



SECRETARY

UNITED STATES
NUCLEAR REGULATORY COMMISSION
WASHINGTON, D.C. 20555-0001

October 29, 2018

COMMISSION VOTING RECORD

DECISION ITEM: SECY-17-0006

TITLE: INTERIM STAFF GUIDANCE ON EVALUATING CHEMICAL
EXPOSURES AT FUEL CYCLE FACILITIES

The Commission acted on the subject paper as recorded in the Staff Requirements Memorandum (SRM) of October 29, 2018.

This Record contains a summary of voting on this matter together with the individual vote sheets, views and comments of the Commission.

A handwritten signature in blue ink, appearing to read "Annette Vietti-Cook", written over a horizontal line.

Annette L. Vietti-Cook
Secretary of the Commission

Enclosures:

1. Voting Summary
2. Commissioner Vote Sheets

cc: Chairman Svinicki
Commissioner Baran
Commissioner Burns
Commissioner Caputo
Commissioner Wright
OGC
EDO
PDR

VOTING SUMMARY – SECY-17-0006

RECORDED VOTES

	<u>APPROVED</u>	<u>DISAPPROVED</u>	<u>ABSTAIN</u>	<u>NOT PARTICIPATING</u>	<u>COMMENTS</u>	<u>DATE</u>
Chrm. Svinicki		X			X	08/29/18
Cmr. Baran	X				X	07/12/17
Cmr. Burns		X			X	09/14/18
Cmr. Caputo		X			X	09/10/18
Cmr. Wright		X			X	08/24/18


NOTATION VOTE

RESPONSE SHEET

TO: Annette Vietti-Cook, Secretary
FROM: CHAIRMAN SVINICKI
SUBJECT: SECY-17-0006: Interim Staff Guidance on Evaluating
Chemical Exposures at Fuel Cycle Facilities

Approved Disapproved Abstain Not Participating

Comments: Below Attached None



SIGNATURE

08/29/18

DATE

Entered on "STARS" Yes No

Chairman Svinicki's Comments on SECY-17-0006
Interim Staff Guidance on Evaluating Chemical Exposures at Fuel Cycle Facilities

I disapprove the issuance of the interim staff guidance (ISG) (Enclosure 1 to SECY-17-0006) and the establishment of quantitative dermal and ocular exposure standards, either through modification of our regulations or through the backdoor of guidance, as attempted here. As the staff has previously concluded, there exists "reasonable assurance that the licensees meet the requirements in 10 CFR 70.61 with respect to the evaluation of acute chemical exposures." Further, the staff has provided no regulatory analysis justifying such a change, as is required under the NRC's Regulatory Analysis Guidelines (NUREG/BR-0058) when proposing to issue Interim Staff Guidance that establishes staff positions that would effect a change in the use of resources by NRC licensees and that has not been previously considered in the analysis of the existing regulatory requirement.

The current relevant NRC performance-based requirements contained in 10 CFR 70.61(b)(4) and (c)(4) define high- and intermediate-consequence exposure events and require licensees to limit the risk of such events by identifying and applying Items Relied Upon for Safety to reduce the event's likelihood or consequences. The Integrated Safety Assessment (ISA) summaries submitted in accordance with these requirements were approved without explicitly documenting a finding on dermal and/or ocular exposure. Approval in this manner is consistent with the agency's existing performance-based requirements, the Commission's prior rejection of including explicit quantitative standards in the rule, and with qualitative consideration of both OSHA and EPA standards in determining the acceptability of the approaches to chemical hazards incorporated in the ISAs themselves. Additionally, OSHA – in the development of its own regulations – has noted the challenge of developing quantitative standards for occupational dermal exposures given the lack of reasonable biological indicators, the difficulty in correlating the amount absorbed with a precise adverse health effect, and the resulting lack of rigor in the purported quantification of risk.

The staff's assertion that the ISG does not impose a "new" requirement is not persuasive when viewed in light of the record as a whole. The staff's further argument that, to the extent anything additional is required, it will simply be imposed as a "forward fit" is similarly unavailing. The NRC has historically invoked the term "forward fit" with respect to applications from existing licensees for license amendments, requests for exemption, and other requests for dispensation from compliance with otherwise-applicable legally binding requirements where the licensee seeks NRC permission *to conduct licensed activities in a manner different than what the NRC previously approved*. I find no such circumstance here. At bottom, the development of this staff guidance has drifted rather far afield from the discipline expected of the agency's work. I disapprove its issuance – and the quantitative standards it would seek to impose - on that basis.



Kristine L. Svinicki

08/29/18

NOTATION VOTE

RESPONSE SHEET


TO: Annette Vietti-Cook, Secretary
FROM: Commissioner Baran
SUBJECT: SECY-17-0006: Interim Staff Guidance on Evaluating
Chemical Exposures at Fuel Cycle Facilities

Approved Disapproved Abstain Not Participating

COMMENTS: Below Attached None

Original vote date: July 12, 2017

Entered in "STARS"
Yes
No



SIGNATURE
7/24/17

DATE

NOTATION VOTE

RESPONSE SHEET

TO: Annette Vietti-Cook, Secretary
FROM: Commissioner Baran
SUBJECT: SECY-17-0006: Interim Staff Guidance on Evaluating
Chemical Exposures at Fuel Cycle Facilities

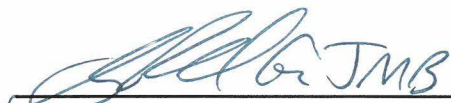
Approved Disapproved Abstain Not Participating

COMMENTS: Below Attached None

Entered in "STARS"

Yes

No



SIGNATURE

07/12/17

DATE

**Commissioner Baran's Comments on SECY-17-0006,
"Interim Staff Guidance on Evaluating Chemical Exposures at Fuel Cycle Facilities"**

Fuel cycle facilities may use hazardous chemicals, such as uranium hexafluoride and hydrogen fluoride, which can cause serious burns or even death if inhaled or absorbed through the skin or eyes. In order to protect the health of workers, it is important for fuel cycle facility licensees to analyze all credible hazardous chemical exposure pathways so that high and intermediate consequence events can be prevented or mitigated. In fact, chemical safety was a central concern when NRC established the integrated safety analysis requirements of Subpart H in September 2000. As the staff explains, "one of the objectives of those requirements was to reduce the frequency and severity of accidents resulting in onsite consequences from acute chemical exposures." Under the Atomic Energy Act, NRC's regulations, and the Memorandum of Understanding (MOU) between NRC and the Occupational Safety and Health Administration (OSHA), the responsibility for ensuring worker safety from chemical hazards associated with licensed material clearly lies with NRC. In order to "ensure clear and consistent reviews of future licensing actions," the staff plans to issue interim staff guidance for the evaluation of acute chemical exposures.

The staff's development of internal guidance is reasonable and prudent. I see no reason to further delay the issuance of the interim staff guidance. The staff's effort to ensure that integrated safety analyses evaluate all credible exposure pathways is consistent with current regulatory requirements, NRC's obligations under the MOU with OSHA, and the agency's safety mission under the Atomic Energy Act. Both the Advisory Committee on Reactor Safeguards and the Committee to Review Generic Requirements support publication of the interim staff guidance. Moreover, I agree with the staff that the guidance does not raise backfit issues. This is internal guidance to assist the staff in evaluating analyses of chemical hazards at fuel cycle facilities that are already required under existing regulations. In addition, the guidance only applies to future licensing actions. Although the guidance does not apply to currently licensed activities and operations, most fuel cycle facility licensees have already amended their integrated safety analysis summaries and modified their chemical safety hazard evaluation programs to explicitly include consideration of dermal and ocular exposures.

For these reasons, I approve prompt publication of the interim staff guidance.

NOTATION VOTE

RESPONSE SHEET

TO: Annette Vietti-Cook, Secretary

FROM: Commissioner Burns

SUBJECT: SECY-17-0006: Interim Staff Guidance on Evaluating Chemical Exposures at Fuel Cycle Facilities

Approved Disapproved Abstain Not Participating

Comments: Below Attached None

I disapprove issuance of the Interim Staff guidance (ISG) ZZ, Revision 0 , "Guidance for the Evaluation of Acute Chemical Exposures and Proposed Quantitative Standards" or the incorporation of the staff's proposed quantitative standards into the NUREG-1520. "Standard Review Plan for the Review of a License Application for a Fuel Cycle Facility". Staff's audits of licensees have determined that there are no immediate safety concerns and the staff has reasonable assurance that the licensees have met the performance requirements in 10 CFR 70.61. The application of the performance requirements ensures that facility design and operations adequately protect the health and safety of workers and the public from the chemical risks in the facility during normal operations and credible accident conditions. Staff's also evaluates chemical safety issues as part of the applicant's integrated safety analysis (ISA) summary. As required in 10 CFR 70.65, "Additional Contents of Applications," the ISA summary must include the evaluation of credible accident sequences at the facility, identification of items relied on for safety (IROFS) where necessary to reduce the likelihood of accident occurrence or to mitigate the consequences of accidents, and identification of the management measures that provide reasonable assurance of the availability and reliability of IROFS when needed. Staff has already made these findings for licensees and verified compliance through its audits.

Based on the NRC staff's audits, NRC regulatory requirements and NRC staff's current licensing guidance I have reasonable assurance the public and workers are adequately protected from chemical exposures and find no substantial safety rationale for issuance of the proposed ISG or the proposed dermal or ocular standards.

Entered in STARS
Yes
No



SIGNATURE

14 September 2018

DATE

NOTATION VOTE

RESPONSE SHEET

TO: Annette Vietti-Cook, Secretary

FROM: Commissioner Caputo

SUBJECT: SECY-17-0006: Interim Staff Guidance on Evaluating
Chemical Exposures at Fuel Cycle Facilities

Approved Disapproved Abstain Not Participating

Comments: Below Attached None

Entered in STARS

Yes

No



SIGNATURE

9-10-18

DATE

Commissioner Caputo's Comments on SECY-17-0006
Interim Staff Guidance on Evaluating Chemical Exposures at Fuel Cycle Facilities

I disapprove issuance of the Interim Staff Guidance (ISG) and the quantitative dermal and ocular exposure standards proposed in SECY-17-0006 due to the inadequate safety justification and lack of the regulatory analysis required by 10 CFR 70.76. In addition, I disapprove further staff effort to establish quantitative dermal or ocular exposure standards either through modification of existing regulations or regulatory documents.

Following the promulgation of 10 CFR 70 Subpart H in 2000, the staff issued NUREG-1520, "Standard Review Plan for the Review of a License Application for a Fuel Cycle Facility," that established acceptance criteria and the review process for the integrated safety assessments required by the new Subpart H. Neither the rule nor the standard review plan included requirements for quantitative dermal or ocular standards. In fact, NUREG-1520 (revisions 0, 1, and 2) states:

The NRC finds the use of the Emergency Response Planning Guidelines (ERPGs) established by the American Industrial Hygiene Association, the Acute Exposure Guideline Levels (AEGs) established by the National Advisory Committee for Acute Guideline Levels for Hazardous Substances, and exposure limits established by the Occupational Safety and Health Administration or contained in International Organization for Standardization (ISO) standards to be acceptable.¹

As Chairman Svinicki notes in her vote, the staff evaluated Integrated Safety Assessments (ISAs) consistent with the performance-based requirements in the rule and with consideration of both Occupational Safety and Health Administration and Environmental Protection Agency standards. The staff documented its findings in the original safety evaluations issued to each fuel facility licensee. Given that the fundamental purpose of licensees' chemical safety programs is prevention, protection, and mitigation, if necessary, there is no basis for concluding quantitative dermal and ocular standards would increase safety.

However, imposing dermal and ocular standards would be a backfit. 10 CFR 70.76(a)(1) states:

Backfitting is defined as the modification of, or addition to, systems, structures, or components of a facility; or to the procedures or organization required to operate a facility; any of which may result from a new or amended provision in the Commission rules or the imposition of a regulatory staff position interpreting the Commission rules that is either new or different from a previous NRC staff position.

¹ "Standard Review Plan for the Review of a License Application for a Fuel Cycle Facility," NUREG-1520, 3-23 (2002); "Standard Review Plan for the Review of a License Application for a Fuel Cycle Facility," NUREG-1520, Rev. 1, 3-26 (2010); "Standard Review Plan for the Review of a License Application for a Fuel Cycle Facility," NUREG-1520, Rev. 2, 3-26 (2015).

Since neither the rule nor the standard review plan include requirements for quantitative dermal or ocular standards, the imposition of such standards reflects a new and different staff position. Management Directive 8.4 states:

No staff position shall be communicated to the licensee unless the NRC official communicating that position has ascertained whether the proposed position is a backfit and, if so, ensured that the proposed position is identified as a backfit and the appropriate material (i.e. documented evaluation or backfit analysis) has been prepared and approved.²

The staff apparently did not follow this directive since no regulatory analysis was prepared for the proposed ISG. Rather, the staff argued that, “With respect to chemical safety hazards, the Subpart H regulations do not contain any language that limits the consequence criteria to only those associated with the inhalation pathway.” The staff in this case seems to believe that silence in any given rule with regard to any particular matter conveys authority to bypass its established processes. I do not agree.

Following review of the original ISA summaries between 2005 and 2007, the staff issued information notice IN-07-22 (the Notice), “Recent Hydrogen Fluoride Exposures at Fuel Cycle Facilities.” The Notice explained that, “HF (hydrogen fluoride) presents a hazard in different stages of the nuclear fuel cycle” and provided information about two events involving exposure to HF.³ The Notice discussed protective measures that would be important in preventing or mitigating potential exposure from HF but did not discuss quantitative dermal or ocular standards.⁴ However, the Notice did state:

It is expected that the recipients will review the information for applicability to their facilities and consider actions, as appropriate, to avoid similar problems. However, suggestions contained in this IN are not new NRC requirements, therefore, no specific action nor written response is required.⁵

The Notice sends a mixed message in “expecting” licensees to consider actions, but stressing the “suggestions” are not new requirements. Now, the staff asserts in SECY-17-0006 that:

Given the 10 CFR 70.61 requirements to limit the risk of credible events and the requirement to “conduct and maintain” an ISA, a fuel cycle facility needs to consider new information on potential chemical exposures at its facility, based on its operating experience.

² “Management of Facility-Specific Backfitting and Information Collection,” MD 8.4, 9 (2013).

³ “Recent Hydrogen Fluoride Exposures at Fuel Cycle Facilities,” IN-07-22, 1-2 (2007).

⁴ *Ibid.*

⁵ *Ibid.* at 1.

While the events cited in the Notice may have been relatively recent, the knowledge that HF posed a hazard was well-established as far back as 1986 and well understood when the NRC approved the original ISAs.⁶

In SECY 17-0006 the staff recounts that, “[a]fter the issuance of IN 2007-22, most fuel cycle facility licensees modified their ISAs and ISA summaries to include information addressing dermal and ocular exposure to hazardous chemicals (e.g. HF, nitric acid).” The staff apparently compelled new requirements for dermal and ocular standards without the analysis required under 10 CFR 70.76 (a)(2) and (3) and as directed in Management Directive 8.4.

Having rejected the industry’s assertion that the requirements are new and represent a backfit, the staff now seeks to institutionalize these new requirements through the issuance of the proposed ISG by arguing, “[t]he staff considered whether issuing the ISG would require licensees to make any changes or modifications to their existing programs and processes for evaluating chemical hazards.”⁷ The staff also found that, “existing licensees have already modified their chemical safety hazard evaluation program processes, as well as their ISA summaries to include consideration of dermal and ocular exposures.”⁸

My conclusion, based on the above, is that the NRC staff pressured licensees into implementing their “suggestions” over the industry’s strong objections, and the staff now uses that implementation both as an argument to reject backfit claims and as a basis for applying the ISG to future licensing actions.

Regarding the staff’s discussion of “forward-fit,” I fully support the position on “forward-fit” offered by the Chairman in her vote. More succinctly, my opinion is that any “forward-fit,” as the staff recommends in this case, should receive the same scrutiny and meet the same requirements contained in the backfit rule. A license, license amendment, or license renewal should not be considered an opportunity to levy extra-regulatory requirements without the scrutiny of a regulatory analysis.

Lastly, the staff states that issuance of the ISG would not constitute backfitting because, “The ISG contains guidance for the NRC staff, and changes in internal staff guidance are not matters for which applicants or licensees have backfit protection under 10 CFR 70.76(a)(1).” This is false since the guidance would result in “the imposition of a regulatory staff position *interpreting* the Commission rules that is either new or different from a previous NRC staff position.”⁹ This is also contrary to NUREG BR-0058 which states, “In general, each NRC office should ensure that all mechanisms used by the NRC staff to establish or communicate generic requirements, *guidance*, requests, or staff positions that would affect a change in the use of resources by its licensees include an accompanying regulatory analysis.”¹⁰

⁶ See “Interim Staff Guidance on Evaluating Chemical Exposures at Fuel Cycle Facilities,” SECY-17-0006, Enclosure 4 at 1.

⁷ “Interim Staff Guidance on Evaluating Chemical Exposures at Fuel Cycle Facilities,” SECY-17-0006 at 7.

⁸ *Ibid.* at 8.

⁹ 10 C.F.R. § 70.76(a)(1) (emphasis added).

¹⁰ “Regulatory Analysis Guidelines of the U.S. Nuclear Regulatory Commission, Draft Report for Comment,” NUREG/BR-0058, 2-2 (2017) (emphasis added).

The promulgation of agency guidance is an inappropriate method for imposing new regulatory requirements on licensees and applicants because such guidance, by its very nature, lacks the “force of law.”¹¹ Yet with its recommendations in SECY-17-0006 the staff attempts to do just that. These requirements have not had the benefit of notice and comment rulemaking as required by the Administrative Procedures Act.

Per NUREG 1409, “The NRC staff is responsible for identifying plant-specific and generic backfits and for determining if proposed new or revised positions would constitute a backfit.”¹² Rather than executing this responsibility in accordance with the long-established rule and management direction, the staff chose instead to pursue a contorted, counterfeit process expending the agency’s resources for nine years. In each future case where staff concludes that revisions are necessary for any guidance, it is my expectation that the staff will pursue the more straightforward path and execute its regulatory responsibilities by completing the necessary backfit evaluations prior to developing and issuing revised guidance.

Given the lack of the required regulatory analysis and any conclusive evidence that quantitative dermal and ocular standards would increase safety, I disapprove of the issuance of the proposed interim staff guidance and the quantitative dermal and ocular standards described therein.

¹¹ See *Perez v. Mortg. Bankers Ass'n*, 135 S. Ct. 1199, 1203-04, 575 US ___, ___ (2015). The Court in *Perez* explains that, per the APA, “the notice-and-comment requirement ‘does not apply’ to ‘interpretative rules, general statements of policy, or rules of agency organization, procedure, or practice.’” *Ibid.* (quoting Administrative Procedure Act, 5 U.S.C. § 553(b)(A)). The Court further stated that, “Interpretive rules ‘do not have the force and effect of law and are not accorded that weight in the adjudicatory process.’” *Ibid.* (quoting *Shalala v. Guernsey Memorial Hospital*, 514 U.S. 87, 99 (1995)). While the APA does not define “interpretive guidance,” and its precise definition remains open for debate, documents that interpret agencies’ regulations by explaining to the agency staff how to proceed in enforcing those regulations – which the ISG purports to do – would seem to fit squarely within the “definition” of interpretive guidance.

¹² “Backfitting Guidelines,” NUREG-1409, 2.1.3.1 (1990).

NOTATION VOTE

RESPONSE SHEET

TO: Annette Vietti-Cook, Secretary

FROM: Commissioner Wright

SUBJECT: SECY-17-0006: Interim Staff Guidance on Evaluating
Chemical Exposures at Fuel Cycle Facilities

Approved Disapproved Abstain Not Participating

Comments: Below Attached None

Entered in STARS

Yes

No


SIGNATURE

8/24/18
DATE

SECY-17-0006: Interim Staff Guidance on Evaluating Chemical Exposures at Fuel Cycle Facilities

I support the staff's desire to limit high and intermediate consequence events and to protect workers from acute dermal and ocular exposures. However, I do not agree that the identification of quantitative dermal and ocular exposure standards is necessary to do so. In developing the interim staff guidance (ISG), the staff discounted aspects of the licensees' layered chemical safety programs that are not items relied on for safety but protect against acute dermal and ocular exposures. I believe a more risk-informed approach is appropriate. In particular, a more risk-informed approach would have considered the totality of the extensive requirements imposed on and mitigative measures in place for licensees with respect to chemical safety programs, including the requirements of state regulators and other federal agencies, such as OSHA and EPA. Further, the staff audited the chemical safety programs of current fuel cycle facility licensees, and concluded that "there are no immediate safety concerns related to dermal and ocular exposures" at these facilities and that there is "reasonable assurance that the licensees meet the requirements in 10 CFR 70.61 with respect to the evaluation of acute chemical exposures." Since the staff has stated that the new requirements in the ISG are not needed for adequate protection and that the current licensees meet the requirements in 10 CFR 70.61, it is unclear why additional measures are needed for new applicants, licensees implementing new processes, or licensees seeking license renewal. For this reason, I am disapproving the issuance of the ISG.

I am also troubled because it appears that the staff did not follow internal procedures and perform a regulatory analysis in accordance with NUREG/BR-0058, Regulatory Analysis Guidelines of the US Nuclear Regulatory Commission, to determine whether the benefits of the action would justify the associated costs. The staff's proposal to impose the requirement to identify quantitative standards for acute dermal and ocular chemical exposures going forward appears to represent a new staff position, the cost of which was not considered in the regulatory analysis for 10 CFR Part 70, Subpart H. The imposition of this new requirement is particularly impactful for licensees seeking license renewal, during which time the staff would impose a *de facto* backfit by requiring licensees to revise their integrated safety analysis for all processes, not just for new processes, to include quantitative standards for acute dermal and ocular exposures. This is especially worrisome since the staff has already concluded that licensees are currently in compliance with the requirements in 10 CFR 70.61. As discussed in the NRC Backfit refresher training, the implementation of revised requirements, guidance, or acceptance criteria for voluntary actions, which is sometimes referred to as a forward-fit, does not constitute backfitting. However, there is no clear guidance on when these forward-fits are appropriate. To provide clarity on this, the staff should work with OGC to develop guidance on the conditions under which forward-fits are appropriate. Additionally, the staff should follow NUREG/BR-0058 and perform a regulatory analysis when it establishes or communicates generic requirements, guidance, requests, or staff positions that would affect a change in the use of resources by our licensees to determine whether the benefits of the action would justify the associated costs.

Finally, I am concerned that the ISG would redefine what is necessary to meet a performance-based rule. My understanding is that performance-based rules do not give the staff permission to redefine what is necessary for adequate protection. Adequate protection decisions are exclusively reserved to the Commission. The staff may not use guidance to add requirements that are beyond the scope of the rule and associated regulatory analysis explicitly approved by the Commission. The staff should work with OGC to update guidance on performance-based rules to account for how to address new information or staff positions that were not considered

in the regulatory analysis for the rule and could redefine what is necessary to meet the performance criteria. The guidance should reflect when Commission direction is needed.