NRIC TECH TALKS

NRIC Quality Assurance Series

QA 101 | *October 12, 2022 | 1-2 PM ET*

NRIC | INL Idaho National Laboratory

How to Participate

- For the best experience, we recommend turning off VPN or Citrix connections
- Submit any questions you might have by typing the question into the question section of the control panel. We will address them at the end during the Q & A section.
- If you have any technical problems, please put them in the chat.
- If you have any programmatic questions, please feel free to email NRIC@inl.gov.
- This event is being recorded and will be posted on the NRIC website and your attendance is consent to that recording.

NRIC INL

NRIC is a DOE-NE program, launched in FY2020

NRIC National Reactor Innovation Center

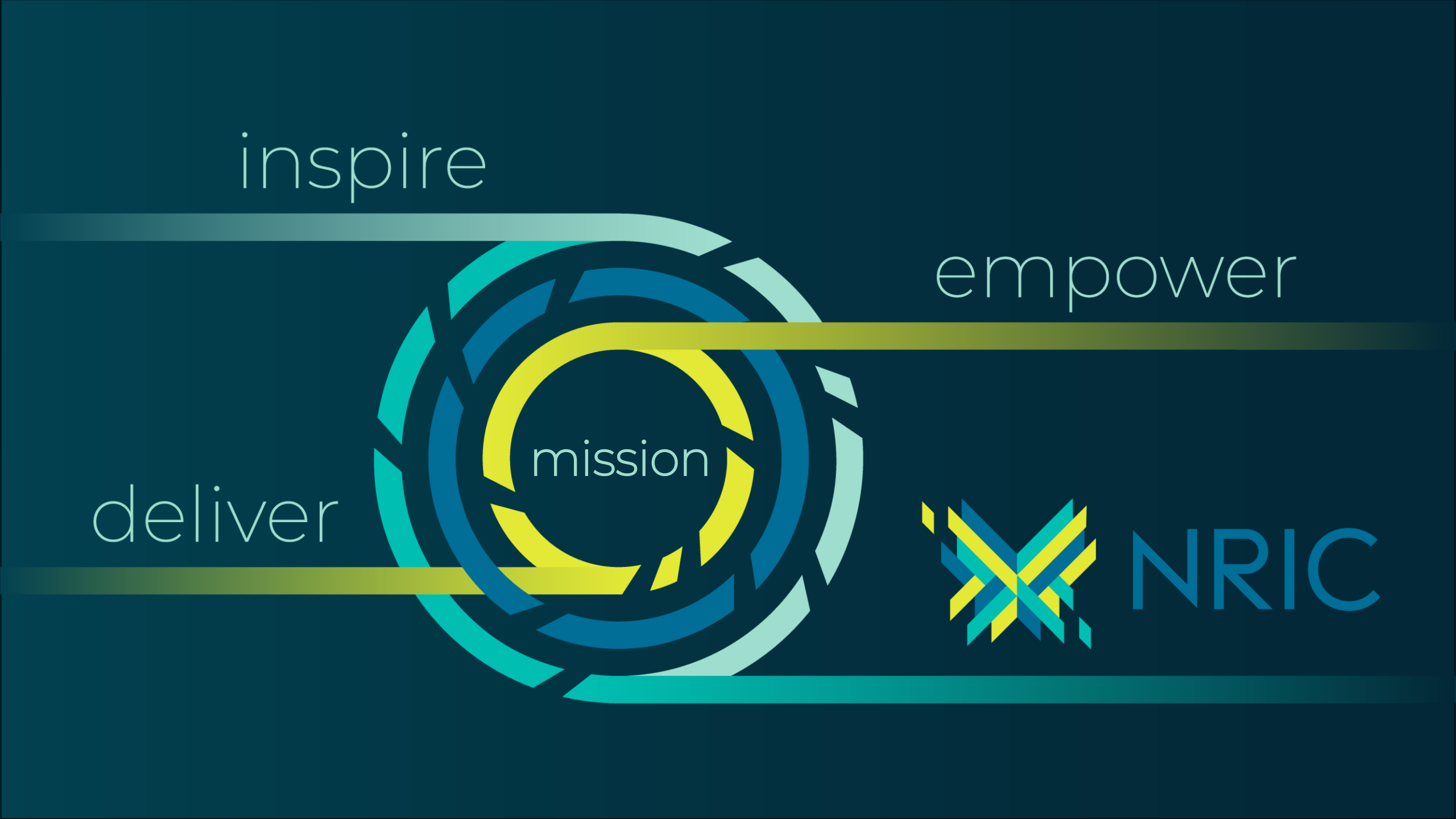
NRIC Accelerates Nuclear Reactor Demonstrations

- Authorized by the Nuclear Energy Innovation Capabilities Act (NEICA)
- Partner with industry to bridge the gap between research and commercial deployment
- Leverage national lab expertise and infrastructure
- Manage demonstrations to success

NRIC INL

NRIC Vision

Commercial Advanced Nuclear by 2030


inspire
empower
mission
deliver
NRIC

NRIC is partnering regionally and nationally to support demonstrations

NRIC INL

Speakers

Paul Prescott
Senior Reactor Operations Engineer, U.S. Nuclear Regulatory Commission

Mark Richter
Technical Advisor, Nuclear Energy Institute

Roger Mills
Chairman, Nuclear Procurement Issues Corporation

NRIC INL

U.S.NRC
United States Nuclear Regulatory Commission
Protecting People and the Environment

Basics of Quality Assurance Meeting with Idaho National Labs (INL) and Stakeholders

Paul Prescott

Quality Assurance and Vendor Inspection Branch (IQVB)

October 12,2022

U.S.NRC
United States Nuclear Regulatory Commission
Protecting People and the Environment

Fundamentals of NRC Quality Assurance (QA)

- Regulatory Basis
  - Criterion 1 (GDC 1), “Quality standards and records,” to 10 CFR Part 50, which requires that a QA program be established and implemented.
  - 10 CFR 52.47(a)(19), “Contents of applications; technical information.”
    - FSAR must include a description of the QA program to be applied to the design of the SSCs of the facility.
    - Requires that the description of the QA program for a nuclear power plant include a discussion of how the applicable requirements of Appendix B to 10 CFR Part 50 are satisfied.
  - Appendix B, “Quality Assurance Criteria for Nuclear Power Plants and Fuel Reprocessing Plants,” to the Title 10 of the Code of Federal Regulations (10 CFR) Part 50, “Domestic Licensing of Production and Utilization Facilities.”

How are QA Requirements Used?

DC / COL Applicant Responsibilities

- Appendix B to 10 CFR 50 applies to the development of safety-related information reflected in a certified design under 10 CFR Part 52.
- Must describe how Appendix B requirements are met.
- For DC applicants (Part 52 Subpart B)
  - 10 CFR 52.47(a)(19)
  - Quality Assurance Program Description (QAPD) should address design QA activities in support of a DC, not construction and design QA activities once construction begins.
  - For COL applicants (Part 52 Subpart C)
  - 10 CFR 52.79(a)(25)
  - QAPD should address all phases of a facility's life, including design, construction, and operation.

Where are QA Requirements Found?

- NUREG-0800, “Standard Review Plan (SRP) for the Review of Safety Analysis Reports for Nuclear Power Plants,” Section 17.5, “Quality Assurance Program Description - Design Certification, Early Site Permit and New License Applicant”

- NRC Regulatory Guide (RG) 1.28, “Quality Assurance Program Criteria (Design and Construction)

NRC's Current Regulatory Position on the Use of ISO 9001

- The NRC staff's position is described in SECY-03-0117
- The paper offered 4 options to meet current NRC regulations:
  - Acceptance of ISO as an alternative to Appendix B
    - ❖ Staff would likely be unable to find this approach acceptable
  - Nuclear sector-specific ISO program
  - Licensee-specific controls for ISO 9001 suppliers
  - ISO 9001 certified suppliers for commercial-grade item procurement

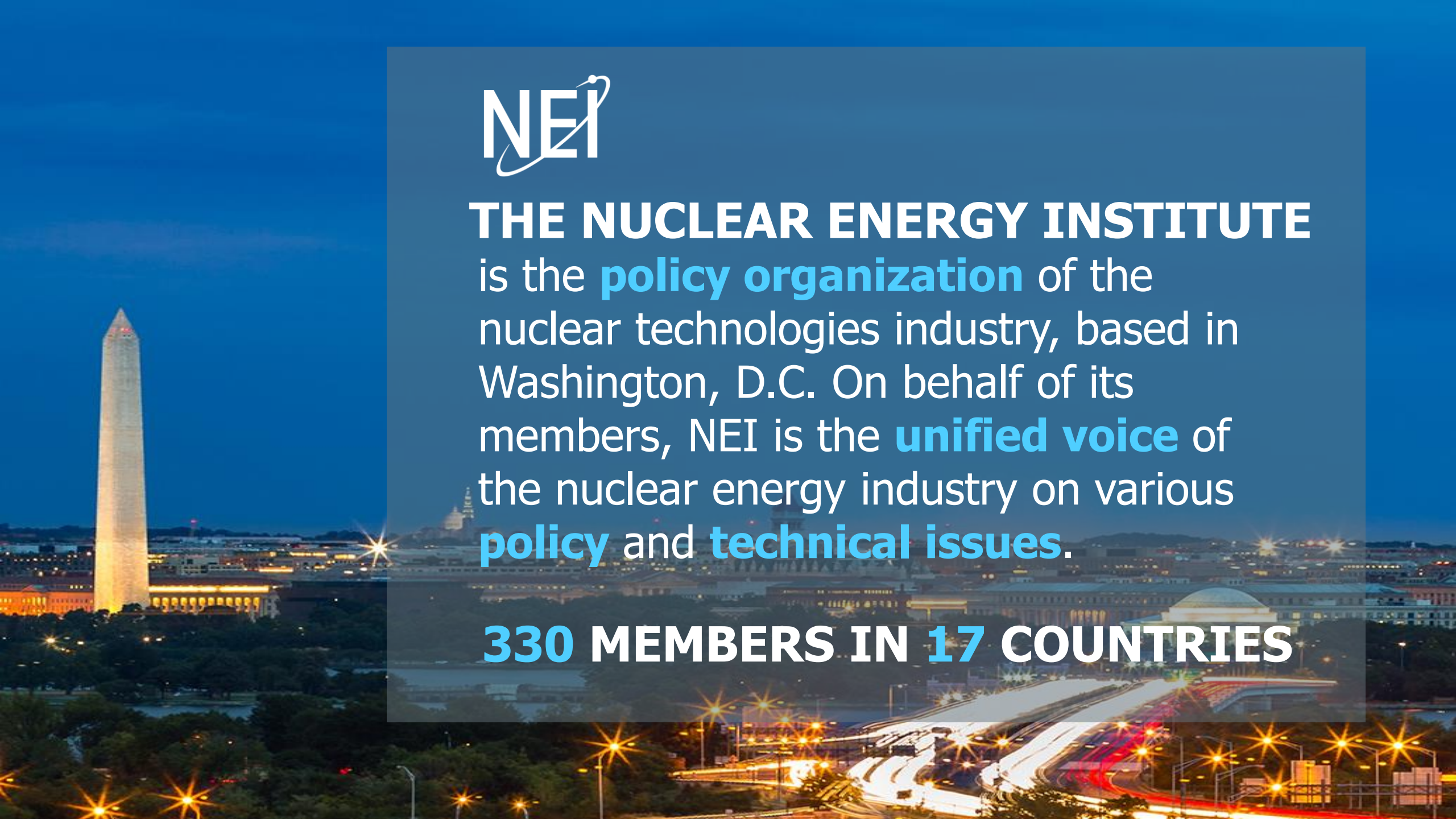
ISO-9001: Meeting 10 CFR 50 Appendix B Requirements

NRIC Tech Talk series on Quality Assurance

Mark Richter - Technical Advisor
Nuclear Energy Institute

October 12, 2022

NUCLEAR ENERGY INSTITUTE



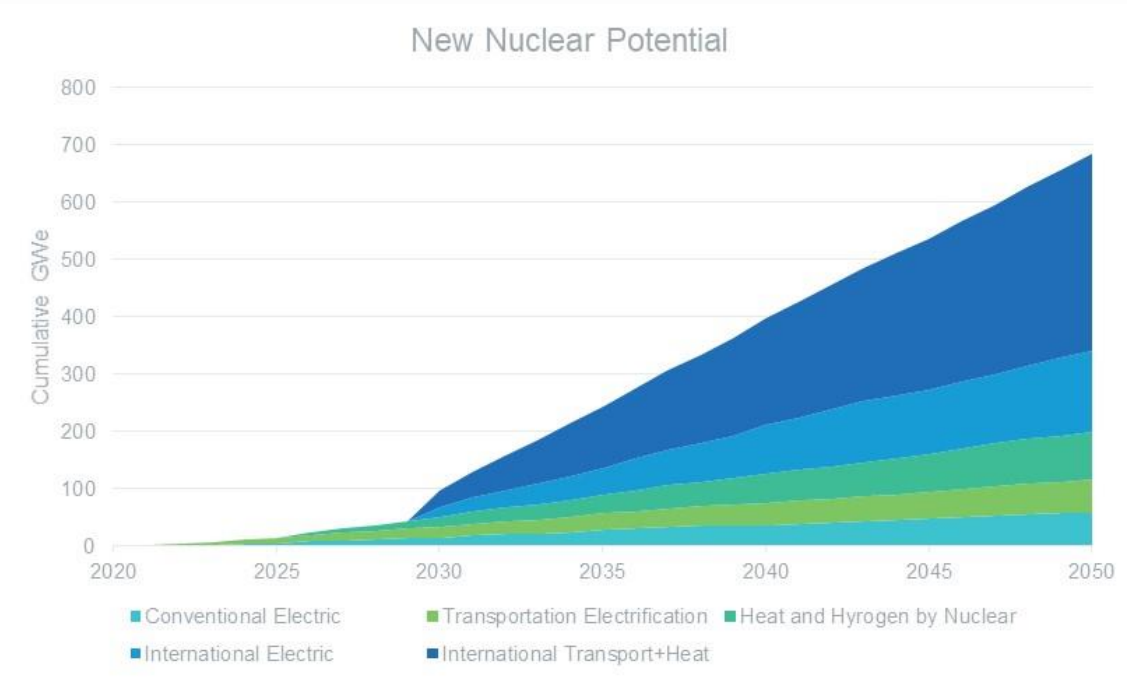
THE NUCLEAR ENERGY INSTITUTE

is the **policy organization** of the nuclear technologies industry, based in Washington, D.C. On behalf of its members, NEI is the **unified voice** of the nuclear energy industry on various **policy** and **technical issues**.

330 MEMBERS IN 17 COUNTRIES

Situational Context

- Increasing urgency for carbon reduction (electric and non-electric)
- Path to zero-carbon must be reliable and affordable
- Nuclear energy must be meaningful part of future energy portfolio
- Advanced reactor deployment plans increasing rapidly and more urgently
- License application load could be more than regulators can currently process



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ISO-9001 Approach to Meet Appendix B

- NEI is developing a process whereby an ISO 9001 QA program could be used as a framework for meeting the requirements of 10CFR50, Appendix B, leading to a more nimble and competitive supply chain while reducing the economic burden of parallel program development

- NOT proposing ISO 9001 as a replacement for 10 CFR Part 50 Appendix B

- ISO-9001 is already employed in many other industries and some nuclear suppliers already have ISO-9001 programs

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Not Starting From Scratch

- NRC SECY-03-0117 “Approaches for Adopting More Widely Accepted International Quality Standards” compares ISO-9001-2000 against the existing 10 CFR Part 50 Appendix B requirements and recommends that supplemental requirements would be needed
- EPRI 1007937 “Analysis and Comparison of ANSI/ISO/ASQ Q9001:2000 with 10CFR50 Appendix B: ISO-9001 Gap Analysis and EPRI 1002976, An In-Depth Review of Licensee Procurement Options for Use with ISO-9001 Suppliers”
- Other regulated industries utilizing an ISO-9001 based quality program and their regulating bodies have recognized the need for and implemented supplemental requirements

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Implementation – Gap Analysis

- Decompose each Appendix B criterion into discrete requirements
- Identify comparable requirements from ISO 9001
- Note potential gaps for compliance with the regulation
- Provide recommendations for addressing the gaps

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Implementation – Gap Analysis Examples

10CFR50, Appendix B, Criterion II *(excerpt)*	**ISO 9001:2015**
The applicant shall establish at the earliest practicable time, consistent with the schedule for accomplishing the activities, a quality assurance program which complies with the requirements of this appendix. This program shall be documented by written policies, procedures, or instructions and shall be carried out throughout plant life in accordance with those policies, procedures, or instructions.	**4.4 Quality management system and its processes** **4.4.1** The organization shall establish, implement, maintain and continually improve a quality management system, including the processes needed and their interactions, in accordance with the requirements of this International Standard. **4.4.2** To the extent necessary, the organization shall: a) maintain documented information to support the operation of its processes; b) retain documented information to have confidence that the processes are being carried out as planned. **8.5 Production and service provision** **8.5.1 Control of production and service provision** The organization shall implement production and service provision under controlled conditions. Controlled conditions shall include, as applicable: a) the availability of documented information that defines: 1) the characteristics of the products to be produced, the services to be provided, or the activities to be performed; 2) the results to be achieved;

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Implementation – Gap Analysis Examples

Fundamental Requirement from 10CFR50, Appendix B:

To establish a QA program in time to accomplish activities in accordance with applicable requirements, which is documented by written policies, procedures, or instructions and complies with the regulation.

ISO 9001 Comparison

ISO 9001 requires a quality management system to be established that includes documented information as needed to ensure the requirements of the ISO standard are satisfied, required processes are implemented properly, and the desired results are achieved.

Potential Gap(s):

ISO 9001 does not identify specific policies, procedures, or instructions that are required to be documented and nuclear regulatory requirements are not considered by most ISO suppliers. As a result, some ISO supplier programs are not documented sufficiently for nuclear applications. However, many ISO suppliers have well documented programs that address quality program attributes comparable to the regulation.

Recommendation(s) (if not addressed within the Supplier's program)**:**

The Purchaser could require submittal of project-specific procedures. However, that may not be practical for programs with only a few documented instructions. ISO suppliers that do not have well documented programs are unlikely to be good candidates for acceptance based on their program.

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Next Steps

- Complete NEI 22-04 Nuclear Supplier QA Program Qualification: ISO 9001 Supplemental Requirements to advance discussion with NRC
  - Perform “dry run” assessments with analysis tools
  - Revise process and tools as informed by dry runs
  - Process Steps Identified and Defined
- NEI 22-04 is revised to reflect dry run experience
- Submit NEI 22-04 to NRC for review and endorsement

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Additional Considerations

- Not one size fits all – not for every supplier or purchaser
- Requires a detailed assessment of the supplier's program to identify gaps and determine appropriate supplemental requirements; followed by periodic reassessments to verify implementation
- Purchaser maintains 10 CFR Part 21 responsibilities, and supplier/vendor will impose the reporting requirements for nonconformances with sub-tier supplier(s)
- Business decision for customer and supplier

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Questions?

mar@nei.org

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Presentation By:

Roger Mills

NUPIC Chairman

www.NUPIC.com

“Nuclear Power is on the brink of a $1 Trillion resurgence, but one accident anywhere could stop that momentum” WWW.MSN.COM 08/04/2022

But that momentum depends on international cooperation around safety and best practices.

"*The issue how nuclear industry works and is perceived globally, any accident anywhere is an accident everywhere*,"

Hamad Al Kaabi, the United Arab Emirates' representative to the IAEA.

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Who we are!

Nuclear Procurement Issues Corporation

Non-Profit organization supporting Nuclear Utility members by providing efficiencies and consistencies in auditing including sharing manpower for performing audits and data storage

Mission Statement

The NUPIC Organization will strive to improve the supplier assurance processes through cooperative efforts while minimizing utility O & M costs and improving plant performance.

Membership

39 Utilities, (active, start-up and decommission)

12 International included

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NUPIC Organization

Executive Steering Committee - 4 Officers

- Chairman – Roger Mills (PSE)
- Vice Chairman – Earl Mayhorn (AUE)
- Treasurer – Mike Buel (WCN)
- Secretary – David Engle (CEG)

Region & International Representatives

- Region 1 Hussain Al Jaberi (ENE)
- Region 2 Mark Coren (DPC)
- Region 3 Tracey Klacey (DTE)
- Region 4 Guy Robinson (ENT)
- International Leon Payne (NBP)

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What We Do!

NUPIC

- Operates as a non-profit corporation.
- Maintains focus on the best interest of its members.
- Provides a cooperative program for the evaluation of vendor/supplier performance. *NUPIC does not perform audits*
- Provides a forum for discussion of Procurement Quality Assurance issues.
- Provides an interface for Procurement Quality Assurance activities.

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What We Do!

NUPIC Interfaces with other organizations

- Nuclear Regulatory Commission (NRC),
- Nuclear Energy Institute (NEI),
- Nuclear, Information Technology Strategic Leadership (NITSL),
- Electric Power Research Institute (EPRI),
- Nuclear Supply Chain Strategic Leadership (NSCSL),
- Nuclear, Quality Management Leadership Forum (NQML),
- Owners Groups.

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NUPIC Committees

Consist of a Committee Chairman and Utility Members that perform and manage the work.

Report to the Steering Committee and Utility Representatives

Committee Benefits:

- Leadership skills
- Networking opportunities.

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NUPIC Committees

Steering Committee

Overall guidance for the operation of NUPIC

Chairman is on Nuclear Quality Management Leadership (NQML) Steering Committee.

Finance Committee

Tracks and projects all income and expenses non-profit organization.

Coordinates financial audits through an accountant

Maintains communication with legal representative

Vendor Interface Committee

Manages our future Meetings – three per year:

Training in Spring, Vendor Meeting in June, and a Working Meeting in Sept/Oct.

Process Management Committee

Guidance and Control of NUPIC Procedures,

Tracks recommendations and Vendor Findings closures.

Maintains Utility Performance Scores

Provides feedback on Team, Lead and Individual Member Audit Performance.

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NUPIC Committees

Fuels Committee

Monitors Framatome, GE, and Westinghouse Fuels manufacturing,

Provides Technical Specialists for the Mega-Audits

Schedules and performs various fuels surveillances.

IT Committee

Interface between NUPIC and Ethany, our database provider.

Ensures all functions of our database system operates correctly.

Vendor Performance Monitoring Committee

Handles all normal scheduling functions for audits and surveys

Maintains control of any vendor that is recommended for additional oversight.

Training Committee

Provides forum for presenting topics or sessions as requested by the NUPIC members.

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NUPIC Committees

International Laboratory Accreditation Cooperation (ILAC) Committee

Oversight and work with ILAC Organization for calibration and testing services

Interface with NRC and 17025:2017 requirements

Vendor Performance Improvement Groups

- Individual Teams that provide additional oversight for vendors that are having difficulties maintaining compliance with appropriate rules.
- Implementation of an Improvement Group is voted on by the Utilities that use that vendor.

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Why be a member of NUPIC?

Increased Efficiencies

- Reduction in number of audits performed per utility.
- Audit participation based on Utility's number of units and number suppliers on Approved Suppliers List (ASL)
- Audit reports are shared between utilities that use the vendor.
- Supplier information maintained in Database

Example:

If a utility has130 Suppliers on ASL; averages 43 audits performed per year

the same utility as a NUPIC member would average 13 per year

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Why be a member of NUPIC?

Shared Knowledge

NUPIC database:

- Maintains supplier locations, scope of supply, QA contacts, certifications, industry issues, and audit reports.
- Tracks all audit activities and identifies overdue items.
- Automated emails to users when changes are made
- Reports and searchable data tables

NUPIC Meetings

- 3 meetings per year
- Present current topics from Organizational Interfaces

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Wrap up

The NUPIC organization provides increased efficiencies, knowledge sharing, and a database for audit scheduling, tracking, assignments, team members, archives.

Advantages of being a NUPIC member:

- Lessons learned for audit performance are shared
- Updates on vendor performance issues
- Opportunity to share in focused oversight of troubled vendors
- Consistent/objective audits/surveys checklists
- Access to continuous improvement opportunities.

Overall, as members of the Nuclear Industry, if there is an accident or incident, it is the “Nuclear Industry” that gets put in the headlines.

NUPIC is here to help in preventing those types of headlines.

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Comments

Questions

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National Reactor
Innovation Center

INL
Idaho National Laboratory

Questions?