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Connecting Visionaries in Radiation Safety, Science and Industry

Conrad Orlando Resort, FL – July 28th – August 1st



## 10 CFR 50.69 in RMS Applications

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Mirion Connect | Annual Users' Conference 2025
Orlando, Florida



#### **Overview**

- 10 CFR 50.69 Overview
- RMS Applications for 50.69
- Mirion's Place in 50.69Applications



## 10 CFR 50.69 Overview





#### 10 CFR 50.69

- One of the most impactful regulatory changes in recent memory
- NRC approved the final rule in October 2004
- Gaining industry momentum as results are realized & shared

#### Okay - but what is it?

- 10 CFR Part 50.69 Risk-Informed categorization and treatment of structures, systems and components for nuclear power reactors
  - 50.69(b)(1): A holder of a license to operate a light water reactor (LWR) nuclear power plant under this part; a holder of a renewed LWR license under part 54 of this chapter; an applicant for a design approval, a combined license, or manufacturing license under part 52 of this chapter; may voluntarily comply with the requirements in this section as an alternative to compliance with the following requirements for RISC-3 and RISC-4 SSCs:
    - (i) 10 CFR Part 21 [Reporting of Defects and Noncompliance]
    - (ii) The portion of 10 CFR 50.46a(b) that imposes requirements to conform to Appendix B to 10 CFR Part 50. [Vents for RCS, RV head, other core cooling systems]
    - (iii) 10 CFR 50.49 [Equipment Qualification Requirements for Safety Related Equipment]
    - (iv) 10 CFR 50.55(e) [License conditions Notifications of Defects, Failure to Comply for Substantial Safety Hazards]



- 10 CFR Part 50.69 Risk-Informed categorization and treatment of structures, systems and components for nuclear power reactors
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    - (v) The inservice testing requirements in 10 CFR 50.55a(f); the inservice inspection, and repair and replacement (with the exception of fracture toughness), requirements for ASME Class 2 and Class 3 SSCs in 10 CFR 50.55a(g); and the electrical component quality and qualification requirements in Section 4.3 and 4.4 of IEEE 279, and Sections 5.3 and 5.4 of IEEE 603-1991, as incorporated by reference in 10 CFR 50.55a(h)
    - (vi) 10 CFR 50.65, except for paragraph (a)(4). [Maintenance Rule Usually applicable to select RMS equipment]
    - (vii) 10 CFR 50.72 [Immediate notifications to NRC Emergency Classifications RMS credited in Emergency Plans]
    - (viii) 10 CFR 50.73 [Licensee event report system RMS could be reason for a licensee event report]
    - (ix) Appendix B to 10 CFR part 50 [Quality Assurance Criteria for Nuclear Power Plants and Fuel Reprocessing Plants]
    - (x) The Type B and Type C leakage testing requirements in both Options A and B of Appendix J to 10 CFR part 50, for penetrations and valves meeting the following criteria [not listed here as they are not applicable to RMS]
    - (xi) Appendix A to part 100, Sections VI(a)(1) and VI(a)(2), to the extent that these regulations require qualification testing and specific engineering methods to demonstrate that SSCs are designed to withstand the Safe Shutdown Earthquake and Operating Basis Earthquake.



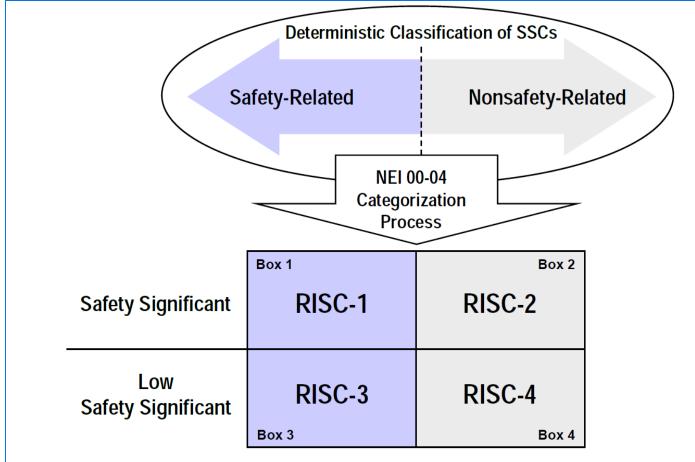


Figure 2-1
Risk Informed Safety Categorizations
Sources: 10 CFR 50.69 and NEI 00-04

10 CFR 50.69 Categorization Guidance Document. EPRI, Palo Alto, CA: 2018. 3002012984.







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#### (a) Definitions.

- Risk-Informed Safety Class (RISC)-1 structures, systems, and components (SSCs) means safety-related SSCs that perform safety significant functions.
- Risk-Informed Safety Class (RISC)-2 structures, systems and components (SSCs) means nonsafety-related SSCs that perform safety significant functions.
- Risk-Informed Safety Class (RISC)-3 structures, systems and components (SSCs) means safety-related SSCs that perform low safety significant functions.
- Risk-Informed Safety Class (RISC)-4 structures, systems and components (SSCs) means nonsafety-related SSCs that perform low safety significant functions.
- Safety significant function means a function whose degradation or loss could result in a significant adverse effect on defense-in-depth, safety margin, or risk.



- 10 CFR Part 50.69 Risk-Informed categorization and treatment of structures, systems and components for nuclear power reactors
  - 50.69(b)(2): A licensee voluntarily choosing to implement this section shall submit an application for license amendment under §50.90 that contains the following information:
    - (i) A description of the process for categorization of RISC-1, RISC-2, RISC-3, and RISC-4 SSCs.
    - (ii) A description of the measures taken to assure that the quality and level of detail of the systematic processes that evaluate
      the plant for internal and external events during normal operation, low power, and shutdown (including the plant-specific PRA,
      margins-type approaches, or other systematic evaluation techniques used to evaluate severe accident vulnerabilities) are
      adequate for the categorization of SSCs.
    - (iii) Results of the PRA review process conducted to meet §50.69(c)(1)(i).
    - (iv) A description of, and basis for acceptability of, the evaluations to be conducted to satisfy §50.69(c)(1)(iv). The evaluations
      must include the effects of common cause interaction susceptibility, and the potential impacts from known degradation
      mechanisms for both active and passive functions, and address internally and externally initiated events and plant operating
      modes (e.g., full power and shutdown conditions).
  - 50.69(c) SSC Categorization Process; (1) SSCs must be categorized as RISC-1, RISC-2, RISC-3, or RISC-4 SSCs using a categorization process that determines if an SSC performs one or more safety significant functions and identifies those functions.
    - Basis is plant-specific PRA model (severe accident scenarios) addresses internal & external initiating events, plant operating modes including those not in the plant-specific PRA.
    - Functions to be identified and considered include design basis functions and functions credited for severe accident mitigation.



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    - Provide reasonable confidence that for SSCs categorized as RISC-3, sufficient safety margins are maintained and that any potential increases in core damage frequency (CDF) and large early release frequency (LERF) resulting from changes in treatment permitted by implementation of 50.69(b)(1) and (d)(2) are small.
    - Categorization must be performed for **entire systems and structures**, **not for selected components within a system or structure**.
    - Categorization of SSCs by integrated Decision-Making Panel (IDP) staffed with expert, plant-knowledgeable members whose expertise includes, at a minimum, PRA, safety analysis, plant operation, design engineering, and system engineering.
  - 50.69(d) Alternative treatment requirements; (1) RISC-1 and RISC 2 SSCs. The licensee or applicant shall ensure that RISC-1 and RISC-2 SSCs perform their functions consistent with the categorization process assumptions by evaluating treatment being applied to these SSCs to ensure that it supports the key assumptions in the categorization process that relate to their assumed performance.



- 10 CFR Part 50.69 Risk-Informed categorization and treatment of structures, systems and components for nuclear power reactors
  - 50.69(d) Alternative treatment requirements; (2) RISC-3 SSCs. The license or applicant shall ensure, with reasonable confidence, that RISC-3 SSCs remain capable of performing their safety-related functions under design basis conditions, including seismic conditions and environmental conditions and effects throughout their service life. The treatment of RISC-3 SSCs must be consistent with the categorization process. Inspection and testing, and corrective action shall be provided for RISC-3 SSCs.
    - (i) Inspection and testing. Periodic inspection and testing activities must be conducted to determine that RISC-3 SSCs will remain capable of performing their safety-related functions under design basis conditions; and
    - (ii) Corrective action. Conditions that would prevent a RISC-3 SSC from performing its safety-related functions under design basis conditions must be conducted in a timely manner. For significant conditions adverse to quality, measures must be taken to provide reasonable confidence that the cause of the condition is determined and corrective action taken to preclude repetition.
  - 50.69(e) Feedback and process adjustment
    - (1) RISC-1, RISC-2, RISC-3, and RISC-4 SSCs. **The licensee shall review changes to the plant,** operational practices, applicable plant and industry operational experience, and, as appropriate, update the PRA and SSC categorization and treatment process. The licensee shall perform this review in a timely manner but no longer than once every two refueling outages.
  - 50.69(f)(1) The licensee or applicant shall document the basis for its categorization of any SSC under paragraph (c) of this section before removing any requirements under §50.69(b)(1) for those SSCs.



## 50.69 Impacts





## 10 CFR 50.69 Categorization Results

#### Approximate categorization results to date can be summarized as follows:

- RISC-1 ~25% of all safety-related SSCs
- RISC-3 ~75% of all safety-related SSCs
- RISC-2 ~1% of all non-safety-related SSCs
- RISC-4 ~99% of all non-safety-related SSCs







#### 10 CFR 50.69 Savings Centers

## **Projects**

- Reduce capital costs
- Examples: Vogtle MSIV Actuators, Hatch Plant Service Water Piping

## **Programs**

- Remove components from special treatment programs and extend or eliminate PMs
- Right Work at the Right Time!

# Procurement - Daily and Outage

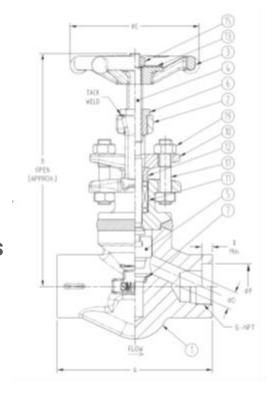
- Reduce parts cost by up to 80%
- Solve obsolescence issues
- Cut lead time in half or more



## 10 CFR 50.69 Savings Centers

Site	Description	Savings
Hatch	PSW Piping – B31.1	\$800/ft
Limerick	RHRSW Piping – ASTM NSR	\$900k
Braidwood	(21) 2" ball valves	\$1.2M

- ~50-70% savings for RISC 3 procurements
- Lead time reduction from years/months to weeks/days
  - 2022 Vogtle MSIV S/R valve unavailable due to delivery delays
  - Identified equivalent valve in stock @ distributor on site within 2 days





## 10 CFR 50.69 Impacts - Programmatic Savings

Local Leak Rate Testing [10 CFR 50 Appendix J] Quality Requirements [10 CFR 50 Appendix B]

In-service Inspection [10 CFR 50.55a(g)]

ASME XI repair & replacements, applicable portions, with limitations [10 CFR 50.55a(g)]

Maintenance Rule [10 CFR 50.65]

In-service Testing [10 CFR 50.55a(f)] Environmental Qualification [10 CFR 50.49]

Event Reporting [10 CFR 50.55(e)]

Seismic Qualification [Portions of Appendix A to 10 CFR Part 100] Deficiency Reporting [10 CFR Part 21] Applicable Portions of IEEE standards [10 CFR 50.55a(h)] Notification Requirements [10 CFR 50.72, 50.73]

#### **Reasonable Assurance**

(Trust but Verify)

- Deterministic approach
- Safety function confirmed using Special Treatments defined by regulation



#### **Reasonable Confidence**

(Trust but Monitor)

- Risk based approach
- Safety function confirmed via Alternative Treatments defined by licensee

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## 10 CFR 50.69 Impacts - Procurement - Daily & Outage

- Up to 80% reduction in parts costs
  - ~30% reduction in Mirion parts costs
- Sites spending \$1-1.5M on RISC 3 & 4 should save ~50% of that
  - Vogtle MSIV cable: 6-12 months -> avoided JCO
- Lead time reductions
- Obsolescence increased options & easier to address with Reasonable Confidence



## 10 CFR 50.69 Impacts - Procurement - Daily & Outage

Component Type	Average Savings	
Gauge, Pressure	85%	
Valve	79%	
Grease and Lubricant	75%	
Oring	68%	
Filter	65%	
Pump	60%	
Regulator	60%	
Relay	58%	
Hose	56%	
Gasket	53%	
Bellows	50%	
Valve Component	49%	
Strainer	48%	
Fastener	46%	
Pipe and Plate	37%	
Electrical Component	32%	
Switch, Pressure	31%	



## 10 CFR 50.69 Categorization Cost

- · Complete system: \$50-150k, avg. \$100k
- Requires ~3 months to go through categorization process
  - Not an emergency bailout
- Even 100% RISC 1 would have value



## RMS Applications in 50.69





## 10 CFR 50.69 – RMS Applications

#### Our site has been approved to use 50.69 and has a 50.69 program - now what?

Entire RMS must be recategorized by the Integrated Decision-Making Panel (IDP).

#### Done! Now what?

- Great! You can start realizing the savings per 10 CFR 50.69 by reducing requirements for certain monitors. Most prominently, SSCs that were recategorized from standard Safety Related SSCs to RISC-3 (Safety Related, Low Safety Significance) will see the largest savings.
- Replacement Parts Savings per spare part purchased now as non-safety instead of safety-related
- Full Monitor Replacements Radiation monitors replaced as non-safety related instead of safety-related







## 10 CFR 50.69 – RMS Applications

#### HOLD ON. NOT QUITE YET.

- The replacement & spare equipment needs to ensure there is **reasonable confidence** that the design function of the equipment and assumptions under which the SSC was recategorized under 50.69.
- The licensee approved to utilize 50.69 for recategorization defines what reasonable confidence is. Alternative treatments per 50.69 and the licensee 50.69 program is the way forward.
- From before....

50.69(d) Alternative treatment requirements; (2) RISC-3 SSCs. The license or applicant shall ensure, with reasonable confidence, that RISC-3 SSCs remain capable of performing their safety-related functions under design basis conditions, including seismic conditions and environmental conditions and effects throughout their service life. The treatment of RISC-3 SSCs must be consistent with the categorization process. Inspection and testing, and corrective action shall be provided for RISC-3 SSCs.







# RMS Applications for 50.69 (Site-Dependent) – SR to RISC-3

#### **PWRs**

- Containment High Range Radiation Monitors
- Fuel Building Vent Monitors
- Stack Monitors
- Containment Atmosphere Monitors
- Control Room Air Intake Monitors

#### **BWRs**

- Drywell High Range Radiation Monitors
- Fuel Pool Monitors
- Stack Monitors
- Containment Atmosphere Monitors
- Control Room Air Intake Monitors



#### **Alternative Treatments for RISC-3**

## Consult your 50.69 Program but ultimately you as the engineer decide.

- Consider the design function and the internal/external events the SSC will be exposed to while carrying out its design function
  - Example: RISC-3 Post-Accident Effluent Monitor
    - Post-accident environment (temp, humidity, pressure, radiation)
    - Withstand OBE and SSE (seismic) and continue operation
    - EMC (if design function is to provide reliable and continuous readout of monitored variable, then equipment should not be susceptible to EMI / RFI)
    - Monitor design is of good quality and based on solid engineering design and analysis. (QA program would be desired)

# As part of EC Package / Change Driver for Plant, Need to Justify Reasonable Confidence.

- What is listed on the left of this slide does sound like requirements for a standard Safety Related monitor, but if you can justify why the design function is still met with less rigorous documentation, that is your engineering judgement.
- If your 50.69 program defines specific alternative treatments for certain RISC-3 equipment, then you would need to follow those.
- There is a lower-risk way too...



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# Mirion's Place in 50.69 Applications





## Mirion's Approach to Safety Related Design

Mirion ATL's approach to Safety Related design is based on Commercial Grade Dedication (CGD)

The modular building blocks of the RAMSYS equipment <u>can</u> be purchased Safety Related in many cases, but not necessarily.

- Integration of RAMSYS equipment purchased from LMN and MUC onto skids and into custom configurations is performed by Mirion's Atlanta office.
  - Purchase additional parts (e.g., valves, tubing, fittings, sample pump, skid interconnecting cabling, etc.) locally as Commercial
    Off-The-Shelf items.
  - LMN and MUC RAMSYS equipment can also be purchased NSR / COTS.
- Mirion's Atlanta office would then perform commercial grade dedication, including testing of the piece-parts and assemblies to ensure they meet the critical characteristics identified for each item.
- Successful testing of all critical characteristics ensure the equipment can perform its safety related design function.
- Equipment is then considered Commercial Grade Dedicated and can be supplied as Safety-Related equipment. Documentation of successful CGD must be retained.



## **Radiation Monitoring Systems**

#### **QA & Standards Compliance**

- Three manufacturing / engineering sites:
- Atlanta, GA, US applications engineering, final assembly, project management & customer support Americas
  - ISO9001
  - 10CFR50 App. B / NQA-1 Atlanta site is NUPIC-audited
- Lamanon, FR electronics, detectors, software, qualification
  - ISO9001
  - 10CFR50 App. B / NQA-1
- Munich, DE detectors, qualification
  - ISO9001
  - 10CFR50 App. B
- RAMSYS instrumentation can be supplied as 1E safety related in accordance with IEEE 323 and IEC 60780 and meets:
- EMI/RFI test IEC 61000-6-2, IEC 61000-6-4, IEC 61000-4-x, EN 550022
- EPRI TR 102323, RG1.180, MIL STD 461E
- Seismic tests IEEE 344, IEC 60980, IEC 60068-3-3
- TID IEC 60544-2
- MTBF MIL HDBK 217F
- Aging analysis IEEE 101



## **Radiation Monitoring Systems**

#### **RAMSYS Qualifications**

**TEST SEQUENCE:** according to IEC 60780 and IEEE 323

Functional and radiological tests EMI/RFI and power supply tests Aging:

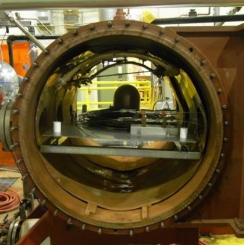
- Storage tests
- Climate tests
- Vibration and shock tests (2g de 1 to 500Hz, 30g 18ms)
- Endurance test (500 hrs at 45°C)
- Total integrated dose (100 Gy [1E4 rad] for mild environment, up to 2 MGy [2E8 rad] for harsh environment)
- Seismic test
- Loss-of-Coolant Accident (LOCA) tests (217°C and 6 bars + chemical spray)



**Climatic tests** 



**Vibration & shocks** 



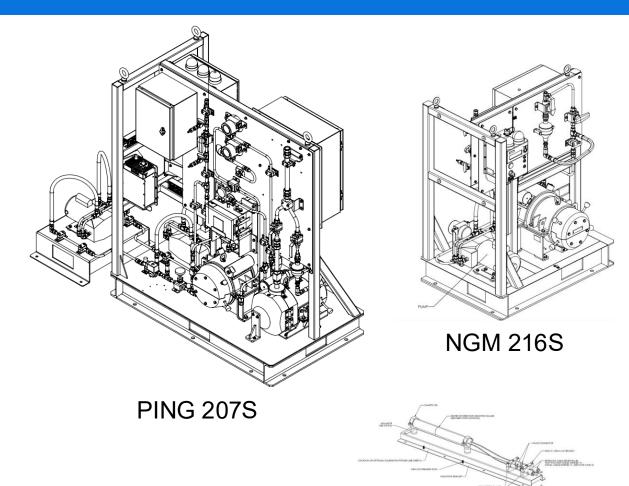
**LOCA test** 



Seismic test

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## CGD Process Benefits 50.69 Customers



KG 50 SEC-2 Part of GIM 206K

- Existing monitor designs that have been sold as Safety Related in the past have documentation of testing to IEEE 323, IEEE 344, EMC standards (e.g., IEC 61000-4), whether these were parts of type tests in previously (LMN-performed for example)
- Site should define which documents are required in procurement documents to support alternative treatments. The supplied documentation can be used in EC packages (or other change driver if applicable) to justify reasonable confidence because the equipment being supplied is physically the same as what is provided for a safety related application – it just doesn't have all the additional safety related paperwork with it.
  - Environmental Qualification Type Test
  - Seismic Qualification Type Test
  - Material Procurement Evaluation Reports (CGD Documents)
  - EMC Test Reports (Surge Protection / ESD, Emissions, Immunity)
- For new customizations that are not directly addressed in existing qualification documents, existing documents / tested configs can be used to create engineering justifications for similar, new configurations. If Mirion needs to update these qualification reports to address a new configuration, there will be NRE associated with that.



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## Mirion's 50.69 Positioning

"I've never met an RMS application that couldn't be recategorized"\*

- Commercial grade CGID S/R
- Reasonable Confidence
  - Seismic / TID / EMI / Software
- Watts Bar Off-line Air Monitors
  - Entire qualification package
- BOMs have S/R & NSR part # columns
- Best positioned in the US RMS industry
- \* Quote by Carrie Gilbreath, SNC 50.69 Program Owner





#### 50.69 Considerations

- Most difficult points to overcome:
  - Procurement (leadership buy-in vital to success)
  - EQ
- Procedures & project implementation
- Regulators
- Education
- Vendors
  - Revenue
  - Cost of doing business



#### 50.69 Considerations

- Constellation: Art Mills
  - Procurement Eng. 50.69 committee member
  - Arthur.Mills@constellation.com
- Constellation: Bob Hoke (RETIRED)
  - Procurement Eng. Mngr 50.69 committee chair
- Southern Nuclear: Carrie Gilbreath
  - SNC 50.69 Program Owner
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- BWROG 50.69 Project Lead: Brad Tyers
  - bradley.tyers@ge.com



# Thank you



