POLICY ISSUE
(Notation Vote)

DATE: January 11, 2017 SECY-17-0006

FOR: The Commissioners

FROM: Victor M. McCree
Executive Director for Operations

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

PURPOSE:

The purpose of this paper is to inform the Commission of the staff's plan to issue the final version of the interim staff guidance (ISG) document, "Guidance for the Evaluation of Acute Chemical Exposures and Proposed Quantitative Standards." This paper describes the objectives of the ISG; the resolution of the public comments related to the draft ISG; and the legal, regulatory, and policy implications regarding the issuance of the final ISG. The staff plans to issue the ISG no less than 20 days following the date of this paper.

SUMMARY:

The ISG (Enclosure 1) provides guidance to the U.S. Nuclear Regulatory Commission (NRC) staff in its review of chemical hazards at fuel cycle facilities. Licensees of such facilities are subject to the integrated safety analysis (ISA) requirements in Title 10 of the *Code of Federal Regulations* (10 CFR) Part 70, Subpart H, "Additional Requirements for Certain Licensees Authorized To Possess a Critical Mass of Special Nuclear Material." The ISG is intended to promote more thorough and uniform staff reviews of how these licensees assess chemical hazards in their ISA summaries. The ISG will be incorporated into NUREG 1520, "Standard Review Plan for the Review of a License Application for a Fuel Cycle Facility," when this NUREG is next revised.

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The draft ISG was published for comment in a March 4, 2015, *Federal Register* notice (FRN), and a supplemental notice regarding the backfitting issues was published in an April 17, 2015, FRN. The final ISG reflects modifications made to the draft in response to the public comments submitted. Several comments related to the backfitting issues and to the table of historical events were included in response to the April 17, 2015, FRN.

The comments on the backfitting issues and the table of historical events, and the staff's responses to those comments, are provided in Enclosure 2. The comments received on the technical contents of the ISG, and the staff's responses to those comments, are provided in Enclosure 3. Enclosure 4 provides a detailed chronology of events relevant to the ISG's development, and discusses the longstanding NRC position that fuel cycle facility licensees are required under the Part 70, Subpart H, regulations to consider chemical hazards associated with their use of NRC-licensed material, including consideration of potential dermal and ocular exposures.

The ISG provides guidance to the NRC staff on the evaluation of chemical hazards, and will be applicable to the review of: (1) license applications for proposed fuel cycle facilities, (2) proposed changes to existing facilities that require the submittal of license amendment requests under 10 CFR 70.72, "Facility changes and change process," and (3) license renewal applications submitted pursuant to 10 CFR 70.73, "Renewal of licenses."

The ISG will not be applicable to an existing fuel cycle facility's currently-licensed activities or operations. The ISG provides staff with useful information for evaluating chemical hazards at fuel cycle facilities.

BACKGROUND:

The NRC regulates radiological, nuclear criticality, and certain chemical hazards at fuel cycle facilities pursuant to the requirements in 10 CFR Part 70, Subpart H. Fuel cycle facilities are generally similar to chemical plants in that their operations generate chemical toxicity hazards that can directly impact onsite workers and, although far less likely, the surrounding public. Some fuel cycle facilities use hazardous chemicals that have the potential to cause serious burns or fatalities if inhaled or absorbed through the skin. Such chemicals include uranium hexafluoride (UF_6), hydrogen fluoride (HF), nitric acid, hydroxylamine, sodium hydroxide, sulfuric acid, ammonia, and uranyl nitrate.

Regulatory Requirements

In September 2000, the NRC amended 10 CFR Part 70 by adding the Subpart H requirements—10 CFR 70.60 through 10 CFR 70.76 (65 Fed. Reg. 56211 [Sept. 18, 2000]). Licensees are required under 10 CFR 70.62, "Safety Program and Integrated Safety Analysis," to establish and maintain a safety program which complies with the 10 CFR 70.61 performance requirements. Under 10 CFR 70.62(c), licensees must conduct and maintain an ISA that includes identifying: (1) the chemical hazards of licensed material and hazardous chemicals produced from licensed material, (2) facility hazards that could affect the safety of licensed material, (3) potential accident sequences, (4) the likelihood and consequences of the potential accident sequences, and (5) each item relied on for safety that is required to meet the 10 CFR 70.61 performance requirements. The provisions of 10 CFR 70.61(b) require that the risk of each credible high-consequence event be limited through the establishment of controls so that such an event will be "highly unlikely" to occur. High-consequence events include those arising from an acute chemical exposure as specified in 10 CFR 70.61(b)(4).

Similarly, 10 CFR 70.61(c) requires that the risk of each credible intermediate-consequence event be limited through the establishment of controls so that such an event will be "unlikely" to occur. Intermediate-consequence events include those arising from an acute chemical exposure as specified in 10 CFR 70.61(c)(4).

For all "credible" event consequences specified in 10 CFR 70.61(b)(4) and (c)(4), the ISA summary must describe the, "proposed quantitative standards used to assess the consequences to an individual from acute chemical exposure to licensed material or chemicals produced from licensed materials," in accordance with 10 CFR 70.65(b)(7). Licensees are further required in their ISA summaries to describe the definitions of "unlikely," "highly unlikely," and "credible" that are used in their ISA evaluations, in accordance with 10 CFR 70.65(b)(9).

The provisions in 10 CFR 70.62(c)(1)(ii) and (iii) and the definition of "hazardous chemicals produced by licensed materials" in 10 CFR 70.4[1] establish the scope of the NRC's authority over chemical hazards at fuel cycle facilities. Examples of specific chemical hazards at fuel cycle facilities that are subject to the NRC's authority include: (1) chemical hazards of NRC-licensed material (e.g., UF_6), (2) substances having NRC-licensed material as precursor compounds (e.g., HF produced from UF_6), (3) substances that physically or chemically interact with NRC-licensed materials (e.g., nitric acid mixed with uranium nitrate), and, (4) chemical hazards that could affect the safety of licensed materials and thus present an increased radiological risk.

As discussed further in Enclosure 4, the scope of the ISA requirements is consistent with a memorandum of understanding established in 1988 between the U.S. Occupational Safety and Health Administration and the NRC (Agencywide Documents Access and Management System [ADAMS] Accession No. ML031140641). Enclosure 4 further includes a detailed discussion of: (1) the Subpart H requirements, (2) the history of their development, (3) the implementing guidance documents issued in 2001 and 2002, (4) the NRC's 2007 information notice, and (5) the ensuing correspondence between the Nuclear Energy Institute (NEI) and the NRC staff that eventually led to the NEI's 2014 backfit claim.

NRC Approval of the Integrated Safety Analysis Summaries and Information Notice 2007-022

A fuel cycle facility licensee must "conduct and maintain" an ISA that evaluates, among other aspects, the chemical hazards of NRC-licensed material used at its facility. The ISA is a comprehensive analysis of facility operations and associated hazards. The ISA is not part of the license and it is not submitted to the NRC for review. Rather, the ISA describes the safety basis for the operating license. Licensees are required to submit an ISA summary under 10 CFR 70.65. An ISA summary, as defined in 10 CFR 70.4, "provides a synopsis of the results" of the ISA.

From 2005–2007, the NRC staff reviewed and approved the initial ISA summaries for existing licensees based on: (1) licensees' general commitments to evaluate acute chemical exposures, and (2) a review of the chemical accident sequences to "confirm the appropriateness and adequacy of the ISA method(s) and completeness of the ISA and accuracy of analysis of accident sequences via horizontal and vertical slice reviews."[2]

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[1] The term "hazardous chemicals produced from licensed materials" is used in 10 CFR 70.62(c)(1)(ii), and is defined in 10 CFR 70.4.

[2] Section 3.5.2.3 of NUREG-1520 discusses these horizontal and vertical slice reviews in detail.

Consistent with staff guidance, the ISA reviews were comprehensive but not all-encompassing. Staff reviews focused on the general methodology used to evaluate the facility hazards, and a sample of the risk-significant scenarios. Additionally, the initial reviews of the ISAs for the fuel cycle facilities focused on toxic hazards that could affect individuals located outside the controlled area, as defined in 10 CFR 20.1003, "Definitions." The ISA summaries for new license applications are reviewed using the same approach. Shortly after approval of the initial ISA summaries, the NRC issued Information Notice (IN) 2007-22, "Recent Hydrogen Fluoride Exposures at Fuel Cycle Facilities," dated June 19, 2007 (ADAMS Accession No. ML071410230). The IN explained that HF presents a significant hazard in different stages of the nuclear fuel cycle. The IN included two events related to acute chemical exposure that occurred in fuel cycle facilities, including one dermal exposure (ADAMS Accession Nos. ML072620314 and ML070650158). The IN stated that licensees should consider all exposure pathways that could lead to intermediate and high consequences and noted that this was not a new requirement. After the IN was issued, NEI raised concerns regarding the basis for evaluating dermal and ocular exposures in the ISA. This letter and subsequent letters which led to the backfit claim are discussed in Enclosure 4.

As discussed further in Enclosure 4, after the issuance of IN 2007-22, fuel cycle facility licensees modified their ISAs to include evaluations of dermal and ocular exposure pathways. These licensees also modified their ISA summaries to include information on dermal and ocular exposures to HF, which is one of the more hazardous chemicals found in these types of facilities.[3] One licensee also identified dermal and ocular exposures to nitric acid as a potential intermediate consequence.

Backfitting Concerns Related to the Draft ISG

As detailed further in Enclosure 4, on March 26, 2014, as staff was developing the ISG, NEI sent a letter (ADAMS Accession No. ML14086A270) to the NRC stating that requiring licensees to develop new quantitative standards for dermal and ocular exposures represented an unanalyzed backfit. The NRC responded to NEI's letter on September 15, 2014 (ADAMS Accession No. ML14251A150), rejecting the backfit claim. NEI then sent a letter to NRC's General Counsel on November 7, 2014 (ADAMS Accession No. ML14322B019), requesting a re-evaluation of its backfit claim. The NRC staff published the draft ISG for comment in an FRN dated March 4, 2015 (80 Fed. Reg. 11692). The staff also sought public comments on the industry's backfit claim in a supplemental FRN dated April 17, 2015 (80 Fed. Reg. 21274).

By letter to NEI dated May 5, 2015 (ADAMS Accession No. ML15126A070), the NRC's General Counsel stated that before issuing the final ISG, the NRC staff would provide its backfit comment responses to the Commission. The enclosures to this paper provide all the comments received during the public comment period and the staff's associated responses. Enclosure 2 provides comments and the staff's responses related to backfitting concerns. Enclosure 3 provides technical comments pertaining to the ISG and the staff's responses. As reflected in the final ISG provided in Enclosure 1, the NRC staff revised the draft ISG, as appropriate, in response to various public comments. As discussed later in this paper, the staff believes that changes to the final ISG have addressed the concerns expressed in the backfit-related comments.

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[3] For example, in January 2009, one licensee proposed a dermal and ocular exposure standard as part of a license amendment submittal requesting approval of a new process line. The safety evaluation report related to this amendment discusses the proposed standard analysis (ADAMS Accession No. ML090490686).

DISCUSSION:

The performance-based and risk-informed Subpart H requirements were established in part to increase confidence in the margin of safety at fuel cycle facilities, and one of the objectives of those requirements was to reduce the frequency and severity of accidents resulting in onsite consequences from acute chemical exposures.[4] The death of a worker at Sequoyah Fuels Corporation in 1986 was directly attributed to an accident involving licensed nuclear material and UF_6. Since then, chemical exposures resulting from the use of NRC-licensed material have caused additional worker injuries. The NRC staff viewed the Subpart H requirements as being necessary to determine safety performance objectives for worker protection. If, in conducting their ISAs, licensees discovered vulnerabilities, they would be able to prevent and mitigate the consequences or likelihood of accidents.[5]

The NRC is responsible for regulating those hazards that are within its jurisdiction. Inhalation exposures are a demonstrated safety concern for workers, as are dermal and ocular exposures. Based on operating experience, the NRC staff finds that these types of acute chemical exposures are credible and have the potential to result in consequences that must be limited, as required by 10 CFR 70.61. Given the 10 CFR 70.61 requirements to limit the risk of credible events and the 10 CFR 70.62(c) requirement to "conduct and maintain" an ISA, a fuel cycle facility licensee needs to consider new information on potential chemical exposures at its facility, based on its operating experience. The staff position has consistently been that the ISA should consider potential acute chemical exposure events, including those involving inhalation, dermal, and ocular exposure pathways. Evaluation of credible exposure pathways in the ISA is important for understanding the risk of potential accident sequences so that actions can be taken to effectively limit the risk. Under 10 CFR 70.65(b)(7), licensees are required in their ISA summaries to describe proposed quantitative standards to identify the thresholds they will use to classify intermediate and high consequence events. As discussed further below, the ISG was developed, in part, to provide guidance to NRC staff reviewers evaluating the proposed quantitative standards.

During the review of the original ISA summaries between 2005 and 2007, the staff did not explicitly document the results of its review of accident scenarios concerning dermal and ocular exposures. Following the issuance of IN 2007-22 in 2007, it became clear that fuel cycle facility licensees had a different understanding of the requirements in 10 CFR 70.61 with respect to acute chemical exposures. As detailed in Enclosure 4, NEI's letter dated September 8, 2008 (ADAMS Accession No. ML083360632), reflected the fuel cycle facility licensees' view that the NRC's initial review of ISA summaries established a new regulatory position with respect to the provisions of 10 CFR 70.65(b)(7), specifically on dermal and ocular exposure standards. As indicated above in the discussion of IN 2007-22, the NRC staff has consistently taken the position that the regulations require licensees to evaluate all credible exposure pathways.

The NRC engaged with stakeholders on multiple occasions (described in Enclosure 4) to understand the different positions held by the NRC and its licensees concerning the evaluation of acute chemical exposures, including dermal and ocular pathways, to demonstrate compliance with 10 CFR 70.61 and 10 CFR 70.65(b)(7) requirements. In written communications (see Enclosure 4), NEI expressed concern about the lack of guidance for evaluating acute chemical exposures. While the NRC and NEI were still discussing the issue of dermal and ocular exposures and standards, licensees were making the necessary

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4 SECY-00-0111, "Final Rule to Amend 10 CFR Part 70, 'Domestic Licensing of Special Nuclear Material,'" Attachment 9, "Part 70 Amendment Regulatory Analysis," dated March 27, 2000 (ADAMS Accession No. ML003715338).

5 SECY-00-0111, Attachment 9, Section 6.1.2.1, "Onsite Consequences."

revisions to their ISAs to include an evaluation of dermal and ocular exposures to hazardous chemicals. Responding to the lack of guidance noted by NEI, the NRC staff developed guidance to address the 10 CFR 70.65(b)(7) requirement and, in 2013, presented a technical paper (ADAMS Accession No. ML13262A131) proposing an approach to identify dermal and ocular exposure standards using available toxicity information. At the time, the staff was weighing the options of preparing an ISG or working with stakeholders to develop a technical paper.

The staff reviewed its existing guidance for chemical safety reviews and determined that it needed to be improved. Specifically, NUREG-1520 did not cover the review of all phases of operations (e.g., normal operations, maintenance, and special operations), toxic and energetic chemical hazards, and credible exposure pathways when evaluating acute exposure to hazardous chemicals. The existing guidance did not address how the staff reviews the proposed quantitative standards required by 10 CFR 70.65(b)(7). For these reasons, the staff determined that additional staff guidance was necessary.

The staff developed the ISG to provide guidance in the areas identified above as being deficient. The ISG is expected to improve the quality, efficiency, clarity, reliability, and uniformity of the staff's reviews of ISA summaries and the underlying ISAs with respect to chemical hazards. The ISG is also expected to provide for consistency in chemical safety reviews. The ISG focuses on: (1) identification of chemical hazards and accident sequences as required by 10 CFR 70.62(c), (2) determination of chemical accident likelihood and consequences under the applicable 10 CFR 70.61(b) and (c) requirements, and (3) ensuring the ISA summary contains the information required by 10 CFR 70.65(b) related to chemical safety, particularly the proposed quantitative standards. For example, Section B.4.1 of the ISG provides the following guidance regarding the quantitative standards required by 10 CFR 70.65(b)(7):

> The proposed quantitative standards should be based on generally available information from independent sources (e.g., government agencies or organizations, well recognized professional organizations) describing the chemical's toxicity and hazardous properties. The applicant's or licensee's discussion of any proposed quantitative standard should describe the information on which the proposed standard is based. Due to the various information sources identified in this ISG, it is not expected that applicants will need to conduct their own experimental testing or toxicity tests to generate data supporting their proposed standards.

Regulatory Audits of Chemical Safety Programs

Since the initial ISA summaries were submitted, reviewed, and approved, ISAs have been updated based on fuel cycle facility changes in accordance with 10 CFR 70.72(d). After the issuance of IN 2007-22, most fuel cycle facility licensees modified their ISAs and ISA summaries to include information addressing dermal and ocular exposures to hazardous chemicals (e.g., HF, nitric acid). Licensees have continued to improve their analyses and associated chemical safety programs since 2007. The NRC staff reviewed information that describes the licensees' ISA methodology with respect to chemical hazards and identified the need for additional information to better understand how licensees are evaluating acute chemical exposures in the context of their ISAs. In this regard, during June and July 2016, the staff audited the chemical safety programs at five of the operating Part 70 fuel cycle facilities.[6] The audits focused on the uranium fuel fabrication facilities regulated under Part 70 because

[6] Audit plans were developed for each facility (ADAMS Accession Nos. ML16167A028, ML16169A089, ML16201A106, ML16197A500, ML16189A405).

their operations have the greatest potential for chemical exposures involving dermal or ocular exposure pathways. The NRC staff did not audit the chemical safety program at the uranium enrichment facility operated by Louisiana Energy Services because operations involving liquid UF_6 are in sealed systems which present limited potential for dermal or ocular exposures. USEC Inc.'s American Centrifuge Plant, the proposed AREVA Eagle Rock facility, and the proposed General Electric Hitachi Global Laser Enrichment facility, are not operational and thus have no chemical safety programs to audit. The Mixed Oxide Fuel Fabrication Facility (MFFF) is under construction, but the applicant has not been issued a license. Before issuing any 10 CFR Part 70 operating license for the MFFF, the NRC staff will ensure that the MFFF applicant addresses all credible exposure pathways that have the potential to result in high or intermediate consequences in its ISA.

During the subject audits, the NRC staff examined commitments made in license applications, ISA evaluations, chemical risk assessments, process hazard analyses, and internal procedures that implement the site specific ISA methodology. The NRC staff walked down the process areas and observed the controls in place to prevent or mitigate chemical consequences. The NRC staff determined that the facilities, operations, hazard analyses, and details of the chemical safety program were different for each licensee. Four out of the five licensees audited have programs that are consistent with the NRC staff interpretation of the requirements of 10 CFR 70.61 and 10 CFR 70.65. Chemical safety programs at these four facilities either include the evaluation of all exposure pathways or the associated licensees are in the process of implementing modifications to their programs to consider all exposure pathways. The fifth licensee had a programmatic weakness in that its ISA methodology considers only the consequences of inhalation exposure. Despite this, staff did not identify any credible dermal or ocular exposures that could result in high or intermediate consequence events at the specific facility given the chemicals and processes currently being used. Based on a discussion in November 2016, this licensee assured the NRC staff that if any chemicals of concern (such as HF) are introduced, then it would evaluate all credible exposure pathways.

Based on the audit results, the staff concluded that there are no immediate safety concerns related to dermal and ocular exposures at the facilities audited. The staff has reasonable assurance that the licensees meet the requirements in 10 CFR 70.61 with respect to the evaluation of acute chemical exposures. Based on the audit results and licensees' actions and commitments to address all credible exposure pathways, the staff plans to issue the ISG to ensure clear and consistent reviews of future licensing actions.

Regulatory, Legal, and Policy Implications

The NRC staff evaluated the regulatory, legal, and policy implications regarding the issuance of the ISG. As previously discussed, NEI requested a re-evaluation of its claim upon receipt of the staff's original response (which invoked the compliance exception in 10 CFR 70.76(a)(4)(i)). With respect to the staff's evaluation of the backfit claim, the regulatory requirements at issue have not changed. Subpart H requires a licensee in its ISA to identify and analyze all credible hazards and assess potential accident consequences. 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 backfit claim is based on the assertion that issuing the ISG would establish a new regulatory position that would require existing licensees to develop new quantitative standards for dermal and ocular exposures. The staff considered whether issuing the ISG would require licensees to make any changes or modifications to their existing programs and processes for evaluating chemical safety hazards, due to the staff position reflected in the ISG, consistent with the backfitting definition in 10 CFR 70.76, "Backfitting." The staff also considered

whether, if a backfit exists, the compliance or adequate protection exception in 10 CFR 70.76(a)(4) would apply. Given 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, and are meeting the performance requirements, staff determined that the ISG should apply only to future licensing actions.

Consequently, the staff plans to apply the ISG to the review of applications: (1) for new licenses, (2) for the renewal of licenses pursuant to 10 CFR 70.73, "Renewal of Licenses," and (3) for license amendments submitted pursuant to 10 CFR 70.72(d)(1). These license amendment requests include those that seek approval of new processes at existing fuel cycle facilities. The staff evaluated whether applying the ISG to future licensing actions would constitute backfitting. As it is guidance only, this ISG does not impose new regulatory actions on existing licensed operations at fuel cycle facilities. The ISG supplements existing guidance in NUREG-1520 and focuses on the staff's review of chemical safety hazards under the requirements of Subpart H to Part 70. The NRC staff will incorporate the ISG into the next revision of NUREG-1520.

For the following reasons, issuance of the ISG would not constitute "backfitting" as defined in 10 CFR 70.76(a)(1):

(1) 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).
(2) The staff plans to apply the ISG to the review of applications: (1) for new licenses, (2) for the renewal of licenses pursuant to 10 CFR 70.73, and (3) for license amendments submitted pursuant to 10 CFR 70.72(d)(1).
(3) The NRC staff does not intend to impose or apply the positions described in the ISG to existing (already issued) licenses unless there is a voluntary request to amend the license, or request the renewal of the license.

CONCLUSION:

The inhalation, dermal, and ocular exposure pathways are important to consider when evaluating potential accident sequences that would result in chemical exposures to workers with high or intermediate consequences, as set forth in 10 CFR 70.61(b)(4) and (c)(4). Similar to inhalation exposures, dermal and ocular exposure pathways are credible and may result in high consequence and intermediate consequence events. Preventing or mitigating these events is important for worker safety.

Based on the audits conducted by the NRC staff at selected fuel cycle facilities, the NRC has reasonable assurance that the existing licensees meet the requirements in 10 CFR 70.61 with respect to the evaluation of acute chemical exposures. Therefore, the ISG will only be applied to future licensing actions. Licensees can modify their existing safety programs and ISAs without NRC pre-approval, in accordance with 10 CFR 70.72(d)(2). The staff plans to continue to monitor any changes made to the chemical safety programs as well as the chemical operations at the fuel cycle facilities. If the staff observes a degradation in a licensee's program with respect to the performance requirements of 10 CFR 70.61, the NRC staff would take the appropriate regulatory action to ensure adequate protection.

COORDINATION:

On October 8, 2015, the staff briefed the Advisory Committee on Reactor Safeguards on the proposed final ISG. In a letter dated October 20, 2015, the committee recommended that the staff issue the ISG (ADAMS Accession No. ML15293A314).

On January 28, 2016, the staff briefed the Committee to Review Generic Requirements (CRGR) on the proposed final ISG. Enclosure 4 reflects CRGR's input. The CRGR endorsed the ISG's issuance by letter dated March 25, 2016 (ADAMS Accession No. ML16032A047).

The Office of the General Counsel has reviewed this paper and has no legal objections.

/RA/

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Enclosures:
1. Interim Staff Guidance
2. Public Comments Related to Backfit
3. Public Comment Resolution of Technical Issues
4. Chronology of Events Relevant to Development of the ISG

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