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Observations on Commercial Grade Item Dedication

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Current Situation

- Licensees understand and are in compliance with existing regulations
- Clarity was established between NRC and Licensees in the late 1980s
- Enhanced guidance is available in NRC inspection plans (38703, 88114, 43004)

Current Situation

- Increased NRC communication with suppliers interested in new build opportunities has created:
 - Some uncertainty about dedication process
 - Perception that dedication is the only way to a “basic component”
 - Opportunity for previously resolved questions to resurface

Current Situation

- Dedication is used more frequently to address:
 - Obsolescence
 - Schedule demand (short lead times)
- New and existing suppliers are expanding application of dedication

Quality Requirements in Procurement Documents

- All orders for basic components are subject to Part 21
- Adequate guidance exists in ANSI N45.2.13 / NQA-1 for other technical and quality assurance requirements

Counterfeit, Fraudulent and Suspect Items

- Counterfeit, fraudulent and suspect items are a subset of nonconforming items
 - Utility investigates and reports for items accepted into stock
 - Supplier investigates and reports for items not accepted
- Reporting of defects and noncompliance for counterfeit and fraudulent items is implemented using the same processes and procedures as other nonconforming items

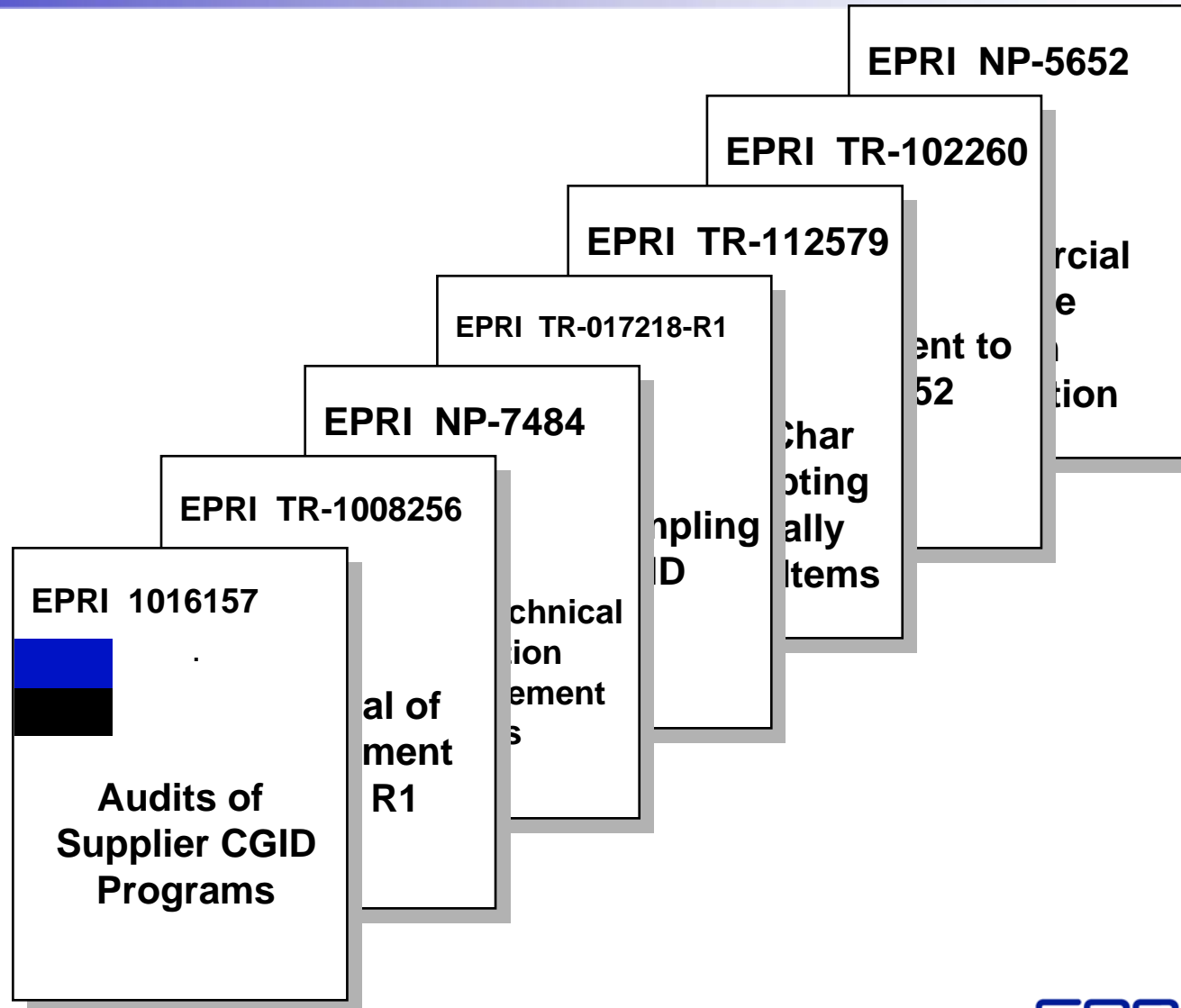
Training

- EPRI will make EPRI training available to interested parties
- EPRI periodically revises existing guidance and training materials

Regulatory Guidance on Dedication

- Regulatory guidance exists in:
 - Generic Letter 91-05
 - Inspection Procedures 43004, 38703, 88114
 - Information Notice 2011-01
- Industry guidance exists
 - ASME NQA-1, 2008 Edition / 2009 Addenda
 - EPRI NP-5652 (endorsed in GL 91-05) and others
- Existing guidance is incorporated in utility procedures
- EPRI guidance is currently available to suppliers

Relative EPRI Guidance is Publically Available



Definition of Dedication

- The current definition is appropriate and functional
- Key considerations
 - Restrictions noted in Generic Letter 91-05 apply
 - Receipt inspection and verification is always performed
 - Item and supplier history is used to select appropriate sampling plans

Definition of Commercial Grade Item

- The current definition is appropriate and well understood
 - Emphasizes that dedication is an acceptance process
 - Dedication may not be used for items when critical characteristics can not be verified after manufacturing

Two basic options exist to perform dedication

- Develop critical characteristics based upon the known safety function(s) of the item
 - Critical characteristics are tied to safety function(s)
- Develop critical characteristics based upon design of the item and known uses
 - Critical characteristics are tied to design requirements
 - Broader scope of critical characteristics is required to address all possible functions
 - Scope of dedication (functions considered) should be clearly communicated

Dedication performed by third parties

- Scope of dedication must be clear
- Considerations
 - Knowledge of past dedications performed by the supplier
 - Utility review and approval of the dedication plan
 - Identification of safety function on purchase order and confirmation that supplier understands safety function
- Guidance is available in EPRI 1016157

EPRI Sampling Guidance

- Originally published EPRI NP-7218
- EPRI TR-017218-R1 (revision) clarifies
 - Lot and batch formation for purchased items
 - Use of destructive testing on small lots
- Current basis for most licensee sampling plans
 - Available to suppliers



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Questions?

A stylized world map is centered on the slide, showing the continents of North America, South America, Europe, Africa, Asia, and Australia. The map is overlaid with a white grid of vertical and horizontal lines, creating a coordinate system across the globe. The map itself is rendered in shades of blue and white, with the landmasses appearing lighter than the surrounding oceans.

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