

10 CFR Part 70, Subpart H

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Enclosure 4



Subpart H

ISA Requirements



- Perform an integrated safety analysis (ISA)
- Comply with performance requirements of 10 CFR 70.61
- Establish management measures
 - Facility Changes
 - Baseline Design Criteria
 - Backfitting
 - Reporting Requirements



Risk-Informed Regulations and Guidance



- Subpart H of 10 CFR Part 70 September 2000
- NUREG-1520, “Standard Review Plan for the Review of a License Application for a Fuel Cycle Facility,” March 2002
- NUREG-1513, “Integrated Safety Analysis Guidance Document” May 2001
- Interim Staff Guidance



10 CFR Part 70 Revision (Subpart H)



- Sequoyah accident and GE Wilmington event
- Integrate radiological, criticality, fire, chemical and environmental safety disciplines
- Use systematic methods to: 1) identify all credible accidents sequences with significant consequences, and 2) estimate their likelihoods and consequences
- Identify items relied on for safety (IROFS)
- Apply management measures to IROFS

Risk Matrix With Risk Index Values

Table A-3 from NUREG-1520



Severity of Consequences	Likelihood of Occurrence		
	Likelihood Category 1 Highly Unlikely (1)	Likelihood Category 2 Unlikely (2)	Likelihood Category 3 Not Unlikely (3)
Consequence Category 3 High (3)	Acceptable Risk 3	Unacceptable Risk 6	Unacceptable Risk 9
Consequence Category 2 Intermediate (2)	Acceptable Risk 2	Acceptable Risk 4	Unacceptable Risk 6
Consequence Category 1 Low (1)	Acceptable Risk 1	Acceptable Risk 2	Acceptable Risk 3

Consequence Severity Categories Based on 10 CFR 70.61

Table A-5 from NUREG-1520



	Workers	Offsite Public	Environment
Category 3 High Consequence	*RD>1 Sievert (Sv) (100 rem) **CD>AEGL-3, ERPG-3	RD>0.25 Sv (25 rem) 30 mg sol U intake CD>AEGL-2, ERPG-2	
Category 2 Intermediate Consequence	0.25 Sv (25 rem) <RD# 1 Sv (100 rem) AEGL-2, ERGP-2 <CD# AEGL-3, ERPG-3	0.05 Sv(5 rem) < RD# 0.25 Sv (25 rem) AEGL-1, ERGP-1 <CD# AEGL-2, ERPG-2	Radioactive release > 5000 x Table 2 Appendix B of 10 CFR Part 20
Category 1 Low Consequence	Accidents of lower radiological and chemical exposures than those above in this column	Accidents of lower radiological and chemical exposures than those above in this column	Radioactive releases with lower effects than those referenced above in this column

* RD - Radiological Dose

**CD - Chemical Dose

Note: > = greater than, < = less than, and # = less than or equal to

Identify Items Relied on for Safety (IROFS)



- Structures, Systems, Equipment, Components, and Activities of Personnel
- Active and Passive Engineered Features, Enhanced Administrative Control, Administrative Control



Management Measures

- Measures to assure that IROFS are available and reliable when needed
 - configuration management, training, QA, audits, procurement, problem identification/control, corrective actions, etc.
 - maintenance (corrective/preventive), functional testing, surveillance, calibration, etc.
 - written policies and procedures, signs, tags, etc.
 - material handling, shipping, storage, etc.
 - human factors, work environment, workload, etc.

Facility Changes

- 10 CFR 70.72, Subpart H, allows licensees to make facility and procedure changes without prior NRC approval if the change does not
 - Create a new type of severe accident
 - Downgrade an IROFS
 - Alter a sole IROFS
- 10 CFR 70.72 requires each licensee to establish a configuration management program to adequately evaluate each proposed change to the facility including worker activities to maintain safety
- Licensees are required to submit a summary of the all such changes to the NRC annually

Baseline Design Criteria



- New Facilities or New Process at Existing Facilities
- Criteria in Following Areas
 - Quality
 - Standards
 - Natural Phenomena hazards
 - Fire Protection
 - Environmental and Dynamic Effects
 - Chemical Protection
 - Emergency Capabilities
 - Utility Services
 - Inspection
 - Testing and Maintenance
 - Instrumentation and controls
- Defense in Depth



Backfitting

- Change in staff position or rule that requires a change in SSCs, procedures or organization
- Staff to qualitatively (non-monetarily) determine value of safety/safeguards improvement (NUREG/BR-0058 “net benefits” approach)
- Other factors such as public confidence should also be taken into consideration in backfitting analyses
- 10 CFR Part 70 backfitting guidance was issued in the form of an updated NMSS Policy and Procedural Letter (P&PL)1-82 in March 2004 (ML040980122)



Reporting Requirements

- 1-Hour and 24-Hour Reports
- Based on exposure/intakes, loss of IROFS
- News release or notification to other government agencies



ISA-Based Licensing Outcomes



- Annual ISA Summary updates could significantly reduce the need and/or scope of renewals
 - 40 Year renewals for 10 CFR Part 70 Facilities
- 10 CFR 70.72 “facility change” analyses could reduce the number of amendments



NRC ISA Review

- ISA review team will consist of at least a primary reviewer, an ISA PM, and specialists in fire, chemical, and radiological safety
- Preliminary review of ISA Summary
- Review ISA onsite
- Conduct confirmatory analyses and write SER



ISA Status

- All but one existing facility' s ISA Summaries have been approved
- Two ISA Summaries for new Enrichment Plants have been approved
- One proposed Plan ISA Summary is under review

