ENCLOSURE 4

SHINE MEDICAL TECHNOLOGIES, LLC

MEETING SLIDES FOR THE MARCH 4 AND 5, 2020 PUBLIC MEETING BETWEEN SHINE MEDICAL TECHNOLOGIES, LLC AND THE NRC

SHINE SAFETY ANALYSIS METHODOLOGY
PUBLIC VERSION

39 pages follow

SHINE Safety Analysis Methodology

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Topics Covered

- Approach to Performing the SHINE Safety Analysis (SSA)
  - Overview
  - Hazard Identification & Evaluation
  - Process Hazard Analysis & Accident Sequence Development
  - Likelihood Evaluation Method
  - Consequence Analysis Method
  - Nuclear Criticality Safety Evaluation Process
  - Safety-Related Controls
  - Integration into the Final Safety Analysis Report & Technical Specifications

Overview

- Guidance documents:
  - Final Interim Staff Guidance (ISG) Augmenting NUREG-1537, Part 1, “Guidelines for Preparing and Reviewing Applications for the Licensing of Non-Power Reactors: Format and Content,” for Licensing Radioisotope Production Facilities and Aqueous Homogeneous Reactors, October 17, 2012
  - Final Interim Staff Guidance (ISG) Augmenting NUREG-1537, Part 2, “Guidelines for Preparing and Reviewing Applications for the Licensing of Non-Power Reactors: Standard Review Plan and Acceptance Criteria,” for Licensing Radioisotope Production Facilities and Aqueous Homogeneous Reactors, October 17, 2012
  - NUREG/CR-6410, Nuclear Fuel Cycle Facility Accident Analysis Handbook, March 1998

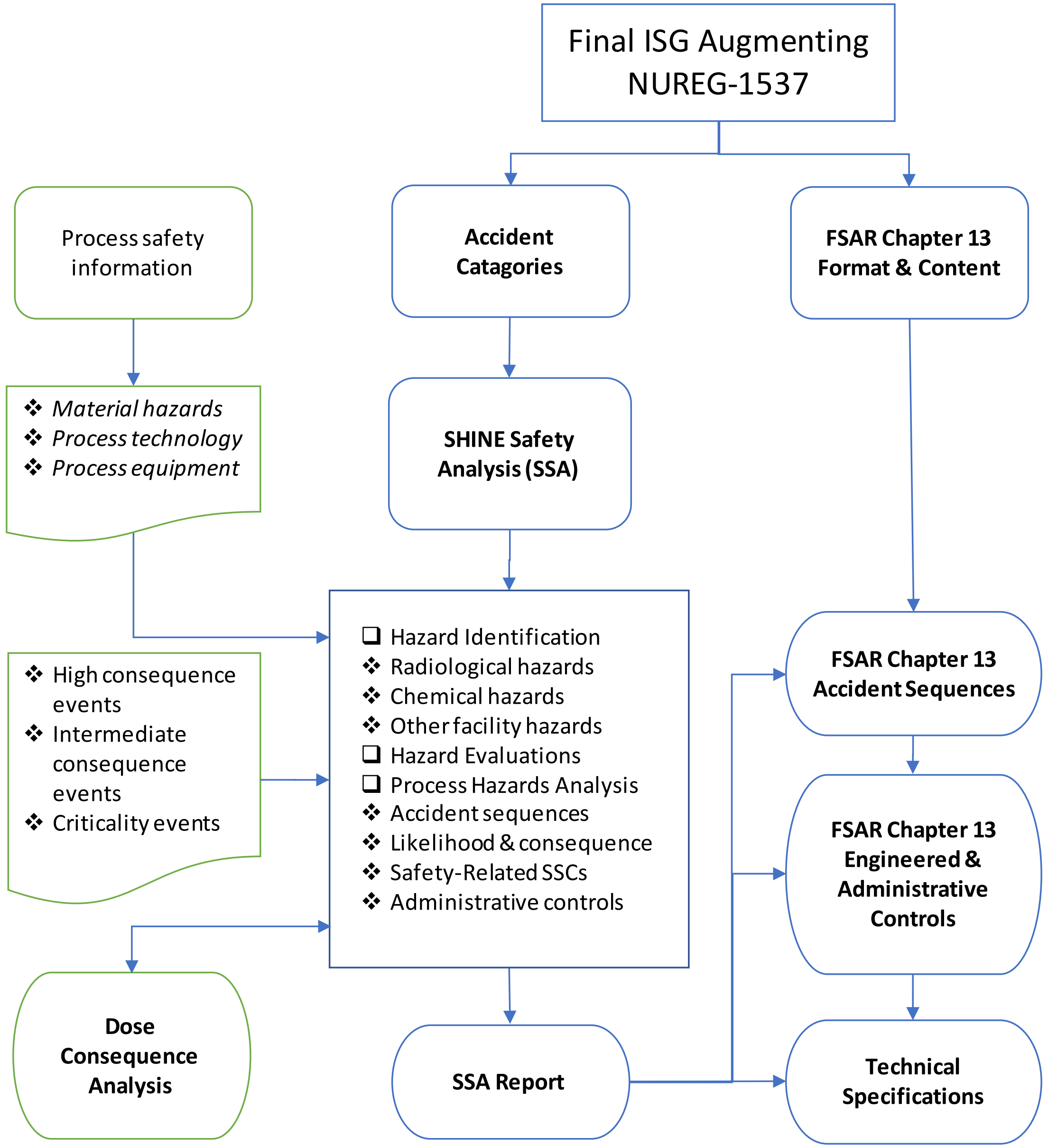
Overview

- The SHINE Safety Analysis (SSA) methodology is based on the guidance in the ISG augmenting NUREG-1537, Parts 1 & 2
  - Chapter 13 of the ISG augmenting NUREG-1537 is the primary guidance for performing the safety analysis for the irradiation facility (IF) and the radioisotope production facility (RPF) as described in Chapter 13 of the Final Safety Analysis Report (FSAR)
    - Subsection 13a2 identifies the categories of accident scenarios that are applicable to aqueous homogeneous reactor accident analysis, which is applied in the SSA for the IF accident analysis
    - Subsection 13b identifies the categories of accident scenarios that are applicable to radioisotope production facility accident analysis, which is applied in the SSA for the RPF accident analysis
  - Provides the content guidance for the licensing basis accident analysis (i.e., FSAR Chapter 13)

Overview

- The SSA methodology is a risk-based approach to develop accident sequences and controls that includes:
  - Identification and evaluation of radiological and chemical hazards
  - Development of accident sequences with estimation of likelihood, and potential consequences categorized as “high”, “intermediate”, and “low”.
  - Risk assessment of unmitigated accident sequences uses a 3x3 matrix to determine the need for additional controls.
  - Identification of controls to reduce risk through reduction of likelihood and/or mitigation of consequences to an acceptable level of risk
- The SSA acceptance criteria for radiological and chemical dose is defined as the SHINE Safety Criteria

Overview


Final ISG Augmenting NUREG-1537
Process safety information
Accident Catagories
FSAR Chapter 13 Format & Content
Material hazards
Process technology
Process equipment
SHINE Safety Analysis (SSA)
High consequence events
Intermediate consequence events
Criticality events
Hazard Identification
Radiological hazards
Chemical hazards
Other facility hazards
Hazard Evaluations
Process Hazards Analysis
Accident sequences
Likelihood & consequence
Safety-Related SSCs
Administrative controls
FSAR Chapter 13 Accident Sequences
FSAR Chapter 13 Engineered & Administrative Controls
Dose Consequence Analysis
SSA Report
Technical Specifications

Hazard Identification and Evaluation

- Hazard identification and evaluations
  - Hazard and Operability (HAZOP) – applied to process-oriented systems
  - Failure Modes and Effects Analysis (FMEA) – applied to complex mechanical systems
  - The hazard evaluation methods are performed in accordance with the *Center for Chemical Process Safety Guidelines for Hazard Evaluation Procedures*
  - The hazard evaluations identify process failures that have the potential to result in adverse radiological or chemical consequences and candidate control for prevention or mitigation
  - Provides input to the accident sequence development step

Hazard Identification and Evaluation

- Hazard identification
  - Hazard categories are initially defined based on the process descriptions
  - Hazards specific to the process being analyzed are identified prior to the hazard evaluation
  - Additional hazards or interactions that are identified during the hazard evaluation are added
  - Example: Subcritical Assembly System (SCAS) hazard identification table from SCAS HAZOP report

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Hazard Identification and Evaluation

- Consequences of interest
  - Consequence categories are defined to characterize the type of consequence that may result from a process deviation or equipment failure
  - Consequence categories may include safety or operational outcomes
  - A process deviation or equipment failure may have more than one consequence
  - Example: SCAS consequence table from SCAS HAZOP report

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Hazard Identification and Evaluation

- Hazard evaluation tables
  - The hazard evaluation team discussions (HAZOP or FMEA) are documented in a set of tables that include:
    - Process deviations and/or equipment failures and their causes
    - Resulting consequences and associated category
    - Possible engineered (passive or active) and administrative controls
    - Recommendations for additional investigation, analysis, or design changes

Hazard Identification and Evaluation

- Hazard evaluation results
  - The results are summarized for each system in a SHINE technical report
  - The results provide a basis for potential accident sequences to be developed in the next analysis phase, the process hazards analysis (PHA)
  - Potential candidates for preventive and/or mitigative controls
  - Recommendations for design improvements
  - Hazard evaluations will be reviewed and updated for final design

Hazard Identification and Evaluation

- Hazard Evaluations Conducted
  - Nuclear Systems
    - SCAS – Subcritical assembly system
    - TOGS – Target solution vessel (TSV) off-gas system
    - NDAS – Neutron driver assembly system
    - TPS – Tritium purification system
  - Process Systems
    - TSPS – Target solution preparation system
    - TSSS – Target solution staging system
    - VTS – Vacuum transfer system
    - PVVS – Process vessel vent system

Hazard Identification and Evaluation

- Process Systems (continued)
  - RLWS – Radioactive liquid waste storage
  - RLWI – Radioactive liquid waste immobilization
  - RDS – Radioactive drain system
  - MEPS – Molybdenum (Mo) extraction and purification system
  - IXP – Iodine and xenon purification and packaging
  - URSS – Uranium receipt and storage system
- Auxiliary Systems
  - RVZ1 – Radiologically controlled area ventilation zone 1
  - RVZ2 – Radiologically controlled area ventilation zone 2
  - RVZ3 – Radiologically controlled area ventilation zone 3
  - N2PS – Nitrogen purge system

Hazard Identification and Evaluation

- Supporting Systems Evaluated During Hazard Evaluations
  - Shielding and Confinement Systems
    - ICBS – Irradiation cell biological shield
    - PFBS – Production facility biological shield
  - Auxiliary Systems
    - PCLS – Primary closed loop cooling system
    - LWPS – Light water pool system
    - RPCS – Radioisotope process facility cooling system
    - FSTR – Facility structure
  - Auxiliary Systems
    - TRPS – TSV reactivity protection system
    - NFDS – Neutron flux detection system
    - ESFAS – Engineered safety features actuation system
    - CAAS – Criticality accident alarm system
    - UPSS – Uninterruptible electrical power supply system

Process Hazard Analysis & Accident Sequence Development

- Identification of relevant accident categories
  - Relevant accident categories as identified in the ISG are carried forward
  - Hazard evaluations identify potential initiating events, consequences, and controls that may be applied
  - Hazard evaluations also identify SHINE specific accident types (e.g., tritium, neutron driver)

Process Hazard Analysis & Accident Sequence Development

- Irradiation facility (IF) accident categories:
  - Maximum hypothetical accident (MHA)
  - Insertion of excess reactivity
  - Reduction in cooling
  - Mishandling or malfunction of fuel (target solution)
  - Loss of normal electric power
  - External events
  - Mishandling or malfunction of equipment
  - Large undamped power oscillations
  - Detonation and deflagration in the primary system boundary
  - Unintended exothermic reaction other than detonation
  - Facility system interactions
  - Facility specific events (e.g., NDAS, TPS, heavy load drop)

Process Hazard Analysis & Accident Sequence Development

- Radioisotope production facility (RPF) accident categories:
  - Malfunction or mishandling of equipment
  - Facility specific events (e.g., heavy load drops)
  - Inadvertent nuclear criticality in the RPF
  - Hazardous chemicals (e.g., uranium uptake)

Process Hazard Analysis & Accident Sequence Development

- External event accident categories:
  - Seismic event
  - Severe weather (e.g., Tornado, high winds, heavy snow, lightning)
  - External flooding events (i.e., probable maximum precipitation)
  - External fire events (e.g., vegetation, natural gas, vehicle fires)
  - Transportation accidents (e.g., aircraft impact, chemical truck accident)
  - Flooding events internal to the IF and RPF
  - On-site chemical/gas releases (e.g., spills)
  - Fire events internal to the IF and RPF are evaluated on a fire area basis

Process Hazard Analysis & Accident Sequence Development

- PHA for internal and external events
  - Identify accident sequences based on the hazard evaluation results and the ISG to NUREG-1537 guidance
  - Estimate a risk index for each potential unmitigated accident sequence (likelihood x consequences)
  - Identify engineered and administrative controls for those sequences which have an unacceptable risk
  - Evaluate controlled risk indices crediting risk reduction from controls
  - Develop list of safety-related controls

Risk Matrix Development

Consequence Category	Workers	Offsite Public
High Consequence 3	RD > 100 rem CD> PAC-3	RD > 25 rem 30 milligrams sol U intake CD > PAC-2
Intermediate Consequence 2	5 rem < RD ≤ 100 rem PAC-2 < CD< PAC-3	0.5 rem< RD ≤ 25 rem PAC-1 < CD ≤ PAC-2
Low Consequence 1	Accidents with lower radiological and chemical exposures than those above	Accidents with lower radiological and chemical exposures than those above

Likelihood Category	Likelihood Index (T)	Event Frequency Limit	Risk Index Limits
Highly Unlikely	1	Less than 10^{-5} per event, per year	T ≤ -5
Unlikely	2	Between 10^{-4} and 10^{-5} per event, per year	-5 < T ≤ -4
Not Unlikely	3	More than 10^{-4} per event, per year	-4 < T

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 3	Unacceptable 6	Unacceptable 9
Consequence Category 2 Intermediate (2)	Acceptable 2	Acceptable 4	Unacceptable 6
Consequence Category 1 Low (1)	Acceptable 1	Acceptable 2	Acceptable 3

Likelihood Evaluation Method

- Initiating events
  - For most accident sequences the failure frequency index number (FFIN) is estimated based on *type of control* (e.g., single specific administrative control, single passive or active control, redundant controls) to represent an initiating event frequency
  - Some accident sequences are based on evidence from published sources (e.g., seismic events, severe weather events, loss of offsite power)
  - A few accident sequences may apply combinations of FFIN, equipment failure probability (FPIN) and recovery times estimation represented by a duration index number (DIN)
- Failure probability estimates for controls
  - For most accident sequences FPIN is also estimated based on type of control (e.g., single specific administrative control, single passive or active control, redundant controls)
  - In general, lower bound estimates are used for FPIN

Likelihood Evaluation Method

Failure Frequency Index Number (FFIN)	Based on Evidence	Based on Type of Control	Comments
-6	External event with freq. < 10^{-6}/yr	N/A	If initiating event, no controls needed.
-5	Initiating event with freq. < 10^{-5}/yr	N/A	For passive safe-by-design components or systems; failure is considered highly unlikely for robust passive engineered controls: 1. Whose dimensions fall within established single parameter limits or that can be shown by calculation to be subcritical including the use of the approved subcritical margin, 2. That have no credible failure mechanisms that could disrupt the credited design characteristics, and 3. Whose design characteristics are controlled so that the only potential means to effect a change that might result in a failure to function would be to implement a design change.
-4	No failures in 30 years for hundreds of similar controls in industry.	1. Exceptionally robust passive engineered control (PEC), 2. Two independent active engineered control (AECs), PECs, or enhanced specific administrative control (SAC)	Rarely can be justified by evidence. Further, most types of single control have been observed to fail.
-3	No failures in 30 years for tens of similar controls in industry.	A single control with redundant parts, each a PEC or AEC	None
-2	No failure of this type in the facility in 30 years.	A single PEC	None
-1	A few failures may occur during facility lifetime.	1. A single AEC 2. Enhanced SAC 3. Redundant SAC	None
0	Failure occur every 1 to 3 years.	A single SAC	None
1	Several occurrences per year.	Frequent event, inadequate control	Not for controls, just initialing events.
2	Occurs every week or more often.	Very frequent event, inadequate control	Not for controls, just initialing events.

Failure Probability Index Number (FPIN)	Probability of Failure on Demand	Based on Type of Control	Comments
-6	10^{-6}		If initiating event, no Control needed.
-4 or -5	10^{-4} - 10^{-5}	1. Passive engineered control (PEC) with high design margin. 2. Inherently safe process. 3. Two redundant controls more robust than a simple AEC, PEC, or enhanced SAC.	Can rarely be justified by evidence. Most types of single controls have been observed to fail.
-3 or -4	10^{-3} - 10^{-4}	1. Single PEC 2. Single AEC with high availability	None
-2 or -3	10^{-2} - 10^{-3}	1. Single AEC 2. Enhanced SAC 3. SAC for routine planned operations	None
-1 or -2	10^{-1} - 10^{-2}	A SAC that must be performed in response to a rare unplanned demand.	None

Duration Index Number (DIN)	Average Failure Duration	Duration in Years	Comments
1	> 3 years	10	
0	1 year	1	
-1	1 month	0.1	Formal monitoring to justify indices < -1
-2	A few days	0.01	
-3	8 hours	10^{-3}	
-4	1 hour	10^{-4}	
-5	5 minutes	10^{-5}	

Example: Process Hazard Analysis Accident Sequence

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Consequence Analysis Method

- Consequence analysis is performed for radiological and chemical hazards as applicable for each accident sequence
  - Radiological and chemical dose cases are defined to represent the potential release conditions for postulated accident scenarios including material-at-risk (MAR) quantities
  - Radiological dose cases are defined to represent the potential release conditions for postulated accident scenarios
  - Hazardous chemical consequence assessment includes release scenarios for all potentially hazardous chemicals within the facility
  - Acceptance criteria for all dose consequence scenarios are defined in the SHINE Safety Criteria

Consequence Analysis Method

- SHINE Safety Criteria
  - An acute worker dose of 5 rem or greater total effective dose equivalent (TEDE)
  - An acute dose of 0.5 rem or greater TEDE to any individual located outside the owner controlled area
  - An intake of 30 mg or greater of uranium in soluble form by any individual located outside the owner controlled area
  - 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 the worker or could cause mild transient health effects to any individual located outside the owner controlled area
  - Criticality in the RPF: under normal and credible abnormal conditions, all nuclear processes in the RPF shall remain subcritical, including use of an approved margin of subcriticality for safety
  - Loss of capability to reach safe shutdown conditions

Consequence Analysis Method

- Radiological consequence analysis
  - Radiological dose cases are defined to represent the potential release conditions for postulated accident scenarios
  - The radiological dose consequence analysis is based on the five-factor formula as described in NUREG/CR-6410, *Nuclear Fuel Cycle Facility Accident Analysis Handbook*
  - Materials at risk are determined for the process locations and conditions, including physical state (e.g., liquid, gas, aerosol)
  - Bounding assumptions in the analysis includes:
    - Corresponding fission power: 137.5 kW (license limit +10%)
    - Irradiation time per cycle: 30 days
    - Total time between irradiations: [ ]PROP/ECI
    - Extraction between irradiations: none
    - Length of target solution recovery: [ ]PROP/ECI

Consequence Analysis Method

- Radiological consequence analysis
  - Radionuclide transport models the initial release location and radionuclide transport (leakpaths) into the RCA and to the environment as a ground release
  - Radionuclides are tracked as noble gases, halogens, and aerosols
  - Atmospheric dispersion (χ/Q) factors are calculated using the PAVAN computer code
  - Dose conversion factors include:
    - Public: ICRP-72 (2012), FGR-12 (1993)
    - Worker: ICRP-68 (2012), FGR-11 (1988), FGR-12 (1993)

Consequence Analysis Method

- Hazardous chemical consequence assessment
  - Chemical release cases are performed for all hazardous toxic chemicals within the facility
  - This assessment determines if the release of hazardous chemicals from the SHINE facility could lead to exceeding Protective Action Guideline (PAC) categories (i.e., PAC-1 (public) or PAC-2 (worker))
  - Meteorological data is obtained from the Southern Wisconsin Regional Airport to estimate evaporation rates and dispersion
  - The analysis for the chemical dose to the public uses the ALOHA (Areal Locations of Hazardous Atmospheres) computer code to determine the exposure at the boundary of the owner-controlled and the nearest resident
  - The analysis for the chemical dose to facility workers uses evaporation or dispersion rates inside the facility and determines an average concentration within the RCA based on building free volume.
  - A worker evacuation time of 10 minutes is assumed in this analysis

Nuclear Criticality Safety Evaluation Process

- SHINE maintains a nuclear criticality safety program (CSP) that complies with applicable American National Standards Institute/American Nuclear Society (ANSI/ANS) standards as endorsed by Regulatory Guide 3.71, Revision 3
  - The CSP meets the applicable criticality safety requirements of 10 CFR Part 70 (i.e., § 70.24(a) and § 70.52)
- Nuclear criticality safety evaluations (NCSEs) are conducted for each fissile material operation within the RPF to ensure that under normal and credible abnormal conditions, all nuclear processes remain subcritical with an approved margin of subcriticality
  - A fissionable material operation is any process or system that has the potential to contain more than 250 g of non-exempt fissile material
- In systems where the equipment is not safe-by-design, the double contingency principle is used ensuring at least two unlikely, independent, and concurrent changes in process conditions are required before a criticality accident is possible

Nuclear Criticality Safety Evaluation Process

- The preferred hierarchy of nuclear criticality safety controls is:
  1. Passive engineered
  2. Active engineered
  3. Enhanced administrative
  4. Administrative
- Control on two independent criticality parameters is preferred over multiple controls on a single parameter
- If redundant controls on a single parameter are used, a preference is given to diverse means of control on that parameter

Nuclear Criticality Safety Evaluation Process

- Nuclear criticality safety (NCS) calculations
- NCSEs
  - What-if checklist to identify process upsets that may challenge typical criticality safety parameters
  - Credible process upsets evaluated if it is “Safe-by-Design”
  - Further evaluation using event tree analysis to identify process changes that must occur to result in criticality
  - Controls are identified as needed to eliminate or reduce the likelihood of occurrence to “highly unlikely”
- Results of the NCSEs are summarized in the SSA and in the FSAR

Safety-Related Controls

- Selection of engineered controls from accident sequences
  - Reduce the likelihood of occurrence of the accident sequence
  - Mitigate the consequences of the accident sequence
- Administrative controls in place
  - Programmatic administrative controls: Ensure that the safety-related SSCs continue to perform their safety-related functions (e.g., surveillance and testing, periodic maintenance)
  - Specific administrative controls to perform some safety-related actions (e.g., operating procedures, sampling)
- Nonsafety-related defense-in-depth controls also identified in the SSA Report
- Safety-related controls are included in the Technical Specifications

Safety-Related Controls

- Types of Controls – Safety-Related
  - Active engineered controls (AEC)
  - Passive engineered controls (PEC)
  - Specific administrative controls (SAC)
- Types of Controls – Nonsafety-Related
  - Defense-in-depth (DID)

Example: Safety-Related Control Selection

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Example: Safety-Related Control Selection (from SSA)

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Integration into the Chapter 13 Accident Analysis

- Accident sequences identified in the SSA and Part 1 of the ISG augmenting NUREG-1537
  - Postulated accident sequences that can result in unacceptable risk are candidates for inclusion in Chapter 13 of the FSAR
  - Initialing events, scenarios, and determination of consequences are detailed
  - Controls that are credited with preventive or mitigative safety functions are identified
  - Engineered and administrative controls (AEC, PEC, and SAC) are included in the Technical Specifications
- An MHA is also defined for the IF and the RPF
  - The MHA is provided as a hypothetical accident scenario with radiological consequences that exceed those of any credible accident
  - The MHA need not be credible, but the potential consequences are evaluated
  - For SHINE, the MHA is provided for information only since radiological consequence analyses are performed to cover all credible accident scenarios

Maximum Hypothetical Accident

- MHA for the IF:
  - The postulated MHA for the IF is a failure of the TSV off-gas system (TOGS) pressure boundary leading to a release of TSV radioactive gases into the TOGS confinement cell.
  - The N2PS actuates, but the PVVS flow path is assumed to be completely blocked, causing a maximum pressurization of the TOGS cell
- MHA for the RPF:
  - The MHA in the RPF is a fire in a carbon guard bed with degraded performance of the downstream carbon delay beds
  - The carbon guard bed releases its inventory to the downstream carbon delay beds which are normally credited with adsorbing 99 percent of the released iodine.
  - For the MHA, the carbon delay beds are assumed to be operating at a reduced efficiency of 95 percent

Integration into the Chapter 13 Accident Analysis

- Results from the SSA are directly mapped into the Chapter 13 accident analysis
  - Postulated accident scenarios identified in the SSA that have potential uncontrolled consequences are included in Chapter 13 of the FSAR
  - Controls that are identified as credited for prevention or mitigation in the SSA are also included in Chapter 13 of the FSAR
  - Consequence analyses results demonstrate that the SHINE Safety Criteria accident dose and hazardous chemical consequence limits are met

Integration into the Technical Specifications

- Section 3.0 of the SHINE Technical Specifications, Limiting Conditions for Operation (LCO) and Surveillance Requirements
  - Includes the safety-related engineered controls identified in the SSA, including a Basis discussion for each LCO identifies the safety function performed by the SSC and the irradiation unit modes or other conditions during which the SSC is required to be operable
- Section 4.0 of the SHINE Technical Specifications, Design Features
  - Identifies aspects of the facility design and other physical conditions (e.g., distance to the site boundary, building free volume) that are inputs or assumptions in the radiological dose calculations that support the SSA dose consequence analysis.
- Section 5.0 of the SHINE Technical Specifications, Administrative Controls
  - Identifies the programmatic administrative controls (e.g., configuration management) that are required to be implemented to ensure that safety-related SSCs will be capable of performing their design functions
  - Development and use of procedures that implement the specific administrative controls identified in the SSA