



Development of Industry Guidance

Clarification of 10CFR, Part 21 Requirements

Marc Tannenbaum

Project Manager

NRC Public Meeting – Rockville, Maryland

January 16, 2012

Industry Guidance and Training Areas

- Commercial Grade Computer Program Dedication
- Commercial Grade Item Dedication Process
- Use of Sampling in the Commercial Grade Item Dedication Process

Development of Guidance for Accepting Commercial Grade Computer Programs

- Current draft developed during 2011 to address design and analysis computer programs
 - Focus on design and analysis computer programs
 - Includes methodology for safety classification of computer programs
 - Guidance for accepting commercial grade computer programs using commercial grade item dedication methodology
- Currently working to complete final draft

Revision to NP-5652

Commercial Grade Item Guideline

- Definitions
 - Dedication
 - Commercial Grade Item
 - Critical Characteristic
- Documentation
 - Safety Function
 - Basis for selection of sampling plan
 - Critical characteristics and acceptance method

Revision to NP-5652

Commercial Grade Item Guideline

- Dedication by third parties
 - Application and Safety function
 - Review of dedication plans when appropriate
- Two Approaches to dedication
 - Develop critical characteristics based upon safety function(s) of the item
 - Develop critical characteristics based upon the item's design requirements

Revision to NP-5652

Commercial Grade Item Guideline

- Authentication
 - Consideration as a characteristic
 - Applicable guidance

Revision to TR-017812-R1

Use of Sampling in Commercial Grade Dedication

- Considerations when selecting sampling plan
- Documentation
 - Basis for selection of sampling plan
 - Considerations (lot homogeneity, type of testing, complexity, etc.)
 - Adjustments based upon historical data

Approach to Development of Guidance

- Input and recommendation from industry and regulator
- Formation of technical advisory group
- Iterative development of draft
- Publish completed draft
- Submit via Nuclear Energy Institute (NEI) for NRC endorsement
- Institutionalize updated guidance through communication and training



Together...Shaping the Future of Electricity