U.S.NRC
United States Nuclear Regulatory Commission
Protecting People and the Environment

Fitness for Duty Drug Testing Requirements Final Rule

Backfit and Issue Finality

CRGR Brief
August 24, 2021

Meeting Purpose

- Discuss final rule backfits with the CRGR
- Answer questions from the CRGR on final rule concurrence
- Obtain the CRGR endorsement of backfits

Schedule

August 30	NRR Office Director provides concurrence
September 1	Final rule provided to the OEDO (concurrence due by September 15)
September 15	Final rule provided to SECY

Background

- Aligning with HHS Guidelines changes in 2008 and 2017 by:
  - Lowering cutoff levels and improving methods for testing of drugs in the testing panel (enhances detection of drug use)
  - Adding substances to the drug testing panel (addresses societal drug use trends)
  - Adding a new test result review for invalid specimens to account for specimen handling conditions (donor protection)
  - Change from limit of detection (LOD) to limit of quantitation (LOQ) for validity testing
- Changing Part 26 based on lessons learned

Description of Backfits

- The final rule consists of nine categories of amendments to 10 CFR Part 26
- The amendments:
  - meet the definition of “backfitting” under 10 CFR 50.109(a)(1) and 70.76(a)(1), and
  - affect the issue finality of a holder of a combined license under 10 CFR Part 52 because they result in modifications to the procedures required to operate a facility

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

- Rule changes:
  - Initial testing cutoff levels in 10 CFR 26.133
  - Initial testing cutoff levels in 10 CFR 26.163(a)(1), and confirmatory testing cutoffs levels in 10 CFR 26.163(b)(1)
- Basis for changes: 2008 HHS Guidelines (lower cutoff levels extend the time that a drug is detectible after use in a urine specimen)

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

- Rule changes:
  - Remove requirement in 10 CFR 26.163(b) that confirmatory testing of 6-AM only proceed after a morphine positive result, and instead
  - Add 6-AM to initial testing panels in 10 CFR 26.133 and 26.163(a)
- Basis for changes: 2008 HHS Guidelines (clinical research demonstrated that existing testing methodology missed some heroin users; the changes address these research findings)

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

- Rule changes add MDMA and MDA to:
  - Initial testing panel in 10 CFR 26.133
  - Initial testing panel in 10 CFR 26.163(a), and confirmatory testing panel in 10 CFR 26.163(b)
  - Annual statistical summary reporting requirements for HHS-certified laboratories in 10 CFR 26.169(h)(3)
- Basis for changes: 2008 and 2017 HHS Guidelines (addresses societal drug use trends)

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

- Rule changes add these substances to:
  - Initial testing panel in 10 CFR 26.133
  - Initial testing panel in 10 CFR 26.163(a), and confirmatory testing panel in 10 CFR 26.163(b)
  - Annual statistical summary reporting requirements for HHS-certified laboratories in 10 CFR 26.169(h)(3)
- Basis for changes: 2017 HHS Guidelines (addresses societal drug use trends)

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

- Rule changes to 10 CFR 26.163(a)(2):
  - Require special analyses testing of:
    - ❑ dilute specimens
    - ❑ specimens collected during suspected subversion attempts
  - Lower immunoassay response to initiate special analyses testing from 50 percent to 40 percent of the cutoff calibrator for each drug
- Basis for changes: lessons learned and subversion attempt trends (using lower testing cutoff levels extends time a drug is detectible after use)

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

- Rule changes replace LOD with LOQ in:
  - § 26.161(c)(3) through (c)(6) for validity testing (adulterants)
  - § 26.161(f)(5) and (f)(7) for validity testing (invalid results)
  - § 26.163(a)(2) for special analyses testing for drugs
- Basis for changes: 2008 HHS Guidelines (validity testing) (LOQ provides additional donor protection on the accuracy of test results)

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

- Rule changes:
  - Add 10 CFR 26.185(f)(3) to require MRO to consider if specimen handling conditions (time and temperature) could cause an invalid validity test result
  - Revise 10 CFR 26.165(b)(2) to require MRO to document date and time of a donor's oral request for retesting/Bottle B testing
  - Revise 10 CFR 26.165(f)(2) to require MRO to cancel a test if a donor specimen is unavailable for retesting/Bottle B testing and order a second specimen collection without prior notice to the donor
- Basis for changes: 2008 HHS Guidelines

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

- Rule change in 10 CFR 26.107(d)(5):
  - Any specimen collected must be tested at an HHS-certified laboratory
  - Previously, any specimen collected could be discarded
- Basis for change: Support root-cause evaluations of accidents

9. Implement drug testing program changes

In response to final rule changes, licensees must make one-time changes to:

- Revise FFD program policies and procedures
- Conduct training of subject personnel
- Revise contracts with HHS-certified laboratories and blind performance test sample providers
- Validate drug testing assays at licensee testing facilities (only 3 sites)

Costs

Backfit Description*	7% Net Present Value	3% Net Present Value
1. Lower cutoff levels for amphetamine, cocaine, methamphetamine	($185,898)	($277,775)
2. Expand testing panel to include initial testing of 6-AM (and revise confirmatory testing cutoff level)	($935,375)	($1,397,666)
3. Expand initial and confirmatory testing panel to include Ecstasy-type drugs	($702,980)	($1,050,415)
4. Expand initial and confirmatory testing panel to include oxycodone, oxymorphone, hydrocodone, hydromorphone	($1,829,243)	($2,733,312)
5. Require special analyses testing of dilute specimens and specimens collected under direct observation	($109,322)	($163,353)
9. Implement one-time drug testing program changes	($136,936)	($136,936)
TOTALS	($3,899,754)	($5,759,457)

* No estimated costs associated with backfits 6, 7 and 8

Cost-Justification Determination

- Drug testing panel changes estimated to result in 16- to 29-percent annual increase in individuals identified using illegal drugs, misusing legal drugs, or attempting to subvert the testing process
- Final rule is estimated to result in averted training costs to licensees of $4.3 million (7% discount rate) or $6.5 million (3% discount rate)
- Drug testing panel changes reduce likelihood individuals can subvert the testing process through temporary abstinence of drug use and improve detection of drugs
- Required special analyses testing of dilute specimens and adding special analyses testing for suspected subversion attempt specimens reduces likelihood individuals can subvert the testing process

Cost-Justification Determination

- Use of LOQ instead of LOD for special analyses and validity testing increases assurance of testing precision
- Final rule enhances consistency with the HHS Guidelines, FFD program integrity, and the protection of individual rights
- Required testing of specimens collected for post-event tests when a refusal to test has been made at the collection site improves root-cause analysis of accidents

Consideration of Backfitting Factors

- The staff completed the 9-point analysis of backfitting factors as required under 10 CFR 50.109(c)
- The assessment is documented in Section VIII of the Backfitting and Issue Finality Assessment (ML21111A030)
- The backfits are final

Issue Finality Assessment

10 CFR 52.103 does not apply and therefore the NRC must satisfy 10 CFR 50.109 to impose the requirements on holders of combined licenses

Conclusion

- The final rule satisfies 10 CFR 50.109
- The NRC staff finds that the backfits contained in the final rule, when considered in the aggregate, constitute a cost-justified substantial increase in public health and safety or the common defense and security under 10 CFR 50.109 and 10 CFR 70.76

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