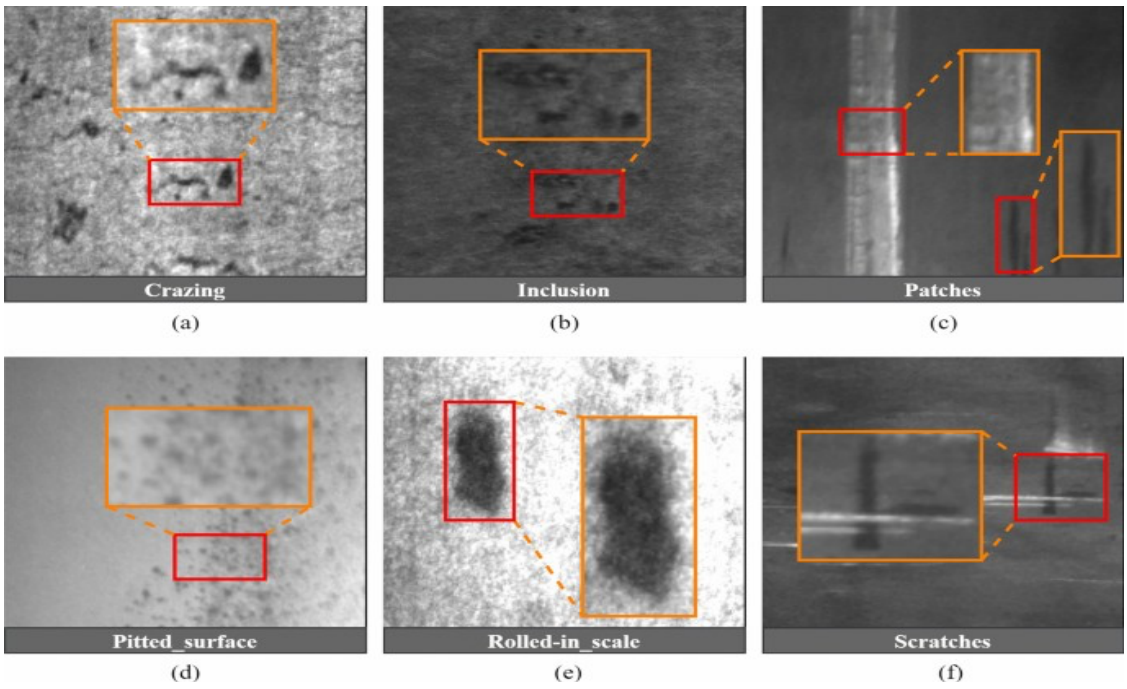
10 CFR Part 21: Purpose, Scope, Timelines, and Reporting Timeframes for Nuclear Industry Suppliers



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1. Introduction

Title 10 of the Code of Federal Regulations Part 21, commonly called 10 CFR Part 21, explains when certain nuclear-related problems must be reported to the U.S. Nuclear Regulatory Commission. The rule focuses on defects and failures to comply that could create a substantial safety hazard. In simple terms, Part 21 helps ensure that safety-related problems are evaluated and reported quickly before they can affect nuclear safety.

This article explains the purpose and scope of 10 CFR Part 21 in plain language. It also summarizes the required evaluation and reporting timelines. These timelines are important for licensees, applicants, suppliers, dedicating entities, and other organizations that support nuclear safety-related work.

This information is useful for quality assurance personnel, engineers, procurement specialists, supplier quality representatives, auditors, corrective action program owners, commercial-grade dedication personnel, and managers who work with nuclear safety-related items or services. It is also helpful for suppliers and service providers who need to understand when a technical issue, nonconformance, or failure to comply may require evaluation and reporting under 10 CFR Part 21.

2. Purpose of 10 CFR Part 21

The primary purpose of 10 CFR Part 21 is to implement Section 206 of the Energy Reorganization Act of 1974. The rule requires certain individuals and organizations to notify the U.S. Nuclear Regulatory Commission when they obtain information that reasonably indicates a defect or failure to comply exists and that the condition could create a substantial safety hazard. In practical terms, Part 21 creates a formal regulatory pathway for identifying, evaluating, and reporting safety-significant issues involving nuclear facilities, activities, and basic components.

The regulation is not intended to capture every nonconformance, documentation error, or quality issue. Instead, it focuses on conditions that could affect the ability of a structure, system, component, activity, or basic component to perform a safety-related function. This distinction is important because a deviation must be evaluated to determine whether it rises to the level of a reportable defect or failure to comply.

10 CFR Part 21 is especially important for companies that implement 10 CFR Part 50, Appendix B, or ASME NQA-1 quality assurance programs. These programs control work that can affect safety-related structures, systems, components, and basic components used in nuclear applications. Appendix B establishes quality assurance requirements for nuclear power plants and fuel reprocessing plants. ASME NQA-1 provides a widely used industry framework for nuclear quality assurance activities such as design, procurement, fabrication, testing, inspection, and documentation. In practice, a quality assurance program must also help the organization identify, evaluate, communicate, and report defects or failures to comply when safety-related items or services are involved.

3. Regulatory Drivers and Industry Applicability

10 CFR Part 21 is driven by federal nuclear safety law and NRC oversight. Its legal basis comes primarily from Section 206 of the Energy Reorganization Act of 1974. That law requires prompt NRC notification when responsible individuals obtain information that reasonably indicates a defect or failure to comply could create a substantial safety hazard. The rule is also supported by the Atomic Energy Act of 1954 and other NRC regulations that govern licensed nuclear activities, materials, facilities, and safety-related components.

The regulation applies to the nuclear industry. This includes commercial nuclear power generation, nuclear fuel cycle work, radioactive materials activities, independent spent fuel storage, high-level radioactive waste activities, and organizations that provide basic components or related services for NRC-regulated facilities and activities. In practice, Part 21 can apply anywhere in the nuclear supply chain where safety-related items or services are designed, purchased, manufactured, tested, dedicated, installed, or maintained.

Organizations that may need to comply include NRC licensees, applicants, construction permit holders, combined license holders, suppliers of basic components, dedicating entities, engineering firms, manufacturers, fabricators, testing laboratories, commercial-grade dedication organizations, and service providers. The key question is whether the organization's work affects a basic component or safety-related function. This means an organization does not have to be located at a nuclear plant to have Part 21 responsibilities. If it supplies items, services, software, analyses, or documentation for safety-related use, 10 CFR Part 21 may apply.

4. Scope of 10 CFR Part 21

10 CFR Part 21 applies broadly across the nuclear supply chain. It applies to entities that hold or apply for NRC licenses or permits, organizations that construct or supply basic components for NRC-regulated facilities or activities, and directors or responsible officers of those organizations. The rule also applies to dedicating entities that accept commercial-grade items or services for use as basic components in safety-related applications.

The scope includes facilities and activities regulated under the Atomic Energy Act and NRC regulations, including production and utilization facilities, independent spent fuel storage installations, and activities involving source, byproduct, or special nuclear material where Part 21 is applicable. Suppliers of basic components are included because defects may originate in design, manufacturing, testing, procurement, dedication, or documentation activities before an item reaches the licensee.

5. Key Terms and Concepts

Most key terms used in the nuclear regulatory framework are defined in NRC regulations, including 10 CFR 50.2. The following terms are especially important when applying 10 CFR Part 21:

- **Basic component:** A structure, system, component, or part that affects a safety function, including items designated under an Appendix B quality assurance program or commercial-grade items that have successfully completed dedication.
- **Deviation:** A departure from technical or quality requirements included in procurement documents or applicable design requirements.
- **Defect:** A deviation in a basic component that, after evaluation, could create a substantial safety hazard.
- **Failure to comply:** A failure to meet applicable NRC requirements, orders, licenses, or regulations that relate to a substantial safety hazard.

- **Substantial safety hazard:** A loss of safety function or condition that could significantly affect the ability to protect public health and safety.

Note that a simple way to understand the difference between a deviation and a defect is this: a deviation is a potential problem, while a defect is a deviation that has been evaluated and found to have possible safety significance. Not every deviation becomes a defect. The evaluation determines whether the issue is reportable under Part 21.

6. Evaluation Timeline

When a deviation or failure to comply is identified, the organization subject to Part 21 must evaluate the condition as soon as practicable. Except in specific circumstances, the evaluation must be completed within **60 days** of discovery. Discovery generally occurs when documentation first identifies the existence of a deviation or failure to comply. The 60-day period is intended to ensure that potentially safety-significant issues are evaluated promptly and are not allowed to remain unresolved.

If the evaluation cannot be completed within **60 days**, an interim report must be prepared and submitted to the NRC within **60 days** of discovery. The interim report should describe the deviation or failure to comply being evaluated and state when the evaluation is expected to be completed. This requirement ensures regulatory visibility when additional time is needed to determine whether the issue is reportable.

7. Supplier Evaluation Responsibilities

Suppliers play a critical role in the Part 21 process because they may be the first organization to identify a deviation affecting a basic component. If a supplier discovers a deviation or failure to comply but determines that it does not have the capability to perform

the required evaluation, the supplier must notify the affected purchasers or licensees within **five (5) working days** of making that determination. This allows the purchaser or licensee to perform the required evaluation and determine whether the condition is reportable.

8. Reporting Timeframes

The reporting timeline is easier to understand as a sequence of required actions. First, the organization completes the evaluation. Second, if the issue is reportable, a director, responsible officer, or designated individual must be informed as soon as practicable and within **five (5) working days** after the evaluation is completed. Third, after that person is informed, the organization must notify the NRC Operations Center within **two (2) days** by telephone or facsimile. This quick notice gives the NRC prompt awareness of a potential substantial safety hazard.

Fourth, the organization must submit a written follow-up report within **30 days** after the responsible officer, director, or designated individual is informed. The written report is the formal record of the issue. It should identify the reporting organization, the affected facility or basic component, the nature of the defect or failure to comply, the possible safety impact, when the information was obtained, corrective actions taken or planned, and any advice provided to affected purchasers, licensees, or other organizations.

9. Summary of Key Timelines

Step	Timeframe	Plain-Language Purpose

Evaluate the issue	As soon as practicable and generally within **60 days** of discovery	Decide whether the issue is reportable.
Submit interim report, if needed	Within **60 days** of discovery	Tell the NRC the evaluation is still in progress.
Supplier notifies purchaser when unable to evaluate	Within **five (5) working days** of that determination	Let the purchaser or licensee complete the evaluation.
Inform responsible management	Within **five (5) working days** after evaluation completion	Make sure responsible leadership knows the issue is reportable.
Notify the NRC Operations Center	Within **two (2) days** after responsible management is informed	Provide quick phone or facsimile notice of the potential safety issue.
Submit written NRC report	Within **30 days** after responsible management is informed	Provide the formal written record and corrective action information.

10. Importance of Strong Part 21 Implementation

Effective Part 21 implementation depends on clear procedures, trained personnel, strong corrective action processes, and well-defined procurement requirements. Organizations should screen deviations for potential Part 21 applicability, assign evaluation responsibilities promptly, and ensure suppliers understand when Part 21 requirements apply. Procurement documents should clearly identify when items or services are basic components and when Part 21 obligations must be flowed down to suppliers.

A strong Part 21 program also depends on timely communication among suppliers, purchasers, dedicating entities, and licensees. Delays in identifying, evaluating, or communicating deviations can affect the organization's ability to determine reportability within the required timeframe. For this reason, Part 21 should be integrated with

nonconformance reporting, corrective action, commercial-grade dedication, procurement, and supplier oversight processes.

11. Government-Industry Data Exchange Program

The Government-Industry Data Exchange Program, commonly known as GIDEP, is a shared technical information program for government and industry members. It is managed through the Defense Standardization Program Office. In plain language, GIDEP gives members a way to learn about known technical problems before those problems affect their own work. GIDEP is not an NRC reporting system and does not replace 10 CFR Part 21 reporting. However, it can support a strong Part 21 program by helping organizations identify known failures, counterfeit or suspect counterfeit items, nonconformances, product changes, obsolescence concerns, and reliability issues.

GIDEP's purpose is to share technical information so organizations can avoid repeating known problems. This information can improve safety, reliability, readiness, quality, procurement decisions, and life-cycle cost control. GIDEP data may include failure experience reports, alerts, safe-alerts, problem advisories, suspect counterfeit reports, nonconformance information, product change notices, obsolescence notices, engineering data, reliability data, metrology data, and urgent data requests.

GIDEP processes generally include screening and reporting. Screening means searching GIDEP data for part numbers, suppliers, materials, equipment, software, product lines, or known issue reports. This can be done during procurement, design, commercial-grade dedication, receiving inspection, corrective action, or supplier

evaluation. Reporting means submitting useful technical information when an organization identifies a significant nonconformance, suspected or confirmed counterfeit item, failure experience, safety concern, product change, obsolescence issue, or other GIDEP data item.

Membership and active participation are useful because they give organizations access to shared experience from other government and industry members. For nuclear suppliers and organizations supporting safety-related work, GIDEP can strengthen procurement controls, counterfeit item prevention, commercial-grade dedication, supplier surveillance, corrective action, and obsolescence management. Reporting incidents to GIDEP also helps other members recognize affected parts, suppliers, or processes before the same issue is repeated elsewhere. This type of shared learning supports safety, quality, readiness, and cost avoidance.

12. Key Takeaway

The most important point is that Part 21 is a timely reporting rule for safety-significant issues. Organizations should evaluate potential problems within 60 days, inform responsible management within five (5) working days after the evaluation is complete, notify the NRC Operations Center within two (2) days when the issue is reportable, and submit the written report within 30 days. A clear process procedure helps organizations meet these deadlines and protect nuclear safety, enhancing the organization's nuclear safety culture.

13. Conclusion

10 CFR Part 21 is a key nuclear safety reporting regulation. It helps ensure that defects and failures to comply are identified, evaluated, communicated, and reported when they could create a substantial safety hazard. The rule applies across the nuclear supply chain, including licensees, applicants, suppliers, dedicating entities, and responsible officers. By using clear procedures and meeting required timelines, organizations can strengthen compliance, improve communication, and support NRC oversight of safety-significant conditions.

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Author Information

Laura Suddath is an NQA-1 subject matter expert and quality assurance professional with experience supporting nuclear quality programs, supplier evaluation and audit, Commercial Grade Dedication guidance, technical documentation, and implementation of quality requirements for safety-related work. Laura is a Quality Engineer, Lead Auditor (AS9100 and NQA-1), and Certified Welding Inspector whose work focuses on translating complex nuclear regulatory and code requirements into practical, auditable controls for engineering, procurement, and fabrication activities.

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For information or questions about this article, please contact Laura Suddath at laurasuddath@gmail.com.