

Quality Assurance Standards ISO-9001 and ANSI/ASME NQA-1 – A Brief Comparison

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Based on the Nuclear Regulatory Commission (NRC) Policy Issue Information, *Approaches for Adopting More Widely Accepted International Quality Standards*, SECY-03-0117, July 9, 2003, and NRC Regulatory Guide 7.10, *Establishing Quality Assurance Programs for Packaging Used in Transport of Radioactive Material*, Rev. 2, March 2005, the QA program requirements in International Organization for Standardization (ISO)-9001-2000 *Quality Management System (QMS) - Requirements* are not equivalent to Subpart H, 10 CFR Part 71. These NRC documents are relevant because the DOE has been granted the authority to certify its own Type B and fissile material transportation packaging based on 49 CFR 173.7(d), which requires certification and use of the packaging to be equivalent to the NRC safety standards. While the QA requirements in Subpart H, 10 CFR Part 71 are applicable for highly radioactive, i.e., Type B, and fissile material transportation packaging, the QA requirements in ISO-9001-2000 are applicable to commercial-grade items and activities. In addition, the NRC rule change that became effective on October 1, 2004 requires appropriate flow-down of the QA requirements from Subpart H to contractors and subcontractors.

The NRC Regulatory Guide 7.10 states that if an applicant wishes to base its QA program on the ISO-9001, the applicant must supplement the QA requirements to satisfy the requirements in Subpart H, 10 CFR Part 71. In addition, the only QA standard endorsed in its entirety in Regulatory Guide 7.10 is the American National Standards Institute/American Society of Mechanical Engineers (ANSI/ASME) NQA-1, 1983 *Quality Assurance Requirements for Nuclear Facility Applications*. However, in SECY-03-0117 the NRC also endorsed the ANSI/ASME NQA-1, 1994.

A detailed gap analysis between ISO-9001-2000 and 10 CFR Part 50, Appendix B was provided in SECY-03-117. For purposes of this discussion, it should be noted that the QA requirements specified in Subpart H, 10 CFR Part 71 are the same as those specified in 10 CFR Part 50, Appendix B. Independent verification of the QA requirements is the major difference between ISO-9001 and Subpart H, 10 CFR Part 71 (and ANSI/ASME NQA-1). For example,

- The ISO-9001 does not require independence in the design review process. Also, the ISO-9001 inspection requirement does not require the inspectors to be independent from the individuals who performed the work.
- The ISO-9001 audit program does not require independent auditors. The ISO-9001 programs are audited by auditors under a commercial contract to the supplier, hence, a possible conflict of interest.

ANSI/ASME NQA-1 has been accepted by NRC for implementation of Subpart H, 10 CFR Part 71 requirements. The list below demonstrates more rigorous requirements in the NQA-1 than the ISO-9001:

- Design Control, including identification of design inputs, independence of individuals conducting design reviews, and review of design changes at the same level in the organization as the original design.
- Software QA requirements for software development, verification, validation, and configuration control.
- Nonconformance and corrective action disposition.

- Audit
- Training and qualification of personnel.

The NRC recommends that should an ISO-9001 supplier be used, additional QA requirements must be added to the purchase order to assure compliance with Subpart H. The additional QA requirements should be part of a dedication process for commercial-grade items and activities. The ASME NQA-1-2004 has a comprehensive dedication process. (See Requirement 7, Section 700, and Nonmandatory Appendix 7A-2, for the dedication process. See NRC Generic Letters (GL) 89-02 and 91-05 for the common mistakes made by licensees using the dedication process.)

In summary, items and activities that are not important to safety can, in most cases, be purchased from an ISO-9001 supplier; however, additional QA requirements must be imposed on the ISO-9001 suppliers in the procurement of important-to-safety items and activities for Type B radioactive and fissile material transportation packagings. This is consistent with the approach described in NRC Regulatory Guide 7.10 (Rev. 2) and SECY-03-0117.