7A Type A (and below) Rad Packaging Supplier QA Change in Paradigm

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Working Subcommittee

- Ronald B. Natali, Chair
- Members of the subcommittee
  - Steve Stein, BNL
  - John (Woody) Woodbury, NR
  - Mike Fish, Hanford
  - Mark Hawk, DOE Subcontractor
  - Dennis Weaver, Subcontractor
Basic Assumptions

- DOE Contractor’s have DOE Order 414.1D, Quality Assurance in their contract
- 414.1D Attachment-1, Contractors Requirement Document, 1 (c).
  - Use appropriate national or international consensus standards consistent with contractual and regulatory requirements, and Secretarial Officer direction. Clearly identify which standards, or parts of the standards, are used. When standards do not fully address the CRD requirements, the gaps must be addressed in the QAP. Select and document the appropriate choice below.
- Hazard Category 1, 2, and 3 nuclear facilities
  - NQA-1-2008/2009 addenda, Quality Assurance Requirements for Nuclear Facility Applications, Part I and applicable requirements of Part II>
Basic Assumptions Cont.

- **Less than Hazard Category 3, non-nuclear or chemically hazardous facilities**
  - ASME NQA-1-2008/2009 addenda, Quality Assurance Requirements for Nuclear Facility Applications, Part I and applicable requirements of Part II.
  - ASME NQA-1-2000, Quality Assurance Requirements for Nuclear Facility Applications, Part I and applicable requirements of Part II.
  - ANSI/ASQ Q9001-2008, Quality Management System Requirements
  - ANSI/ASQ Z1.13-1999, Quality Guidelines for Research

- **DOE Order 414.1D states, “Select and document the appropriate choice”**
  - Environmental Management has determined that “EM” sites will use ASME NQA-1-2008/2009 addenda, Quality Assurance Requirements for Nuclear Facility Applications, Part I and applicable requirements of Part II.
The Graded Approach

- NQA-1 allows implementing the requirements through the use of a graded approach. Although there are many interpretations or definitions of the “Graded Approach,” The one we will use for our discussion today comes from NQA-1, Part IV: Non-mandatory Appendices – Positions and Applications Matrices, Subpart 4.2, paragraph 300.

- Graded approach is the application process for administrative controls. It is a process by which the level of analysis, extent of documentation, and degree of rigor of process control are applied commensurate with their significance, importance to safety, life cycle state of a facility or work, or programmatic mission.
The Graded Approach

- The graded approach does not allow for a requirement to be waived, but rather allows for varying levels of managerial controls to be applied to provide adequate assurance, commensurate with risk, that the requirement is being met.

- As such, for all procurement activities the expectation is that all areas are addressed.

- However, the methods used to implement the requirement can vary commensurate with the risk of the activity.
How to Start the Graded Approach

Requirement 4, Procurement Document Control – 202, Technical Requirements

- Technical requirements shall be specified in the procurement documents. These requirements shall be specified, as appropriate by reference to specific drawings, specifications, codes, standards, regulations, procedures, or instructions, including revisions thereto that describe the items or services to be furnished. The procurement documents shall identify appropriate test, inspection, and acceptance criteria for determining acceptability of the item or service.

- Draft DOE/OPT – D01, Technical Requirements and Description for the Procurement of a 208-Liter (55-Gallon) Removable Head, Performance-Oriented Package (POP) and 7A Type A, Carbon Steel Drum with Closure Ring, Revision 2.
How to Start the Graded Approach

Requirement 4, Procurement Document Control – 203, Quality Assurance Program Requirements

- Quality assurance program requirements shall be specified in the procurement documents. These requirements shall be consistent with importance and/or complexity of the item or service being procured. The procurement documents shall require the Supplier to incorporate appropriate quality assurance program requirements in sub-tier procurement documents.

- Based on the Technical Requirements identified the Quality Assurance requirements based on the graded approach are selected.
Questions/Comments