends between Nuclear Quality Assurance and ISO 9001

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## 1. Introduction

Nuclear facilities must be designed, constructed, and operated in a manner that ensures the prevention of accidents that cause undue risk to the health and safety of the public and the mitigation of adverse consequences of such accidents if they should occur. A primary means for achieving these objectives is by establishing and effectively implementing a nuclear QA program. International and foreign QA standards and requirements for implementing this QA program have been continually revised and improved, based on performance-based approach. This study is to introduce recent development process and history of major changes in international standards and requirements related to nuclear quality assurance. And it is to review and analyze major changes of nuclear QA standards and requirements recently revised and to study the approaches for adopting more widely accepted international and foreign QA standards and requirements.

## 2. Recent trends of Nuclear Quality Assurance in Foreign Countries

### *General*

The development process and history of major changes in international regulations and standards related to quality assurance have been examined in foreign countries. To promote a comprehensive understanding of them, the processes through which regulations and standards of quality assurance have been legislated are outlined in Fig. 1.

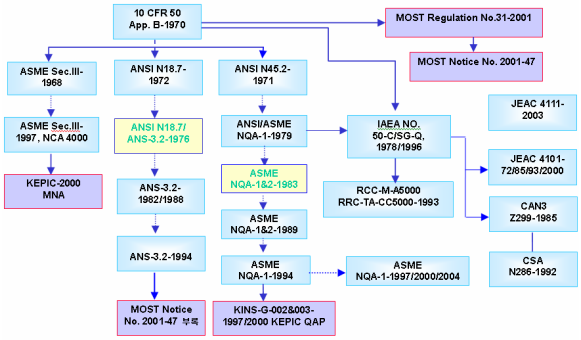


Fig. 1 The history of development of quality assurance regulations and standards

### *2.1 U.S.A (United States of America)*

After two revisions of 10 CFR 50 App. B, "Quality Assurance Standards on Nuclear Power Plants and Nuclear Fuel Reprocessing Plants" in 1971 and 1975, this regulation currently consists of 18 criteria. Quality assurance systems established by 10 CFR 50 App. B have been applied over the last 30 years. Since the 1980s, NRC staff has proposed several regulatory positions to enhance the efficiency of quality assurance systems. NRC issued GL 89-02 "Actions to Improve the Detection of Counterfeit and Fraudulent Marketed Products." in 1989 and GL 91-05 "Licensee Commercial-Grade Procurement and Dedication Programs" in 1991. In GL 89-02, the staff conditionally approved EPRI NP-5652 "Guideline for the Utilization of Commercial Grade Items in Nuclear Safety Related Applications (NCIG-07)" of June 1998. Historically, the commercial-grade dedication process has proven to be an effective method for procuring items from the commercial market and demonstrating their suitability for use in safety-related applications. And through SECY-03-0117, NRC provided options for adopting more widely accepted international quality standards like ISO 9001. NRC developed four potential approaches for licensee implementation of ISO 9001, two of which are considered more suitable for further development. These are two licensee's imposing specific controls for ISO 9001 certified suppliers during procurement and using ISO 9001 certified suppliers for procuring commercial grade items. Requirements in ASME NQA-1 & 10 CFR 50 App. B were found to be more definitive than ISO 9001 in areas such as:

- Design controls, including identification of design inputs, independence of personnel performing design verification, and review of design changes at the appropriate levels
- Software controls, including software development, verification and validation
- Inspection control, including independence of inspection personnel, hold points for
- Configuration control requirements and disposition of nonconforming items
- Internal and external audits/Indoctrination, training, qualification and evaluation of personnel, etc.

As NRC endorsed Reg. Guides 1.176, "An Approach for Using Probabilistic Risk Assessment in Risk-Informed Decision-making: Graded Quality Assurance", NRC interpreted quality assurance standards in 10 CFR 50 App. B as already implicitly including the concept of performance-based approach. Consequently, it has been verified that the NRC does not need to revise QA regulations.

10 CFR 50.69 regulations provide alternative plans to the application of special treatment requirements in 10 CFR 50 App. B in accordance with risk significant safety-related SSC. Such regulations render the licensees' quality assurance programs more flexible, thus making it possible to use quality standards that meet systematic requirements such as international standards or industrial standards.

### *2.2 CANADA*

CSA N286.0 was firstly published and revised in 1982 and 1992, respectively. In 1982 edition, it contains the QA requirements applied to both the licensee and its contractor. In 1992 edition, it contains only the QA requirement directly applied to the licensee and surveillance provisions of its contractor without specifying the applicable requirements of its contractor. And, detailed CSA N286

series has been revised as follows.

• CSA N286.1: 1979, 1984 and 2000/CSA N286.2: 1986, 2000/CSA N286.3: 1983, 1999/ CSA N286.4: 1986, 2000/CSA N286.5: 1985, 1995/CSA N286.6: 1998/CSA N286.7: 1999

CAN3 Z299 Series was firstly published in 1979 and then revised in 1985. CAN3 Z299 Series will be no longer revised because ISO 9000 is recognized as national standard in Canada. AECL Quality Program Standard proposed the additional provisions to achieve the equivalence between CAN3 Z299 and ISO 9001.

### *2.3 JAPAN*

The JEAG 4101-Quality Assurance Guides for Construction of Nuclear Power Plants, which was firstly established in, consists of 13 standards at present in accordance with the IAEA safety series. And it was revised in 1985, 1993, and 2000, respectively. The Japan Electric Association (JEA) developed JEAC 4111-2003, "Rules of quality assurance for safety of nuclear power plants" based on the ISO 9001:2000. The features of JEAC 4111 are as follows. It takes account of IAEA Safety Standards for Quality Assurance 50-C/SG-Q (1996). And explanation is added on the terms, "product," "customer," and "quality" in the requirements of ISO 9001:2000. Moreover, NISA is studying to clarify requirements of quality assurance during not only operating stage but also construction stage in legislation.

### *2.4 FRANCE*

The French RCC-M edition (1993) and addenda implement IAEA 50-C-Q Code quality assurance requirements. While the current French regulatory framework recognizes ISO 9001, it adds several supplementary requirements for procurement of components. These requirements include additional provisions for design verification, document and data control, purchasing data, product identification and traceability, inspection and testing, and control of nonconforming products.

### *2.5 IAEA*

The IAEA issued 50-C-QA Code in 1978 and later announced 10 Safety Guides. IAEA Code of Practice 50-C-QA including 14 Safety Guides were revised in 1996, based on performance-based approach. The IAEA is developing safety guides that combine IAEA Safety Series 50-C/SG-Q (Nuclear Power Plant Quality Assurance) and three ISO requirements like ISO 9001 (2000)/ISO 14001/ISO 18001.

The IAEA 50-C-Q requirements not contained in ISO 9001:2000 are as follows.

• Demonstrating the effective fulfillment of the QA requirements to the satisfaction of the regulatory body

• A graded approach based on the relative importance to nuclear safety of each item, service or process

• The training and qualification of supplier staff

• Independence of design verifier and validation of the computer codes prior to use

• The degree of independence of inspection personnel

It also identifies those areas (documentation, inspection and testing, nonconformance control, corrective actions, document control and records, and audits) where ISO 9001 is not consistent with the IAEA 50-SG-Q safety guide guidance.

The concept of quality systems has been changed from QA (quality assurance) to QM (quality management) (DS 338 DS 339 and DS 349). The relationship between 50-C/SG-Q and the new set of Management system safety standards is shown in the following Fig 2.

The focus of IAEA 50-C-Q is on achieving nuclear safety, the focus of ISO 9001:2000 on achieving customer satisfaction. The IAEA will plan to develop QM requirements in a broader sense that will comprehensively add to customer satisfaction, environmental issues, and the occupational health and safety of the workers involved including nuclear safety considerations.

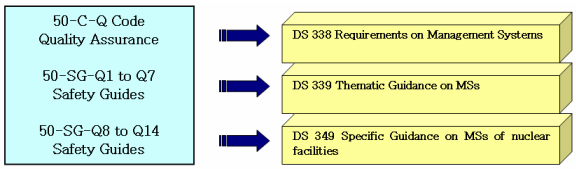


Fig. 2 The relationship between 50-C/SG-Q and the new set of Management system safety standards

## 3. Conclusion

The recent trends of nuclear QA for U.S.A, Canada, Japan, France and the IAEA were reviewed and analyzed. Each country has developed and applied the approaches for adopting more widely accepted QA standard like ISO. In view of recent trend of ISO standard's application, it is expected that this standard will be extensively applied in nuclear industry.

Among various potential approaches for licensee implementation of ISO 9001, to impose specific controls for ISO 9001 certified suppliers during procurement are considered more suitable for the application of nuclear industry.

To develop ISO-based standard for the nuclear industry, it is generally required to provide guidance on additional requirements (such as the independence of the inspector and design verifier, grading of QA, etc.) that ISO standard would need to include to meet nuclear QA standard and requirements.

## REFERENCES

[1]ISO quality assurance requirements (quality management systems), ISO 9001:2000/ ISO environmental requirements (environmental management systems), ISO 14001/ISO safety and health requirements (occupational health and safety management systems), ISO 18001

[2]DS 338, Management systems for nuclear reactor facility/DS 339, Guidelines on management systems for nuclear reactor facility safety/DS 349, Application of the Management System for Nuclear Facilities

[3]SECY-03-0117, Approaches for adopting more widely accepted international quality standards

[4]IAEA-TECDOC-1182, Quality assurance standards: comparison between IAEA 50-C-/SG-Q and ISO 9001:1994

[5]IAEA Safety reports series No.22, Quality standards: comparison between IAEA 50-C/SG-Q and ISO 9001:2000

[6]NQA–1993, Comparison NQA-1 and ISO 9001 Technical Report

[7]AECL Quality Program Standard (00-933.4.2)