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

Medical Review Officer (MRO) Training

10 CFR Part 26 Final Rule (November 2022)

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Part 26 Final Rule (November 2022)
MRO Training Topics

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- Drug testing panel changes (cutoffs, substances)
- Invalid specimen review (pH 9.0 – 9.5)
- Special analyses testing, 26.163(a)(2)
- Definition updates (new and revised)
- Documenting donor retest requests
- Documenting collector observations on the Federal CCF
- Direct observation of urine – use of mirrors
- Oral fluid – observed collection conditions (optional use)
- Blind performance test samples
- Observing a hydrating donor (use of hydration monitors/other collectors)
- Implementation resources and guidance

Before We Start on the Final Rule… Who is an MRO under 10 CFR Part 26?

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26.183(a) Qualifications – the MRO shall:

- **Be knowledgeable of Part 26** and of the **licensee's/other entity's FFD policies**
- **Be a physician** holding either a Doctor of Medicine or Doctor of Osteopathy degree who is licensed to practice medicine by any State or Territory of the United States, the District of Columbia, or the Commonwealth of Puerto Rico.
- **Have passed an examination administered by a nationally-recognized MRO certification board or subspecialty board** for medical practitioners in the field of medical review of Federally mandated drug tests.

26.183(b) Relationships – the MRO **may NOT:**

- **Be** an **employee or agent** of, or have **any financial interest in** an HHS-certified **laboratory** for whom the MRO reviews drug test results.
- **Derive any financial benefit** by having the licensee/other entity use a specific HHS-certified laboratory for testing.
- **Have any agreement with** an HHS-certified **laboratory** that may be construed as a **potential conflict of interest**.

Before We Start on the Final Rule… Who is an MRO under 10 CFR Part 26?

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26.183(c) Responsibilities:

- **Primary role: review and interpret** positive, adulterated, substituted, invalid, and dilute test results AND **identify any evidence of subversion** of the testing process.
- Also **identify any issues** associated **with collecting and testing specimens** AND **advising and assisting FFD program management** in planning/overseeing the overall FFD program.
- **Shall examine alternate medical explanations** for ANY positive, adulterated, substituted, invalid or dilute test result. This action may include, but is not limited to:
  - **conducting a medical interview with the donor**,
  - **reviewing the donor's medical history**, or
  - **reviewing any other relevant biomedical factors**.
- **Shall review ALL medical records** a **donor may make available** when a positive, adulterated, substituted, invalid, or dilute test result could have resulted from **responsible use of legally prescribed medication**, a **documented condition or disease state**, or the **demonstrated physiology of the donor**.
- **May only** consider test results of specimens collected and processed under 10 CFR Part 26.

Before We Start on the final rule…
Who is an MRO under 10 CFR Part 26?

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26.183(d) MRO staff provide **administrative support to the MRO**

- **MRO is directly responsible for** all administrative, technical and professional activities of **individuals while performing MRO staff functions**
- **MRO staff may:**
  - ❑ **Review** Federal **CCFs** for positive, adulterated, substituted, invalid, and dilute test results **to identify errors that may require corrective action**
  - ❑ **Resolve** Federal **CCF errors** (BUT the **MRO must review and approve**)
- **MRO staff may NOT:**
  - × **Conduct interviews with donors** to discuss test results (**positive, adulterated, substituted, invalid, dilute**) NOR **request medical information** from a donor (only can be performed by the MRO)
  - × **Report/discuss HHS-certified laboratory test results with anyone except the MRO/MRO staff** before the MRO reviews and confirms the results
  - × **Reveal quantitative test results** OR **any personal medical information** the MRO obtained about the donor in the course of reviewing confirmatory test results

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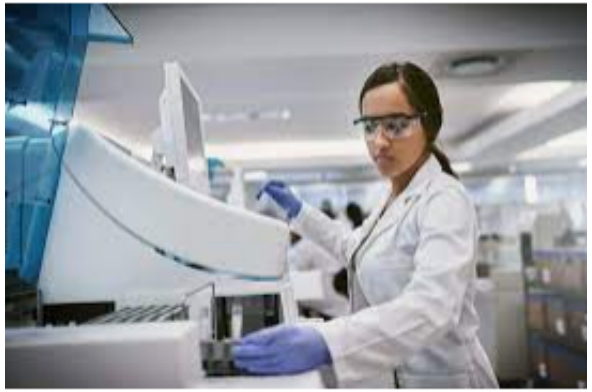
Aligns Part 26 drug testing requirements more closely with the U.S. Department of Health and Human Services' 2008 and 2017 Mandatory Guidelines for Federal Workplace Drug Testing of urine specimens. Also incorporates lessons learned from implementing Part 26.



- **Published**: November 22, 2022 (87 FR 71422)
- **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 heroin metabolite, 6-acetylmorphine (6-AM)
- ❑ Improves methods to detect donor subversion attempts (special analyses testing)
- ❑ Includes option to collect and drug test oral fluid 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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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**."

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

Part 26 Final Rule (November 2022)
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 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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26.5 Definition Updates

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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*

Part 26 Final Rule (November 2022)
26.5 Definition Updates

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[***New***] "***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."

"***Dilute specimen*** means a urine specimen with creatinine and specific gravity ~~concentrations~~ **values** that are lower than expected **but are still within the physiologically producible ranges** ~~for~~ **of** human urine.

Part 26 Final Rule (November 2022)
26.5 Definition Updates

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[***New***] "***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."

"***HHS-certified laboratory*** means a laboratory that is certified to ~~perform urine drug testing under the Department of Health and Human Services~~ **meet the standards of the** Mandatory Guidelines for Federal Workplace Drug Testing Programs (the HHS Guidelines) **at the time that testing of a specimen is performed for a licensee or other entity and performs that testing for a licensee or other entity in accordance with the HHS Guidelines, unless otherwise specified in this part**~~, 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).~~"

Part 26 Final Rule (November 2022)
26.5 Definition Updates

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"***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~~."

"***Limit of quantitation (LOQ)*** means **for quantitation assays,** the lowest concentration ~~of an analyte~~ at which the **identity and** concentration of the analyte can be accurately **established** ~~determined under defined conditions~~.

Part 26 Final Rule (November 2022)
26.5 Definition Updates

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[***New***]"***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."

"***Substituted specimen*** means a specimen **that has been submitted in place of the donor's urine, as evidenced by** ~~with~~ creatinine and specific gravity values that are ~~so diminished or so divergent that they are not consistent with normal~~ **outside the physiologically producible ranges of human urine** ~~physiology~~."

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)
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 "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)
Direct Observation of Urine, Use of Mirrors - 26.115(f)(2)

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[***New flexibility***] **Provides option to use a reflective mirror to assist in directly observing the provision of a urine specimen under a limited circumstance:**

26.115 Collecting a urine specimen under direct observation…
"**(f)(2)** The observer shall watch the donor urinate into the collection container. Specifically, the observer shall watch the urine go from the donor's body into the collection container. **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."

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

Part 26 Final Rule (November 2022)
Observed Collections – Option 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)).

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

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- **Must be tested at an HHS-certified laboratory**

  26.153(a) "Licensees and other entities who are subject to this part shall use only **HHS-certified** laboratories **as defined in 26.5**."

  26.31(d)(3)(i) "Testing of urine specimens for drugs and validity, except validity screening and initial drug and validity tests performed by licensee testing facilities under paragraph (d)(3)(ii) of this section, must be performed in a laboratory that is certified by HHS for that purpose, consistent with its standards and procedures for certification. **Urine** ~~S~~ **s**pecimens sent to HHS-certified laboratories must be subject to initial validity and initial drug testing by the laboratory. **Oral fluid specimens sent to HHS-certified laboratories must be subject to initial drug testing by the laboratory**. . . ."

- Updated numerous Part 26 requirements to remove/clarify references to specimens. For example,
  - "26.117 Preparing **drug testing** ~~urine~~ specimens for storage and shipping"

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

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- **Specimen collector qualifications:**

  26.85(a) "~~Urine c~~ **C**ollector qualifications. **Each** ~~Urine~~ collector~~s~~ shall be knowledgeable of the requirements of this part and the FFD policy and procedures of the licensee or other entity for whom collections are performed, and shall keep current on any changes to ~~urine~~ **the** collection procedures **for each specimen the individual is qualified to collect under this part**. **Each** ~~C~~**c**ollector~~s~~ shall receive qualification training that meets the requirements of this paragraph and demonstrate proficiency in applying the requirements of this paragraph before serving as a collector

- **Collection condition (visual privacy):**

  26.87 Collection Sites…"**(b)**~~The collection site must provide for the donor's v~~ **V**isual privacy **must be provided to** ~~while~~ the donor and collector **when** ~~are~~ viewing **alcohol test** ~~the~~ results ~~of an alcohol test~~, **and during the collection of an oral fluid specimen for drug testing**. **The donor must be provided with** ~~and for~~ individual privacy while ~~the donor is~~ submitting a urine specimen, except if a directly observed urine specimen collection is required…."

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

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- **Specimen storage condition (as specified by the device manufacturer):**

  26.117(j) "Collection site personnel shall arrange to transfer the collected specimens to the HHS-certified laboratory….**Oral fluid specimens shall be stored under the conditions specified by the oral fluid specimen collection device manufacturer**."

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)
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.

Part 26 Final Rule (November 2022)
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 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)
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)
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)

- **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).

  Covers 3 topics:
  - ❑ Donor hydration during shy-bladder events
  - ❑ Observed collections using mirrors
  - ❑ MRO review of invalid specimens, pH 9.0 to 9.5

Additional MRO Guidance

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- **HHS Medical Review Officer Guidance Manual for Federal Workplace Drug Testing Programs (Revised July 2022)**. (https://www.samhsa.gov/sites/default/files/2020-mro-manual.pdf)
  - Specifically, Chapter 5, "Interpretation of Results and Drug Information), which provides information on the routes of administration, metabolism and excretion, and pharmaceuticals and use.
  - Remember though, this manual is for Federal agency drug testing programs that implement the "HHS Mandatory Guidelines for Federal Workplace Drug Testing Programs" and not 10 CFR Part 26.

- **National Laboratory Certification Program (NLCP), Drug Testing Matters**. A continuing education newsletter on topics of interest to laboratories, laboratory staff, and NLCP inspectors. For a free email subscription, send an email with your name and the phrase "**Subscribe-DTM"** in the email subject line to NLCP@rti.org.