

# **Commercial Grade Dedication & Certification of Digital Equipment**

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# Discussion Topics

- Key Messages
- Integrated Action Plan (IAP) – Strategy for Modernizing Digital I&C Regulatory Infrastructure
- Current Regulatory Framework for Dedication of Commercial Grade Digital Equipment
- Regulatory Infrastructure Modernization Plan for Acceptance of Commercial Digital Equipment in Safety Critical Applications
- Status of Modernization Plan (MP) #3, “Acceptance of Digital Equipment”

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# Key Messages

- NRC Staff has undertaken activities approved under SRM-SECY-16-0070 to modernize the digital I&C regulatory infrastructure
- Integrated Action Plan (IAP) to Modernize Digital I&C Regulatory Infrastructure (ML17102B307) created with stakeholders inputs
- Staff is working with industry to produce implementable guidance
- Frequent staff engagement in public workshops and meetings with industry and other external stakeholders to reach a common understanding of the digital I&C regulatory challenges, priorities, and potential solutions

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# IAP – Strategy

- Objective: Modernize the digital I&C regulatory infrastructure to enhance the NRC’s capability to be more timely, efficient and effective in ensuring safety, and provide a consistent and predictable regulatory process
  - Tactical - Continue to prioritize and implement the regulatory activities needed to provide regulatory clarity and support industry confidence in using digital I&C (MPs #1-3 and MP #4A)
  - Strategic - Assess and implement broader modernization of regulatory infrastructure (MP #4B)

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# Modernization Plans (MPs)

- **MP #1 - Protection Against Common Cause Failures**
  - Development of guidance for using effective qualitative assessments of the likelihood of failures, use of defensive measures, bounding and coping analysis, and evaluation of the NRC's existing positions on CCF of digital I&C.
- **MP #2 - Considering Digital I&C in accordance with 10 CFR 50.59**
  - Address the need for mutual clarity between industry and NRC staff to ensure NRC guidance is being properly translated into industry actions while performing 10 CFR 50.59 evaluations of digital I&C upgrades.

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# Modernization Plans (MPs)

- **MP #3 - Acceptance of Digital Equipment**
  - Identify needed improvements to the regulatory infrastructure to ensure efficient implementation of digital devices is being appropriately evaluated by licensees, applicants, and suppliers (compliance with regulations and policy)
- **MP #4 - Assessment for Modernization of the Instrument & Control Regulatory Infrastructure**
  - Comprehensive modernization assessment to identify further improvements to the regulatory infrastructure and develop plans for accomplishing such improvements.

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# MP #3 - Acceptance of Digital Equipment

- Key Attributes:
  - I&C and other digital equipment readily available do not meet 10 CFR Part 50 Appendix B QA requirements
  - Industry and NRC staff are seeking efficient and effective means for acceptance of commercial grade digital equipment in accordance with 10 CFR Part 21
- Objectives:
  - Improvements to regulatory infrastructure for acceptance of commercial grade digital equipment for safety applications

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# Current CGD Regulatory Framework

- 10 CFR Part 21:
  - NRC regulations permit use of commercial grade items (CGI) in safety systems provided the item has been dedicated as defined in 10 CFR Part 21
  - Dedication is an acceptance process undertaken to provide reasonable assurance that a CGI to be used as a basic component will perform its intended safety function and, in this respect, is deemed equivalent to an item designed and manufactured under a 10 CFR Part 50, Appendix B, QA program
  - This assurance is achieved by **identifying the critical characteristics** of the item and **verifying their acceptability** by inspections, tests, or analyses performed by one or more of the following: commercial grade surveys; product inspections or witness at the manufacturer's facility, and analysis of historical records for acceptable performance



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# Current CGD Regulatory Framework

- EPRI TR-106439:
  - NRC endorsed EPRI TR-106439, “Guideline on Evaluation and Acceptance of Commercial-Grade Digital Equipment for Nuclear Safety Applications” contains an acceptable method for dedicating digital CGI
  - EPRI TR-106439 categorizes critical characteristics of a digital item into three areas: (1) physical characteristics, (2) performance characteristics, and (3) dependability characteristics (unique for digital items)
  - EPRI TR-106439 references EPRI NP-5652, “Guideline for Utilization of CGI in Nuclear Safety Related Applications,” which discusses four methods for verifying critical characteristics of the item: (1) special tests and inspections, (2) commercial-grade survey of supplier, (3) source verification, and (4) acceptable supplier/item performance record

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# Regulatory Framework Modernization Plan for Acceptance of Digital CGI

- IEC 61508 / 61511:
  - Acceptance process for most digital CGI comprise of a variety of technical activities conducted in significant details per guidance in EPRI TR-106439
  - Most digital CGI acceptance require first-of-a-kind efforts, involving uncertainties in duration, cost, and overall success
  - Digital safety instrumentation used in process industries such as pharmaceutical, oil & gas, and fossil power plants are certified in accordance with IEC 61508 / 61511, a suit of functional safety standards on digital items for process industry

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# Regulatory Framework Modernization Plan for Acceptance of Digital CGI

- IEC 61508 / 61511:
  - Nuclear power plant instrumentation & control have similarities in risk and equipment used to many other process industries
  - One of MP #3 task is to investigate the process used to certify digital items to Safety Integrity Levels (SIL) described in IEC 61508 / 61511
  - Objective of MP #3 is to leverage technical activities conducted for SIL-3 certification of a digital item as verification of certain dependability critical characteristics identified per EPRI TR-106439

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# Regulatory Framework Modernization Plan for Acceptance of Digital CGI

- MP #3:
  - The goal MP #3 is to:
    - Leverage global standards and best practices applicable to use of digital equipment in safety critical application
    - identify needed improvements to the regulatory infrastructure
  - The objective of any regulatory improvement is to ensure that the implementation of digital devices in nuclear power plants is being appropriately evaluated by licensees, applicants, and suppliers; and in compliance with regulations and policy

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# Status of MP #3 Activities

Activity	Schedule
Issue Regulatory Guide RG 1.164 (DG-1292), “Dedication of Commercial-Grade Items for Use in Nuclear Power Plants”	July 2017
EPRI research report on SIL certification	April 2018
Analyze acceptability 3 <sup>rd</sup> party SIL certification technical activities in relation to EPRI TR-106439 guidance for acceptance of digital equipment	CY 2018
Determine improvements to regulatory infrastructure for acceptance of digital equipment	CY 2018