ASME Nuclear Quality Assurance NQA-1

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Birth of Commercial Nuclear Power

- The U.S. was the cradle of commercial nuclear power.
- Development of reactor technologies and principles of safe operation were direct results of military research into atomic energy.
- The origins of this organization – IAEA - and of the US commercial nuclear power program were established in President Eisenhower’s “Atoms for Peace” speech presented to the United Nations in 1953.
- Gave formal recognition that the immense potential of atomic energy could and should be harnessed for peaceful means and the betterment of mankind as long as the terrible consequences of mishandling the technology could be managed
- One immediate impact in the US was the Atomic Energy Act of 1954
Energy Reorganization Act of 1954

• The 1954 Energy Reorganization Act, for the first time, legally permitted the wide use of atomic energy for peaceful purposes.
• The Act redefined the atomic energy program by ending the US government’s monopoly on technical data and making the growth of a private commercial nuclear industry an urgent national goal.
• The measure directed a US Atomic Energy Commission "to encourage widespread participation in the development and utilization of atomic energy for peaceful purposes."
• At the same time, it instructed the agency to prepare regulations that would protect public health and safety from radiation hazards.
• Although it took many forms and many years to become federal law, the basic formation of Title 10 of the Code of Federal Regulations – Part 50 was initiated.
Application of Existing Codes & Standards to Nuclear Power

• Even though the materials and processes required for wartime atomic facilities were new and unique, the design, fabrication and construction still relied on traditional US suppliers and construction contractors and utilized existing codes and standards developed for pressure vessel technology for the utility and chemical process industries.

• These were the very same specifications, codes and standards that were put forward by professional societies such as the American Concrete Institute, the American Petroleum Institute, the American Chemical Society and the American Society of Mechanical Engineers for industrial applications.

• Valuable lessons were learned where existing technology and knowledge were not adequate for nuclear applications and structures, systems and components required by the technology.
Evolution of Nuclear Regulation in the US

• As a result of lessons learned in initial “proof of concept” Generation 1 nuclear plants, codes and standards were revised and modified to accommodate the special demands posed by the commercial utilization of nuclear energy.
• The realization that a purely commercial environment, reacting to a competitive marketplace could not be relied upon to consistently apply the most stringent technical requirements without fail for those things nuclear, federal regulations were promulgated that focused on the inherent protection to the public afforded by the actual design and construction of these facilities.
• The result – for light water reactor technology – was an Appendix A - General Design Criteria - to 10 CFR 50.
Because of costly mistakes in ship building for the war effort and from construction and operation of nuclear facilities by the military, there was an acknowledgement that achieving all the possible technical requirements would not be effective unless there was some means to verify that activities and items had been fabricated and installed as designed.

As a result, the very first Criteria in Appendix A described the need for a **Quality Assurance Program**
10 CFR 50 Appendix A

- **Criterion 1—Quality standards and records.** Structures, systems, and components important to safety shall be designed, fabricated, erected, and tested to quality standards commensurate with the importance of the safety functions to be performed. Where generally recognized codes and standards are used, they shall be identified and evaluated to determine their applicability, adequacy, and sufficiency and shall be supplemented or modified as necessary to assure a quality product in keeping with the required safety function. **A quality assurance program shall be established and implemented in order to provide adequate assurance that these structures, systems, and components will satisfactorily perform their safety functions.** Appropriate records of the design, fabrication, erection, and testing of structures, systems, and components important to safety shall be maintained by or under the control of the nuclear power unit licensee throughout the life of the unit.
In order further define the expectations for such a quality system, 10 CFR 50 Appendix B was quickly promulgated.

The 18 Criteria are well established and well known to all.

If one were to compare ASME NQA-1 1994, DOE 5700.6C, ISO 9001-1994, and IAEA Safety Guide 50-C statements of requirements, a clear line of sight could be made to the 18 Criteria of 10 CFR 50.

As the need for commonality for the sake of enabling better commerce in the EU grew with the addition of widely disparate member countries, ISO 9001 necessarily evolved to include commercial aspects that did not by themselves significantly improve the ability to assure the health and safety of the public against the risks posed by the commercial use of nuclear power.
10 CFR 50 Appendix B

• In the US, there was no such need for descriptions of business processes and practices since 10 CFR 50 Appendix A and Appendix B are federal law and subject to invasive and rigorous oversight and enforcement by the US Nuclear Regulatory Commission.

• The human performance aspects of commercial nuclear power such as rigorous causal analysis of events and dissemination of a nuclear safety culture is assured through self imposed practices through organizations such as the Institute of Nuclear Power Operations (INPO).

• Under the US regulatory framework, the achievement of consistent technical excellence for items and activities is considered the final measure of quality.

• “Breaker-to-breaker” runs with no human performance errors and 90+% availabilities are no longer considered rare in the US
US Regulatory Framework

• A similar arrangement also exists in the nuclear facilities and projects administered and regulated by the US DOE in accordance with 10 CFR 830

• Because 10 CFR 50 Appendix B was required to be “technology neutral” and is a statement of requirements of federal law, it is necessarily broad in its language.

• The owner/operators of nuclear facilities and those industries and organizations supporting the design, construction, operation and decommissioning phases of these facilities were encouraged to develop Codes and Standards to further describe in sufficient detail what and how to implement the requirements of Appendix B.

• A national framework of sponsoring and accrediting codes and standards developed by Standards Developing Organizations is vested in the American National Standards Institute (ANSI).
US Regulatory Framework

• ANSI is not a government agency but rather a Voluntary Conformity Assessment process that Standards Developing Organizations (SDOs) submit to and ANSI assures that all stakeholders are given a voice, all business is conducted in a open and public forum, a consensus process is utilized for final standards actions, a balance of interest is maintained that assures that no one business interest dominates the standards’ development process, and provides for public interpretations of the code or standard in response to technical inquiries by any inquiring party.

• ANSI also requires that Codes and Standards be subject to periodic review and reaffirmation for continued relevancy
US Regulatory Framework

• The US government is compelled to make use of national and international codes and standards in lieu of writing their own special requirements if such C&S are shown to be applicable and sufficient to meet federal requirements.

• As such, ASME NQA-1 2008 Edition with 2009 Addenda were found sufficient to implement the requirements of 10 CFR 50 Appendix B; therefore its use was endorsed by the US government in Regulatory Guide 1.28, Rev. 4 (2010) as one means to meet the requirements for a nuclear quality assurance program.
In the following US regulations, ASME NQA-1 is cited as an acceptable means of assuring technical requirements are met:

- Reg. Guide 1.8 Qualification and Training of Personnel for Nuclear Power Plants
- Reg. Guide 1.142 Safety Related Concrete Structures for Nuclear Power Plants …
- Reg. Guide 1.52 Design Inspection and Testing of Air Filtration … for Post Accident …Cleanup Systems….
US Adoption of Other Quality Standards

• Over the last 20 years, in recognition of the expansion of the global supply chain, formal reviews have been made of possibly adopting of quality standards other than ASME NQA-1 an acceptable means of meeting the requirements of Appendix B

• The most relevant effort resulted in an NRC position taken in SECY 03-117 in which found only two viable approaches to accepting services and parts affecting safety that have been produced or supplied under a Quality Management System only such as ISO 9001
The two most acceptable alternatives for US licensees to utilize ISO 9001 QMS (only) type suppliers was:

– Procurement documents from a US customer would need to include in detail all the applicable elements of Appendix B that are not explicitly present in the supplier’s Quality program – implicit in this is approach is that the supplier’s contract review process will identify this as requirements and the supplier is willing to accept these additional requirements as part of the executed procurement.

– US customers could use a supplier registered Quality Management System as evidence of quality program as part of a Commercial Grade Item Dedication (CGD). The customer would then need to make a decision that the cost of buying an item or service under a QMS and then performing CGD at an added cost makes the purchase a solid business decision.
US NRC SECY 03-117 Positions

• The possibility of a nuclear sector specific ISO 9001 QMS (only) was discussed.

• Allowance was given in the SECY that if a sector specific Quality Management System along the lines of the Aviation and Aerospace ISO AS-9100 or the Medical Device ISO 13485 were developed and included all the additional requirements that would assure compliance with the provisions for the assurance of the health and safety of the public, then perhaps a sufficiency review could be performed against the provisions of Appendix B.

• The SECY paper also stated that this was a very unlikely possibility and, even such a program was initiated, the US industry was very unlikely to adopt such arrangements.
US Adoption of Other Quality Standards

- It contains discussions on ISO 16949, ISO QS9100, ISO AS9100, and ISO 13485, and ISO 17025 and a frank assessment on any applicable lessons-learned for the US nuclear industry
- The most likely configuration that could be considered similar to the meeting the needs of nuclear power was the ISO AS 9100 Aerospace and Aviation standard.
- The conclusion was that ISO sector specific Quality Management Systems are going to proliferate as the global supply chain grows but there was very little incentive for US customers and US manufacturers to embrace these programs for nuclear safety related procurements.
Applicability of ASME NQA-1 as an inclusive Quality Management System Description

• From the preceding discussion, one could incorrectly conclude that ASME NQA-1 is incompatible as a Description of a Quality Management System.

• However, the nature of ASME Codes and Standards is that they are in continuous review and revision to reflect advances in technology and to reflect the lessons learned from the hundreds of years of safe and reliable commercial nuclear operations with an impeccable safety record. Overall US nuclear plant availabilities often exceeding 90%.

• The nature of the commercial nuclear industry in the US includes rigorous causal analysis and dissemination of lessons learned. The ultimate destination for many of the corrective actions are revisions to Codes and Standards… ASME NQA-1 is a prominent recipient.
Applicability of ASME NQA-1 as an inclusive Quality Management System Description

• In the US, the totality of a Quality Management System to fully address GS-R-3 and the upcoming GS-Part 2 would be made up of:
  – ASME NQA-1 Part 1 and 2 for requirements
  – ASME NQA-1 Part 3 for recommended practices and Lessons Learned
  – ANS 3.2 for administrative details including specific roles and responsibilities and qualification requirements for all personnel
  – Institute for Nuclear Operations recommended practices to address human performance improvement and safety culture deployment – self imposed by the owner operators of nuclear power facilities
  – Malcom Baldridge criteria for continuous improvement and total quality practices

• All essential elements are present, they are just not in one inclusive document
Currently, only ASME NQA-1 Part 1 & 2 and ANS 3.2 are required by federal law for commercial nuclear power construction and operation.

Several examples of areas where ASME NQA-1 has more definitive requirements are:

- Design Control
- Independence of inspections and verifications
- Qualification of suppliers
- Corrective Actions
- Configuration management
- Generation and retention of records
- Commercial grade dedication of items and activities affecting safety functions
- Flow-down of quality requirements to sub-suppliers
Applicability of ASME NQA-1 as an inclusive Quality Management System Description

• While the other documents may be prudent and good practices, the inclusion and adoption of their precepts is purely a business decision
• For those organizations holding an ASME Certificate of Authorization, only the adoption of Section III NCA 4000 which includes adoption of ASME NQA-1 Part 1 is the only acceptable position
• Although not an essential requirement of those using NQA-1, the standard itself is subject to continuous improvement. This is intrinsic in the Codes and Standards development process involving the input, review and consensus decisions from thousands of involved stakeholders from every corner of the globe in an open and public forum.
• If an essential attribute of a quality management system is to describe a consistent means of achieving a specific result, then NQA-1 does serve as one way of assuring the health and safety of the public from the special risks posed by commercial nuclear power.
ASME NQA-1 Updates

- The current 2012 Edition of NQA-1 includes
  - strengthened requirements addressing the need for better control of design activities,
  - better configuration management practices,
  - a new focus on improving corrective action systems to reduce errors and rework,
  - adoption of new requirements when quality records are only generated and approved in electronic media,
  - control of computer software utilized in the development of detailed design or as a discreet item to be incorporated into a plant’s control systems,
  - Updates on current Commercial Grade Dedication practices - especially the dedication of services and use of software
ASME NQA-1 Updates

• The 2014 Edition (due out in January 2015)
  – contains guidance on how to detect suspect, counterfeit and fraudulent items
  – Includes updated side by side comparisons of NQA-1 based program requirements with IAEA GS-R-3 based program requirements
• The 2016 Edition – Issuance due before 2017
  – will include methods to adopt Risk Informed Methodology per 10 CFR50.59
  – Most likely will contain further dialog on acceptance of other quality models
  – Requirements appropriate to the establishment and use of commercial offsite data colocation facilities i.e. permanent quality records stored “in the cloud”
A Question of Convergence

• A quality system, built in accordance with the model expressed in IAEA GS-R-3 is not incompatible with ASME NQA-1
• The requirements of NQA-1 can be considered as special requirements requiring the development of additional processes per Section 5 - Process Implementation
• Those with existing ASME NQA-1 based programs could augment their core Quality program in accordance with NQA-1 (2014) Subpart Part 4.1.4 Table 2 for a specific project or procurement
• Those with existing IAEA GS-R-3 based programs could augment their core Quality Management Systems in accordance with NQA-1 (2014) Subpart 4.1.4 Table 1 for a specific project or procurement
SUMMARY & CONCLUSION

• The end goals of protecting the health and safety of the public and of workers from the special hazards posed by the commercial utilization of nuclear energy are identical in US Codes and Standards and in the IAEA Safety Guides.

• The means to achieve this end however, must be executed by learning organizations who can react to advances in technology as well as adapt to unforeseen manmade and natural events that present challenges to this fundamental precept.

• Commercial considerations and harmonious business environments have little or no relevancy when the health and safety assurance of the public are involved.
Danke & Thank you

Questions