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United States Nuclear Regulatory Commission
Protecting People and the Environment

10 CFR Part 26, Fitness for Duty Programs

Question and Answer Session on Implementing the November 2022 Final Rule

April 26, 2023
(Webinar)

Discussion Topics

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- Opening Remarks and Agenda
- Resources for Final Rule Implementation
- Questions Received
- Question and Answer Session

Opening Remarks

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- The purpose of this meeting is to provide licensees and other entities with an opportunity to ask the NRC technical staff questions on implementing the November 22, 2022, "Fitness for Duty Drug Testing Requirements" 10 CFR Part 26 Final Rule.

- This is an Information Meeting with a Question-and-Answer Session. Attendees will have an opportunity to ask questions of the NRC staff or make comments about the issues discussed throughout the meeting; however, the NRC is not actively soliciting comments towards regulatory decisions at this meeting.

Agenda

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Time	Topic	Speaker
1:00 – 1:05 PM	Opening Remarks	NRC
1:05 – 1:30 PM	NRC Review of Questions Already Received	NRC
1:30 – 2:30 PM	Question and Answer Session	Industry/NRC

Resources for Final Rule Implementation

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- **November 22, 2022, Part 26 Final Rule (87 FR 71422 - 71463)** https://www.federalregister.gov/documents/2022/11/22/2022-24903/fitness-for-duty-drug-testing-requirements
- **eCFR track changes version of Part 26 - final rule** https://www.ecfr.gov/compare/current/to/2022-11-21/title-10/chapter-I/part-26
- **Regulatory Guide 5.89**, Fitness-For-Duty Programs For Commercial Power Reactor and Category I Special Nuclear Material Licensees **[New]** https://www.nrc.gov/docs/ML2014/ML20143A034.pdf

Questions Received

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1) **How many blind performance test samples (BPTSs) must we submit per quarter to comply with the final rule changes?**

2) **I noticed a discrepancy in the revisions to 26.117(j) appearing in the eCFR version of 10 CFR Part 26 and on the NRC's website for 10 CFR Part 26. Which is correct?**

3) **If an individual tests positive under the new rule at one site and then applies for access at another site yet to implement the new rule - does the site yet to implement the rule have to honor the denial?**

Question 1: How many BPTSs must we submit per quarter to comply with the final rule changes?

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- The final rule did not change the BPTS submission requirements in 10 CFR 26.168 but did add new substances to the required testing panel and lowered the testing cutoff levels for some substances already in the testing panel.

- Most sites submit less than 1,000 donor specimens per calendar quarter for testing at an HHS-certified laboratory. Therefore, the minimum number of BPTSs per quarter applies to most sites.

Question 1 (continued)

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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 panel: (1 containing MDMA/MDA; 1 containing HYC/HYM; and 1 containing OXYC/OXYM)

Question 2: Discrepancy in revisions to 26.117(j) appearing in the e-CFR and NRC website versions of 10 CFR Part 26

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- Discrepancies did exist in both versions.
- Both versions have been updated.

The correct version of 10 CFR 26.117(j), with final rule changes highlighted:

Collection site personnel shall arrange to transfer the collected specimens to the HHS-certified laboratory or the licensee testing facility. Licensees and other entities shall take appropriate and prudent actions to minimize false negative results from specimen degradation. ~~Specimens~~ Urine specimens that have not ~~been~~ shipped to the HHS-certified laboratory or the licensee testing facility within 24 hours of collection and any urine specimen that is suspected of having been substituted, adulterated, or tampered with in any way must be maintained cooled to not more than 6 °C (42.8 °F) until they are shipped to the HHS-certified laboratory. Oral fluid specimens shall be stored under the conditions specified by the oral fluid specimen collection device manufacturer. Specimens must be shipped from the collection site to the HHS-certified laboratory or the licensee testing facility as soon as reasonably practical but, except under unusual circumstances, the time between specimen shipment and receipt of the specimen at the licensee testing facility or HHS-certified laboratory should not exceed 2 business days.

Question 3: An individual tests positive under the new rule at one site and then applies for access at a second site yet to implement new rule – does the site yet to implement the rule have to honor the denial?

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- Yes, the denial under 10 CFR 26.75(e) applies.

- This situation is no different than a site that utilizes an expanded drug testing panel and an individual tests positive for a substance not in another licensee's testing panel. If that individual applied for access at another licensee site, 10 CFR 26.69, "Authorization with potentially disqualifying fitness-for-duty information" applies (including followup testing).

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Question and Answer Session

Where Can I Get Help?

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