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Protecting People and the Environment

10 CFR Part 26, Fitness for Duty Programs

Question and Answer Session on Implementing the November 2022 Final Rule

August 23, 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.

- This is the second Question-and-Answer Session on the November 2022, Part 26 final rule. The first was held on April 26, 2023.

Agenda

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Time	Topic	Speaker
1:00 – 1:05 PM	Opening Remarks	NRC
1:05 – 1:45 PM	NRC Review of Questions Already Received	NRC
1:45 – 2:30 PM	Question and Answer Session	Industry/NRC

Implementation Resources

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- **Part 26 Final Rule, November 22, 2022 (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 (RG) 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)

  RG 5.89 covers three topics:
  - ✓ Donor hydration during shy-bladder events
  - ✓ Observed collections using mirrors
  - ✓ MRO review of invalid specimens, pH 9.0 to 9.5

Implementation Resources (Cont.)

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- **NRC Presentations on the November 2022, Part 26 Final Rule** (July 2023 Nuclear Energy Institute's Access Authorization and Fitness For Duty Workshop):
  - Main Conference Presentation – July 12, 2023 (https://www.nrc.gov/docs/ML2318/ML23181A098.pdf)
  - Medical Review Officer Training – July 10, 2023 (https://www.nrc.gov/docs/ML2318/ML23181A095.pdf)
  - FFD Program Manager/Auditor Training – July 10-11, 2023 (https://www.nrc.gov/docs/ML2318/ML23181A096.pdf)

[Note: duplication of content exists amongst the presentations, but additional material is included based on target audience.]

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) **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 new rule have to honor the denial?**

3) **Will the final rule require the use of a different Federal Custody and Control Form (Federal CCF) because of the expanded drug testing panel?**

4) **Special analyses testing under 26.163(a)(2) – Can you explain the final rule changes and required testing conditions?**

Questions Received

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5) **Observing a donor during the hydration process:**

   a) **Can a hydration monitor have a personal relationship with the donor?**

   b) **Can an individual not screened for unescorted access (UA)/ unescorted access authorization (UAA) serve as a hydration monitor?**

   c) **Can a donor in the hydration process be remotely monitored?**

   d) **Can another specimen collector complete the collection process for a donor in the hydration process?**

Questions Received

6) Alternate specimen testing – did the final rule change anything?

7) Dilute specimen test results:

   a) Is an MRO review required under 26.185(a)?

   b) The MRO and MRO staff responsibilities in 26.183(c) and (d) appear inconsistent with 26.185(a) – are they?

8) I've noticed an inconsistency between the 10 CFR Part 26 text appearing on the NRC website and that in the eCFR version of 10 CFR Part 26, which is correct?

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 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
  - ✓ the substances added to the testing panel.
- The next slide provides an example of the minimum number of quarterly BPTSs a licensee site would need to submit to an HHS-certified laboratory to comply with the final rule changes.

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:

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 new rule have to honor the denial?

- 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).

Question 3:
Will the final rule require the use of a different Federal CCF because of the expanded drug testing panel?

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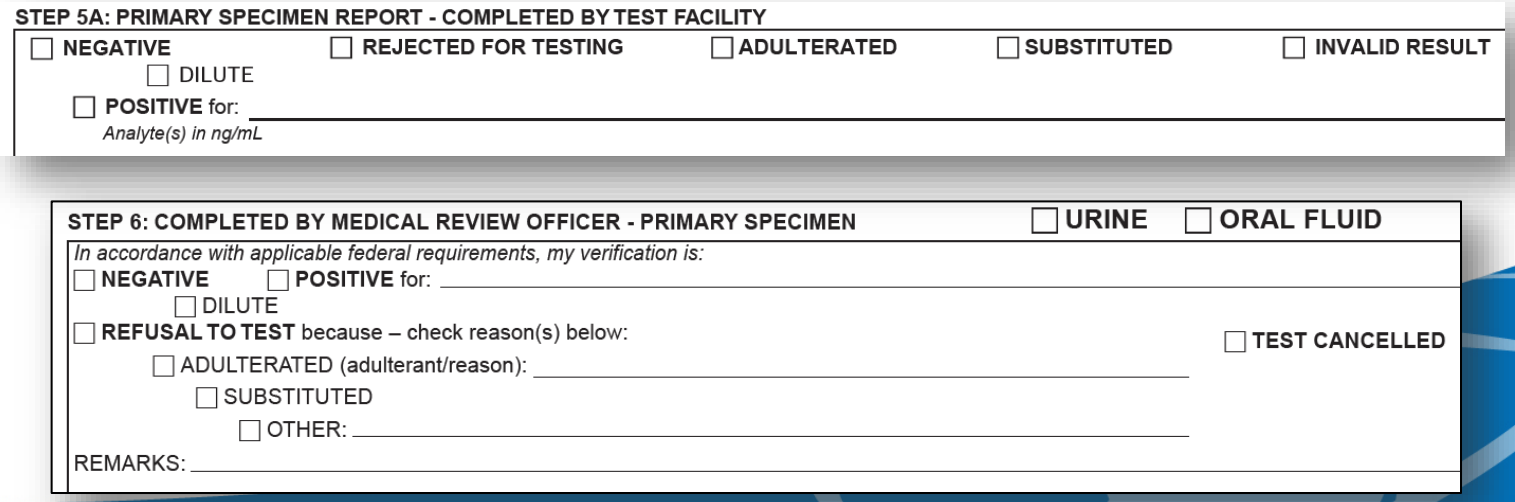
- No. The current HHS-approved Federal CCF is to be used for the collection and drug testing of specimens under the final rule.

- If a specimen is positive for one or more drugs, the testing laboratory and the MRO write the name of the drug(s) on the "**Positive** for:" line on the appropriate copy of the Federal CCF.



STEP 5A: PRIMARY SPECIMEN REPORT - COMPLETED BY TEST FACILITY

☐ **NEGATIVE** ☐ **REJECTED FOR TESTING** ☐ **ADULTERATED** ☐ **SUBSTITUTED** ☐ **INVALID RESULT**

☐ DILUTE

☐ **POSITIVE** for: _____

Analyte(s) in ng/mL

STEP 6: COMPLETED BY MEDICAL REVIEW OFFICER - PRIMARY SPECIMEN ☐ **URINE** ☐ **ORAL FLUID**

In accordance with applicable federal requirements, my verification is:

☐ **NEGATIVE** ☐ **POSITIVE** for: _____

☐ DILUTE

☐ **REFUSAL TO TEST** because – check reason(s) below: ☐ **TEST CANCELLED**

☐ ADULTERATED (adulterant/reason): _____

☐ SUBSTITUTED

☐ OTHER: _____

REMARKS: _____

Question 4:
Special analyses testing under 26.163(a)(2) – Can you explain the final rule changes and required testing conditions?

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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)***)

Question 5a:
Observing a donor during the hydration process:

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Can a hydration monitor have a personal relationship with the donor ?

Regulatory Guide 5.89 addresses this topic in Section C.1.A(6) and states:

"If a collector transfers responsibility for monitoring a donor to a hydration monitor, the collector should verbally confirm that the hydration monitor does not have a personal relationship with the donor(s)."

Question 5b:
Observing a donor during the hydration process:

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Can an individual not screened for UA/UAA serve as a hydration monitor?

Neither the final rule nor Regulatory Guide 5.89 address this issue.

The final rule does explain under 10 CFR 26.109(b)(1) that if a hydration monitor is used to observe a donor that was unable to provide an acceptable quantity of urine during the initial specimen collection attempt (i.e., a shy bladder), the collector must first explain the hydration process and acceptable donor behavior to the hydration monitor and then record the name of the hydration monitor on the Federal CCF.

Question 5c:
Observing a donor during the hydration process:

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Can a donor in the hydration process be remotely monitored?

Neither the final rule nor Regulatory Guide 5.89 discuss this topic.

However, Section C.1.A(1) in Regulatory Guide 5.89 states that:

"The NRC intends the term "monitoring" to mean that the collector or hydration monitor maintains visual (i.e., direct line of sight) and aural contact with the donor to ensure that the donor is adhering to the hydration process instructions and is not attempting to subvert the collection process."

Question 5d:
Observing a donor during the hydration process:

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Can another specimen collector complete the collection process for a donor in the hydration process?

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 meeting the requirements in 10 CFR 26.85(a).

Part 26 does not prohibit another trained collector meeting the requirements under 10 CFR 26.85(a) from completing the collection process for a donor in the hydration process.

Question 6:
Alternate specimen testing – Did the final rule change anything?

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No changes were made in the final rule with respect to the collection and testing of alternate specimens.

Part 26 permits the collection and testing of an alternate specimen from a donor in three circumstances:

1) Medical condition prevents providing urine (shy-bladder) – 26.119(g)(3)
2) Acceptable medical explanation for an invalid result that would affect the testing of another urine specimen – 26.185(f)(2)
3) Medical condition makes collecting a urine specimen difficult/hazardous – 26.31(d)(5)(i)

Question 7(a): Dilute specimen test results – Is an MRO review required under 26.185(a)?

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10 CFR 26.185, "Determining a fitness-for-duty policy violation."

26.185(a) MRO required review. A positive, adulterated, substituted, dilute, or invalid drug test result does not automatically identify an individual as having used drugs in violation of the NRC's regulations… or as having attempted to subvert the testing process. An individual who has a detailed knowledge of possible alternate medical explanations is essential to the review of the results. The MRO shall review all positive, adulterated, substituted, and invalid test results from the HHS-certified laboratory to determine whether the donor has violated the FFD policy…."

- **No,** if the HHS-certified laboratory reports the specimen results are "dilute and negative", an MRO review is not required – 26.185(g)(4)

- **Yes,** if 26.163(a)(2) special analysis testing is performed, the specimen result is drug positive (i.e., drug positive and dilute), and no legitimate medical explanation for the drug positive, **THEN** the MRO must evaluate if the "donor has diluted the specimen in a subversion attempt" – 26.185(g)(2)

Question 7(b): Dilute specimen test results – the MRO and MRO staff responsibilities in 26.183(c) and (d) appear inconsistent with 26.185(a) – are they?

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10 CFR 26.183, "Medical review officer."

(c) Responsibilities. "The primary role of the MRO is to review and interpret positive, adulterated, substituted, invalid, and dilute test results…and to identify any evidence of subversion of the testing process…."

(1) In carrying out these responsibilities, the MRO shall examine alternate medical explanations for any positive, adulterated, substituted, invalid, or dilute test result.

This question is still under review.
No update today.

(d) MRO staff.

(2) MRO staff responsibilities…

(i) The staff under the direction of the MRO may receive, review, and report negative test results to the licensee's or other entities designative representative.

(ii) The staff reviews of positive, adulterated, substituted, invalid, and dilute test results must be limited to reviewing the Federal CCF to determine whether it contains any errors that may required corrective action…

Question 8:
I've noticed an inconsistency between the 10 CFR Part 26 text appearing on the NRC website and that in the eCFR version of 10 CFR Part 26, which is correct?

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- Three discrepancies have been reported by licensees and other entities to the NRC (i.e., 26.117(j), 26.183(d)(2)(ii), 26.185(j)).
- In each instance, the November 22, 2022, final rule text was correct.
- Updates to the NRC's 10 CFR Part 26 website and eCFR have been made when appropriate.

Please continue to contact the NRC if you identify any inconsistencies so that we can research and address the issue.

10 CFR Part 26 websites:

- **NRC:** https://www.nrc.gov/reading-rm/doc-collections/cfr/part026/full-text.html
- **eCFR:** https://www.ecfr.gov/current/title-10/chapter-I/part-26

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Where Can I Get Help?

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