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

September 3, 2021

MEMORANDUM TO: Margaret M. Doane
Executive Director for Operations

FROM: Stephanie M. Coffin, Chairman
Committee to Review Generic Requirements

Signed by Coffin, Stephanie
on 09/03/21

SUBJECT: COMMITTEE TO REVIEW GENERIC REQUIREMENTS:
MINUTES OF MEETING NUMBER 457

On August 24, 2021, the Committee to Review Generic Requirements (CRGR, the Committee) held Meeting No. 457. The purpose of this meeting was to review the Regulatory Analysis document and rule language for the Draft Final Rulemaking 10 CFR Part 26, "Fitness for Duty Programs" (ML21111A017).

The staff from both the Office of Nuclear Material Safety and Safeguards and the Office of Nuclear Security and Incident Response presented a joint discussion focused specifically on the draft final rule language and the staff's positions regarding the changes that imposed backfitting. The staff's presentation materials are located in ADAMS (ML21237A068). Enclosure 1 provides the list of meeting attendees.

Because of the voluminous nature of the review package and time constraints within the staff's schedule, the CRGR and staff collaborated to review the draft final version. This review took place in parallel with the Office of the General Counsel (OGC) review in preparation for the complex review scheduled for August 24, 2021. During this early review, the CRGR provided minor comments (via e-mail) that the staff addressed ahead of the complex review along with its opinion that the staff's backfit determination complied with the agency backfitting policy. This preliminary review in parallel with the OGC review was conducted to assist the staff in meeting their abbreviated scheduled deadlines.

In its discussion, the staff indicated that the specific objectives of the rule are to (1) maintain reasonable assurance of a drug-free workplace through the enhanced detection of individuals who are not fit for duty and not trustworthy and reliable because of illegal drug use, legal drug misuse, or an attempt to subvert the drug testing process; (2) harmonize select drug-testing requirements under 10 CFR Part 26 with the 2008 HHS Guidelines (73 FR 71858, November 25, 2008) and the 2017 HHS Guidelines (81 FR 7920, January 23, 2017); and (3) enhance

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donor protection and due process requirements for individuals subject to drug testing. In support of these three objectives, the final rule also contains amendments to improve the clarity, organization, and flexibility of 10 CFR Part 26.

In its review of this subject rulemaking, the CRGR engaged the staff in discussions regarding the purpose, backfitting approach, and aspects of the regulatory analyses and the effects of this rulemaking such as cost benefit and scope of applicability. The staff indicated that the rule would ensure that 10 CFR Part 26 drug testing programs are effective, strengthen the defense-in-depth regulatory framework associated with access authorization, and increase the overall level of protection of public health and safety or the common defense and security.

Moreover, the staff indicated that the draft final rule constitutes a backfit largely because of mandated changes to the drug testing panel that must be used by licensee and other entities performing testing of individuals under 10 CFR Part 26. To this end, the rule set forth the following nine proposed categories of changes:

1. Lower initial and confirmatory cutoff levels for amphetamines and cocaine metabolites.

2. Expand initial drug testing panel to include heroin metabolite 6-acetylmorphine (6-AM) and revise confirmatory testing cutoff level for 6-AM.

3. Expand initial and confirmatory drug testing panels to include Ecstasy-type drugs.

4. Expand initial and confirmatory opioid testing panel to include hydrocodone, hydromorphone, oxycodone, and oxymorphone.

5. Require special analyses testing of dilute specimens and suspected subversion attempt specimens.

6. Require use of limit of quantitation (LOQ) instead of limit of detection (LOD) for special analyses testing and adulterant testing of specimens.

7. Required MRO actions for invalid validity test results (high pH, 9.0 to 9.5) and donor requests for additional testing.

8. Require specimen testing even if a refusal to test is determined at the collection site (post-event tests).

9. Implement drug testing program changes.

In addition, the staff indicated that they adhered to the backfit criteria (i.e., the nine-point analysis of backfitting factors as required under 10 CFR 50.109(c)) while conducting this rulemaking and determined that the changes in the final rule are cost justified and substantially increase public health and safety or the common defense and security.

To reiterate from above, the CRGR asked various questions regarding the purpose, backfitting approach, and aspects of the regulatory analyses and the effects of this rulemaking such as cost benefit and scope of applicability. Consequently, the CRGR did not identify any concerns in its review of the staff's backfitting analysis accompanying the draft final rule.

As a side note, the CRGR found the staff's product that was a culmination of a multi-office effort to be well thought out and of outstanding quality.

CONCLUSIONS and RECOMMENDATIONS

Following the review of the regulatory analysis document, backfitting and issue finality assessment document, and the draft final rule language, the CRGR endorsed the rulemaking package without any recommendations.

Enclosure:
List of Attendees for CRGR Meeting No. 457

CRGR MEETING No. 457
LIST OF ATTENDEES
(August 24, 2021)

CRGR Members
Stephanie M. Coffin, Chairman
Andrea L. Kock, NRR
Craig G. Erlanger, NSIR
Robert Lewis, NMSS
Raymond K. Lorson, RI
Tison A. Campbell, OGC

CRGR Staff
Les R. Cupidon, CRGR Staff

NRC Staff
Ilka Berrios, NMSS/REFS/RRPB
Cindy Bladey, NMSS/REFS/RASB
Helen Chang, NMSS/REFS/RASB
Kevin Coyne, NMSS/REFS
Karen Dickey, ADM/DRMA/MDMRT
Doris Duran-Hernandez, NMSS/REFS/RASB
Mike F. King, NRR
Angella Love Blair, NMSS/REFS/RASB
Stewart Schneider, NMSS/REFS
Fred Schofer, NMSS/REFS/RASB
Justin A. Vazquez, NRR/DRO/IOLB/HFT
Antoinette Walker-Smith, NMSS/REFS/ERMB
Brian Zaleski, NSIR/DPCP

OGC Staff
Howard Benowitz, OGC/GCRPS

Enclosure

COMMITTEE TO REVIEW GENERIC REQUIREMENTS: MINUTES OF MEETING NUMBER 457 DATE September 3, 2021

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RLewis, NMSS
RLorson, R-I
TCampbell, OGC/GCHA/AGCOR/NLO

ADAMS Accession No.: ML21242A517 *** via email**

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NAME	LCupidon *LC*	JZabel *JZ*	SCoffin *SC*	
DATE	Sep 3, 2021	Sep 3, 2021	Sep 3, 2021	

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