

A large, stylized graphic of an atomic symbol, consisting of a central blue sphere and several intersecting blue elliptical orbits, is positioned on the left side of the slide.

Interim Staff Guidance – Guidance for Evaluation of Acute Chemical Exposures and Quantitative Standards

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Committee to Review Generic Requirements

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Objective

- Obtain CRGR approval of the staff's plans to issue an interim staff guidance (ISG)
 - Staff will use the guidance in its reviews of new licenses, license renewals, and applications pursuant to 10 CFR 70.64 that seek approval for new facilities or new processes at existing facilities.
- Staff seeks CRGR approval of the regulatory position that the issuance of the ISG does not constitute backfitting (10 CFR 70.76).

Interim Staff Guidance

- Provides additional guidance on staff review of licensee programs for addressing chemical safety.
 - For chemicals not regulated by US Occupational Safety and Health Administration (OSHA).
- Major Topics
 - Energetic reactions and toxic hazards
 - Consideration of non-routine phases of operation
 - Consideration of non-inhalation exposure pathways
 - Guidance for reviewing proposed standards with existing and available information.

Chemical Safety Requirements

- 10 CFR 70.62 requires safety programs that include (a) process safety information, (b) integrated safety analysis and (c) management measures.
- 10 CFR 70.61 presents risk performance requirements which include requirements for acute chemical exposure resulting in high and intermediate consequences.
- 10 CFR 70.65 requires submittal of ISA Summary to support demonstration of compliance with performance requirements. 70.65(b)(7) includes a requirement to include proposed standards used to assess compliance with performance requirements.

Note: NRC chemical safety requirements are intended to complement and be consistent with non-overlapping OSHA and EPA regulations

Chemical Safety Chronology

- Sequoyah Fuels event
- OSHA_NRC MOU

- Rulemaking to include all hazards.
- consistent with OSHA and EPA regulations.

- ISA summaries were approved.
- Information Notice 2007 HF exposures at FCF.

- 2013 Public meeting and white paper.
- 2014 NEI claimed backfit.
- 2015 draft ISG was published.

1986-1988

1990-1996

1999

2000

2005-2007

2007-2009

2013-2015

- NEI Petition (PRM 70-7) proposed an HF criteria for air
- Proposed rulemaking to include chemical hazards

- Final rule approved
- Conduct and maintain an ISA
- Submit an ISA Summary

- Multiple letters between NEI and NRC
- NRC stated no new position.
- Lack of guidance does not eliminate the requirement

Backfit Claim

- Staff position is that the ISA should consider chemical hazards, including: inhalation, dermal and ocular exposures.
- NEI claimed that requiring licensees to develop new quantitative dermal and ocular exposure standards is an unanalyzed backfit in March 26, 2014 letter (ML14086A270).
 - NRC rejected the claim in a September 15, 2014 response (ML14251A150).
 - NEI sent a letter to NRC General Counsel requesting NRC to reconsider staff response provided in September 15, 2014 (ML14322B019) .
 - The Commission directed staff to submit an information paper addressing the backfit issue and public comments received on the draft ISG and backfit.

Chemical Safety Programs at existing licensees

- Licensees have different levels of commitment for scope of analysis and consideration of all reasonable exposure pathways.
 - In 2009, one licensee proposed an HF dermal and ocular exposure standard.
 - All fuel fabrication plants have adopted the same HF standard in their ISAs.
 - In 2015, another licensee submitted a request for approval of new HF dermal and ocular exposure standard.
- Staff plans to gather information on licensee's chemical safety programs, analysis and practices through inspections.



No Backfit

- The ISG will be applied to new license applications, amendments filed pursuant 70.64, and license renewals.
- No backfit is now associated with the issuance of the ISG
 - The ISG will not be applicable to an existing fuel cycle facility's currently-licensed activities or operations.
 - ISG will apply to applications requesting NRC approval.
 - Guidance documents are not a substitute for NRC regulations, and compliance with guidance is not required.



Stakeholder involvement with ISG

- March 4, 2015 public meeting
- Public Comments on draft ISG
 - Comments from NEI (ML15189A076)
 - Comments from two fuel cycle licensees (ML15188A028 and ML15208A098)
 - Two members of the public (ML15189A073 and ML15189074)
 - Staff resolution of comments (ML14328A028)
- ACRS recommended publication of ISG (ML15293A314)

Next Steps

- Inform the Commission of staff plans to issue ISG.
- Issue ISG, use when reviewing new applications, license renewal applications and applications requesting NRC approval for new facilities or processes at existing facilities (70.64).
- Increase understanding of existing licensee programs related to chemical safety through inspections conducted under a temporary instruction.

Summary

- The ISG will provide guidance to:
 - Ensure the ISA review considers all exposure pathways.
 - Ensure “proposed quantitative standards” are identified when necessary and consistent with available information
- ISG does not constitute backfitting.



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Questions?