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

Fitness for Duty Drug Testing Requirements

Proposed Rule

Public Meeting
November 7, 2019

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Announcements

- Category 3 Public Meeting
- Teleconference Number
  - 1-888-469-0877 passcode: 1813919
- WebEx
  - https://usnrc.webex.com/usnrc/j.php?MTID=m315cddca3c9cfc61e9d6b05fcb70037a
- If you are participating via phone, please send an email to Stewart.Schneider@nrc.gov confirming your attendance.

Agenda—Morning

9:00–9:10 AM	Welcome/Introductions/Logistics
9:10–9:20 AM	Agenda/Meeting Purpose
9:20–9:30 AM	Rulemaking Background/Schedule
9:30–10:30 AM	**Proposed Rule Changes**
10:30–10:40 AM	BREAK
10:40–11:40 AM	**Specific Requests for Comment**
11:40–12:00 PM	Open Discussion
12:00–1:00PM	LUNCH

Agenda—Afternoon

1:00–1:45 PM	**Draft Regulatory Guidance**
1:45–2:15 PM	Open Discussion
2:15–2:25 PM	BREAK
2:25–3:00 PM	**Draft Regulatory Analysis**
3:00–3:50 PM	Open Discussion/Questions
3:50–4:00 PM	Closing Remarks/Adjourn

Meeting Purpose

- Provide an opportunity for the NRC and the public to exchange information on the proposed rule to update the fitness for duty (FFD) drug testing requirements in 10 CFR Part 26.
- Discuss the following rulemaking items:
  - Proposed rule changes
  - Specific requests for comment
  - Draft regulatory guidance
  - Draft regulatory analysis

Meeting Purpose (cont.)

- NRC will not provide written responses to any comments made at this meeting.
- NRC will consider, to the extent possible, feedback from today's meeting in developing the final rule, regulatory guidance, and regulatory analysis.

Background

Mar. 31, 2008	NRC published revised FFD program requirements (62 FR 16966) that aligned with the 2004 HHS Guidelines.
Nov. 25, 2008	HHS published a revision to its guidelines (i.e., 2008 HHS Guidelines) (73 FR 71858).
July 1, 2013	NRC published a regulatory basis (78 FR 39190) that recommends developing a proposed rule to align NRC's regulations with select drug testing provisions in the 2008 HHS Guidelines.
Feb. 22, 2017	NRC staff submitted a paper to the Commission to obtain approval to publish a proposed rule to align NRC's drug testing requirements with the 2008 HHS Guidelines, SECY-17-0027.
June 3, 2019	The Commission approved publishing the proposed rule and draft regulatory guide, SRM-SECY-17-0027.
Sept. 16, 2019	NRC published the proposed rule and draft regulatory guide for public comment (84 FR 48750).

Rulemaking Schedule

Dec. 2, 2019	Proposed rule comment period closes
Feb. 26, 2021	Final rule to the Commission*
May 26, 2021	Final rule publication date*

*Date is subject to change.

Proposed Rule Changes

Drug Testing Changes

The proposed rule would make three types of changes:

1. Update the initial drug testing cutoff levels in § 26.133 for licensee testing facilities (LTFs) and in § 26.163(a)(1) for HHS-certified laboratories.
2. Update the confirmatory drug testing cutoff levels in § 26.163(b)(1) for HHS-certified laboratories. By rule, an LTF cannot conduct confirmatory drug testing.
3. Update the drugs and drug metabolites specified for testing by LTFs and HHS-certified laboratories in § 26.133 and § 26.163 respectively.

Drug Testing Cutoff Changes

- Amphetamines:
  - Lower initial test cutoff from 1000 nanograms/milliliter (ng/mL) to 500 ng/mL
- Amphetamine (AMP):
  - Lower confirmatory test cutoff from 500 ng/mL to 250 ng/mL
- Methamphetamine (MAMP)
  - Lower confirmatory test cutoff from 500 ng/mL to 250 ng/mL
  - Lower the AMP concentration in a specimen that also must be present to confirm a MAMP positive (from 200 ng/mL to 100 ng/mL)
- Cocaine metabolite
  - Lower initial test cutoff from 300 ng/mL to 150 ng/mL
  - Lower confirmatory test cutoff from 150 ng/mL to 100 ng/mL

Drug Testing Panel Additions

Include two amphetamine-based drugs:

- Methylenedioxymethamphetamine (MDMA)
  - Initial test cutoff 500 ng/mL
  - Confirmatory test cutoff 250 ng/mL
- Methylenedioxyamphetamine (MDA)
  - Initial test cutoff 500 ng/mL
  - Confirmatory test cutoff 250 ng/mL

Drug Testing for the Heroin Metabolite 6-Acetylemorphine (6-AM)

- Currently, § 26.163(b)(1) only requires confirmatory testing for 6-AM when a specimen also tests positive for morphine.
- The proposed rule would:
  - Add 6-AM to the initial testing panel (10 ng/mL cutoff)
  - Perform 6-AM confirmatory testing independent of morphine concentration (clinical data demonstrates that some individuals test positive for 6-AM and at the same time test negative for morphine)

Note: No change is proposed to the 10 ng/mL confirmatory test cutoff.

Validity Testing for Adulterants

- The proposed rule would change the confirmatory validity test cutoff from the limit of detection (LOD) to the limit of quantitation (LOQ) for oxidizing adulterants:
  - § 26.161(c)(3) for chromium (VI)
  - § 26.161(c)(4) for halogen,
  - § 26.161(c)(5) for glutaraldehyde, and
  - § 26.161(c)(6) for pyridine.
- The current rule in § 26.161(b) requires HHS-certified laboratories to perform initial validity tests for one or more oxidants.

Subversion Attempt Detection

- Section 26.5 defines "*subversion and subverting the testing process*" as "a willful act to avoid being tested or to bring about an inaccurate drug or alcohol test result for oneself or others at any stage of the testing process (including selection and notification of individuals for testing, specimen collection, specimen analysis, and test result reporting), and adulterating, substituting, or otherwise causing a specimen to provide an inaccurate test result."

- The proposed rule would revise the drug testing methods used when a possible subversion attempt is suspected by modifying the special analyses testing provisions in § 26.163(a)(2).

Special Analyses Testing – Dilute Specimens

Section 26.163(a)(2) currently provides the option to conduct confirmatory testing to the LOD for a drug or drug metabolite if:

- The specimen has a dilute validity test result

AND

- Any drug or drug metabolite concentration in the specimen is within 50 percent of the initial test cutoff

Note: As of 2018, 66 of 71 sites adopted the optional § 26.163(a)(2) testing.

Special Analyses Testing – Dilute Specimens (cont.)

In § 26.163(a)(2)(ii), the proposed rule would:

1. Require special analyses testing of a specimen with a dilute validity test result when any drug or drug metabolite concentration is equal to or greater than 40 percent of the initial test cutoff level.
2. Change the confirmatory test cutoff for special analyses testing from the LOD to LOQ.

Special Analyses Testing – Observed Specimens

In § 26.163(a)(2)(i), the proposed rule would add required special analyses testing of a specimen collected under the following four direct observation conditions:

- § 26.115(a)(1) – Donor at this or a prior collection provided a urine specimen with a substituted, adulterated, or invalid test result with no adequate medical explanation
- § 26.115(a)(2) – Donor presented at this collection a specimen outside the required temperature range of 90 to 100 degrees Fahrenheit
- § 26.115(a)(3) – Conduct by the donor indicates an attempt to subvert the testing process
- § 26.115(a)(5) – Bottle B or the single specimen is not available for retesting

Changes to Definitions § 26.5

Added Definitions	Revised Definitions
cancelled test*	calibrator
carryover	control
Certifying Scientist	dilute specimen
Federal custody and control form (Federal CCF)*	HHS-certified laboratory*
lot	invalid result*
rejected for testing*	limit of quantitation
Responsible Person	substituted specimen

* *Discussed in subsequent slides*

New Definition

Cancelled test means the test result reported by the MRO to the licensee or other entity when a specimen has been

- reported to the MRO by the HHS-certified laboratory as an invalid result (for which the donor has no legitimate explanation),
- a specimen has been rejected for testing by the licensee testing facility or HHS-certified laboratory, or
- the retesting of a single specimen or the testing of Bottle B of a split specimen fails to reconfirm the original test result.

For alcohol testing only, cancelled test means a test result that was not acceptable because testing did not meet the quality assurance and quality control requirements in § 26.91.

New Definitions

Federal custody and control form (Federal CCF) means any HHS-approved form, which has not expired, that is published in the *Federal Register* and is used to document the collection, custody, transport, and testing of a specimen.

Rejected for testing means the result reported to the MRO by a licensee testing facility or HHS-certified laboratory when no tests can be performed on a specimen.

Revised Definition

HHS-certified laboratory means a laboratory that is certified ~~to perform urine drug testing under the Department of Health and Human Services~~ to meet the standards of the Mandatory Guidelines for Federal Workplace Drug Testing Programs (the HHS Guidelines) at the time that drug and validity testing of a specimen is performed for a licensee or other entity~~, which were published in the Federal Register on April 11, 1988 (53 FR 11970), and as amended, June 9, 1994 (59 FR 29908), November 13, 1998 (63 FR 63483), and April 13, 2004 (69 FR 19643)~~.

Revised Definition

Invalid result means the result reported by an HHS-certified laboratory in accordance with the criteria established in § 26.161(f) when a positive, negative, adulterated, or substituted result cannot be established for a specific drug or specimen validity test ~~for a specimen that contains an unidentified adulterant, contains an unidentified interfering substance, has an abnormal physical characteristic, contains inconsistent physiological constituents, or has an endogenous substance at an abnormal concentration that prevents the laboratory from completing testing or obtaining a valid drug test result~~.

Shy-Bladder Process – Use of a Hydration Monitor

- Currently, if a donor cannot provide a urine specimen of the required minimum volume on the first attempt, the shy-bladder process is initiated to permit the donor to hydrate. Under § 26.107(b), the collector must "pay careful attention to the donor during the entire collection process." Therefore, the collector must remain with the donor during the hydration process (which can be up to 3 hours).

- The proposed rule would revise and add requirements to permit a member of the FFD program personnel to observe a donor during the hydration process. This change would permit the initial collector to perform other activities (e.g., other collections).

Shy-Bladder Process – Use of a Hydration Monitor (cont.)

The proposed rule would:

1. Update the list of FFD program personnel activities to include § 26.4(g)(6) "All persons monitoring a donor during the hydration process described in § 26.109(b)."

2. Revise § 26.107(b) to (b)(1) and edit the first sentence as follows: "The collector shall pay careful attention to the donor during the entire collection process, except as provided in § 26.109(b)(1)…"

3. Add § 26.107(b)(2) "If a hydration monitor is used to observe a donor during the § 26.109(b)(1) hydration process, this individual shall immediately inform the collector of any donor conduct that may indicate an attempt to subvert the testing process (e.g., donor leaves the collection site, donor refuses to follow instructions)."

Shy-Bladder Process – Use of a Hydration Monitor (cont.)

4. Add to § 26.109(b)(1) the following:

> "Alternatively, as specified in the licensee's or other entity's FFD program procedures, the collector may assign responsibility for monitoring a donor during the hydration process to another collector who meets the requirements in § 26.85(a) or to a hydration monitor who meets the requirements in § 26.4(g)(6). If another collector or hydration monitor is used, the collector:
>
> (i) Shall explain the hydration process and acceptable donor behavior to the hydration monitor;
>
> (ii) Shall record the name of the other collector or hydration monitor, as applicable, on the Federal CCF and then provide the Federal CCF to this individual for the duration of the hydration process; and
>
> (iii) May perform other collections while the donor is in the hydration process;"

Donor Protection – MRO Review of Invalid Specimens (pH 9-9.5)

- Currently, § 26.185(f)(2) requires a second specimen to be collected under observation if a valid medical explanation does not exist for an invalid test result (i.e., indication of a possible subversion attempt).
- The proposed rule would add § 26.185(f)(3) to permit the MRO to require a second non-observed collection be performed if the MRO determined that evidence of elapsed time, exposure of the specimen to high temperature, or both could account for a pH from 9 to 9.5.

  Clinical data demonstrate that both elapsed time from specimen collection and exposure to high temperature can cause the pH of a urine to rise in the range of 9.0 to 9.5, conditions not indicative of a possible subversion attempt.

Donor Protection – Retest Request

Section 26.165(b) permits a donor to request 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 current rule in § 26.165(b)(2) states that the "donor's request may be oral or in writing," but does not include a requirement for the MRO to maintain a record to demonstrate the timely receipt of an oral request from the donor.
- The proposed rule would add to § 26.165(b)(2) the sentence:

  "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."

Donor Protection – Retest Request

- Currently, § 26.165(b)(3) requires the donor to provide permission for retesting of an aliquot of the single specimen or the testing of Bottle B and states:

  "Neither the licensee, MRO, NRC, nor any other entity may order retesting of the single specimen or testing of the specimen in Bottle B without the donor's written permission, except as permitted in § 26.185(l)."

- The proposed rule would revise § 26.165(b)(3) to state that:

  "No entity, other than the MRO as permitted in § 26.185(l), may order the retesting of an aliquot of a single specimen or the testing of the Bottle B split specimen."

- The proposed change would address an inconsistency where some licensees interpret § 26.165(b)(3) to require the MRO to receive the donor's written permission prior to initiating retesting of a specimen, even though § 26.165(b)(2) permits a donor to make an oral request for retesting.

Donor Protection – Collector Instructions for Testing Refusals

The proposed rule would add instructions for the collector to follow in the instance when a refusal to test is determined:

"§ 26.107(d) If a refusal to test is determined at any point during the specimen collection process, the collector shall do the following:

(1) Inform the donor that a refusal to test has been determined;

(2) Terminate the collection process;

(3) Document a description of the refusal to test on the Federal CCF;

(4) Discard any urine specimen(s) provided by the donor, unless the specimen was collected for a post-event test under § 26.31(c)(3); and

(5) Immediately inform the FFD program manager."

Blind Performance Test Sample Lot In-Service Requirement

- The proposed rule would eliminate the current requirement in § 26.168(h)(1) that blind performance test sample (BPTS) suppliers place a sample lot in service for no more than 6 months.
- Feedback received from industry and BPTS suppliers indicates that sample lots can remain viable for much longer than 6 months (e.g., 2 years). Further, Section 10.2 of the 2008 HHS Guidelines does not impose an in-service limit on BPTS lots.
- The current rule requirement in § 26.168(h)(2) already requires the BPTS supplier to provide an expiration date for each BPTS to ensure that each sample will have the expected value when tested.

LTF Quality Control Samples

- The proposed rule would correct two inaccuracies described in an NRC enforcement guidance memorandum (EGM–09–003, dated March 31, 2009) that pertain to the LTF quality control sample requirements for initial validity testing in § 26.137(d)(5) and for initial drug testing in § 26.137(e)(6)(v).
  - The phrase ‘‘donor specimen’’ would be replaced with the phrase ‘‘normal specimen’’ in § 26.137(d)(5) and (e)(6)(v).
  - The phrase ‘‘at least one positive control, certified to be positive by an HHS-certified laboratory’’ would be replaced with the phrase ‘‘at least one quality control sample’’ in § 26.137(e)(6)(v).
- The NRC would rescind EGM–09–003 if the proposed rule changes correcting these inaccuracies are finalized.

Specific Requests for Comment

Specific Requests Topics

1. *Alignment With the HHS Guidelines*
2. *Special Analysis Testing*
3. *Provide Flexibility to Conduct Additional Specimen Validity Tests*
4. *Effective Date of the Final Rule*
5. *Direct Observation of Specimen Collection*
6. *2017 HHS Guidelines—New Test Analytes*
7. *Methylenedioxyethylamphetamine*

1. Alignment With the HHS Guidelines

The proposed rule would eliminate redundant provisions in two sections of Part 26 that also appear in the HHS Guidelines (i.e., HHS-certified laboratory personnel qualifications requirements in § 26.155, "Laboratory personnel," and HHS-certified laboratory procedures requirements specific to the HHS Guidelines in § 26.157, "Procedures"). Because the National Laboratory Certification Program (NLCP) inspection process verifies laboratory compliance with the HHS Guidelines, additional review and oversight by NRC licensees and other entities (e.g., of laboratory security requirements) would be duplicative.

The NRC is seeking comment on additional provisions in Part 26 that are consistent with the HHS Guidelines and could be eliminated from Part 26.

2. Special Analyses Testing

The proposed rule would require special analyses testing under § 26.163(a)(2) for dilute specimens with any drug or drug metabolite concentration on initial testing that is at least 40 percent of the initial test cutoff. The proposed rule also would expand special analyses testing to specimens collected under direct observation as required by § 26.115(a)(1) through (a)(3) and a new paragraph (a)(5).

The NRC is seeking comment on whether special analyses testing should also apply to the testing of individuals that already have tested positive on a 10 CFR part 26 test (i.e., denied unescorted access authorization by § 26.75(d) for a first or second drug testing positive result). Requiring special analyses testing in this case would add a level of assurance to follow-up testing required by § 26.69(b)(6), which is conducted to confirm continued abstinence from illegal drug use and/or the misuse of legal drugs.

3. Provide Flexibility to Conduct Additional Specimen Validity Tests

Section 26.31(d)(1)(i)(D) permits a licensee or other entity to utilize lower cutoff levels and drug testing assays without forensic toxicologist review if the HHS Guidelines are revised to authorize use of the assay and testing cutoff levels. However, § 26.161(h) prohibits licensees and other entities from using more stringent cutoff levels for validity tests.

The NRC is seeking comment on whether § 26.161(h) should be revised to provide a licensee or other entity with the option to conduct additional specimen validity tests and/or to utilize lower cutoff levels if the HHS Guidelines are revised in the future to include such testing.

4. Effective Date of the Final Rule

If the proposed rule is finalized, the NRC anticipates providing a 60-day implementation period from the date that the final rule is published in the *Federal Register*. The effective date of the final rule and the compliance date for licensees and other entities would be 60 days after the date that the final rule is published in the *Federal Register*.

The NRC is seeking comment on whether this implementation time period is appropriate based on the proposed rule changes.

5. Direct Observation of Specimen Collection

The proposed rule retains the requirement for direct observation during the collection of a second sample when there are indications of a subversion attempt during the initial collection.

The NRC is seeking comment on whether there are any effective alternatives to direct observation that will assist in preventing subversion of the drug testing process.

6. 2017 HHS Guidelines — New Test Analytes

On January 23, 2017, HHS issued its latest revision of the Mandatory Guidelines for Federal Workplace Drug Testing Programs Using Urine Specimens (82 FR 7920). Subpart C, "Urine Drug and Specimen Validity Tests," of the 2017 HHS Guidelines was revised to include additional initial and confirmatory test analytes for certain opioids; specifically, hydrocodone, hydromorphone, oxycodone, and oxymorphone.

The NRC is seeking comment on whether §§ 26.31(d)(1) and 26.405(d) should be revised to identify hydrocodone, hydromorphone, oxycodone, and oxymorphone test substances, and whether §§ 26.133 and 26.163(a)(1) and (b)(1) should be revised to require initial and confirmatory testing of these drugs at the cutoff levels recommended in the 2017 HHS Guidelines.

7. Methylenedioxyethylamphetamine (MDEA)

The 2008 HHS Guidelines adds MDEA as a confirmatory analyte to the drug testing panel in Section 3.4. However, when the HHS revised the mandatory guidelines in 2017, HHS removed MDEA from Section 3.4 stating that "[t]he Department has evaluated the comments and has removed MDEA from the Guidelines (i.e., MDEA is no longer included as an authorized drug in Section 3.4). The number of positive MDEA specimens reported by HHS-certified laboratories (i.e., information provided to the Department through the NLCP) does not support testing all specimens for MDEA in federal workplace drug testing programs." (82 FR 7920, 7923; January 23, 2017).

The NRC is not proposing to adopt the 2008 HHS Guidelines' addition of MDEA as *a confirmatory test analyte at this time.* As a result, the NRC is also proposing to add MDA to the initial testing panel to fully align with the "Ecstasy drugs" testing panel in the 2017 guidelines.

The NRC is seeking comment on these changes.

Draft Regulatory Guide DG-50.40

Urine Specimen Collection and Test Results Review under 10 CFR Part 26, Fitness for Duty Programs

Purpose and Applicability

- DG-5040 describes methods and procedures the NRC staff considers acceptable for licensees and other entities described in 10 CFR 26.3, “Scope,” to demonstrate compliance with specific requirements in 10 CFR Part 26 pertaining to the collection of urine specimens and the review of test results.

- This guide was written to provide guidance for the NRC staff proposed rulemaking “Fitness for Duty Drug Testing Requirements”; NRC–2009–0225; RIN 3150–AI67.

Related Guidance

1. RG 5.84, “Fitness-For-Duty Programs at New Reactor Construction Sites,” endorses the methods used to develop a fitness-for-duty (FFD) program at new reactor construction sites as described in the industry guidance document Nuclear Energy Institute (NEI) 06-06, “Fitness-for-Duty Guidance for New Nuclear Power Plant Constructions Sites,” Revision 6, issued April 2013.

2. U.S. Department of Health and Human Services (HHS), “Mandatory Guidelines for Federal Workplace Drug Testing Programs” (HHS Guidelines).

Summary of Guidance

DG-5040 provides guidance on three areas:

1. The monitoring of a donor during the 3-hour hydration process.
2. The optional use of mirrors to assist in conducting observed collections.
3. The conduct of an additional review by the MRO for urine specimens with invalid test results due to high pH values in the range of 9.0 to 9.5.

Monitoring a Donor During Hydration

Principle Guidance

1. Must be instructed per proposed § 26.109(b)(1)(i).
2. Direct line of sight and aural contact with the donor or multiple donors.
3. Collector-Monitor should have communication, control, and documentation protocols:
   a) Protect donor privacy
   b) CCF control and documentation
   c) Clear communications regarding who is responsible for the donor
4. Control of donor's personal belongings.
5. Actions if the donor attempts to subvert the testing process.
6. Actions if the donor decides to leave the collection facility.

Hydrating a Donor

Principle Guidance

1. Cannot use donor-provided liquid; cannot be brought into collection facility (§ 26.87(e)(3) and § 26.105(a) and (b)).
2. Known quantity of liquid not to exceed 40 ounces per § 26.109(b)(1) (e.g., 5-8 ounce water bottles). A jug of water and a cup is not an acceptable delivery method.
3. Liquid consumed at a reasonable rate (8 ounces every 30 minutes).
4. Do not urge a donor to drink – he/she is not required to drink.
5. A failure to provide a successful volume of urine during the collection does not reset the 3-hour clock or the 40 ounce liquid limit.
6. At about 15 and 30 minutes prior to the end of the 3-hour hydration period, the collector/monitor should inform the donor of the inevitable end of the hydration/ collection process.
7. At 3-hours, the donor should be provided one last opportunity to provide a urine specimen.

Optional Use of Mirrors During a Directly Observed Collection

The proposed rule would add the following sentence to § 26.115(f)(2).

> "A reflective mirror may be used to assist in observing the provision of the specimen only if the physical configuration of the room, stall, or private area used for urination is not sufficient to meet this direct observation requirement; the use of a video camera to assist in the observation process is not permitted."

Optional Use of Mirrors During a Directly Observed Collection

Principle Guidance

1. The preferred method is to directly observe the urine stream leave the body.
2. Permanent or temporary (case specific) mirrors are acceptable – must have instructions in a procedure.
3. Toilet, hand held, and two-way mirrors are not allowed – licensees and other entities must maintain a reasonable expectation of privacy.
4. Collector/observer is allowed to incrementally adjust a mirror.
5. Guidance on “size and special relationship” considerations.
6. Guidance on the use of medical appliances (e.g., uroscopy bag).

MRO Review of pH Test Results

What is pH?

- pH is a numeric expression of the acidity or alkalinity of a solution on a logarithmic scale where 7 is neutral, values <7 are acidic, and values >7 are alkaline
- pH is essentially the hydrogen ion concentration in moles per liter

When is pH determined?

pH is determined during initial and confirmatory validity testing of a urine specimen conducted at an HHS-certified laboratory, § 26.161

What is a ”normal” pH in human urine?

The American Association of Clinical Chemistry reports that an average value for urine pH is 6.0, but it can range from 4.5 to 8.0

MRO Review of pH Test Results

Current Rule

Adulterated:

- The pH is < 3 or ≥ 11, using either a pH meter or a colorimetric pH test for the initial test on the first aliquot and a pH meter for the confirmatory test on the second aliquot; § 26.161(c)

Invalid:

- The pH is ≥ 3 and < 4.5, or
- The pH is ≥ 9 and < 11, using either a colorimetric pH test or pH meter for the initial test and a pH meter for the confirmatory test on two separate aliquots; § 26.161(f)(2)

MRO Review of pH Test Results

Proposed Rule

- No changes to adulterated or invalid test result criteria.
- Add a new § 26.185(f)(3) requirement for review of invalid test results:
  - the MRO shall consider whether there is evidence of elapsed time, exposure of the specimen to high temperature, or both that could account for a pH value in the range of 9.0 to 9.5.
  - If an acceptable explanation exists, 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.

MRO Review of High pH Results

Principle Guidance

1. MRO interviews the donor for an acceptable medical explanation for the high pH.
2. If no acceptable medical explanation, MRO evaluates time and temperature:
   - Evaluate the time-temp profile from collection to completion of pH test
   - Interview individuals at the site, those in transportation, and at the la
   - Evaluate other test results in other specimens transported
   - Evaluate MRO guidance documents (next slide)
3. If there is an acceptable nonmedical explanation, then recollect as soon as reasonably practicable.
4. MRO shall document the basis for his/her determination.

MRO Review of High pH Test Results

MRO Guidance*

1. For an elapsed time greater than 48 hours, consider cancelling the test and requiring a second unannounced collection (not observed) (10 CFR 26.185(f)(2)).
2. For an elapsed time between 24 and 48 hours, when the urine was transferred or stored at a temperature greater than 98 degrees Fahrenheit, consider cancelling the test and requiring a second unannounced collection (not observed) (10 CFR 26.185(f)(2)).
3. For an elapsed time less than 24 hours, consider cancelling the test and requiring a second unannounced collection under direct observation (10 CFR 26.185(f)(4)).

*Shults, T.F., "Medical Review Officer Handbook," 10th Edition, Quadrangle Research, April 2014; (800) 489-1839; https://www.aamro.com/mro-store.aspx

Draft Regulatory Analysis

Analytical Highlights

- Evaluated site-specific FFD testing data submitted under §§ 26.717 and 26.417 (utilized 6 years of results, 2009-2014, see Appendix A).
- Evaluated U.S. DOT testing data of analogous worker populations to model the 2008 HHS Guidelines detection enhancements:
  - Utilized positive rate changes in first year of testing (amphetamines, cocaine)
  - Utilized positive rates from 2010 through 2014 (6-AM and Ecstasy drugs)
- Specimen testing costs based on stakeholder feedback (e.g., prior public meetings) and NRC staff professional judgement.
- Inputs and data sources presented in Appendix B.
- Assumptions, calculations, and results presented in Appendices C – E.

Affected Attributes Evaluated

- Quantified benefits and costs for three affected attributes (industry implementation, industry operation, NRC implementation).
- Difficulty in monetizing benefits associated with seven affected attributes, evaluated qualitatively:
  - Public health (accident)
  - Occupational health (accident)
  - Offsite property
  - Onsite property
  - Regulatory efficiency
  - Safeguards and security considerations
  - Other considerations (i.e., public perception, workplace productivity, workplace safety, and improved protection of individual rights)
- For more information, see Section 4.1 of the Regulatory Analysis.

Benefits of Proposed Rule

- Increased detection of illegal drug use, misuse of legal drugs, and subversion attempts (10–12% increase in detection).
- Improved alignment of Part 26 testing with HHS Guidelines.
- Addresses multi-year drug testing trends in Part 26 programs:
  - Increasing amphetamine and methamphetamine positives
  - High prevalence of subversion attempts
- Strengthens proactive, risked-informed testing (since 1990, approximately 68% of positives identified at pre-access testing).
- Averted training costs for some licensees (individuals testing positive on pre-access testing before completing training).

Costs of Proposed Rule

One-time (average $5,031 per site):

- Revise FFD program policy and procedures.
- Update contracts with HHS-certified laboratories and blind performance test sample suppliers.
- If use licensee testing facility (LTF), LTF technician training and initial test assay validations.
- Conduct employee training on rule changes (~85% anticipated one-time cost).

Annual (average $2,516 per site):

- Cost per specimen to test for new substances (MDMA, MDA, 6-AM).
- Medical Officer Review (MRO) time to evaluate additional positives.
- Licensee time associated with additional individuals testing positive or identified as subverting a test (denial of authorization, sanctions).

Results

- The proposed rule results in the following estimated costs to industry:
  - One-time = $337,100
  - Annual = $168,600
- The net present value of the estimated costs:
  - $2.4 million, using a 7-percent discount rate
  - $3.4 million, using a 3-percent discount rate
  - These values cover a 25-year period of time
- NRC is estimated to incur a one-time cost of $273,000 to complete the final rulemaking and issue regulatory guidance

Backfit and Issue Finality

- Changes in the proposed rule fall under the backfitting requirements in § 50.109(a)(3), § 50.109(c), and § 70.76, "Backfitting," and the issue finality requirement in § 52.98.
- The proposed rule constitutes a backfit because it imposes new requirements on licensees.
- The backfit analysis in Appendix F determined that the proposed rule:
  - Results in a substantial improvement in public health and safety or the common defense and security from the enhanced detection of individuals identified as using illegal drugs, misusing legal drugs, or attempting to subvert the drug testing process (estimated 10- to 12-percent increase per year).
  - The direct and indirect costs of implementing the proposed rule are justified in view of the increased protection.

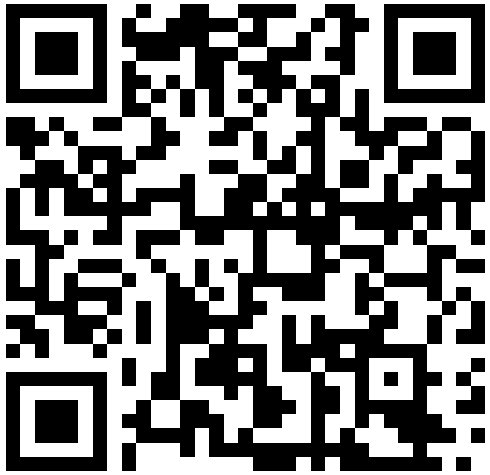
Open Discussion and Questions

Where to Find Information

Search for docket ID NRC-2009-0225

How did we do?

- NRC Public Meeting Feedback Form



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Thank You