A 21st Century Nuclear Industry Needs a 21st Century Quality Approach

Mark Richter – Director
Nuclear Energy Institute

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NUCLEAR ENERGY INSTITUTE

Proposal: Why Modernization is Needed

- Performance - Based Quality Management System (QMS)

- Drivers:
  - 50+ year-old QA framework
  - Appendix B is prescriptive and static-essentially unchanged since 1970
  - Policy alignment with RIPB approaches
  - Advanced reactors and modern supply chains

Appendix B Context and Limitations

- Construction-era checklist model
- Proof of conformity focus
  - Inspection over prevention
  - Compliance mindset
  - Paperwork over performance
- Not an integrated management system (top to bottom organizational ownership)

Appendix B Paradox: IN 2025-06 and CGD

- IN 2025-06 shows that
  - CGD is failing in practice, with repeated findings related to unidentified critical characteristics, missing documentation, and uncontrolled embedded digital devices
  - Failures are driven by procurement of items built to unknown requirements, not by deficiencies in commercial manufacturing quality systems such as ISO 9001
  - Strict reliance on Appendix B/NQA-1 is creating a perverse incentive, pushing licensees toward higher-risk CGD rather than allowing suppliers to build to nuclear requirements from the start
  - Nuclear procurement using a recognized QA standard with nuclear requirements flowed down would directly prevent the failure modes cited in the IN

Regulatory Evolution

- Pivot from prescriptive QA to outcome-based QMS oversight
- What is QMS?
  - Organization-wide system with leadership accountability and ownership
  - Recognized consensus standards
  - Risk-based thinking
  - Integrated safety, quality, economics-NOT mutually exclusive

Core QMS Elements

- Leadership
- Design control
- Supplier oversight
- Corrective action
- Risk management

What Does This Look Like?

- Three-Tier Framework
  - Tier 1: NRC QMS requirement (10 CFR)
  - Tier 2: Consensus standards
    - ISO 9001 / 19443
    - ASME NQA-1
    - AS9100, API Q1/Q2
  - Tier 3: Industry best practices-the key
    - It’s not the standard that is utilized, but the execution of the standard and meeting performance requirements that matters most

QMS: Preserving Safety

- Meets Appendix B intent
- Addresses root causes
- Modernizes method, not safety
- Focuses more resources on greatest safety significance and less resources on low or no safety significance

Key Take-Aways

- Nuclear never updated QA regulations - we can learn from other industries that have modernized
- Core theme is that Appendix B is one piece of a QMS, but there are other more important pieces
- Moving to a holistic approach that emphasizes leadership ownership, (which has the biggest impact on quality), over the conformance checklist, prescriptive formula will allow implementation of modern standards
- The overall outcome is increased confidence in quality, and flexibility so that those that are comfortable with NQA-1 can continue to use it, and those that already use other robust standards can use those

Questions?