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

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Previous paradigm for DOE Contractor to Supplier flow-down of QA Program requirements was ASME NQA-1 Part 1 Section 100, “Basic”

- Basic 100 paragraphs a summary or “what to do”
- Use of supplemental Part 1 “how to” paragraphs was not mandated
- Suppliers used varying [NQA-1] QA program strategies and alternate standards (e.g., ISO based) for program and associated controls and still aligned with the Basic 100 requirements

2011 – 2012 DOE Contractors began a transition to flow-down all of NQA-1, Part 1 requirements (basic and supplemental)

- Underway at the SRS in 2011; other sites impacted by ASME Committee/DNFSB Letter of Interpretation (March, 2012)
- Suppliers with the NQA-1 basic QA program were no longer aligned with the additional requirements. They either had to modify their QA program or they were no longer “NQA-1 qualified”
Challenges with NQA-1 as a Basis for Packaging Supplier QA

- NQA-1 developed for nuclear facilities and facility SSCs; not always a good fit for the manufacture of packaging
- Transportation activities (includes packaging) are excluded from 10CFR Part 830 (per 830.2(c)) for nuclear facilities work
- DOE Order 414.1D allows QA program standards other than NQA-1 for 7A Type A (and below) packaging; Contractor QA programs may or may not permit this flexibility
- For commercial grade packaging, NQA-1 Commercial Grade Item definitions are not an exact fit
- Many suppliers are small businesses with limited products, processes and resources; full NQA-1 Part 1 often proves difficult and cost prohibitive to fully implement and maintain
EFCOG/PMC Packaging Procurement Working Group

- EFCOG Supply Chain Quality and Packaging Management Council (PMC) Packaging Procurement Working Group formed in the fall of 2012

- Working Group purpose and goal:
  - Develop a process to use the graded approach for the flow-down of NQA-1 full Part 1 requirements to Suppliers
  - Determine the necessary and sufficient requirements prescribed by NQA-1 and appropriate utilization of tools contained therein (e.g., graded approach, commercial item procurements) to –
    - Ensure the manufacture and receipt of quality packaging; and
    - Work in harmony with program/process QA controls typical for the packaging supply industry
  - Deliver documented guidance of good practices to the DOE and DOE contractors
    - Goal is to document a reasoned and practical application of NQA-1 Requirements on packaging procurements and for flow-down to packaging suppliers.
EFCOG/PMC Working Group Progress

- SRS document set for commercial item procurement of 7A Type A Drums was distributed for review/comment October, 2012 (i.e., strawman for DOE complex version)
- Multiple video-conferences, informal training and webinars conducted to enlighten working group team members on subject matter and foster dialog over challenges and solutions
- Task description and guidance document in draft form
- Subgroup teams formed for two complimentary tasks and subsequent deliverables
  1. Strategy and good practices for a graded approach to the supplier flow-down of NQA-1 Part 1 requirements (Ron Natali, Team Lead)
  2. Strategy and good practices for use of NQA-1 commercial item procurement tools including those aligned with commercial grade dedication from NQA-1 Part II, Subpart 2.14 (Mark Bowers, Team Lead)
Practical Use of EFCOG/PMC Working Group Deliverables

- Development of a DOE Complex-wide guidance document
- Make guidance available to DOE sites and Contractors for use
- Incorporate into the DOE-EM 33 Office of Packaging and Transportation, DOE Complex 55 Gallon Drum Specification and two (2) Low-level Waste Box Specifications
  - Drum specification** developed/issued circa 2000
  - Box specifications** developed/issued circa 2005
    - **All specifications currently under revision; on hold pending the graded approach and commercial grade item guidance document deliverables
- Enhancement/further development of training for Commercial Grade Item Procurement/Commercial Grade Packaging Dedication (all Packaging Types)
  - Reference: Commercial Grade Training Course (for Type B Packaging) conducted at DOE HQ, Germantown Sept., 2013
Developing a Common Approach to Achieve Common Goals

In summary-
DOE contractors share many common suppliers but are quite diverse in imposing QA program/process control requirements; the EFCOG/PMC deliverables are intended to promote complex-wide uniformity and consistency for the acquisition of packaging
Packaging Procurement Chart of Applying QA Controls

- Packaging type and use
  - Quality level
    - Standard commercial practices
    - Quality of design/construction
    - Markings
      - 49CFR req’d docs
  - Lower procurement level
    - Verif/insp at receipt or prior to use
      - Validate DOT compliance prior to use
        - Validate DOT compliance prior to use

- NQA-1 requirements applied/higher procurement level
  - Graded approach applied
    - Non-NQA-1 Supplier
      - Accept. Method 1 thru 4
        - Review supplier document submittals - materials, fabrication, inspection, test
      - NQA-1 Part 1 Supplier
        - Supplier assessment/audit
          - Qualified Part I; work independently

- Basic receipt insp.
Questions/Comments
Procurement of 7A Type A “Rad Packaging” Drums
Regulatory & DOE Directive Drum Procurement QA References

  - User/shipper responsible to verify quality of design and construction prior to use
- DOE 460.1C, *Packaging and Transportation Safety*, Contractor Requirements Document
  - Contractors participating in design, fabrication, procurement, use, or maintenance of hazmat packaging must have a [DOE] approved and audited QA program
7A Type A Drum, 49 CFR
Summary of Requirements

- **178.350**
  - Specification packaging requirements

- **Design and construction**
  - 173.410 General Design
  - 173.412 Additional Type A design
  - 173.504 Steel drum construction

- **Performance Testing** (Physical, Modeling, Analysis)
  - 173.461-465 Water Spray, Penetration, Drop, Stack

- **Documentation**
  - 173.415 Test Reports, Materials of Construction, Evaluation
  - 178.2 Notification (i.e., closure instructions)

- **Markings**
  - 178.350 Specification Markings
  - 178.3 Marking Requirements
Drum Availability and Supply?

- NQA-1 Requirement 7, 200 Supplier Evaluation and Selection

Commodity Applicability, Suitability, & Sustainability

- Applicability – Research, reviews, discussions, etc. to find potential suppliers of desired commodity
- Suitability – Will supplier’s commodity be suitable for intended use? Will supplier qualify to minimum standards?
- Sustainability – Reasonable expectation supplier will continuously provide an acceptable, quality product
Qualify Supplier/Qualify Commodity

- Some drum supplier’s QA programs may qualify as a full NQA-1 Part I using a graded approach
  - Forward and request completion of a NQA-1 compliance survey
  - Request submittal of QA program documents
  - Assess or audit
- Compensatory Action Plans (CAPs) may be used for minor program non-compliances during corrective action phase
- Commercial Grade Packaging Dedication available to qualify the commodity when unable to qualify supplier
7A Type A Drum CGPD Document Set

- Commercial Grade Packaging Dedication Plan
- Technical Evaluation Report
- Commercial Grade Survey Checklist
- Surveillance Plan
- Receipt Inspection Plan
- Specification**
  - ** Existing DOE Complex 55 Gallon Drum Specification will be used