



U.S.NRC

United States Nuclear Regulatory Commission

Protecting People and the Environment

10 CFR Part 21 Rulemaking

Sabrina Atack



10 CFR Part 21 Rulemaking Status

- ▶ SECY-11-0135, “Staff Plans to Develop the Regulatory Basis for Clarifying the Requirements in Title 10 of the *Code of Federal Regulations* Part 21, “Reporting of Defects and Noncompliance,” (ML112430138)
- ▶ Revision 0 of draft regulatory basis for rulemaking, December 5, 2012 (ML12248A200)
- ▶ Public Meeting, January 24, 2013 (ML13052A700)
- ▶ NEI Letter to NRC, March 11, 2013 (ML13073A195)



10 CFR Part 21 Rulemaking Status

- ▶ Series of public meetings to discuss follow-up topics from January 24, 2013, public meeting
- ▶ Revision 1 to draft regulatory basis
 - ▶ Modifications resulting from public meeting discussions
 - ▶ Revised definition of basic component for fuel cycle facilities
 - ▶ Additional description of basis for development of basic component definition for fuel cycle facilities
 - ▶ Further clarification of evaluating and reporting process
 - ▶ Sample language for commercial grade dedication rule text



10 CFR Part 21: Tentative Goals

- ▶ Finalize Regulatory Basis – September 2013
- ▶ Issue Proposed Rule – September 2014
- ▶ Issue Final Rule – September 2015



Definitions:

substantial safety hazard and basic component

- ▶ NRC staff determined that *substantial safety hazard* definition is universal enough to remain unchanged in the rule

“loss of safety function to the extent that there is a major reduction in the degree of protection provided to public health and safety”

- ▶ Clarity will be enhanced through revision of the *basic component* term for fuel cycle facilities
 - ▶ Consistent with exemption requests and license amendment requests
 - ▶ Use of terminology that is relevant to fuel cycle community (i.e., performance requirements, items relied on for safety (IROFS))



Basic Component: Proposed Definition

- ▶ Elements of definition proposed in draft regulatory basis
 - ▶ System, structure, or component (SSC) designated as an IROFS
 - ▶ Defect or failure to comply could cause the performance requirements of § 70.61 to be exceeded
 - ▶ SSC is not a basic component if diverse SSC's (but not redundant SSC's) exist whose independent action could prevent the performance requirements of § 70.61 from being exceeded
 - ▶ Note: Presence of administrative IROFS does not affect designation of SSCs as basic components



Basic Component: Proposed Definition

IROFS A (engineered)

Capable of independently preventing/mitigating accident

IROFS A is a basic component

IROFS A (administrative)

IROFS B (engineered)

Capable of independently preventing/mitigating accident

IROFS B is a basic component

IROFS A (administrative)

IROFS B (engineered)

Not capable of independently preventing/mitigating accident

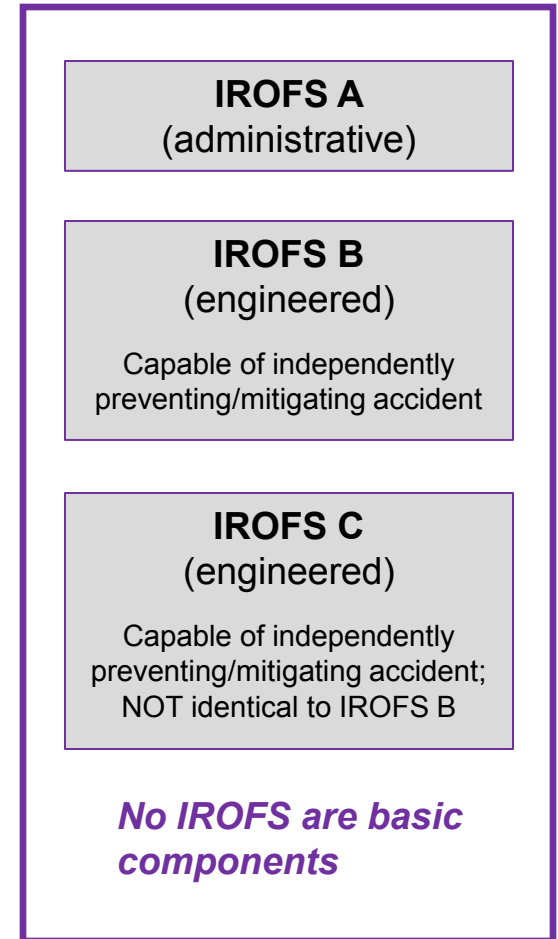
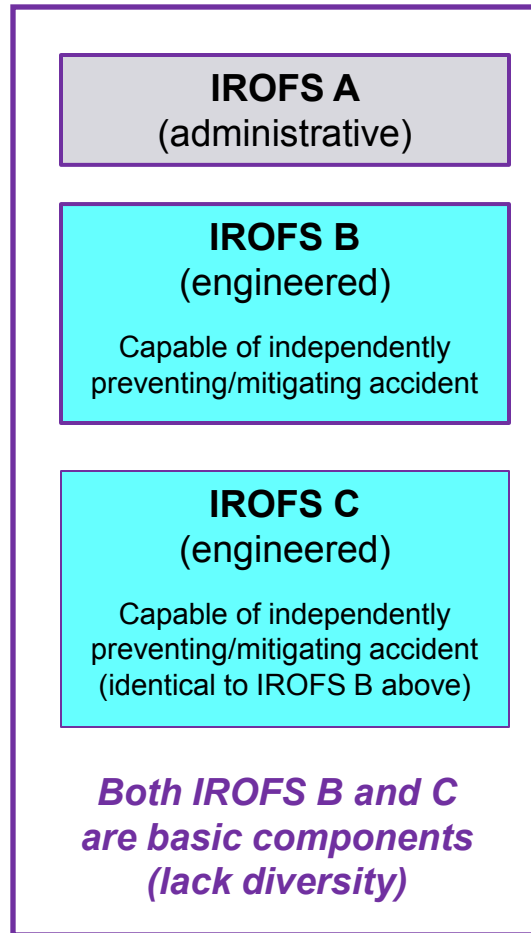
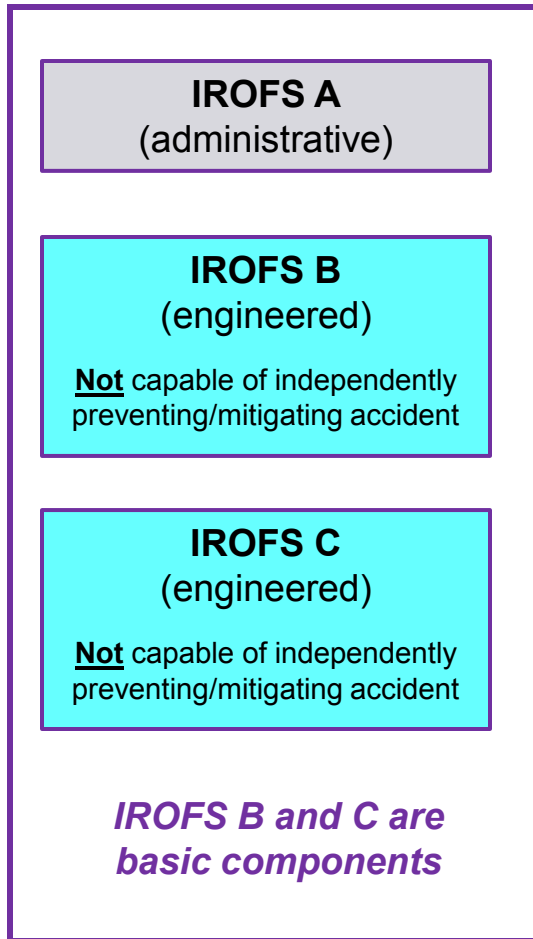
IROFS C (engineered)

Capable of independently preventing/mitigating accident

IROFS C is a basic component



Basic Component: Proposed Definition





Basic Component

- ▶ NRC staff developed the proposed clarified definition for basic component for fuel cycle facilities using multiple information sources
 - ▶ Precedent
 - ▶ Regulatory guidance
 - ▶ Memorandum of Understanding (MOU) with the Occupational Safety and Health Administration (OSHA)



Basic Component: Precedent

- ▶ Precedent has been established through exception requests and license amendment requests received from multiple licensees
 - ▶ Ex: *basic component* means a structure, system, or component, or part thereof that affects their item relied on for safety (IROFS) function, that is directly procured by the licensee or activity subject to the regulations in part 70 and in which a defect or failure to comply with any applicable regulation in this chapter, order, or license issued by the Commission could create a substantial safety hazard (i.e., exceed performance requirements of 10 CFR 70.61)



Basic Component: Regulatory Guidance

- ▶ NUREG-0302, “Remarks Presented (Questions/Answers Discussed) at Public Regional Meetings to Discuss Regulations (10 CFR Part 21) for Reporting of Defects and Noncompliance,” Revision 1, dated July 1977
- ▶ Commission's Policy Statement on Abnormal Occurrence Reports (71 FR 60198), updated most recently in 2006
- ▶ NRC Information Notice (IN) 91-39, “Compliance with 10 CFR Part 21, ‘Reporting of Defects and Noncompliance’”



Basic Component: Regulatory Guidance

- ▶ NUREG-0302, Revision 1: Basis for inclusion of worker consequences in determination of existence of a substantial safety hazard
 - ▶ The term "public" includes all individuals
 - ▶ Degree of protection afforded depends on type of individual
 - ▶ Criteria include probability of release, consequences, and extent of area affected
 - ▶ This message was repeated in IN 91-39



Basic Component: Regulatory Guidance

- ▶ NUREG-0302, Revision 1
 - ▶ Criteria for the determination of substantial safety hazard
 - ▶ moderate exposure to, or release of, licensed material
 - ▶ major degradation of essential safety-related equipment
 - ▶ major deficiencies involving design, construction, inspection, test or use
 - ▶ Supporting information related to radiological consequences and their relation to substantial safety hazards
 - ▶ Unintended radiation exposure to an adult of 25 rem
 - ▶ Unintended radiation exposure to an individual in an unrestricted area of 0.5 rem
 - ▶ 24-hour averaged release of radioactive material to an unrestricted area in excess of 5000 times the values in Table 2 of Appendix B to Part 20



Basic Component: Regulatory Guidance

- ▶ **IN 91-39: Supporting information related to radiological consequences and their relation to substantial safety hazards**
 - ▶ Exposure to an occupationally exposed worker of greater than 25 rem (whole body or its equivalent to other body parts) in a period of a year or less
 - ▶ Exposure to an individual in an unrestricted area of 0.5 rem (whole body or its equivalent to other body parts) in a period of a year or less
 - ▶ Release of radioactive material in amounts reportable under the provisions of 10 CFR 20.403(b)(2) [refers to concentrations which, if averaged over 24 hours, would exceed 500 times the values in Table 2 of Appendix B to Part 20]



Basic Component: Regulatory Guidance

- ▶ **Commission Policy Statement on Abnormal Occurrences:**
Supporting information related to radiological and chemical consequences and their relation to substantial safety hazards
 - ▶ Any unintended radiation exposure resulting in:
 - ▶ An annual total effective dose equivalent (TEDE) of 25 rem to an adult or 5 rem to a minor (age 18 years or less)
 - ▶ Permanent functional damage to an organ or a physiological system
 - ▶ 24-hour averaged release of radioactive material to an unrestricted area in excess of 5000 times the values in Table 2 of Appendix B to Part 20
 - ▶ Accidental Criticality
 - ▶ Condition in which there are no safety or security related controls in place to protect against an NRC-regulated lethal chemical or radiological hazard.



Basic Component: MOU with OSHA

- ▶ **MOU between the NRC and the OSHA: Delineates the general areas of responsibility of each agency**
 - ▶ NRC: Radiation risk produced by radioactive materials
 - ▶ NRC: Chemical risk produced by radioactive materials
 - ▶ NRC: Plant conditions which affect the safety of radioactive materials
 - ▶ OSHA: Plant conditions which do not affect the safety of radioactive materials



Conclusions Regarding Designation of Fuel Cycle Facility Basic Component

- ▶ **Conclusions reached from precedent, regulatory guidance, and MOU with OSHA**
 - ▶ Chemical hazards can create a substantial safety hazard
 - ▶ Scope of “public” includes the worker
 - ▶ Radiation doses and releases of radioactive material identified in the high and intermediate performance requirements are consistent with existing guidance on substantial safety hazards
 - ▶ Inadvertent criticality is a significant event



Reactor Basic Components

- ▶ Reactor basic components include SSCs that ensure:
 - ▶ the integrity of the reactor coolant pressure boundary;
 - ▶ the capability to shut down the reactor and maintain it in a safe shutdown condition; or
 - ▶ the capability to prevent or mitigate the consequences of accidents which could result in potential offsite exposures (~25 rem)
- ▶ The integrity of these SSCs will protect against both worker and public consequences, but separate criteria are not delineated for worker protection
- ▶ Reactors do not give credit for human actions in determining if an SSC is a basic component
- ▶ Multiple layers of protection are provided
- ▶ Reactors are primarily concerned with radiological risk while fuel cycle facilities also deal with chemical and criticality hazards
- ▶ Must consider risk and probability in designating basic components



Further Considerations

- ▶ Relationship between administrative IROFS and engineered IROFS
 - ▶ Purpose of Part 21

- ▶ Compliance with Part 21
 - ▶ Procurement
 - ▶ Verify that supplier implements apply appropriate quality assurance elements (i.e., management measures, Appendix B, etc.) and impose Part 21 on supplier, or
 - ▶ perform commercial grade dedication
 - ▶ Evaluate and report defects and failures to comply
 - ▶ Administrative requirements (postings, procedures, etc.)



Open Discussion

- ▶ Industry ideas for clarifying definition of basic component and justification
- ▶ What are concerns with implementation of Part 21?
- ▶ What do licensees do currently to ensure compliance with Part 21?



Backup Slides





10 CFR Part 21

► Public meeting follow-up items

Draft Regulatory Basis Area	Description	Reactor Facility Applicability	Non-Reactor Facility Applicability
2.	Quality Requirements in Procurement Documents (including question of international applicability)	YES	YES
3.	Definition of Basic Component for Non-Reactor facilities – to include discussion on Substantial Safety Hazard as a potential starting point	NO	YES
5.	Deviation and Delivery – Flow Chart of Part 21 process	YES	YES
8.	Use of 50.72/73 (LERs) to satisfy Part 21 requirements	YES	NO
C.	Definition of Dedication <ul style="list-style-type: none"> - Impact on non-reactor facilities - Impact on DOE/NRC licensed facilities - What “proposed language” might look like 	YES	YES
ii.	Applicability to Part 76 licensees (RESOLVED)	NO	YES



10 CFR Part 21 Rulemaking

- ▶ On September 29, 2011, NRC staff issued SECY-11-0135 to the Commission to inform them of the staff's intent to pursue rulemaking to 10 CFR Part 21 (ML112430138)

- ▶ Issuance of the rule will be complemented by two regulatory guides:
 - ▶ DG-1291, "Evaluating Deviations and Reporting Defects and Noncompliance"
 - ▶ DG-1292, "Sampling and Dedication of Commercial Grade Items"

- ▶ The staff has had multiple public meetings to discuss the rulemaking efforts and to solicit feedback
 - ▶ August 1, 2011 (meeting summary: ML112650090)
 - ▶ January 26, 2012 (meeting summary: ML12027A133)
 - ▶ January 24, 2013 (meeting summary: ML13052A700)

- ▶ NRC staff has identified the 25 areas of the rule that may be subject to improvement through rulemaking. They fall into three categories:
 - ▶ Administrative Changes
 - ▶ Evaluating and Reporting
 - ▶ Commercial-Grade Dedication