Accepting Supplier ISO 9000 Quality Programs

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Project Overview

ISO 9000 Phase I
- Initiated in May 2000, completed in 2001
- Investigated two key processes of ISO 9000 QMS and documented how it is organized and implemented
  - Registrar accreditation
  - Supplier certification
- Evaluated potential for crediting ISO 9000 programs as part of Commercial Grade Item dedication process

ISO 9000 Phase II
- Kicked off in May 2002
- Evaluate potential for more generally crediting ISO 9000 as an alternative means of meeting the intent of 10CFR50 Appendix B for suppliers
The Case for Change

- Many suppliers of items to the nuclear power industry are adopting ISO 9000 as their primary Quality Management System
  - Safety related item suppliers
  - Commercial grade item suppliers
- Some suppliers have abandoned their 10CFR50 Appendix B quality assurance (QA) programs
  - Declining nuclear sales
  - Adoption of ISO 9000 QMS
- Trend expected to continue and strengthen
The Case for Change

Licensees must adapt to this market reality

• Learn to effectively cope with a dynamic and limited source of 10CFR50 Appendix B nuclear suppliers

• Find even more cost-effective ways to procure and accept items for safety related applications

• Obtain access to new equipment manufactured to ISO 9000 as potential replacements for obsolete items

• Increase market pressure on product costs
PSE ISO 9000 Task—Phase I

- Plant Support Engineering (PSE) kicked off task to evaluate ISO 9000 in May 2000
- Utility procurement engineering and supplier quality assurance personnel invited to participate
  - 27 attendees representing 20 utilities
  - Relatively even split between procurement engineering and supplier QA representatives
- Strong Joint Utility Task Group (JUTG) support
- Mixed reviews from QA community
- First of several “difficult” meetings….procurement and QA personnel seem to have very different perspectives
PSE ISO 9000 Task—Phase I

Project Objective(s)

• Evaluate the existing ISO 9000 QMS registrar accreditation and supplier certification processes (as administered by the US Registrar Accreditation Board) to determine if they could be relied upon to provide objective evidence of a supplier’s quality controls in lieu of a licensee conducting a commercial grade survey at the supplier’s facility

• Develop guidance on how to apply the results of the evaluation within the context of commercial grade dedication—to more effectively procure and accept commercial grade items from ISO 9000 suppliers
PSE ISO 9000 Task—Phase I

Project Technical Issue(s)

“Is the audit process used by the Registrars rigorous enough to provide an adequate level of assurance that the necessary controls are in place and properly implemented by the supplier?”

– Onsite assessment of the US Registrar Accreditation Board’s (RAB) implementation of the registrar accreditation process
– Detailed review of supplier certification processes at three registrars accredited by the RAB
– Detailed review of several ISO 9000 audit reports and supporting documentation
– Observation of registrar auditing practices
PSE ISO 9000 Task—Phase I

Project Regulatory Issue(s)

“Is the use of such an approach allowed under current regulatory requirements and licensee commitments?”

– Regulatory analysis
  - Did not support the original objective of directly substituting the audit activities performed by ISO 9000 Registrars for a licensee’s commercial grade survey activities

– Revised project objective
  - To what extent can licensees credit the ISO 9000 QMS Registrar accreditation and supplier certification processes as part of the commercial grade dedication process within the existing regulatory framework?
Reaching the First Milestone

- Phase I results were published in two reports
- EPRI Report 1003104, *Assessment of the ISO 9000 Quality Management System (QMS) Registrar Accreditation and Supplier Certification Processes*
- EPRI Report 1003105, *Dedicating Commercial Grade Items Procured from ISO 9000 Suppliers*
PSE ISO 9000 Task—*Phase II*

- *Phase II* presented to the PSE Subcommittee in August 2001
  - Highest ranked task in PSE Subtarget (Technical Issues and Industry Initiatives)
  - 15 votes in favor / 4 votes opposed
- Endorsed by the Nuclear Supply Chain Strategic Leadership (NSCSL) Group in February 2002
- Level of participation similar to Phase I
- Continues to receive mixed reviews from Licensee QA organizations
- ASME NQA-1 Committee voices opposition
- Select suppliers take an interest
PSE ISO 9000 Task—Phase II

Project Objective(s)

• Pursue a broader acceptance of supplier ISO 9000 quality programs when procuring items intended for safety-related applications
  – Build upon the results of the evaluation performed in Phase I
  – Explore two paths
    • Basic component
    • Commercial grade item
• Interface with NRC, NEI and other industry organizations, as necessary, to facilitate the recommended changes
Phase II Project Boundaries

Existing US Nuclear Power Plants

Retain their 10CFR50, Appendix B QA Program

The intent of this project is NOT to replace existing utility QA programs with ISO 9000
Key Issue

How can existing US Nuclear Power Plants maintaining a 10CFR50 Appendix B QA program, take full advantage of the growth in the number of ISO 9000 certified suppliers without adversely affecting the quality of procured items?
PSE ISO 9000 Task—*Phase II*

**Key Activities**

- Gap analysis—comparison between the requirements of 10CFR50 Appendix B and ISO 9000:2000 as they apply to a supplier
- Evaluate Licensee procurement options
  - Address technical and programmatic concerns
  - Recommended licensing strategies
  - Business case
- Evaluate industry experience with ISO 9000 certified suppliers
- Develop implementation guidance
PSE ISO 9000 Task—Phase II

Gap Analysis

• Detailed comparison of the upper tier QMS requirements of ISO 9000:2000 with the requirements 10CFR50 Appendix B
  – Identify any “gaps”
  – Discuss differences in approach

• Determine whether a supplier satisfactorily complying with the quality requirements of ISO Q9001:2000 also meets the quality requirements of 10CFR50, Appendix B
PSE ISO 9000 Task—Phase II

Gap Analysis

• Did not include comparisons of previous versions of ISO 9000 requirements with 10CFR50, Appendix B

• Does not speculate on the extent to which an organization effectively implements their quality assurance program/system requirements

• Does not compare the requirements of ANSI/ISO/ASQ Q9001:2000 with those of 10CFR50, Appendix B as they would be implemented by a licensee

• Does not examine the gaps between 10CFR50, Appendix B and ANSI/ISO/ASQ Q9001:2000 in those instances where the ISO requirements exceed those of 10CFR50, Appendix B
Gap Analysis

- The methodology used to perform this comparison of quality requirements does not attempt to interject the requirements, intent or merit of any implementing standards (e.g., ANSI N45.2, ISO 10011, etc.) or implementation tools (i.e., quality program documents, licensee-specific procedures, etc.) into the analysis.
PSE ISO 9000 Task—Phase II

Tools Used to Perform the Analysis

• The most current version of the NUPIC checklist was used

• The NUPIC checklist provided a means for understanding how the requirements of 10CFR50, Appendix B are interpreted and applied to a nuclear supplier in today's procurement environment
Overview of quality standards

10CFR50, Appendix B

18 Criteria

I  Organization
II  Quality Assurance Program
III  Design Control
IV  Procurement Document Control
V  Instructions, Procedures, and Drawings
VI  Document Control
VII  Control Purchased Material, Equipment and Services
VIII Identification and Control of Materials Parts and Components
IX  Control of Special Processes
X  Inspection
XI  Test Control
XII  Control of Measuring and Test Equipment
XIII  Handling, Storage, and Shipping
XIV  Inspection, Test, and Operating Status
XV  Nonconforming Materials, Parts, and Components
XVII  Quality Assurance Records
XVIII Audits

ANSI/ISO/ASQ Q9001:2000

4 General Areas of Quality

4. Quality management system
5. Management responsibility
6. Product realization
8. Measurement, analysis and improvement
Resulting quality requirements

10CFR50, Appendix B

18 Criteria

69 quality requirements

ANSI/ISO/ASQ Q9001:2000

4 General Areas of Quality

89 quality requirements
Summary of results

All but two of the 69 quality requirements of 10CFR50, Appendix B are addressed by ANSI/ISO/ASQ Q9001:2000
Identification of “gap”

- Criterion III of 10CFR50 Appendix B (Design Control) states the following:
  - “The design control measures shall provide for verifying or checking the adequacy of design, such as by the performance of design reviews, by the use of alternate or simplified calculational methods, or by the performance of a suitable testing program.”
  - “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.”

- The requirement regarding the independence of the design verifier(s) is less definitive and not as explicitly worded in ANSI/ISO/ASQ Q9001:2000
Identification of “gap”

• Criterion X of 10CFR50 Appendix B (Inspection) states the following:
  – “such inspection shall be performed by individuals other than those who performed the activity being inspected”

• This requirement is not specifically addressed in the requirements of ANSI/ISO/ASQ Q9001:2000
PSE ISO 9000 Task—Phase II

Licensee Procurement Options

• Basic component
  – Crediting a supplier's ISO 9000 QMS program as an alternate means to procure Basic Components, in lieu of requiring the supplier to maintain a QA program specifically designed to meet 10CFR50 Appendix B and its implementing standards

• Commercial Grade Item
  – Crediting a supplier's ISO 9000 QMS program as an alternate means to procure and dedicate commercial grade items, in lieu of the dedication process described in EPRI NP-5652
PSE ISO 9000 Task—Phase II

Basic Component Option

- Items are *not* procured as CGIs
- Dedication by the licensee is *not* required
- ISO 9000 certified supplier *must* accept the applicable requirements of 10CFR21
- Basic premise is ANSI/ISO/ASQ Q9001:2000 requirements are similar to 10CFR50, App. B requirements (with two exceptions)
- Licensee should establish means to address gaps
- Option addressed in APS white paper
PSE ISO 9000 Task—Phase II

Commercial Grade Item Option

• Items are procured as CGIs and dedication is required
• Take credit for the supplier's ISO 9000 program controls as an alternative and new process for dedicating the item in lieu of using the process described in EPRI NP-5652
• Only the licensee accepts 10CFR21
• Basic premise is ANSI/ISO/ASQ Q9001:2000 requirements are similar to 10CFR50, App. B requirements (with two exceptions)
• Licensee should establish means to address gaps
• Should not be interpreted as attempting to substitute a Registrar audit in lieu of performing a commercial grade survey (i.e., EPRI NP-5652 Acceptance Method 2)
PSE ISO 9000 Task—Phase II

Technical and Programmatic Concerns

• Adequacy of ISO 9000 QMS for nuclear-specific applications
  – ISO 9000 does not contain the same level of detailed requirements as found in the implementing standards (i.e. ANSI N45.2, ASME NQA-1)
  – Gaps between ISO 9000 and Appendix B
  – Evaluating product design changes

• Registrar Audits

• Sub-Suppliers
PSE ISO 9000 Task—*Phase II*

**Licensing Issue(s)**

- **Basic Component Option**
  - Quality Assurance Program Description of vendor’s Quality Systems would be altered
    - “Reduction in Commitment” requires prior NRC approval
    - 10CFR Part 21

- **Commercial Grade Item Option**
  - Quality Assurance Program Description of Dedication Process would not change
    - EPRI NP-5652 typically is not described
    - No NRC approval required
      - NRC involvement is highly desirable
PSE ISO 9000 Task—Phase II

Industry Experience with ISO 9000 Certified Suppliers

• Industries that developed a sector-specific ISO 9000 QMS
  – Motivation for developing QMS
  – Perceived benefits
  – Initial development
  – Lessons learned

• Industries that did not develop sector-specific ISO 9000 QMS

• International utility experience with ISO 9000 suppliers

• Evidence of product quality issues associated with items procured from ISO 9000 suppliers
PSE ISO 9000 Task—*Phase II*

**Implementation Guidance**

- Initial ISO 9000 supplier qualification
- Specification of procurement requirements
- Acceptance activities
Implementation Guidance

Initial ISO 9000 Supplier Qualification – CGI Option

• Verify supplier has a valid and current ISO 9000 certification from an accredited Registrar
• Review the supplier’s QMS including applicable procedures and Quality Assurance program documents to:
  – Ensure they are capable of furnishing the scope of supply
  – Determine if gaps are programmatically addressed
  – Identify current programmatic findings, if any
  – Evaluate the impact of:
    • Open findings
    • Gaps that are not addressed in the QMS
Implementation Guidance

Initial ISO 9000 Supplier Qualification – CGI Option

• Verify the supplier is implementing their quality program controls by performing one or more of the following:
  – Review the Registrar’s audit report
  – Review previous commercial grade survey report(s) (Method 2)
  – Perform an independent source evaluation (i.e., full scope audit, partial-scope audit, etc.)
  – Perform source verification
  – Credit prior CGI dedications performed with special tests/inspections (Method 1)
  – Observe Registrar audit(s)

• Method(s) chosen will depend on item complexity, supplier history (new or existing supplier), etc.
Implementation Guidance

Specification of Procurement Requirements – CGI Option

• Technical procurement requirements
  – Critical characteristics (as defined in 10CFR21)
  – Other item design information as necessary
  – Notification of any changes to the item design

• Quality procurement requirements
  – ISO 9000 QMS
  – Quality controls to fill gaps, if necessary
  – Other quality controls not inherent to the supplier’s QMS
  – Notification of changes to the supplier’s:
    • Registrar
    • Certification status
Implementation Guidance

Specification of Procurement Requirements – CGI Option

• Supplier documentation requirements
  – Certificate of conformance
  – Test reports, qualification reports, as needed

• 10CFR21
  – Not applicable to the ISO 9000 supplier
  – Should NOT be specified
Implementation Guidance

Product Acceptance Activities – CGI Option

• CGI is dedicated as defined in 10CFR21
  – Primary reliance upon inspection of item at receipt (i.e., standard receipt inspection)
  – Supplemented with results of the supplier/source evaluation (i.e., audits performed by the Registrar)

• Licensee retains the options of obtaining additional assurance the CGI conforms to purchase documents by:
  – Verifying specified critical characteristics by:
    • Conducting tests/inspections at receipt
    • Witnessing tests/inspections at the supplier’s/manufacturer’s facility
  – Considering past performance of both the ISO 9000 supplier and the CGI in service
Implementation Guidance

Initial ISO 9000 Supplier Qualification – Basic Component Option

• The same activities suggested for the CGI Procurement and Dedication option are appropriate for this option
Implementation Guidance

Specification of Procurement Requirements – Basic Component Option

• Technical procurement requirements
  – Item design information, as necessary
  – Notification of any changes to the item design

• Quality procurement requirements
  – ISO 9000 QMS
  – Quality controls to fill gaps, if necessary
  – Other quality controls not inherent to the supplier’s QMS
  – Notification of changes to the supplier’s:
    • Registrar
    • Certification status
Implementation Guidance

Specification of Procurement Requirements – Basic Component Option

• Supplier documentation requirements
  – Certificate of conformance
  – Test reports, qualification reports, as needed

• 10CFR21
  – Applicable to the ISO 9000 supplier
  – Should be specified
Implementation Guidance

**Product Acceptance Activities – Basic Component Option**

- Basic component is accepted to meet 10CFR50, App. B, Criterion VII
  - Primary reliance upon the results of the supplier/source evaluation (i.e., audits performed by the Registrar)
- Licensee retains the options of obtaining additional assurance the basic component conforms to purchase documents by:
  - Verifying specified requirements by:
    - Conducting tests/inspections at receipt
    - Witnessing tests/inspections at the supplier’s/manufacturer’s facility
  - Performing independent audit(s)
  - Observing Registrar audit(s)
Other Industry Activities

• APS/STARS
  – APS draft license submittal
  – Working closely with EPRI Task Group to develop licensing strategy

• ASME NQA-1 Committee
  – Letter sent to NRC/DOE
  – Requested meeting with NRC staff to discuss concerns

• NRC SECY
  – NRC staff – Richard McIntyre and Ken Heck
  – Site visits at Framatome and Westinghouse
  – Discussions with Boeing
  – Input from industry stakeholders
  – Broader look than EPRI task