



Part 21: Requirements & New Guidance (RG 1.234 & NEI 14-09) and Applying Appendix B & Part 21 - Augmented Quality, Along with Risk and Procurement Requirements

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Part 21: Requirements & New Guidance (RG 1.234 & NEI 14-09)





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Topics for Part 21: Requirements & New Guidance (RG 1.234 & NEI 14-09)

- **Problem Statement/Solution**
- **Notable Clarifications**



Part 21: Requirements & New Guidance (RG 1.234 & NEI 14-09)

Problem Statement/Solution

- NRC guidance was never revised to incorporate amendments or issues identified over time with 10 CFR Part 21.
- NUREG 0302, "Remarks Presented Questions/Answers Discussed) at Public Meetings to Discuss Regulations (10 CFR Part 21) for Reporting of Defects and Noncompliance," Revision 1, dated July 12-26, 1977. (ML062080399)



Part 21: Requirements & New Guidance (RG 1.234 & NEI 14-09)

Problem Statement/Solution

- The NRC determined that Part 21 Rulemaking was a low priority as part of Project Aim 2020.
- Solution was to develop guidance with the Nuclear Energy Institute (NEI).
- Goal was to address longstanding clarification issues with specific meaning of certain terms in Part 21.
- Result of collaborative efforts was development of NEI 14-09, "Guidelines for Implementation of 10 CFR Part 21 Reporting of Defects and Noncompliance," Revision 1, dated February 2016. (ML14085A084)



Part 21: Requirements & New Guidance (RG 1.234 & NEI 14-09)

Problem Statement/Solution

- Regulatory Guide (RG) 1.234, “Evaluating Deviations and Reporting Defects and Noncompliance Under 10 CFR Part 21, Revision 0, dated April 2018. (ML17338A072)
 - There are no Regulatory Positions in RG 1.234; however,
 - The “Background” section does have *Notable Clarifications* for certain guidance contained in NEI 14-09 related to posting and training requirements.



Part 21: Requirements & New Guidance (RG 1.234 & NEI 14-09)

Notable Clarifications

Posting

- NEI 14-09 interprets the regulation to allow postings to be hard copies, digital copies, or a combination of both.
- Staff clarification: If posting is not practicable at remote work location, digital access is acceptable.
 - §21.6 Requirements
 - Current copy of Part 21,
 - Section 206 of the Energy Reorganization Act of 1974, and
 - Procedure to evaluate potential defects with appropriate reporting (timeliness) requirements.



Part 21: Requirements & New Guidance (RG 1.234 & NEI 14-09)

Notable Clarifications

Training

- NEI 14-09 interprets the regulation that it is good practice to provide familiarization and training on Part 21. Also, an organization should designate individuals capable of assisting staff in the Part 21 process.
- Staff clarification: Personnel covered under §50.120, “Training and qualification of nuclear power plant personnel,” should be trained in Part 21 if they are considered to be performing relevant tasks under the associated evaluation criterion of the regulation.



Part 21: Requirements & New Guidance (RG 1.234 & NEI 14-09)

Notable Clarifications

Delivered

There is no definition on *delivered* as used under *defect*.

- NEI 14-09 interprets the regulation as a basic component is considered *delivered* when the purchaser has taken control of the item or service following completion of the acceptance process (i.e., receipt inspection and in some cases acceptance functional testing).
- For certified designs, *delivered* is based upon whether it has been offered for use.



Part 21: Requirements & New Guidance (RG 1.234 & NEI 14-09)

Notable Clarifications

Discovery/Point of Discovery

Under Part 21, *discovery* means the completion of the documentation first identifying the existence of a deviation or failure to comply potentially associated with a substantial safety hazard (SSH)...

- NEI 14-09 interprets the *point of discovery* as not being complete until the documentation identifying the existence of a deviation or failure to comply is complete.
 - In some instances, an initial investigation (e.g., inspection(s), test(s)) may be necessary to determine whether a deviation or failure to comply exists.
 - The 60-day 'clock' for completing the evaluation begins at the *point of discovery*.



Part 21: Requirements & New Guidance (RG 1.234 & NEI 14-09)

Notable Clarifications

Notification and Reporting

- *Notification* means the telephonic communication to the NRC Operations Center or written transmittal of information to the NRC Document Control Desk.
- *Notification* includes both the telephonic communications and written transmittals of information to the NRC. The term *reporting* is used to only mean written *notification* to the NRC in the form of a *report*.
- A written *report* transmitted to the NRC is required to communicate the attributes of a Reportable condition pursuant to 10 CFR 21.21(d) (where a deviation or failure to comply could create an SSH, if it were to remain uncorrected) or a 60-Day Interim *Notification* pursuant to 10 CFR 21.21 (a)(2) (where the evaluation will continue past the 60 days from the Point of Discovery).
- A *notification* may take the form of telephonic communication or Facsimile to the NRC. All telephonic communications shall be followed by a written *report*.



INTERMISSION





United States Nuclear Regulatory Commission

Protecting People and the Environment

Applying Appendix B & Part 21 - Augmented Quality, Along with Risk and Procurement Requirements

QUALITY ASSURANCE AND VENDOR INSPECTION BRANCH

OFFICE OF NUCLEAR REACTOR REGULATION



Definitions & Terms in 10 CFR 50.69

RISC-1: Safety-Related SSCs that perform safety significant functions.

RISC-2: Nonsafety-related SSCs that perform safety significant functions.

RISC-3: Safety-related SSCs that perform low safety significant functions.

RISC-4: Nonsafety-related SSCs that perform low safety significant functions.

Alternative Treatment Requirements:

- RISC 1&2: treatment being applied to these SSCs to ensure that it supports the key assumptions in the categorization process that relate to their assumed performance.
- RISC 3&4: 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 (**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.)



Definitions & Terms in the Federal Register (FR)

Treatment: As a general term refers to activities, processes, and/or controls that are performed or used in the design, installation, maintenance, and operation of SSCs as a means of:

- Specifying and procuring SSCs that satisfy performance requirements;
- Verifying over time that performance is maintained;
- Controlling activities that could impact performance; and
- Providing assessment and feedback of results to adjust activities as needed to meet desired outcomes.

Treatment includes, but is not limited to, quality assurance, testing, inspection, condition monitoring, assessment, evaluation, and resolution of deviations.

The distinction between “treatment” and “special treatment” is the degree of NRC specification as to what must be implemented for particular SSCs or for particular conditions.

Reasonable Confidence: A somewhat reduced level of confidence as compared with the relatively high level of confidence provided by the current special treatment requirements.



Alternative to compliance with the following requirements for RISC-3 and RISC-4:

- (i) 10 CFR part 21.
- (ii) The portion of 10 CFR 50.46a(b), "Acceptance criteria for emergency core cooling systems for light-water nuclear power reactors," that imposes requirements to conform to Appendix B to 10 CFR part 50.
- (iii) 10 CFR 50.49.
- (iv) 10 CFR 50.55(e).
- (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).



Alternative to compliance with the following requirements for RISC-3 and RISC-4:

(vii) 10 CFR 50.72.

(viii) 10 CFR 50.73.

(ix) Appendix B to 10 CFR Part 50.

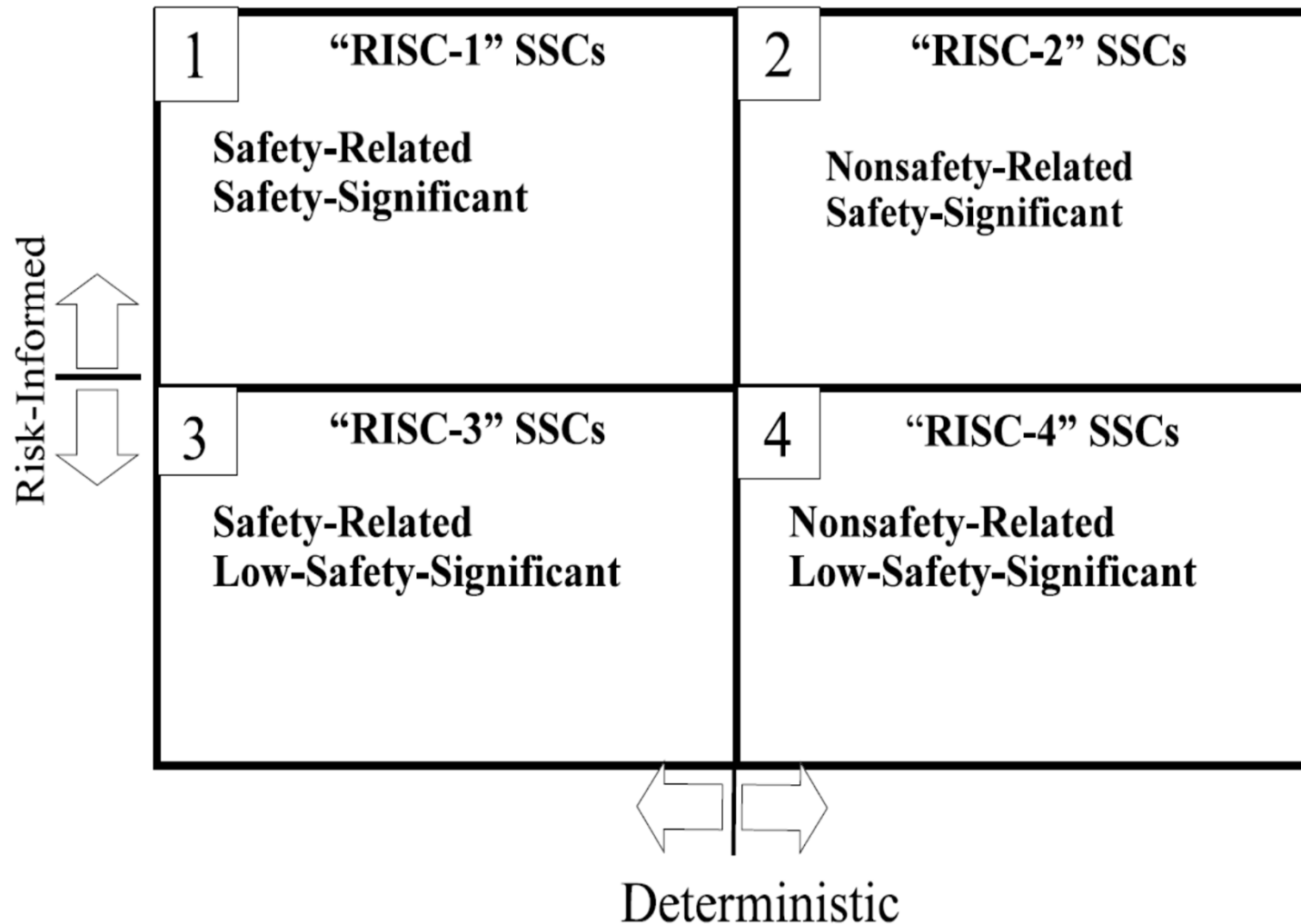
(x) The Type B and Type C leakage testing requirements in both Options A and B of Appendix J to 10 CFR part 50, for penetrations and valves meeting the following criteria:

- (A) Containment penetrations that are either 1-inch nominal size or less, or continuously pressurized.
- (B) Containment isolation valves that meet one or more of the following criteria:
 - (1) The valve is required to be open under accident conditions to prevent or mitigate core damage events;
 - (2) The valve is normally closed and in a physically closed, water- filled system;
 - (3) The valve is in a physically closed system whose piping pressure rating exceeds the containment design pressure rating and is not connected to the reactor coolant pressure boundary; or
 - (4) The valve is 1-inch nominal size or less.

(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.



Four Risk-Informed Safety Class (RISC) Categories





RISC-1

1

“RISC-1” SSCs

Safety-Related Safety-Significant

FR Discussion on RISC-1:

§50.69(d)(1) does not require licensees or applicants to evaluate the application of special treatment requirements to RISC-1 SSCs. The special treatment requirements remain intact and unchanged...

Reg Guide 1.201

- RISC-1 SSCs are safety-related SSCs that the risk-informed categorization process determines to be significant contributors to plant safety.
- Licensees must continue to ensure that RISC-1 SSCs perform their safety-significant functions consistent with the categorization process, including those safety-significant functions that go beyond the functions defined as safety-related for which credit is taken in the categorization process.



RISC-2

2

“RISC-2” SSCs

Nonsafety-Related Safety-Significant

FR Discussion on RISC-2:

It is not the intent of §50.69(d)(1) to simply extend special treatment Requirements such as Appendix B to RISC-1 and RISC-2 beyond design basis functions.

RISC-2 SSCs are those that are defined as nonsafety-related, although the risk-informed categorization process determines that they are significant contributors to plant safety on an individual basis.

The NRC staff recognizes that some RISC-2 SSCs **may not have existing special treatment requirements**.

As a result, **the focus for RISC-2 SSCs is on the safety-significant functions for which credit is taken in the categorization process.**



RISC-3

3

“RISC-3” SSCs

Safety-Related Low-Safety-Significant

FR Discussion on RISC-3: Fracture Toughness, Voluntary Consensus Standards, §50.59 Applicability, Exemption from special treatment for qualification methods for environmental conditions and effects and seismic conditions, Corrective Actions.

RISC-3 SSCs are those that are defined as safety-related, although the risk-informed categorization process determines that they are not significant contributors to plant safety.

Special treatment requirements are **removed** for RISC-3 SSCs and **replaced** with **high-level requirements**.

These **high-level requirements** are intended to provide sufficient regulatory treatment, such that these SSCs are still expected to perform their safety-related functions under design-basis conditions, albeit at a reduced level of assurance compared to the current special treatment requirements.

§50.69 does not allow these RISC-3SSCs to lose their functional capability or be removed from the facility.



RISC-4

4

“RISC-4” SSCs

**Nonsafety-Related
Low-Safety-Significant**

RISC-4 SSCs are those that are defined as nonsafety-related, and that the risk-informed categorization process determines are not significant contributors to plant safety.

Section 50.69 does not impose alternative treatment requirements for these RISC-4 SSCs.

As with the RISC-3 SSCs, changes to the design bases of RISC-4 SSCs must be made in accordance with current applicable design change control requirements (if any), such as those set forth in 10 CFR 50.59



Treatment Requirements

The final rule applies treatment requirements to SSCs commensurate with their safety significance.

RISC-1 and RISC-2

- For SSCs determined by the IDP to be safety significant (*i.e.*, RISC-1 and RISC-2 SSCs), § 50.69 maintains the current regulatory requirements (*i.e.*, it does not remove any requirements from these SSCs) for special treatment. These current requirements are adequate for addressing design basis performance of these SSCs. Additionally, § 50.69(d)(1) requires that sufficient treatment be applied to support the credit taken for these SSCs for beyond design basis events.
- In some cases, licensees might need to enhance the treatment applied to RISC-1 or RISC-2 SSCs to support the credit taken in the categorization process, or conversely adjust the credit for performance of the SSC in the categorization process to reflect actual treatment practices and/or documented performance capability. In addition, § 50.69(e) requires monitoring and adjustment of treatment processes or categorization decisions as needed based upon operational experience.



Treatment Requirements

RISC-3

- Section 50.69(d)(2) imposes requirements that are intended to maintain RISC-3 SSC design basis capability.
- § 50.69(d)(2) requires that licensees or applicants 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.
- § 50.69(d)(2) contains **inspection, testing**, and **corrective action** requirements, and in addition requires that the treatment of RISC-3 SSCs be consistent with the categorization process. The requirements are performance-based and give licensees the flexibility to implement treatment that they have determined is needed, commensurate with the low safety significance of the SSCs in order to provide reasonable confidence that their safety-related functional capability is maintained.



Treatment Requirements

RISC-4

- Section § 50.69 does not impose any new treatment requirements on RISC-4 SSCs. Instead, RISC-4 SSCs are simply removed from the scope of any applicable special treatment requirements identified in § 50.69(b)(1).
- Requirements applicable to RISC-4 SSCs not removed by § 50.69(b)(1) continue to apply.

Through the application of § 50.69, RISC-3 and RISC-4 SSCs are removed from the scope of the specific special treatment requirements listed in § 50.69(b)(1).



Reporting Requirements under Part 21 and §50.55(e)

RISC-1 SSCs **ARE** subject to the reporting requirements in Part 21 and §50.55(e) because of their high safety significance.

RISC-2 SSCs are **NOT** subject to the reporting requirements in Part 21 and §50.55(e) because they are **NOT** safety related.

RISC-3 are **NOT** subject to the reporting requirements in Part 21 and §50.55(e) because of their low safety significance.

RISC-4 SSCs continue to be beyond the scope of, and **NOT** subject to, Part 21 and 50.55(e).

** Thus, a vendor who supplied a safety-related component to a licensee that was subsequently classified by the licensee as RISC-3 would no longer be legally obligated to comply with Part 21 or § 50.55(e) reporting requirements.



Questions?

