

**NRC/NEI WORKSHOP ON
INTEGRATED SAFETY ANALYSIS
(ISA)**



September 23-24, 2003

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Overview of Experiences

- ISA Summary should provide the bases, assumptions, and rationales to support understanding of conclusions described in the ISA Summary.

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**Overview of Experiences
and Perspectives Related to
the New Part 70**

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Overview of Experiences

- Supporting information should be made readily available to reviewers for understanding of ISA Summary.
 - Ideally, the ISA Summary will be a stand-alone, self-supporting document.
 - Original intent behind ISA Summary was to limit the amount of material placed on the docket.
 - Original expectation was that NRC would go onsite to do more detailed ISA reviews. Alternate locations are acceptable.

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Overview of Experiences

- **Standard Review Plan (SRP) presents one method to meet the regulations.**
- **Applicants must demonstrate compliance with regulations.**
 - **Information must be sufficient for staff to conclude regulations have been met.**

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Application of the Standard Review Plan (SRP)

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Overview of Experiences

- **ISA Plans have been submitted and accepted.**
- **Deviations from ISA Plans should be clearly articulated and, as applicable, justified technically.**

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Application of the SRP

- **Types of NRC documents**
 - **NRC regulations**
 - **Regulatory guides**
 - **Branch technical positions (published in the Federal Register)**
 - **SRP/NUREG**

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Application of the SRP

- **Purpose of using an SRP**
 - **NRC:** To allow for the consistent review of license applications.
 - **Industry:** To provide a standardized format and to understand how NRC views each regulatory requirement.
 - **Both:** A NUREG/SRP is not a regulatory requirement and cannot be used as such.

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Application of the SRP

- **Incorporation into license**
 - **10 CFR 70.62 and 70.65:** The Safety Program and Management Measures are incorporated into the license. NRC expects both to be incorporated into the license application.
 - **Per 10 CFR 70.65,** the ISA Summary shall not be incorporated into the License.

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Application of the SRP

- **Purpose of using an SRP (cont'd)**
 - **An applicant must provide an application** describing how each regulatory requirement has been met.
 - **An application with approaches different from the SRP may require longer review times and a greater expenditure of NRC resources**

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Application of the SRP

- **To what extent does an applicant have to address every attribute in the SRP?**
 - **SRP attributes do not have to be met.**
 - **Staff requests for additional information (RAIs) are likely for approaches different from the SRP.**
 - **Possible impacts to review time.**
 - **Technical justification of different approaches is essential.**

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Review Process for Balance of Plant vs. License Amendment

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Review Process for Balance of Plant vs. License Amendment

- 70.62(c)(3) requires existing licensees to submit sitewide ISA Summaries.
 - Review process should be more efficient than for license amendment.
 - Fewer requirements.
 - However, site-wide ISAs will be more voluminous.

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Review Process for Balance of Plant vs. License Amendment

- License amendments are governed by Subparts D and E, as well as Subpart H, to 10 CFR Part 70.
 - Some difficulties encountered with the relationship between ISA Summary and license amendment.
 - Clarity on this matter within submittals reduces the need for RAIs and onsite follow-up.

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Baseline Design Criteria

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Baseline Design Criteria

- 10 CFR 70.64 requires applicants and licensees to address baseline design criteria (BDC) in the design of new facilities or new processes at existing facilities.

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Baseline Design Criteria

- BDC include:
 - 1) quality standards
 - 2) natural phenomena hazards
 - 3) fire protection
 - 4) environmental and dynamic effects
 - 5) chemical protection
 - 6) emergency capability
 - 7) utility services
 - 8) inspection, testing, and maintenance
 - 9) criticality control
 - 10) instrumentation and control.

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Baseline Design Criteria

- NUREGs 1520 and 1718
 - Baseline Design Criteria: A set of criteria specifying design features and management measures that are required and acceptable under certain conditions for new processes or facilities specified in 10 CFR 70.64. In general, these criteria are the acceptance criteria that apply to safety design for new facilities and new processes, as described in the chapters of this SRP.

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Baseline Design Criteria

- BDC are analogous to 10 CFR Part 50, Appendix A, General Design Criteria
- BDC apply to design of new facilities and processes but does not require retrofits to existing facilities or processes
 - However, all facilities and processes must comply with the performance requirements in 10 CFR 70.61.

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Baseline Design Criteria

- Originally, BDC were to provide a base, i.e., a minimum, that must be included in an application regardless of what the ISA concluded.
- During rulemaking, following was added: Must maintain application of these criteria [the BDC] unless the analysis performed pursuant to 70.62(c) [Integrated Safety Analysis (ISA)] demonstrates that a given item is not relied on for safety or does not require adherence to the specified criteria.
- BDC Issues (in general):
 - BDC acceptance criteria are general
 - Relation of BDC to the performance requirements

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Baseline Design Criteria

• ISSUES RAISED DURING BDC REVIEW OF FUEL CYCLE FACILITIES (OTHER THAN MOX)

• Note: Answers to these example questions need not be addressed in a "BDC" section of your application. They may be addressed in the 70.61 section. However the staff should be given a pointer to where the information on compliance with the BDCs may be found.

- 1) NATURAL PHENOMENA HAZARDS (BDC 2) - Discussed in more detail in this workshop.
- 2) ENVIRONMENTAL AND DYNAMIC EFFECTS (BDC 4) - Has the applicant sufficiently described its design for protection from environmental conditions and dynamic effects associated with normal operations maintenance, testing and postulated accidents. The Part 70, Subpart H, S.O.C. stated that this criterion does not require a formal EQ Program. This criterion applies only to new facilities and new processes and is intended to ensure that potential ambient conditions are considered during design of a facility.

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Baseline Design Criteria

- HOW AND WHERE DO BDC APPLY - The BDC are required to be addressed in the design of new facilities and in the design of new processes at existing facilities. Issues:
 - Has (or how has) a licensee defined its "new facility" and "existing facility?"
 - How is legacy equipment to be used that is different from the type of material from that it was originally designed be handled?
 - Could this introduce new credible accident scenarios?

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Baseline Design Criteria

- 3) CHEMICAL PROTECTION (BDC 5) - 70.64(a)(5) and related 70.64(a)(3) for chemical risks produced from licensed material, facility conditions affecting the safety of licensed material, and hazardous chemicals produced from licensed materials. Has the applicant provided a list of hazardous chemicals produced from licensed materials at the proposed site? What exposure limits have been specified? Have they been properly supported? Has the applicant provided a sufficient technical basis for its specified explosive limits? Has the applicant sufficiently addressed IROFS operator actions outside of the control room? Has the applicant considered toxic chemical effects that would impede its ability to meet 70.64(a)(6)?

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Baseline Design Criteria

- 4) UTILITY SERVICES (BDC 7) - The design must provide for continued operation of essential utility services. What are essential utility services? Does this mean redundancy and diversity are needed? Would these utility services have to be IROFS in order to meet "continued operation" and to be considered "essential"?
- 5) INSTRUMENTATION AND CONTROLS (BDC 10) - The requirement specifies that the design must provide for I&C systems to monitor and control IROFS. Has the licensee included the I&C system as an IROFS? Is it necessary? Does the design of the I&C system have a higher pedigree than other "commercial-grade" systems (non-IROFS)? Would the failure of the system create a credible accident or cause an IROFS to fail?

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Choice of IROFS

- Items Relied On For Safety (IROFS)
 - 10 CFR 70.4 - IROFS means structures, systems, equipment, components, and activities of personnel that are relied upon to prevent potential accidents at a facility that could exceed the performance requirements in 10 CFR 70.61.
 - 10 CFR 70.61(e) - Each engineered or administrative control or control system necessary to comply with paragraphs
 - (b) credible high-consequence events, or
 - (c) credible intermediate-consequence events, or
 - (d) nuclear criticality accidents,shall be designated an IROFS.

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Choice of Items Relied on For Safety (IROFS)

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Choice of IROFS

- Items Relied On For Safety (IROFS)
 - 10 CFR 70.4 - Does not limit the licensee from identifying structures, systems, equipment, components, or activities of personnel (i.e., beyond those in the minimum set necessary for compliance with the performance requirements) as items relied on for safety.
 - NRC staff does not require structures, systems, equipment, components, or activities of personnel necessary only for compliance with 10 CFR 70.64 (defense in depth and reduction of challenges to IROFS) to be identified as IROFS.

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Choice of IROFS

- IROFS Level of Detail - ISA Summary
 - 10 CFR 70.65(b)(6) - The ISA Summary must contain a list briefly describing each IROFS in sufficient detail to understand its function in relation to the performance requirements in 10 CFR 70.61.
 - SOC Comment E1.1 - The description of IROFS in the ISA Summary must be in sufficient detail for NRC staff to make the finding required in 10 CFR 70.66 (that performance requirements are satisfied).
 - SOC Comment E1.2 - The description of administrative IROFS may describe the personnel action without listing specific procedures in the ISA Summary.

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Choice of IROFS

- IROFS Level of Detail – ISA
 - NRC Issue - Components and support systems associated with an administrative IROFS, should be identified and subject to management measures also.
 - Includes signals to prompt personnel actions.
 - Includes equipment that personnel must use to accomplish safety function (i.e., switches, valves, etc.)

Note: The term "Augmented Administrative Control" is defined in the glossary of NUREG-1520 and NUREG-1718. However, the term "Enhanced Administrative Control" is used in the discussion. It is unclear whether these terms are being used consistently.

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Choice of IROFS

- IROFS Level of Detail – ISA
 - NRC Issue - The boundaries of an IROFS must be clear. What is subject to management measures and what isn't?
 - 10 CFR 70.62(c)(4) - Each licensee shall conduct and maintain an ISA that identifies each IROFS, the characteristics of its safety function, and the assumptions and conditions under which it is relied upon.
 - SRP Section 3.4.3.2(6)(a) - The ISA Summary need not provide a breakdown of hardware IROFS by component or identify all support systems. However, the ISA documentation maintained onsite should contain sufficient detail about items within a hardware IROFS, such that it is clear what structure, system, equipment or component is included within the hardware IROFS' boundary and would, therefore, be subject to management measures.

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Choice of IROFS

- Management Measures
 - 10 CFR 70.62(a) - Each licensee shall establish and maintain a safety program that includes management measures.
 - 10 CFR 70.62(d) - Each licensee shall establish management measures to ensure that each IROFS is available and reliable to perform its safety function (i.e., comply with the performance requirements in 70.61).
 - 10 CFR 70.62(d) - Management measures may be graded commensurate with the risk reduction of the IROFS.
 - 10 CFR 70.65(a) - The license application must include a description of the safety program established under 70.62.

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Choice of IROFS

- **Monitoring of IROFS (new facilities and new processes only)**
 - NRC Issue - How is the behavior of each IROFS monitored and controlled?
 - Manual initiation of active engineered controls?
 - Information read-out of variables (e.g., temperature, pressure, etc.)?
 - 10 CFR 70.64(a)(10) - The design must provide for inclusion of instrumentation and control systems to monitor and control the behavior of IROFS.

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Choice of IROFS

- **Defense-in-Depth (new facilities and new processes only)**
 - 10 CFR 70.64(b) - Facility and system design and facility layout must be based on defense-in-depth practices.
 - 10 CFR 70.64(b) footnote - Defense-in-depth means successive levels of protection such that health and safety will not be wholly dependent upon any single element of the design, construction, maintenance, or operation of the facility.
 - Defense-in-depth controls may not be IROFS. If a sole IROFS satisfies 70.61(e), a second control established to satisfy 70.64(b) doesn't have to be identified as an IROFS.

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Choice of IROFS

- **Challenging of IROFS (new facilities and new processes only)**
 - 10 CFR 70.64(b)(2) - The design must incorporate, to the extent practicable, features that enhance safety by reducing challenges to IROFS.
 - NRC Issue - Reviews have identified IROFS where the safety function may be cycled repeatedly during routine operations. Licensee/applicant needs to articulate the basis for the acceptability of such designs.

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Choice of IROFS

- **Other Issues arising from reviews of applications:**
 - Basis and Justification of Failure Indices.
 - Common mode failures with independent IROFS

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Natural Phenomena

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Natural Phenomena

- SRP - 1.3 Site Description
 - The site description will be considered acceptable if it includes:
 - Appropriate meteorological data, including a summary of design basis values for accident analysis of maximum snow or ice load, and probable maximum precipitation, as may be developed by the applicant and presented in the ISA Summary. The applicant presents appropriate design-basis values for lightning, high winds, tornado, hurricane and other severe weather conditions that are applicable to the site.
 - A summary description of the hydrology and geology (including seismicity) for the area, and cites the design-basis flood event for which the facility may be safely shut down.
 - Earthquake accelerations for the site associated with a 250-year and 500-year earthquake.
- NRC Expectation
 - The site description will contain site-specific information with respect to natural phenomena.

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Natural Phenomena

- 10 CFR 70.62(c)(iv)
 - Each licensee shall conduct and maintain an ISA ... that defines potential accident sequences caused by process deviations or other events internal to the facility and credible external events, including natural phenomena.
- NRC Expectation
 - Through the ISA process, the licensee will identify high and intermediate consequence events that are caused by natural phenomena. IROFS will be assigned to lower the risk to acceptable levels.

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Natural Phenomena

- SRP - 3.1.2 ISA Summary
 - The purpose of the ISA Summary is to establish that the applicant has performed the following tasks:
 - Identified and evaluated, in the ISA, all credible events (accident sequences) involving process deviations or other events internal to the facility (e.g., explosions, spills, and fires); and credible external events that could result in facility-induced consequences to workers, the public, or the environment, that could exceed the performance requirements of 10 CFR 70.61. As a minimum external events normally include the following:
 - Natural phenomena events such as floods, high winds, tornadoes, and earthquakes
 - fires external to the facility
 - transportation accidents and accidents at nearby industrial facilities
- NRC Expectation
 - Natural phenomena events will be evaluated to assure that the performance requirements of 10 CFR 70.61 are met.

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NRC/Licensee Communication Challenges

- Rules of engagement (SFPO)
- Docketing of Vertical Slice Results
- Mechanism for Solidifying Commitments
- Continuity of Staff and Review Assignments

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NRC/Licensee Communication Challenges

- Docketing of vertical slice results.
 - In general:
 - For ISA Summaries associated with license amendment requests, vertical slice results would be included in the amendment SER.
 - For site-wide ISA Summaries, we expect to issue approval letters, similar to NRC practice in other areas (e.g., emergency plans).
- This issue is more complicated for amendments than site-wide ISA Summaries.

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NRC/Licensee Communication Challenges

- Docketing of vertical slice results
 - Section 70.65 describes ISA Summary content.
 - Section 70.66 describes additional requirements for approval of license applications.

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NRC/Licensee Communication Challenges

- Mechanism for solidifying commitments
 - What is the meaning of NRC approval of an ISA Summary?
 - NRC has reasonable assurance that the licensee met the requirements of 70.60 through 70.65.
 - Certain requirements become effective - e.g., backfit provisions, annual updates of the ISA summary, facility change process.
 - Approval does not mean that NRC has approved all analyses of accident scenarios nor IROFS.

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NRC/Licensee Communication Challenges

- Mechanism for solidifying commitments
 - What flexibility will NRC have to cause a licensee to revise its ISA Summary after approval?
 - If after approval, the NRC identifies that the licensee has not implemented the ISA and/or ISA Summary in accordance with the regulations, NRC will handle this through the normal inspection and enforcement process.
 - The NRC will identify specifically how the licensee did not meet the regulatory requirements. Licensees will be able to respond to the issue as part of the currently established inspection and enforcement processes.
 - The draft backfit guidance published for comment addressed this issue.

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Nuclear Criticality Safety Evaluations

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NRC/Licensee Communication Challenges

- Mechanism for solidifying commitments
 - Establish policy or guidance that provides an efficient and reasonable review of site-wide ISA summary using risk-informed approach.
 - NRC is working on this process, including the use of contract support.

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Nuclear Criticality Safety Evaluations

- Double Contingency vs. Highly Unlikely
 - Two separate requirements.
 - Two separate regulations.
 - 70.61(b) Criticality must be highly unlikely.
 - 70.64 (a)(9) Double Contingency Principle.

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Nuclear Criticality Safety Evaluations

- **Double Contingency vs. Highly Unlikely**
 - **Double Contingency Principle**
 - **New facilities and new processes.**
 - **Definition from 70.4.**
 - **Sufficient factors to require.**
 - » **At least two**
 - » **Unlikely**
 - » **Independent**
 - » **Concurrent**
 - **Changes in process conditions.**

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Nuclear Criticality Safety Evaluations

- **Identification of other key issues**
 - **Assurance of subcriticality by approved margin.**
 - **Normal and credible abnormal.**
 - **Primary protection.**
 - **Preventive controls and measures.**
 - **Adequate justification.**
 - **Defense in Depth.**
 - **Margin.**

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Nuclear Criticality Safety Evaluations

- **Double Contingency vs. Highly Unlikely**
 - **Both Regulations must be met for new facilities and new processes.**
 - **DCP does not equal Highly Unlikely.**
 - **Highly Unlikely does not equal DCP.**
 - **Example of highly Unlikely that is not DCP.**
 - **Example of DCP that is not Highly Unlikely.**

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NRC Regulation of Chemical Accident Sequences

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NRC Regulation of Chemical Accident Sequences

- Breadth of NRC regulatory authority for chemical hazards.
 - 10 CFR 70.62(c) Integrated safety analysis.
 - Radiological hazards related to possessing or processing licensed material.
 - Chemical hazards of licensed material and hazardous chemicals produced from licensed material.
 - Facility hazards that could affect the safety of licensed materials and thus present "an increased radiological risk".
 - Memorandum of Understanding between NRC and OSHA.
 - Radiation risk produced by radioactive materials.
 - Chemical risk produced by radioactive materials.
 - Plant conditions that affect the safety of radioactive materials and thus present an increased radiation risk to workers.
 - 10 CFR 70.64(a)(5) Chemical Protection.
 - The design must provide for adequate protection against chemical risks produced from licensed material, facility conditions which affect the safety of licensed material, and hazardous chemicals produced from licensed material.

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NRC Regulation of Chemical Accident Sequences

- Setting thresholds for chemical exposures.
 - High consequence [10 CFR 70.61(b)(4)]: An acute chemical exposure to an individual from licensed material or hazardous chemicals produced from licensed material that
 - Could endanger the life of a worker, or
 - Could lead to irreversible or other serious, long-lasting health effects to any individual located outside the controlled area.
 - Intermediate consequence [10 CFR 70.61(c)(4)]: An acute chemical exposure to an individual from licensed material or hazardous chemicals produced from licensed material that
 - Could lead to irreversible or other serious, long-lasting health effects to a worker, or
 - Could cause mild transient health effects to any individual located outside the controlled area.

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NRC Regulation of Chemical Accident Sequences

- Determination of likelihoods and consequences of chemical accident sequences.
 - 10 CFR 70.62(c)(v) Identify the consequence and the likelihood of occurrence of each potential accident sequence identified and the methods used to determine the consequences and likelihoods.

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NRC Regulation of Chemical Accident Sequences

- Should have consistent methods to establish thresholds. For example:
 - ERPGs
 - AEGLs
 - Or other accepted standards
- Should be consistent with the ISA Plan; if not, provide justification for other approaches.

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NRC Regulation of Chemical Accident Sequences

- Identification of accident sequences (how far should they be taken, and how they interact with other discipline areas like fire, criticality, and radiation).
 - 10 CFR 70.62(c)(iv): Identify potential accident sequences caused by process deviations or other events internal to the facility and credible external events, including natural phenomena.

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NRC Regulation of Chemical Accident Sequences

- Selection of IROFS.
 - 10 CFR 70.61(e) Each engineered or administrative control or control system necessary to comply with the performance requirements shall be designated as an IROFS.
 - 10 CFR 70.64(c)(vi) Identify each item relied on for safety, the characteristics of its preventive, mitigative, or other safety function, and the assumptions and conditions under which the item is relied upon to support compliance with the performance requirements.

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