



Acute Chemical Exposures for Integrated Safety Analysis

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Agenda

- Regulatory Requirements
- Background
- ISG General Approach
- Next Steps



Regulatory Requirements

- 10 CFR Part 70.61(b)(4) and (c)(4) require the Integrated Safety Analysis (ISA) to consider acute chemical exposures.
- 10 CFR Part 70.65(b)(7) requires a description of the proposed quantitative standards used to assess the consequences to an individual from acute chemical exposure to licensed material or chemicals produced from licensed material.

Background

- Chemical exposures at FCF
 - NRC and NEI have discussed compliance with Part 70.65(b)(7) in multiple meetings and correspondence
 - NRC staff position: consider all pathways
 - October 3rd 2013 public meeting identified a method to propose quantitative standards for dermal and ocular exposures in the ISA
 - March 26, 2014 NEI Letter claims that the NRC Staff position constitutes an unanalyzed backfit.

Chemical Exposure Review Guidance

- General Criteria
 - Consideration of all exposure pathways in ISA
 - Identify credible events that can produce effects comparable to those define in 70.61 including inhalation, dermal and ocular exposures.
 - Historical experience shows that dermal and ocular exposures have occurred in manual and non-routine operations.

Chemical Exposure Review Guidance (cont'd)

- Proposed Quantitative Standards for chemical consequences
 - For chemicals associated with credible events in the ISA
 - Consistent with available information (e.g. toxicological data, past experience)
 - Do not result in serious underestimate of consequences

Chemical Exposure Review Guidance (cont'd)

- Examples of information sources to support development of proposed ISA standards
 - AEGLs, ERPGs, TEELs
 - Globally Harmonized System of Classification and Labelling of Chemicals (GHS) Hazard Statements
 - NIOSH Skin Notations



Next Steps

- Staff determination on backfit assertion
- Interim Staff Guidance
- Engage NEI/Industry