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Presentation to the Nuclear Energy Institute's Access Authorization and Fitness for Duty Workshop

10 CFR Part 26 Final Rule (November 2022)

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Office of Nuclear Security and Incident Response
Brian Zaleski, Specialist - Fitness For Duty / Access Authorization
Brian.Zaleski@nrc.gov (301-287-0638)

Part 26 Final Rule (November 2022)

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Aligns Part 26 drug testing requirements more closely with the U.S. Department of Health and Human Services' 2008 and 2017 Mandatory Guidelines for Federal Workplace Drug Testing of urine specimens. Also incorporates lessons learned from implementing Part 26.

- **Published**: November 22, 2022 (87 FR 71422)
- **Rule changes effective**: December 22, 2022
- **Compliance required by**: November 22, 2023

Substantive changes:

- ❑ Adds testing for MDMA, MDA, hydrocodone, hydromorphone, oxycodone, oxymorphone
- ❑ Lowers drug testing cutoff levels for amphetamine, methamphetamine, cocaine
- ❑ Improves testing method to identify the heroin metabolite, 6-acetylmorphine (6-AM)
- ❑ Improves methods to detect donor subversion attempts (special analyses testing)
- ❑ Adds option to collect and drug test oral fluid specimens for most observed urine collection conditions

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Drug Testing Panel Changes - Urine, 26.163

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Drugs or drug metabolites	Testing Cutoff Levels (ng/mL)	
	Initial	Confirmatory
Cocaine metabolites	~~300~~150	~~150~~100
Opioids ~~Opiate metabolites~~:		
6-acetylmorphine (6-AM)	10	10[1]
Hydrocodone	300	100
Hydromorphone		100
Oxycodone	100	100
Oxymorphone		100
Amphetamines		
Amphetamine	~~1000~~500	~~500~~250
Methamphetamine		~~500~~250[2]
Methylenedioxymethamphetamine (MDMA)	500	250
Methylenedioxyamphetamine (MDA)		250

[1] ~~Confirmatory testing for 6-AM performed only when morphine concentration exceeds 2,000 ng/mL~~

[2] To be reported positive for methamphetamine, a specimen must also contain amphetamine at a concentration equal to or greater than ~~200~~100 ng/mL

Only substances with changes displayed

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Special Analyses Testing, 26.163(a)(2)

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Required for:

- ❑ **Dilute specimens** (***before was optional***) AND
- ❑ **Directly observed specimens** collected under four conditions (***new***):
  - ✓ 26.115(a)(1): Donor provided a urine specimen with a substituted, adulterated, or invalid result with no adequate medical explanation
  - ✓ 26.115(a)(2): Donor presents at this collection a urine specimen outside the required temperature range of 90 to 100°F
  - ✓ 26.115(a)(3): Donor conduct indicates an attempt to subvert the testing process
  - ✓ 26.115(a)(5): Donor requests a retest and either Bottle B or the single specimen is not available for testing

When: The initial drug test concentration is 40% of the cutoff level or greater (***before was 50% of the initial test cutoff or greater***)

Then: Conduct confirmatory drug testing to the Limit of Quantitation (LOQ) (***before was to the Limit of Detection (LOD)***)

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Observing a Hydrating Donor, 26.109(b)(1)

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When a donor is unable to provide a urine specimen of at least 30 mL on the initial attempt, the donor is provided with up to 40 ounces of fluid over 3 hours to provide a specimen.

[***New flexibility***] Under 10 CFR 26.109(b)(1), the collector that initiated the collection process with a donor **may assign responsibility for monitoring a donor during the hydration process** to:

- ❑ **Another trained collector** that meets the 10 CFR 26.85(a) requirements, **OR**
- ❑ **A hydration monitor**

- The original collector MUST "**record the name** of the other collector or hydration monitor **on the Federal CCF**"
- **If a hydration monitor is used**, the initial collector MUST "**explain the hydration process and acceptable donor behavior** to the hydration monitor"
- The **original collector may perform other collections** while the donor is in the hydration process

See also new Regulatory Guide 5.89, November 2022, for guidance

Part 26 Final Rule (November 2022)
Blind Performance Test Samples (BPTS), 26.168

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BPTS Lot In-Service Requirement – 10 CFR 26.168(h)(1) [*revised*]

- Eliminated requirement that BPTS suppliers place a sample lot in service for no more than 6 months.
- The BPTS supplier is already required to provide the expiration date for each BPTS provided – 10 CFR 26.168(h)(2).

BPTS Formulation Requirements – 10 CFR 26.168(g)

- The final rule did not change the BPTS formulation requirements, BUT the final rule DID:
  - ❑ lower the testing cutoff levels for some substances, and
  - ❑ add new substances to the testing panel.

  As a result, a licensee/other entity needs to purchase new BPTSs for the substances with lower cutoff levels, and new BPTSs for substances added to the testing panel.

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BPTS Quarterly Submission Example, 26.168

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BPTS Formulation Requirements	BPTS submissions for a site that tests 1,000 or fewer specimens per quarter			
	Quarter (Q)1 (Jan-Mar)	Q2 (Apr-Jun)	Q3 (Jul-Sept)	Q4 (Oct-Dec)
Positive BPTSs - All drugs in panel (1 time/quarter) - 2 Marijuana / quarter - Replace PCP with Cocaine in 2 quarters	01: Marijuana 02: Marijuana 03: AMP, MAMP **04: MDMA, MDA** 05: COD, MOR, 6-AM **06: HYC, HYM** **07: OXYC, OXYM** 08: Cocaine 09: PCP	01: Marijuana 02: Marijuana 03: AMP, MAMP **04: MDMA, MDA** 05: COD, MOR, 6-AM **06: HYC, HYM** **07: OXYC, OXYM** 08: Cocaine 09: Cocaine (replaces PCP)	01: Marijuana 02: Marijuana 03: AMP, MAMP **04: MDMA, MDA** 05: COD, MOR, 6-AM **06: HYC, HYM** **07: OXYC, OXYM** 08: Cocaine 09: PCP	01: Marijuana 02: Marijuana 03: AMP, MAMP **04: MDMA, MDA** 05: COD, MOR, 6-AM **06: HYC, HYM** **07: OXYC, OXYM** 08: Cocaine 09: Cocaine (replaces PCP)
False Negative BPTS (min. 1 per quarter)	10: Substance(s)	10: Substance(s)	10: Substance(s)	10: Substance(s)
Validity Test BPTSs (min. 3 per quarter) - 1 Adulterated - 1 Substituted - 1 Dilute	11: Adulterated 12: Substituted 13: Dilute	11: Adulterated 12: Substituted 13: Dilute	11: Adulterated 12: Substituted 13: Dilute	11: Adulterated 12: Substituted 13: Dilute
Negative BPTSs	14: Negative	14: Negative	14: Negative	14: Negative

Notes: 6-AM: 6-acetylmorphine; AMP: amphetamine; COD: codeine; HYC: hydrocodone; HYM: hydromorphone; MAMP: methamphetamine; MDA: Methylenedioxyamphetamine; MDMA: Methylenedioxymethamphetamine; MOR: morphine; OXYC: oxycodone; OXYM: oxymorphone

Red font identifies the 3 new BPTS submissions per quarter covering the substances added to the testing panel for an existing HHS-certified laboratory (1 containing MDMA/MDA; 1 containing HYC/HYM; and 1 containing OXYC/OXYM)

Part 26 Final Rule (November 2022)
Donor Retest Requests, 26.165(b)(2) and (b)(3)

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- **26.165(b)(2) [*New*] documentation requirement** when a **donor** makes **a written or oral request** to the MRO **to initiate** the **retesting** of **a single specimen or** the **testing of Bottle B** of a split specimen for a confirmed positive, adulterated or substitute test result:

  "The MRO shall **document** in his or her records **when (i.e., date and time)** the **request was received** from the donor to retest an aliquot of the single specimen or to test the Bottle B split specimen."

- **26.165(b)(3) [*Revised*]** Addresses an inconsistency where some licensees interpreted 26.165(b)(3) to require the MRO to receive a donor's written permission prior to initiating retesting, even though 26.165(b)(2) permits the donor to make an oral request to test:

  "~~The donor shall provide his or her permission for retesting an aliquot of the single specimen or the testing of Bottle B. Neither the licensee, MRO, NRC nor any other~~ No entity, other than the MRO as permitted in § 26.185(l), may order the retesting of an aliquot of the single specimen or the testing of the Bottle B split specimen ~~in Bottle B without the donor's written permission, except as permitted in § 26.185(l)~~."

Part 26 Final Rule (November 2022)
Observed Collections – Optional Use of Oral Fluid

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- **Enabled the option to collect and drug test oral fluid specimens under four observed specimen collection conditions** [***new***]:

  26.83 Specimens to be collected.

  "**(b)** Collect only urine specimens for both initial and confirmatory tests for drugs**, unless the licensee or other entity establishes through its policy and procedures that an oral fluid specimen can be collected and tested for any of the observed specimen collection conditions under § 26.115(a)(1) through (3) and (a)(5). For each observed collection condition under § 26.115(a)(1) through (3) and (a)(5), the licensee or other entity shall always collect and test the same specimen type**."

- **Must be established through the FFD policy and procedures.**

- **Must use the same specimen for a directly observed collection condition** (e.g., collect urine for 26.115(a)(2) and (a)(3); and collect oral fluid for 26.115(a)(1) and (a)(5)).

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Observed Collections – Optional Use of Oral Fluid

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- **Must be tested at an HHS-certified laboratory** – 26.153(a), 26.31(d)(3)(i)
- **Tables added for initial and confirmatory test cutoff levels for drugs and drug metabolites** – 26.163(a) and 26.163(b), respectively
- **Specimen collector must meet same training requirements as for alcohol and urine specimen collectors** – 26.85(a)
- **Visual privacy must be provided to the donor and collector during the collection of an oral fluid specimen** – 26.87
- **Store specimens under the conditions specified by the device manufacturer** – 26.117(j)

NOTE: No changes in the final rule on when alternate specimens may be collected:
- Medical condition prevents providing urine (shy-bladder) – **26.119(g)(3)**
- Acceptable medical explanation for an invalid result that would affect the testing of another urine specimen – **26.185(f)(2)**
- Medical condition makes collecting a urine specimen difficult/hazardous – **26.31(d)(5)(i)**

Part 26 Final Rule (November 2022)
Documenting Observations on the Federal CCF, 26.107(b)(1) and (d)(3), 26.111(b)

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Part 26 requires a specimen collector to document observations on the Federal CCF in several instances. However, the Federal CCF only contains a single blank line to write text (i.e., on the "Remarks" line of the form).

[***New flexibility in three circumstances***] **If sufficient space does not exist on the Federal CCF**, **the collector may document information using "another documentation method consistent with the collection procedures of the licensee or other entity**":

- ❑ Conduct indicating an attempt to subvert the testing process – **26.107(b)(1)**
- ❑ Refusal to test description – **26.107(d)(3)**
- ❑ Unusual findings about specimen color, clarity, and any signs of contaminants or adulteration – **26.111(b)**

Part 26 Final Rule (November 2022)
Invalid Specimen Review (pH 9.0-9.5) - 26.185(f)(3) [*New*]

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- "If the MRO and the laboratory agree that further testing would not be useful and there is **no legitimate technical or medical explanation, and** the **invalid result is** based on **pH in the range of 9.0 to 9.5**, the MRO shall consider whether there is evidence of **elapsed time, exposure** of the specimen **to high temperature, or both that could account for the pH value**."

- "If an acceptable explanation exists for the invalid test result due to pH, based on objective and sufficient information, that elapsed time, high temperature, or both caused the high pH and donor action did not result in the invalid pH result, the MRO shall report a cancelled test result to the licensee or other entity, cancel the test result, and direct the licensee or other entity to collect a second urine specimen from the donor as soon as reasonably practicable. The **second specimen collected may not be collected under direct observation**."

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Regulatory Guidance

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Regulatory Guide 5.89, Fitness-for-Duty Programs for Commercial Power Reactor and Category I Special Nuclear Material Licensees [***new***]

- Provides guidance on three topic areas:
  - ❑ Monitoring a donor during the 3-hydration period (shy-bladder)
  - ❑ Use of mirrors to assist in observed urine collections
  - ❑ MRO review of invalid specimens, pH 9.0 to 9.5

- Available for download at: https://www.nrc.gov/docs/ML2014/ML20143A034.pdf

Part 26 Final Rule (November 2022)
Final Rule Implementation Resources

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- **Part 26 Final Rule, November 22, 2022** (87 FR 71422) (https://www.federalregister.gov/documents/2022/11/22/2022-24903/fitness-for-duty-drug-testing-requirements)
- **eCFR track changes version of Part 26 (identifies all final rule changes)** (https://www.ecfr.gov/compare/current/to/2022-11-21/title-10/chapter-I/part-26)
- **Part 26 Final Rule Q&A Session** – Public Meeting held on April 26, 2023 Discussed 8 questions received on the final rule. Responses captured in the following two documents:
  - NRC slide presentation (ML23122A176)
  - Meeting summary (ML23146A126)