U.S. DEPARTMENT OF ENERGY

SRS

Price Anderson Amendment Act

D. Scott Nicholson

Director, Office of Safety and Quality Assurance

Savannah River Site Citizens Advisory Board
July 23-24, 2018

Presentation Objectives

- Understand aspects of both PAAA and the NQA-1 Program (QAP)
- Understand purpose of the PAAA Program and drivers
- Understand how QA reduces risks
- Understand and recognize the Department of Energy (DOE) QA Expectations and requirements
- Understand how DOE provides oversight of Contractor QA Programs

PAAA History

- Atomic Energy Amendments Act of 1954
- 1957 Price-Anderson Act
- Price-Anderson Amendments Act (1988)
- Energy Policy Act of 2005

PAAA Purpose

- Protection of the environment, health, and safety of the public and workers.
- Indemnifies (insures) DOE contractors against public liability for a nuclear incident.
- Establishes quality and nuclear safety requirements.
- Provides DOE enforcement authority.

PAAA Applicability

- Applies to contractors, subcontractors, and suppliers conducting activities that may affect the DOE nuclear facilities or activities.
- All work must be accomplished with established Quality and Nuclear Safety requirements as set forth by contract.
- Nuclear facilities, including any location where work is performed to support any nuclear activities.
- Activities that can cause or contribute to nuclear or radiological incidents, or potential for radiological harm.

PAAA Contractor Responsibilities

- Understand and implement nuclear safety requirements.
- Critically self-assess activities.
- Promptly identify, report, and correct noncompliances.
- Conduct work activities in compliance with applicable procedures.
- Assure the subcontractors performance meets requirements.

Reporting Criteria

- Noncompliance associated with ORPS reports
- Programmatic/Repetitive Issues
- Security Incident Notification Reports
- Intentional Violation or Misrepresentation
- Violations with “High” Risk (WSH)
- Computerized Accident/Incident Reporting System (CAIRS)
- Employee Concerns

PAAA Process Overview

- Identification of potential sources of issues to be screened for noncompliance.
- Review for DOE Noncompliance Tracking System (NTS) reportability
- If NTS Reportable
  - DOE-SR Enforcement Coordinator notified and event entered into NTS and local tracking system.
  - Investigation/causal analysis
  - Corrective action development
  - Formally track to closure
  - Verification for closure

Noncompliance Closure

- Contractor Coordinator validates completion of corrective actions prior to Closure.
- Contractor Coordinator marks the NTS report as complete.
- DOE-SR Enforcement Coordinator verifies completion of corrective actions (Facility Representative, SMEs)
- DOE-SR Enforcement Coordinator enters verification results into NTS with clear recommendation for closure.

Noncompliance Closure

- Office of Enforcement personnel:
  - Monitor completion status of NTS reports.
    Review corrective action completion and closure recommendation from the local DOE Enforcement Coordinator.
  - If in agreement with recommendation, closes the NTS report.
  - If not in agreement proceed to Enforcement Process.

Base Civil Penalties

- The respective enforcement policies establish base civil penalty amounts by severity level that are a percentage of the maximum civil penalty allowed per violation per day.
- DOE is required by the Federal Civil Penalties Inflation Adjustment Act of 1990 to periodically adjust the maximum, per-day civil penalty amounts for inflation.
- This Act was amended by the Federal Civil Penalties Inflation Adjustment Act Improvements Act of 2015, which requires Federal agencies to make an initial “catch-up” adjustment and then make subsequent inflation adjustments to the civil penalty amounts annually.

Base Civil Penalties, cont.

- The respective enforcement policies establish base civil penalty amounts by severity level that are a percentage of the maximum civil penalty allowed per violation per day.
- DOE is required by the Federal Civil Penalties Inflation Adjustment Act of 1990 to periodically adjust the maximum, per-day civil penalty amounts for inflation.
- This Act was amended by the Federal Civil Penalties Inflation Adjustment Act Improvements Act of 2015, which requires Federal agencies to make an initial “catch-up” adjustment and then make subsequent inflation adjustments to the civil penalty amounts annually beginning in January 2017.
- The actual “catch-up” adjusted maximum civil penalty amounts, effective as of July 28, 2016.

Summary/Questions

- The rule was developed to govern the conduct of individuals involved in DOE nuclear activities
  - To achieve compliance with the DOE Nuclear Safety requirements
- Establishes civil penalties designed to emphasize the importance of compliance and to deter future violations mas well as to encourage early identification and reporting of violations and prompt correction

U.S. DEPARTMENT OF ENERGY

SRS

Quality Assurance and NQA 1 Standards

D. Scott Nicholson

Director, Office of Safety and Quality Assurance

Savannah River Site Citizens Advisory Board
July 23-24, 2018

What does Quality Assurance do for us?

- **Consistency: Doing it the same time every time.**
- **Efficiency: Doing it the best way.**
- **Productivity: Actually getting it done.**

There are variables that will try to prevent us from being consistent, efficient, and productive. Those variables are RISKs and can be minimized through proper planning, performing, and assessing of work. Examples of risks:

- Human error
- Equipment failure/degradation
- Lack of Knowledge
- Inadequate design/manufacturing
- Incorrect/Lack of resources
- No documentation
- Wrong specifications
- Unsafe environment

Why QA is Relevant?

- Provides management with confidence and assurance that people, processes, and implementation will meet requirements and performance expectations.
- Risk is reduced by a process of verifying some or all aspects of an activity, e.g.:
  - Plan or design
  - Materials used
  - Attention to detail during construction
  - Thoroughness of testing
  - Conduct of maintenance and operations
  - Control of procurement spare parts
  - Document control
- Each interrelated control and check performed along the way increases the confidence that the final product, system, and facility will meet performance expectations.

Chain of events…

- Until 1954, only the federal government could develop nuclear power. The Atomic Energy Act of 1954 radically changed that by allowing private industry to participate in the development.
- Even though the Act's overriding thrust was to develop a viable commercial nuclear industry, at an early point it was recognized that nuclear technology posed a unique threat to the public welfare, and that any proposal to move it into the public domain must include some regulatory provision.
- DOE establishes "The Rule" which is 10CFR830 and its Subpart A (830.120). It provides the DOE with the ability to levy civil and criminal penalties for noncompliance of nuclear safety and quality requirements.
- Through many iterations and revisions, DOE established the current QA requirements of the Rule in DOE Order 414.1D for both external and internal programs.

Quality Assurance Program Requirements

- The QAP must:
  - Submit QAP to designated DOE approval authority
  - Conduct work in accordance with the QAP
  - Annually submit changes to the QAP to DOE for approval
  - Describe the basis for a graded approach
  - Discuss how the quality (10) criteria of DOE) 414.1D are satisfied using a graded approach
  - Integrate the criteria into the safety management program system
  - Describe how subcontractors and suppliers meet the QAP
  - Identifies Federal Technical Capability and Qualifications for QA and SQA
  - Requires use of appropriate national or international consensus standards (DOE has adopted AMSE NQA-1)

DOE Order 414.1D

- Criterion 1, Program
  - Establish the structure, determine who will be responsible, and determine interfacing points for those managing, performing and assessing work.
  - Ensure management processes exist for planning, scheduling, and providing resources for work.
- Criterion 2, Personnel Training and Qualification
  - A process to ensure personnel are qualified and trained to perform assigned work.
  - Ensure personnel have access to continued training to maintain job proficiency.
- Criterion 3, Quality Improvement
  - Establish processes to detect and prevent quality problems by ensuring only acceptable items are used by indicating operating status through tags, labels, or markings.
  - If an item is not acceptable, it cannot be used and must be controlled to prevent inadvertent installation or use.
  - Identify causes of problems and include prevention of recurrence in corrective action planning.

DOE Order 414.1D

- Criterion 4, Documents and Records
  - Ensure documents prescribe processes, specify requirements, or establish design.
  - Records should be specified, prepared, reviewed, approved, and maintained.
- Criterion 5, Work Processes
  - Work should be performed consistent with all technical standards and administrative and hazard controls under approved procedures.
  - Ensure all items are maintained and used properly.
  - Equipment for process monitoring or data collection should be calibrated and maintained.
- Criterion 6, Design
  - Control all design aspects including input, interfaces, activities, verification, changes, software design, and configuration management to ensure use of appropriate standards and requirements.
  - Verify or validate adequacy of design products using individuals or groups outside of who performed work before approval and implementation of design.

DOE Order 414.1D

- Criterion 7, Procurement
  - Obtain items and services meeting established requirements and performing as specified.
  - Evaluate and select prospective suppliers based on specified criteria and establish and implement processes to ensure approved suppliers continue to provide acceptable items and services.
- Criterion 8, Inspection and Acceptance Testing
  - Ensure the item is of acceptable operating status through inspection and testing based on established acceptance and performance quality criteria.
  - Plan and document testing on specified quality characteristics and compare results to acceptance quality criteria to ensure accuracy of instruments.

DOE Order 414.1D

- Criterion 9, Management Assessment
  - Managers must assess management processes and identify and correct problems hindering the organization from achieving its objectives.
- Criterion 10, Assessment/Independent Assessment
  - Independent assessments must be planned and conducted based on acceptance quality criteria established to measure item and service quality, adequacy of work performance, and to promote improvement.
  - Sufficient authority and freedom from line management must be established for independent assessment teams.
  - Persons performing such assessments must be technically qualified and knowledgeable in areas to be assessed.

NQA-1 Requirements

- 1 Organization
- 2 Quality Assurance Program
- 3 Design Control
- 4 Procurement Document Control
- 5 Instructions, Procedures and Drawings
- 6 Document Control
- 7 Control of Purchased Material, Equipment and Services
- 8 Identification and Control of Materials Parts and Services
- 9 Control of Special Processes
- 10 Inspection
- 11 Test Control
- 12 Control of Measuring and Test Equipment
- 13 Handling, Storage and Shipping
- 14 Inspection, Test and Operating Status
- 15 Nonconforming Items
- 16 Corrective Action
- 17 Quality Assurance Records
- 18 Audits

NQA-1 Oversight

- NQA-1 Assessments/Audits
- DOE QA Personnel are trained in the QA Technical Qualification Program and as NQA-1 Lead Auditors
- Shadow Contractor assessments
- Monthly feedback
- Report Analysis

Summary/Questions

- The QA/NQA-1 programs are designed to:
  - Provides confidence and assurance that people, processes, and implementation will meet requirements and performance expectations
  - Reviews validate a quality program has been implemented through audits/assessments that demonstrates effective implementation
  - Each nuclear organization's quality program must address all the DOE QA Criteria and NQA-1 Requirements for which they perform related activities.
- The cost of quality cannot be ignored in order to meet deadlines, cut costs, or grow a company