

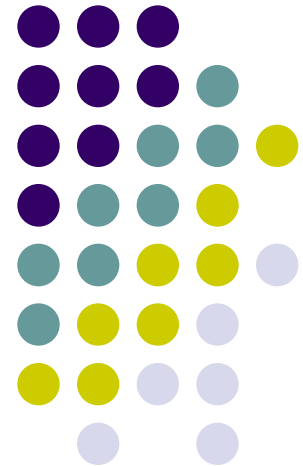
7A Type A (and below) Rad Packaging Supplier QA Change in Paradigm



Mark Bowers

Savannah River Nuclear Solutions, LLC – Savannah River Site
EFCOG Supply Chain QA/PMC Working Group Co-chair

December 5, 2013
EFCOG ISM & QA Working Group Meeting
Las Vegas, NV



ASME NQA-1 Requirements – Basic 100 to Full Part 1



- **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/DNFBSB 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

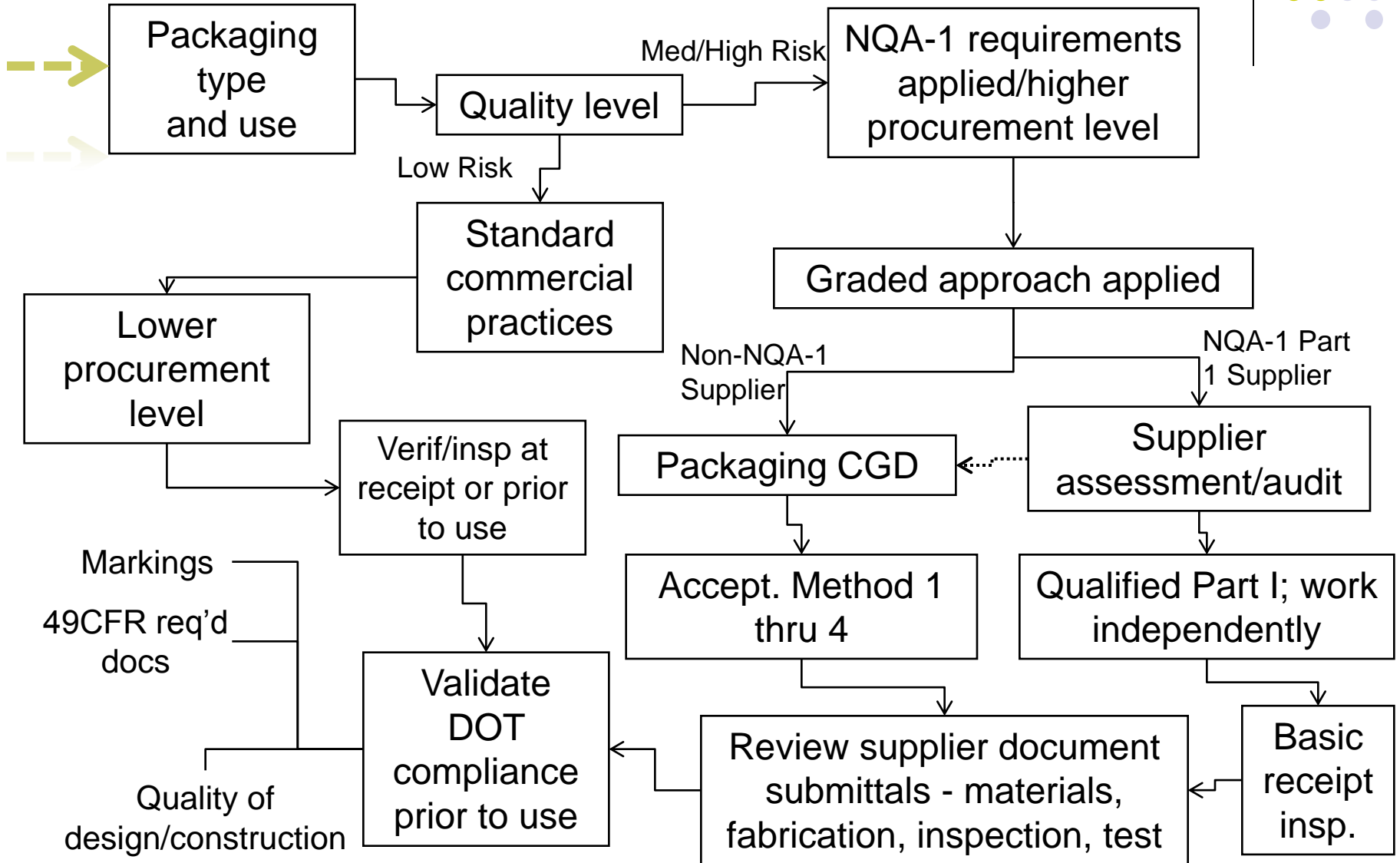
Developing a Common Approach to Achieve Common Goals



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





Questions/Comments





Procurement of 7A Type A “Rad Packaging” Drums

Regulatory & DOE Directive Drum Procurement QA References



- 49 CFR [Hazardous Materials Regulations] 173.474
 - 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

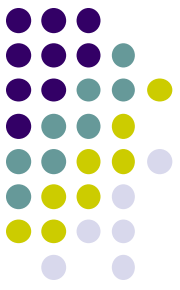
7A Type A Drum, 49 CFR

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