
INSPECTION PROCEDURE 81000.08

FITNESS-FOR-DUTY PROGRAM

Effective Date: January 1, 2025

PROGRAM APPLICABILITY: IMCs 2200 A, 2562

81000.08-01 INSPECTION OBJECTIVES

- 01.01 To verify that the licensee has developed and is properly implementing or is prepared to implement Fitness-for-Duty (FFD) requirements under Title 10 of the *Code of Federal Regulations* (10 CFR) Part 26 (Subparts A through H, N, and O), and any other applicable requirement that assures licensee personnel (including contractors and vendors) will perform their tasks in a reliable and trustworthy manner and are not under the influence of any substance or mentally or physically impaired from any cause that may affect their abilities to perform their duties safely and competently.
- 01.02 To verify that changes to the licensee's FFD program made since the last inspection:
 - (a) meet commitments to resolve previously identified issues or U.S. Nuclear Regulatory Commission (NRC) requirements under 10 CFR Part 26; and
 - (b) do not adversely affect the performance requirements as prescribed by regulatory requirements and any other applicable requirements.
- 01.03 To verify that the licensee has developed and is properly implementing or is prepared to implement FFD requirements pertaining to fatigue management under Subpart I of 10 CFR Part 26 and any other applicable NRC requirement to ensure, in part, that nuclear facility security force personnel are not assigned to duty while in a fatigued condition that could reduce their alertness or ability to perform functions necessary to identify and promptly respond to plant security threats.
- 01.04 To verify that the licensee has developed and is properly implementing or is prepared to implement the physical protection program associated with this sample and the program is designed and implemented to meet the general performance objective of 10 CFR 73.55(b).

81000.08-02 INSPECTION REQUIREMENTS

General Guidance

This inspection procedure (IP) was developed to ensure the operational program established for implementation at a plant licensed in accordance with 10 CFR Part 50 and 10 CFR Part 52 meet all NRC requirements and objectives for operational program readiness. Note that this inspection is conducted as licensees activate their operational program in accordance with IMC 2200, Appendix A, "Security Construction Inspection Program," or IMC 2562, "Light Water Reactor Inspection Program for Restart of Reactor Facilities Following Permanent Cessation of

Power Operations.” For reactors under construction, this IP is applicable to all power reactors under construction that are subject to oversight under the NRC’s Construction Reactor Oversight Process (cROP). For restart of reactor facilities following termination of an operating license, this IP is applicable for transitioning from a decommissioned or extended shutdown reactor facility to an operational power reactor facility subject to the Reactor Oversight Process (ROP). Therefore, verification through observation of activities may not be possible. In such cases, the inspector(s) should review the appropriate licensee procedures and conduct inspections of all associated areas to ensure program compliance upon implementation.

Through verification of the inspection requirements within this IP, inspector(s) shall ensure that the licensee’s FFD program associated with this sample is designed and implemented to meet the general performance objectives of 10 CFR 26.23 and 10 CFR 73.55(b).

In preparation to complete this IP, the inspector(s) should become familiar with relevant documentation that may include, but is not limited to, the licensee’s physical security plan, all open allegations, or past allegation trends pertaining to areas to be inspected during inspection preparation, site-specific and/or corporate FFD policy statement and FFD procedures, the access authorization provisions that adjudicate FFD authorization under 10 CFR Part 26, Subpart C, and sanctions under 10 CFR 26.75. The inspector(s) should apply additional attention to recent security plan changes that could be relevant to the inspection activity.

The inspector(s) are responsible for ensuring that every sample in the IP is completed and evaluated to a level which provides adequate assurance that licensees are meeting NRC regulatory requirements within the FFD program.

The guidance in this IP will assist inspector(s) by: (1) recommending methods and techniques for determining licensee FFD program compliance and effectiveness related to inspection requirements; and (2) clarifying regulatory requirements associated with inspection requirements.

Where a minimum sample number is indicated (e.g., sample at least (three) pre-access drug testing records, or sample at least 20 percent of the total personnel that had a pre-access drug and alcohol test in the last month), the inspector(s) should adhere as closely as possible to the numbers identified in the guidance. The inspector(s) may expand the minimum number to aid in determining the extent of the condition, should compliance concerns arise. Completion of other recommended actions contained in this IP should not be viewed as mandatory and is intended to assist the inspector(s) in determining whether an inspection sample has been adequately addressed. Should questions arise regarding IP requirements or guidance, inspector(s) should consult with regional management or the program office in the Office of Nuclear Security and Incident Response (NSIR).

Inspection Guidance

The appendices to this IP provide materials to assist the inspector(s) in conducting this inspection.

The questionnaires (Urine Collection, Breath Collection, Medical Review Officer, and Substance Abuse Expert) provide a uniform method to collect information from some of the key personnel that support a licensee’s FFD program.

The inspector(s) should interview the primary FFD program staff along with any key personnel who have a role in implementing the licensee’s FFD program. Additionally, a cross-section of

contractor personnel responsible for assisting with the implementation of the licensee or other entity's FFD program should be interviewed. The inspector(s) should visit the collection site(s) to interview specimen collectors and to evaluate the facility and collection process.

At a minimum, the inspector(s) should consider reviewing the following FFD program elements:

- a. The licensee's FFD policy statement and FFD procedures. The onsite inspection should focus on the licensee's implementation of the FFD policy statement and FFD procedures, and compliance with 10 CFR Part 26.
- b. As applicable, review a sample of testing records (pre-access; random; for cause; post-event; follow-up), include tests determined to be subversion attempts.
- c. Behavioral observation program. May include any for cause testing documentation produced during the inspection period.
- d. As applicable, any reports submitted to the NRC under 10 CFR 26.719(c) on significant FFD policy violations, programmatic failures, and drug and alcohol testing errors since the implementation of the FFD program.
- e. As applicable, determinations of fitness, specifically how the licensee adjudicated individuals prior to placing them back into a covered work status, including NRC-licensed operators (10 CFR 55.53(j)) and NRC-required security officers (10 CFR Part 73, Appendix B).
- f. As applicable, the results of licensee audits conducted under 10 CFR 26.41(e).
- g. As applicable, any corrective actions implemented as a result of identified FFD noncompliance's.
- h. Management of fatigue – security force work hours.
- i. Granting and maintaining authorization.
- j. Conduct interviews. A critical element to the inspection is conducting interviews with key personnel who support the FFD program. This IP provides questionnaires for interviewing the Medical Review Officer (MRO) and the Substance Abuse Expert (SAE). In addition, the inspector(s) should interview the FFD program manager and may need to interview personnel such as those who make determinations of fitness, supervisors, union shop stewards, FFD program personnel who administer the random testing program (e.g., generate random selections, notify individuals about test selection, update the random testing pool), and representatives of the licensee testing facility (if applicable). These questionnaires and interviews are referenced under the applicable inspection requirement or associated guidance.
- k. Review records. The drug and alcohol testing records generated under the FFD program provide inspectors with another source of information on the quality of the FFD program. As applicable, inspectors should consider contacting the NRC's FFD program office in NSIR to acquire FFD trend information to inform their review.
- l. Evaluate facilities (collection site(s) and licensee testing facility, if applicable). A central element of the FFD program is the facilities used to collect and analyze donor

specimens. The inspector(s) should visit the collection site(s) and use the Urine Collection and Breath Collection questionnaires to interview the specimen collector(s). These questionnaires include mock urine and breath specimen collection scenarios, which evaluate the collector's knowledge of the collection process. Visiting collection sites also provides inspectors information about the collection and testing environment, which may affect the quality of the FFD program (e.g., donor privacy, security, specimen integrity, ability of donors to subvert the testing process). (Note: This IP does not include a visit to the licensee's U.S. Health and Human Services (HHS)-certified laboratory, but multiple IP requirements do evaluate laboratory performance, as well as the licensee's auditing of its laboratories.)

02.01 Policy and Procedures Review

a. Verify that individuals identified in 10 CFR 26.4(a)-(e) and (g) are subject to drug and alcohol testing under the following conditions:

- 1. Pre-access (10 CFR 26.31(c)(1))**
- 2. For cause (10 CFR 26.31(c)(2))**
- 3. Post-event (10 CFR 26.31(c)(3))**
- 4. Follow-up (10 CFR 26.31(c)(4))**
- 5. Random (10 CFR 26.31(c)(5))**

Specific Guidance

The inspector(s) should interview the FFD program manager to confirm the manager's understanding of the FFD program, and in particular, the drug and alcohol testing conditions. Further, the inspector(s) should verify that the written FFD procedures state that individuals are subject to drug and alcohol testing under the following conditions:

1. Pre-access
2. For cause
3. Post-event
4. Follow-up
5. Random

02.02 Test Results Review and Medical Review Officer Interview

a. Verify that individuals identified in 10 CFR 26.4(a) that have been subject to the following drug and alcohol testing conditions and have had their test results reviewed by the MRO and interviews conducted, when appropriate.

- 1. Pre-access (10 CFR 26.31(c)(1))**
- 2. For cause (10 CFR 26.31(c)(2))**
- 3. Post-event (10 CFR 26.31(c)(3))**
- 4. Follow-up (10 CFR 26.31(c)(4))**
- 5. Random (10 CFR 26.31(c)(5))**

Specific Guidance

The inspector(s) should evaluate a sample of negative, positive, substituted, adulterated, invalid, and subverted test result records (e.g., Federal custody and control forms (Federal CCFs), verified test results) to confirm compliance for each test type:

1. Pre-Access (10 CFR 26.31(c)(1))

- (a) The inspector(s) should obtain a list of all individuals subject to testing under the FFD program for the time period covered by the inspection. The information requested should include: name, dates of verified negative pre-access drug and alcohol test results, and date unescorted access was granted. The inspector(s) should confirm by a sampling of individuals that “covered” activities were not performed without having authorization.
- (b) The inspector(s) should verify that the negative test results date preceded the date unescorted access was granted. For a sample of individuals, the inspector(s) should review the verified negative test results and compare to the information provided by the licensee.

2. Random (10 CFR 26.31(c)(5))

- (a) The inspector(s) should request a list of all random tests conducted in the period of the inspection review. The information should include: name, date of test, and results of test.

3. For Cause (10 CFR 26.31(c)(2))

- (a) The inspector(s) should request a list of all for cause tests conducted in the period of the inspection review. The information should include: name, date of test, and results of test.
- (b) The inspector(s) should evaluate the positive result rates for the current inspection period of review (by reviewing the FFD performance reports from the licensee submitted under 10 CFR 26.717). Because for cause testing is only to be conducted when an individual demonstrates detectable sign(s) of impairment (visual, odor, etc.), or a credible report is received on substance abuse, the positive result rate is typically much higher than that for any other test type. For example, the rate could be as high as 100 percent if one test was conducted in a year, and it was positive.

Note: A low positive rate may indicate that testing may have been conducted in the absence of sign(s) of impairment (evaluate decision-making), or that observable impairment may have been the result of other issues (e.g., use of substance(s) not in the testing panel, illness, fatigue).

- (c) The inspector(s) should evaluate for cause testing determinations (i.e., how does the licensee ensure that correct decisions are being made?). A licensee may use a checklist or other method to assist staff in correct decision-making and documentation.

4. Post-Event (10 CFR 26.31(c)(3))

- (a) The inspector(s) should request a list of all post-event tests conducted in the period of the inspection review. The information provided should include: name, date of test, results of test.
- (b) The licensee must use a method to document that at least one testing threshold specified in 10 CFR 26.31(c)(3)(i) – (iii) was met to support testing.
- (c) The inspector(s) should evaluate how the licensee determines who is authorized to make post-event testing decisions (including any required training necessary to make determinations). Two cases exist for post-event testing: Case 1 human error (a subjective determination) and Case 2 human error that results in an illness, injury, or other Occupational Safety and Health Administration (OSHA)-condition (10 CFR 26.31(c)(3)(i)). For Case 1 human error, the licensee can elect to conduct either a post-event or for cause test. This determination should be described in the licensee's procedure. Additionally, the licensee should have guidance on what constitutes a human error so that unnecessary testing is prevented. These instructions will help prevent licensees from leaning forward to test everyone just in case a Case 2 human error may be determined at a later time.
- (d) The inspector(s) should consider requesting a list of OSHA-reportable events to evaluate if any may have met the post-event testing criteria in 10 CFR 26.31(c)(3)(i) – "A significant illness or personal injury to the individual...which within 4 hours after the event is recordable under the Department of Labor standards contained in 29 CFR 1904.7, "General Recording Criteria.""
- (e) The inspector(s) should review decision-making on testing determinations for a sample of tests conducted. For example, does the licensee use a checklist or standard form to complete and document a post-event testing determination?
- (f) The inspector(s) should review positive test results (time of test, substance(s) detected, the time from accident/event to testing (important for alcohol testing), and what licensee personnel made the testing determination). The inspector(s) can consult with the FFD program performance reports submitted under 10 CFR 26.717 for the period of inspection to identify information on post-event tests. The Annual Reporting Form for Drug and Alcohol Tests (ARF), contains information on the number of post-event tests conducted, and the number of positive results. The Single Positive Test Form (SPTF) submitted for each positive result provides event specific information.

5. Follow-Up (10 CFR 26.31(c)(4))

- (a) The inspector(s) should request a list of tests conducted during the period of the inspection review. The information provided should include: name, date of test, results of test.
- (b) The inspector(s) should evaluate the follow-up testing requirements established by the SAE for a sample of individuals in the follow-up testing program. For these individuals, review all follow-up tests (Federal CCFs, MRO-verified drug test

results, alcohol test results). The inspector(s) should evaluate if the licensee is complying with the follow-up testing plan per 10 CFR 26.69(b)(6) (e.g., the number of tests to be conducted, the frequency and timing of tests).

6. Subversion Attempts Review

- (a) Evaluate subversion attempts identified during the period of inspection. NRC staff assessment of FFD program performance data indicates that over 75 percent of subversion attempts occur at pre-access testing, a predictable testing event, with well over 90 percent of all subversion attempts committed by contractors and vendors. If subversion attempts were observed on random, for cause, post-event, or follow-up tests, focus on reviewing situations where the specimen temperature was out of range on the initial specimen, or subversion paraphernalia was identified (i.e., these observations suggest that the individual obtained cheating paraphernalia prior to arriving for testing). The SPTFs submitted each year under 10 CFR 26.717 include detailed information on each subversion attempt.

02.03 Behavioral Observation Program

- a. **Verify that the licensee has developed, implemented, or is prepared to implement a program that ensures that individuals are subject to behavioral observation. (10 CFR 26.33 and 10 CFR 26.31(b)(v))**

Specific Guidance

The inspector(s) should verify that the licensee has developed, implemented, or is prepared to implement a behavior observation program. In particular, the inspector(s) should:

1. Review the licensee procedure to ascertain how individuals may make a behavioral observation that results in a for cause test. Assess how the licensee defined "FFD concern" and whether the process enables a timely for cause test for short-lived substances, such as alcohol.
2. Verify that only trained personnel make for cause testing determinations. For a sample of for cause tests, verify that the staff making the determination had received appropriate training prior to making the determination (e.g., evaluate training certificate, evaluate training completion date).
3. Evaluate the training requirements for staff authorized to make for cause testing determinations. Is training and frequency adequate to meet the 10 CFR 26.29 requirement?
 - (a) How did the licensee determine that the level of training provided was appropriate?
 - (b) How did the licensee determine that the training materials provided were appropriate?
4. The inspector(s) should review any random, follow-up, and for cause tests where an alcohol positive test result was reported during the period of inspection, especially if the blood alcohol concentration (BAC) of 0.04 percent or greater was reported

(i.e., the higher the BAC level, the more likely impairment could be identifiable). Each SPTF submitted under 10 CFR 26.717 for an alcohol positive will capture the BAC level exceeded (i.e., 0.04 or greater; 0.03 and in work status at least 1 hour; 0.02 and in work status at least 2 hours).

- b. Verify that the licensee's FFD policy statement requires individuals to report any FFD concerns about other individuals to the personnel designated in the FFD policy. Assess whether the procedure describes behavioral observations and "FFD concerns" that occur both on and off site. (10 CFR 26.33)**

Specific Guidance

The inspector(s) should review the FFD policy statement to ensure that it requires individuals to report any FFD concerns about other individuals to designated personnel.

- c. Verify that the licensee's program to allow off-site employees to maintain unescorted access contains provisions for initial and annual re-qualification of behavior observation training for both the employees and their supervisors. (10 CFR 73.56(f)(2)(i))**

Specific Guidance

No inspection guidance.

02.04 Sanctions and Substance Abuse Expert Interview

- a. Verify that the licensee has established sanctions in accordance with 10 CFR 26.75 that are imposed when an individual has violated the drug and alcohol provisions in the FFD policy statement.**

Specific Guidance

1. The inspector(s) should review the licensee's FFD policy statement to ensure that it specifies the FFD policy violations.
2. As applicable, the inspector(s) should examine cases of FFD program violations (e.g., positive drug and/or alcohol test result; testing refusal) and ensure that the correct sanction was assessed to each individual, as specified in the FFD policy statement.
 - (a) Ensure for the sample reviewed, that information on the FFD sanction was entered into the industry's access authorization database. The database is used by licensees and other entities to evaluate if an individual has an FFD policy violation under 10 CFR Part 26.
 - (b) Ensure for the sample reviewed, that no individual denied access under a 10 CFR 26.75 sanction subsequently has been granted authorization, unless the denial period is no longer applicable and the licensee implemented the requirements under 10 CFR 26.69(b), "Authorization after a first confirmed positive drug or alcohol test result or a 5-year denial of authorization."

- b. Verify that the licensee has developed, implemented, or is prepared to implement management actions that must be taken when an individual shows indication that**

**they may not be fit to perform their duties safely and competently.
(10 CFR 26.77, 10 CFR 26.35)**

Specific Guidance

1. The inspector(s) should review the licensee's FFD policy statement or FFD procedures to confirm that it specifies the management actions to be taken when an individual shows indication that they may not be fit for duty (i.e., not able to perform assigned duties safely and competently).
 2. The inspector(s) should review the licensee's FFD procedures or contract with the Employee Assistance Program (EAP) provider to ensure that FFD program management is notified if EAP personnel determine that an individual poses or has posed an immediate hazard to themselves or others (e.g., likely to commit self-harm or harm to others; has been impaired using drugs or alcohol while in a work status and has a continuing substance abuse disorder that makes it likely that they will be impaired while in a work status in the future; has engaged in any act that would be reportable to the NRC under 10 CFR 26.719(b)(1) through (b)(3). (10 CFR 26.35)
 3. As applicable, the inspector(s) should examine cases where FFD management took action when an individual was determined not to be fit for duty (e.g., observed behavior, odor of alcohol, slurred speech, credible report of substance abuse) and ensure that the action(s) were consistent with the FFD policy statement and FFD procedures.
- c. Verify that the licensee has developed, implemented, or is prepared to implement procedures for the review of FFD policy violations. (10 CFR 26.39)**

Specific Guidance

1. The inspector(s) should evaluate the licensee's FFD policy statement and FFD procedure(s) to verify that it includes an objective and impartial review process to assess the facts related to the determination that an individual has violated the FFD policy.
2. As applicable, the inspector(s) should examine cases of FFD policy violations to verify that a review of the policy violation determination was conducted, if requested by the individual. If an FFD policy violation was overturned, were any corrective actions implemented as a result of this review; and did the licensee make a 30-day report to the NRC under 10 CFR 26.719(c)(1)?

02.05 FFD Program Policy Statement and FFD Procedures Review

The inspector(s) should evaluate the FFD program policy statement and FFD procedures and discuss the information with the FFD program manager and/or staff directly responsible for the FFD policy, FFD procedures, and the implementation of the FFD program.

- a. Verify that all FFD program personnel involved in the day-to-day operations of the program and whose duties require access or the performance of activities specified in 10 CFR 26.4(g)(1) through (5) are or will be subject to the FFD program. (10 CFR 26.4(g))**

Specific Guidance

The inspector(s) should interview the FFD program manager and obtain a list of all FFD program personnel involved in the day-to-day operations of the FFD program and whose duties require them to have the types of access or perform the activities described in 10 CFR 26.4(g)(1) through (5), to confirm that each individual is subject to an FFD program.

- b. Verify that all contractor and vendor (C/V) personnel performing activities within the scope of 10 CFR Part 26 are or will be subject to either the licensee's FFD program, or to the C/Vs FFD program that has been formally reviewed and approved by the licensee. (10 CFR 26.21)**

Specific Guidance

The inspector(s) should interview the FFD program manager to confirm that all C/V personnel performing activities within the scope of 10 CFR Part 26 have been or will be subject to an FFD program.

- c. Verify that the licensee makes its FFD policy statement readily available to all individuals subject to the policy. (10 CFR 26.27(b))**

Specific Guidance

The inspector(s) should confirm, through discussion with the FFD program manager and through review of available documentation, that the most up to date FFD policy statement is readily available to all individuals subject to the policy. For example, is the FFD policy statement available for review on a company website or posted on bulletin boards, and are individuals knowledgeable about how to obtain the FFD policy statement?

- d. Verify that the licensee's written FFD policy statement is consistent with rule requirements. (10 CFR 26.27(b) and 10 CFR 26.203(a))**

Specific Guidance

The inspector(s) should review the written FFD policy statement to ensure that it addresses the following:

1. Consequences of the use, sale, or possession of illegal drugs on or off-site, the abuse of legal drugs and alcohol, and the misuse of prescription and over-the-counter drugs;
2. The requirement that individuals who are notified that they have been selected for random testing must report to the collection site within the time period specified by the licensee;
3. The actions that constitute a refusal to provide a specimen for testing, the consequences of a refusal to test, as well as the consequences of subverting or attempting to subvert the testing process;

4. Prohibits the consumption of alcohol, at a minimum, within an abstinence period of 5 hours preceding the individual's arrival at the licensee's facility, and during the period of any tour of duty;
 5. Conveys that abstinence from alcohol for 5 hours preceding any scheduled tour of duty is considered to be a minimum that is necessary, but may not be sufficient, to ensure that the individual is fit for duty;
 6. Addresses other factors that could affect FFD, such as mental stress, fatigue, or illness, and the use of prescription and over-the-counter medications that could cause impairment;
 7. Provides a description of any program available to individuals seeking assistance in dealing with drug, alcohol, fatigue, or other problems that could adversely affect an individual's ability to perform safely and competently the duties that require an individual to be subject to this subpart;
 8. The consequences of violating the policy;
 9. The individual's responsibility to report legal actions, as defined in 10 CFR 26.5;
 10. The responsibilities of managers, supervisors, and escorts to report FFD concerns; and
 11. The individual's responsibility to report FFD concerns.
- e. **Verify that the licensee's FFD procedures are consistent with rule requirements. (10 CFR 26.27(c) for FFD procedures on drug and alcohol testing, specific guidance items 1 through 4; and 10 CFR 26.203(b) for the fatigue management procedures for the security force, specific guidance items 5 through 8)**

Specific Guidance

The inspector(s) should verify that written FFD procedures exist that describe:

1. The methods and techniques to be used in testing for drugs and alcohol, including procedures for protecting the privacy and other rights (including due process) of an individual who provides a specimen, procedures for protecting the integrity of the specimen, and procedures used to ensure that the test results are valid and attributable to the correct individual.

For special analyses testing performed under 10 CFR 26.163(a)(2) on specimens with dilute validity test results and specimens collected under the direct observation conditions specified in 10 CFR 26.115(a)(1) through (3) and (5), confirm that the testing process is documented in the FFD policy statement and FFD procedures.

2. Immediate and follow up actions that will be taken, and the procedures to be used, in cases in which an individual is determined to have:
 - (a) Been involved in the use, sale, or possession of illegal drugs;

- (b) Consumed alcohol to excess before the mandatory pre-work abstinence period, or consumed any alcohol during the mandatory pre-work abstinence period or while on duty, as determined by a test that measures BAC;
 - (c) Attempted to subvert the testing process by adulterating or diluting specimens (in vivo or in vitro), substituting specimens, or by any other means;
 - (d) Refused to provide a specimen for analysis; or
 - (e) Had legal action taken relating to drug or alcohol use.
3. The process that the licensee will use to ensure that individuals who are called in to perform unscheduled work are fit for duty;
 4. The process to be followed if an individual's behavior raises a concern regarding the possible use, sale, or possession of illegal drugs on or off site; the possible possession or consumption of alcohol on site; or impairment from any cause which in any way could adversely affect the individual's ability to perform their duties safely and competently. The procedure must require that individuals who have a FFD concern about another individual's behavior shall contact the personnel designated in the FFD policy statement or FFD procedures to report the concern;
 5. The process to be followed when a security officer makes a self-declaration that they are not fit to perform their duties safely and competently for any part of a working tour as a result of fatigue;
 6. The process for implementing the work hour controls for security officers;
 7. The process to be followed when conducting a fatigue assessment of a security officer; and
 8. The disciplinary actions that the licensee may impose on a security officer following a fatigue assessment, and the conditions and considerations for taking those disciplinary actions.
- f. Verify that the licensee has developed, implemented, or is prepared to implement an auditing program that:**
- 1. Assures continuing effectiveness of the FFD program, including an audit of the FFD program elements provided by C/V programs accepted by the licensee, the FFD programs of C/Vs accepted by the licensee, and the management of security officer fatigue. (10 CFR 26.41(a) and 10 CFR 26.203(f))**
 - 2. Audits the entire FFD program on at least a 24-month frequency and ensures that corrective actions are implemented to resolve problems identified in accordance with the licensee's corrective action program. (10 CFR 26.41(b), 10 CFR 26.41(f), and 10 CFR 73.55(b)(10))**
 - 3. Audits program services provided to a licensee or other entity by C/V personnel that are off-site or are not under the direct daily supervision or observation of the licensee or other entity on a nominal 12-month frequency. (10 CFR 26.41(c))**

Specific Guidance

The inspector(s) should verify that the licensee's audit program is developed, implemented, or prepared to implement according to the following criteria:

1. The inspector(s) should verify that the licensee is performing audits to assure the effectiveness of the FFD program, including FFD elements that are provided by C/V programs as well as the FFD programs of C/Vs that are accepted by the licensee. In particular, the inspector(s) should review:
 - (a) The audit methodology;
 - (b) The audit reports completed; and
 - (c) The oversight exercised over C/V programs.
 2. The inspector(s) should verify that the licensee is conducting FFD program audits at least once every 24 months, and that corrective actions are taken to address identified deficiencies. In particular, the inspector(s) should:
 - (a) Evaluate corrective actions implemented by the licensee as a result of audit findings.
 - (b) Assess identified FFD program deficiencies identified in the NRC inspection to determine if the licensee's audit program needs improvement and or revised auditing approaches/strategies.
 3. The inspector(s) should verify that the licensee is conducting audits on a 12-month frequency of the FFD services provided to the licensee by C/V personnel who are off-site or are not under the direct daily supervision or observation of the licensee and HHS-certified laboratories providing service to the licensee. The inspector(s) should verify that corrective actions are taken to address identified deficiencies. In particular, the inspector(s) should:
 - (a) Evaluate corrective actions implemented by the licensee, C/V, and/or HHS-certified laboratory as a result of audit findings.
 - (b) Assess identified FFD program deficiencies identified in the current NRC inspection to determine if the licensee's audit program needs improvement and/or revised auditing approaches/strategies.
- g. Verify that initial, and as applicable, refresher training has been provided and taken, as required. (10 CFR 26.29(c))**

Specific Guidance

The inspector(s) should review the FFD training records and personnel records to ensure that individuals have been trained as follows:

1. Individuals have completed training before granting initial authorization, or training is current before granting an authorization update or authorization reinstatement.

2. Individuals have completed refresher training on a nominal 12-month frequency, or more frequently if a need is indicated.

h. Verify that the training content and comprehensive examination incorporated the required knowledge and abilities (KAs). (10 CFR 26.29(a) and 10 CFR 26.203(c))

Specific Guidance

The inspector(s) should review the training materials to ensure that they address the following KAs:

1. Knowledge of the FFD policy and FFD procedures that apply to the individual, the methods that will be used to implement them, and the consequences of violating any FFD policy or FFD procedure;
2. Knowledge of the individual's role and responsibilities under the FFD program;
3. Knowledge of the roles and responsibilities of others, such as the MRO, human resources, FFD, and EAP staff;
4. Knowledge of the EAP services available to the individual;
5. Knowledge of the personal and public health and safety hazards associated with abuse of illegal and legal drugs and alcohol;
6. Knowledge of the potential adverse effects on job performance by prescription and over-the-counter drugs, alcohol, dietary factors, illness, mental stress, and fatigue;
7. Knowledge of the prescription and over-the-counter drugs and dietary factors that have the potential to affect drug and alcohol test results;
8. Ability to recognize illegal drugs and indications of the illegal use, sale, or possession of drugs;
9. Ability to observe and detect performance degradation, indications of impairment, or behavioral changes;
10. Knowledge of the individual's responsibility to report an FFD concern and the ability to initiate appropriate actions, including referrals to the EAP, and person(s) designated by the licensee to receive FFD concerns;
11. Knowledge of the contributors to worker fatigue, circadian variations in alertness and performance, indications and risk factors for common sleep disorders, shiftwork strategies for obtaining adequate rest, and the effective use of fatigue countermeasures; and
12. Ability to identify symptoms of worker fatigue and contributors to decreased alertness in the workplace.

Note: Many licensees and other entities utilize a standard web-based training created by the National Academy for Nuclear Training e-Learning (NANTeL) for generic FFD program and behavioral observation training. If a deficiency in the training materials is identified, the impact may be larger than for just the current site under inspection.

- i. **Verify, by reviewing procedures and records, that the licensee has developed, implemented, or is prepared to implement a method to ensure that all individuals who maintain unescorted access to the protected area (PA), including supervisors and escorts, are subject to a behavioral observation program and receive behavioral observation training. (10 CFR 26.33, and 10 CFR 73.56(f)(1))**

Specific Guidance

When inspecting this requirement, the inspector(s) should review the licensee's implementing procedures, training records, access authorization records, etc., to determine that the licensee maintains a behavioral observation program, and that all personnel with unescorted access to the PA are included in the program and receive the appropriate initial and requalification behavioral observation training in accordance with 10 CFR 73.56(f).

- j. **Verify that the licensee developed, implemented, or is prepared to implement procedures that provide details on behavioral observation training. (10 CFR 73.56(f)(2)(ii))**

Specific Guidance

1. When inspecting this requirement, the inspector(s) should review the licensee's implementing procedures and/or behavioral observation training material to ensure that the training addresses the detection of behaviors and activities that constitute an unreasonable risk to the health and safety of the public and common defense and security, including the potential threat to commit radiological sabotage. The training should also address the individual's responsibilities for reporting behavioral observation concerns in accordance with 10 CFR 73.56(f)(3).
2. The inspector(s) should verify that the licensee has established a method that demonstrates that individuals have completed this training in accordance with 10 CFR 73.56(f)(iii) and (iv). For example, comprehensive examination for initial training and either refresher training or comprehensive examination for nominal annual requalification.

- k. **Verify, through a review of records, that the licensee effectively developed, implemented, or is prepared to implement a pre-access drug and alcohol testing program for persons requesting unescorted access and a random drug and alcohol testing program for persons maintaining unescorted access. (10 CFR 26.65, 10 CFR 26.67)**

Specific Guidance

No inspection guidance.

- l. **Verify that the licensee documents behavioral observation program training and, as applicable, refresher training. (10 CFR 26.713(b)(1), 10 CFR 73.56(o)(3)(i))**

Specific Guidance

No inspection guidance.

02.06 Test Results Review and Medical Review Officer Interview

- a. Verify that each MRO used by the FFD program meets the requirements in 10 CFR 26.183.**

Specific Guidance

1. The inspector(s) should refer to the MRO Questionnaire (Attachment 3) of this IP.
2. For utilities with multiple operating power reactor facility locations in the same NRC Region and that use the same MRO, the inspector(s) should consider if completing the Medical Review Officer Questionnaire is necessary when performing each site-specific inspection during the same inspection cycle (i.e., 1-year time period). A more targeted interview with the MRO may still be needed based on site-specific records reviews conducted by the inspector(s), as well as if follow-up actions were identified during a prior inspection conducted in the same year.

- b. Verify that an MRO review is performed on all positive, adulterated, substituted, dilute, and invalid specimen test results received from the HHS-certified laboratory. (10 CFR 26.185(a), (c), and (f) – (n))**

Note: The MRO may permit MRO staff to review negative drug test results. (10 CFR 26.183(d)(2))

Specific Guidance

The inspector(s) should refer to the MRO Questionnaire (Attachment 3) of this IP.

- c. Verify the method(s) that the HHS-certified laboratory used to transmit drug test results to the MRO maintain(s) the confidentiality and security of the information. (10 CFR 26.169(e) and (f))**

Specific Guidance

The inspector(s) should verify the security of the communication method(s) used by the HHS-certified laboratory to transmit test results to the MRO and/or the MRO staff are in accordance with site FFD policy and FFD procedures.

- d. Verify that the MRO is receiving drug test results from the HHS-certified laboratory within 5 business days after the laboratory receives each specimen for testing. (10 CFR 26.169(a))**

Specific Guidance

The inspector(s) should verify that the MRO is receiving drug test results from the HHS-certified laboratory within 5 business days after the laboratory receives each specimen for testing, by evaluating a sample of test results reviewed under this IP. Laboratories typically report negative results to the MRO within 24 hours of receipt of a specimen for testing and may take several days to report a positive result (which is dependent on the drug or drug metabolite identified in the donor's specimen).

- e. Verify that the MRO completes their review and notifies the licensee's designated representative within 10 business days of receiving: (1) any positive, adulterated,**

substituted, or invalid test result from the HHS-certified laboratory; and (2) in instances where no legitimate medical explanation for the test result(s) exist(s). (10 CFR 26.185(p))

Specific Guidance

The inspector(s) should verify that the MRO(s) supporting the FFD program complies with the FFD policies and 10 CFR Part 26 requirements by completing the following activities:

Validate through reviews of the Federal CCF, the laboratory test result, and the MRO-verified result for a sample of tests (i.e., drug positive; adulterated; substituted; invalid) that the MRO is conducting the required reviews and that each review is completed, and the licensee is notified within 10 days of the MRO receiving the result from the laboratory. The inspector(s) may need to request from the MRO the laboratory test result, as the licensee may not be in possession of this document.

- f. Verify that the licensee is conducting confirmatory alcohol testing for any individual with an initial alcohol test result of 0.02 percent BAC or greater. (10 CFR 26.99)**

Specific Guidance

The inspector(s) should review a sample of positive alcohol test results to ensure that:

1. Confirmatory alcohol testing was conducted in instances where an initial alcohol test result was 0.02 percent BAC or greater.
 2. The positive alcohol test determinations for confirmatory test results less than 0.04 percent BAC include documentation/evidence such that the inspector can confirm the amount of time each individual was in work status and verify the licensee's positive test decision.
- g. Verify the licensee's determination process for positive alcohol test results associated with work hour status (i.e., confirmatory results of 0.03 percent BAC and the individual was in work status at least 1 hour or 0.02 percent BAC and the individual was in work status for at least 2 hours). (10 CFR 26.103(a)(2))**

Specific Guidance

Review the FFD procedure that the licensee uses to determine the time the individual was in work status to make the determination on positive alcohol test results.

02.07 Collection Site Inspection and Urine and Breath Collection Interviews

- a. Verify that the licensee uses a designated collection site meeting the requirements in 10 CFR 26.87(a), (b), (d), and (e).**

Specific Guidance

Administer the Urine Collection Questionnaire (Attachment 1) and Breath Collection Questionnaire (Attachment 2) to evaluate the compliance of the licensee's collection site, alcohol testing equipment, and specimen collection procedures with requirements in

Subpart E of 10 CFR Part 26. If the licensee uses more than one dedicated collection site, the inspectors(s) should determine which collection site(s) to evaluate (e.g., sites could be selected based on a large number of collections, identified errors in collections, or cancelled tests identified in records reviews).

Note: Under 10 CFR 26.83, "Specimens to be collected," the NRC permits the collection of breath or oral fluid for initial tests for alcohol, and the collection of urine specimens for drug testing unless the licensee adopts through policy and procedure to collect and drug test oral fluid specimens for any of the direct observation collection conditions specified in 10 CFR 26.115(a)(1) through (3) and (5).

This inspection procedure only includes standardized questionnaires for the collection and testing of a breath specimen for alcohol (Attachment 2) and the collection of a urine specimen for drug testing (Attachment 1). If a licensee uses an alcohol screening device (ASD) to test oral fluid or collects oral fluid specimens for drug testing, in addition to delivering the Urine and Breath Collection questionnaires, the inspector(s) also should evaluate the specimen collection process for oral fluid specimens.

To verify collector compliance, obtain the instructions provided by the test device manufacturer and evaluate through an actual or mock collection that the collector correctly completes the specimen collection.

- b. Verify that the licensee only uses devices that meet the requirements in 10 CFR 26.91(a) to conduct initial alcohol testing and that the collection site maintains the devices according to the quality assurance and quality controls requirements in 10 CFR 26.91(d).**

Specific Guidance

The inspector should reference the specific guidance listed under 02.07 (a).

- c. Verify that the oral fluid specimen collection and testing process for alcohol is conducted in accordance with the applicable requirements in Subpart E of 10 CFR Part 26. (10 CFR 26.89, 10 CFR 26.93, 10 CFR 26.97, 10 CFR 26.99, 10 CFR 26.101, and 10 CFR 26.103)**

Specific Guidance

The inspector should reference the specific guidance listed under 02.07 (a).

- d. Verify that the oral fluid specimen collection process for drug testing is conducted in accordance with the applicable requirements in Subpart E of 10 CFR Part 26. (10 CFR 26.89, 10 CFR 26.97, 10 CFR 26.105, and 10 CFR 26.117)**

Specific Guidance

The inspector should reference the specific guidance listed under 02.07 (a).

- e. Verify that the specimen collectors used by the licensee meet the collector qualification requirements in 10 CFR 26.85(a) and (d).**

Specific Guidance

The inspector should reference the specific guidance listed under 02.07 (a).

02.08 Sanctions and Substance Abuse Expert Interview

- a. **Verify that the licensee only uses SAEs that meet the requirements in 10 CFR 26.187.**

Specific Guidance

Administer the Substance Abuse Expert Questionnaire (Attachment 4) to evaluate the training and credentials of the SAE, the SAE's knowledge of the treatment and follow-up testing requirements associated with FFD program policy violations, and the SAE's knowledge of the determination of fitness process.

For utilities with multiple operating power reactor facility locations in the same NRC Region and that use the same SAE, the inspector(s) should consider if completing the Substance Abuse Expert Questionnaire is necessary when performing each site-specific inspection during the same inspection cycle (i.e., 1-year time period). A more targeted interview with the SAE may still be needed based on site-specific records review conducted by the inspector(s), as well as if follow-up actions were identified during a prior inspection conducted in the same year.

- b. **Verify that the SAE is knowledgeable of the responsibilities related to evaluating individuals who have violated the substance abuse provision(s) of the FFD policy (10 CFR 26.187(g)) and performs each determination of fitness in accordance with 10 CFR 26.189.**

Specific Guidance

The inspector should reference the specific guidance listed under section 02.08 (a).

02.09 Licensee Testing Facility and/or Health and Human Services-Certified Laboratory

- a. **Verify that the licensee is or is prepared to test each urine specimen, at a minimum, for the substances specified in 10 CFR 26.31(d)(1) and at the cutoff levels specified in 10 CFR 26.133 (Licensee Testing Facilities) and/or 10 CFR 26.163 (HHS-certified laboratories).**
 1. **If the licensee is using more stringent cutoff levels than specified in 10 CFR 26.163, verify that the cutoff levels have been evaluated and certified, in writing, by a forensic toxicologist meeting the requirements in 10 CFR 26.31(d)(1)(i)(D) (or NRC-approved the lower cutoff levels before April 30, 2008).**
 2. **If the licensee is testing for drug(s) in addition to those specified in 10 CFR 26.31(d)(1), verify that:**
 - (a) **Each drug is listed in Schedules I through V of Section 202 of the Controlled Substances Act [21 U.S.C. 812]. (10 CFR 26.31(d)(1)(i)(A))**

- (b) The assay and cutoff levels used for each drug have been certified in writing by a forensic toxicologist as scientifically sound and legally defensible. Certification of the assay and cutoff levels by a forensic toxicologist is not required if the HHS Guidelines are revised to authorize use of the testing assay and cutoff levels. (10 CFR 26.31(d)(1)(i)(D))
3. For special analyses testing of specimens with a dilute validity test result and specimens collected under the direct observation conditions specified in 10 CFR 26.115(a)(1) through (3) and (5), verify that the process is implemented as described in 10 CFR 26.163(a)(2). This only pertains to testing performed at an HHS-certified laboratory.

Specific Guidance

The inspector(s) should review drug and validity testing results provided by the licensee's testing facility (as applicable) and the HHS-certified laboratory to the MRO. The MRO may provide these results as part of the verified results sent to the FFD program. If so, inspector(s) should evaluate the test results during the records reviews conducted under this inspection. If not, request that the MRO provide, for a sample of selected testing events, the laboratory test results to verify drug and validity testing requirements (substances tested, cutoff levels used, etc.).

1. If the licensee tests for drugs in addition to those specified in 10 CFR 26.31(d)(1), ensure that each drug is listed in Schedules I through V of Section 202 of the Controlled Substances Act [21 U.S.C. 812].
 2. Review the forensic toxicologist certification for any additional drugs and/or more stringent cutoff levels used by the licensee. Ensure that the documentation is consistent with the requirements in 10 CFR 26.31(d)(1)(D).
 3. The inspectors may also review the contract with the HHS-certified laboratory to confirm the drug testing program used by the licensee (substances tested, cutoff levels used, validity tests performed, etc.).
 4. If special analyses testing has been performed on specimens with dilute validity test results and specimens collected under direct observation conditions, ensure that the HHS-certified laboratory test results and MRO reviews are consistent with the requirements in 10 CFR 26.163(a)(2) and 10 CFR 26.185. Request from the licensee the Federal CCF, MRO-verified result, and HHS-certified laboratory test results for each specimen subject to special analyses testing.
- b. **Verify that the licensee is or is prepared to conduct validity testing at an HHS-certified laboratory for all urine specimens as described in 10 CFR 26.31(d)(3)(i) and 10 CFR 26.161. Validity screening and/or initial validity testing also may be performed at a licensee testing facility (LTF) as described in 10 CFR 26.131.**

Specific Guidance

The inspector(s) should review the licensee's FFD policy statement to ensure that it specifies that validity testing is to be performed on all urine specimens. Review the HHS-certified laboratory contract to ensure that validity testing is being performed in

accordance with 10 CFR 26.31(d)(3)(i) and 10 CFR 26.161 and review a sample of urine specimen test results to confirm that validity testing has been performed. The inspector(s) should examine any FFD program violations for adulterated and substituted validity test results.

c. If the licensee uses an LTF, verify the following:

- 1. LTF personnel meet the training and credential requirements in 10 CFR 26.125.**
- 2. The LTF is submitting a minimum of 5 percent (or at least one) of donor specimens screened as negative from each analytical run to the HHS-certified laboratory for testing. (10 CFR 26.137(e)(5))**
- 3. The licensee is receiving testing information from the LTF to assess LTF performance (10 CFR 26.75(i) and 26.719(c)), and to inform the annual FFD performance report to the NRC. (10 CFR 26.139(d) and (e))**
- 4. The LTF is reporting testing program errors. (10 CFR 26.137(f))**

Specific Guidance

The inspector(s) should verify the following elements of the LTF's testing program (only applicable if the licensee uses an LTF).

1. Request and review the training and credential requirements for LTF staff to confirm compliance with 10 CFR 26.125.
2. Speak with staff at the LTF to verify the procedure used to ensure that a minimum of 5 percent (or at least one) of donor specimens screened as negative from each analytical run are sent to the HHS-certified laboratory for quality control testing. Request a list of the specimens sent for testing and review a sample of the test results received from the LTF.
3. If applicable, review the annual statistical summary report provided to the licensee that details tests conducted at the LTF. The FFD performance report submitted by the licensee will consist of data supplied by the LTF and the HHS-certified laboratory.
4. If applicable, evaluate any reports submitted to the licensee related to testing errors required to be reported under 10 CFR 26.137(f). Ensure that corrective actions have been implemented.

d. Verify each HHS-certified laboratory used by the licensee to conduct drug testing of specimens, ensure that:

- 1. The laboratory is an HHS-certified laboratory. (10 CFR 26.31(d)(3) and 10 CFR 26.153(a))**
- 2. The licensee is receiving the annual statistical summary of testing as specified in 10 CFR 26.169(h).**

Specific Guidance

Inspector(s) should verify the following regarding the HHS-certified laboratory(s) used by the licensee to conduct testing on urine specimens:

1. That each laboratory used is listed on the current list of HHS-certified laboratories available at: <https://www.samhsa.gov/workplace/drug-testing-resources/certified-lab-list>.
 2. Request that the licensee provide a copy of the latest annual statistical summary of testing provided by the HHS-certified laboratory and evaluate the document for compliance with 10 CFR 26.169(h).
- e. Verify the following about the blind performance test samples (BPTSs) that the licensee's FFD program is submitting to the HHS-certified laboratory:**
- 1. The licensee is submitting the minimum number of BPTSs each quarter, as specified in 10 CFR 26.168(a).**
 - 2. The licensee is submitting each BPTS type (i.e., negative, drug positive, false negative challenge, adulterated, substituted, dilute) and in the correct percentages of samples submitted for testing. (10 CFR 26.168(b) – (f))**
 - 3. All BPTSs used by the licensee are certified by the supplier and formulated as specified in 10 CFR 26.168(g) and (h).**
 - 4. The licensee is submitting all BPTSs in a manner such that each sample is indistinguishable to laboratory personnel from a donor's specimen. (10 CFR 26.168(i))**

Specific Guidance

Inspector(s) should evaluate the following about the BPTSs submitted to the HHS-certified laboratory by the licensee:

1. Discuss with the licensee the method used to track the number and type (e.g., adulterated, negative, etc.) of BPTSs submitted each quarter and evaluate how the licensee ensures that it meets the minimum number of BPTSs and in the correct percentage by type for testing each quarter.
2. Request for each quarter of testing covered by the period of the inspection or since the FFD program was implemented:
 - (a) the total number of donor specimens tested at the HHS-certified laboratory;
 - (b) a list of the BPTSs submitted for testing to include the date each sample was submitted and the type of each sample (e.g., positive for marijuana, substituted, etc.). See Attachment 5, Blind Performance Test Sample Submissions, for information to assist the inspector(s) in evaluating the number and types of BPTSs submitted each quarter.
3. Does the licensee send BPTSs to each HHS-certified laboratory that the licensee is under contract with to perform drug and validity testing of specimens?

4. Ask the licensee to explain who reviews the BPTS test results from the HHS-certified laboratory (i.e., the MRO or MRO staff), and what is the review procedure used to ensure that any unsatisfactory performance from the laboratory is identified in a timely manner?
5. Ask the licensee's staff to explain when BPTSs are submitted in each quarter. Is the frequency consistent with normal specimens submitted throughout the quarter, or are all BPTSs submitted at one time towards the end of the quarter? The later approach would alert the laboratory to the likelihood that the specimens were not donor specimens, because of the high number of positive results.
6. Ask the licensee's staff to explain how it completes the Federal CCF for a BPTS. Review the CCFs for a sample of BPTSs submitted for testing. Verify that each Federal CCF was completed as though it were a donor sample.
7. Request that the licensee provide documentation from the BPTS supplier that confirms that the BPTSs meet the requirements in 10 CFR 26.168(g) and (h).
8. Evaluate the process the licensee uses to ensure that no BPTS is submitted for testing that has exceeded the product expiration date. (10 CFR 26.168(h))

02.10 FFD Program Policy and FFD Procedures Review

- a. **Verify that time limit(s) have been established in the FFD policy statement that is reasonable and practicable for individuals to report to the collection site for random testing once notified. (10 CFR 26.27(b)(2) and 10 CFR 26.31(d)(2)(iii))**

Specific Guidance

The inspector(s) should verify that the FFD policy statement and FFD procedures state that individuals must report to the collection site in the time frame specified by the licensee.

1. The inspector(s) should verify that a time limit is specified in the FFD policy statement for an individual to report to the collection site. This time period should accommodate for travel time to the collection from the location of notification. An individual should not be notified to appear for testing prior to their availability to report for the test (i.e., notifying an individual at the start of shift to report to testing at the end of shift).
2. The inspector(s) should review the FFD policy statement and procedures to verify that the licensee uses a method to document the time of notification and the time of arrival at the collection site to ensure that individuals report within the required amount of time.

02.11 Random Testing Program, Test Results Review, and Medical Review Officer Interview

- a. **Verify the licensee has developed, implemented, or is prepared to implement the following about the random testing program:**
 1. **Each individual in the population subject to testing has an equal probability of being selected and tested, and each individual tested is immediately eligible to**

be selected for another test each time a random selection list is generated. Ascertain how FFD program personnel are randomly tested (i.e., are FFD personnel in another entity's random testing pool?). (10 CFR 26.31(d)(2)(iv) and (vi))

2. Individuals selected for random testing, but not available to appear for testing (either off-site or not reasonably available for testing when selected), are tested at the earliest reasonable and practical opportunity and without prior notice of the test. (10 CFR 26.31(d)(2)(v))
3. Testing is conducted at a minimum on a nominal weekly frequency, including conducting testing on weekends and holidays. (10 CFR 26.31(d)(2)(i)(B) and (d)(2))
4. Testing is conducted in a manner that provides reasonable assurance that individuals cannot predict the days and time periods when specimens will be collected, such as taking reasonable steps to either conceal from the workforce that collections will be performed during a scheduled collection period, or create the appearance that specimens are being collected during a portion of each day on at least 4 days in each calendar week at the site. In the latter instance, the portions of each day and the days of the week must vary in a manner that cannot be predicted by donors. (10 CFR 26.31(d)(2)(i))
5. Each individual notified to appear for a test, reports to the collection site as soon as reasonably practicable after notification and within the time period specified in the FFD policy statement. (10 CFR 26.31(d)(2)(iii))
6. The number of random tests conducted each calendar year is equal to at least 50 percent of the population subject to testing. (10 CFR 26.31(d)(2)(vii))

Specific Guidance

Inspector(s) should evaluate the following elements of the licensee's random testing program:

1. The inspector(s) should verify that all individuals in the population subject to testing have an equal probability of being selected and tested.
 - (a) Testing pool maintenance. The inspector(s) should verify that all individuals subject to testing are included in the random testing pool. If the list of covered personnel is not up to date when a random selection list is created, each person does not have an equal probability of selection and testing. The inspector(s) should:
 - (1) Request all random selection lists generated during the period of review. Request a list of all random tests conducted for the period of review (date of test, individual name, results).
 - (2) Request a list of all staff start dates and termination dates during the period of the inspection review. The inspector(s) should evaluate if the random testing pool is updated effectively (examples could include, are individuals that have

been granted authorization not included in the random selection pool? Does the selection pool include individuals who no longer have authorization?)

- (3) The inspector(s) should speak to the individual(s) who maintain(s) the random testing pool and discuss: (1) how updates are made (is the pool updated before each selection list is generated – very important to ensure new hires are included in the pool and subject to testing); and (2) how frequently random lists are generated (if the employee's population changes frequently the random testing pool must be updated frequently and the period that a random selection list is valid would be limited). The inspectors may wish to assess how the FFD program personnel are randomly tested.
 - (4) The inspector(s) should verify that each individual completing a test is immediately eligible for another random test. The inspector(s) should evaluate the random selection method used (how is the random selection list created; does an opportunity exist for any tested individual to be removed from the testing pool?).
 - (5) The inspector(s) should evaluate the security of the random selection lists to ensure limited access. How does the licensee communicate the selection of an individual for random testing to ensure that the individual receives no prior notice of the selection for a test?
2. The inspector(s) should evaluate the instances where individuals selected for random testing were not initially tested (i.e., verify why the person was not tested the day originally intended for the testing event). This is a key component of the random testing program, ensuring that the licensee is not exercising discretion when to excuse or test a selected individual. If an individual is not tested on the day of selection for testing, what method does the licensee use to ensure that testing is completed at the earliest reasonable and practical opportunity when both the donor and collector are available to collect specimens for testing and without prior notice of the test?
 3. Ensure that testing is conducted at least on a nominal weekly frequency. The inspector(s) should request a list of all random tests (e.g., date of each test) to verify compliance during the period of review. The inspector(s) should consider using a spreadsheet analysis method for this step. For example, one method to determine testing frequency is to sort the list of test dates in chronological order and then evaluate the number of days between tests. Another possible method is to use the "weeknum" formula in Microsoft Excel which will assign a week number (i.e., 1 to 52) based on the date of the test entered into the formula.
 4. The inspector(s) should verify that random testing is conducted in a manner that provides assurance that individuals cannot predict the days and time periods when specimens will be collected.
 - a. The inspector(s) should evaluate if the subject population is likely to detect any patterns regarding when random testing is to be conducted. Examples of predictable patterns include only testing one day in each 7-day calendar week (e.g., test on Monday this week, no tests until at least the following Sunday which is the start of the next week), testing on the same day of each week; only testing during limited time periods each day when testing is performed (e.g., 8:00 a.m. to

10:00 a.m.; 3:00 p.m. to 5:00 p.m.), not conducting testing on weekends or holidays.

1. To evaluate if predictability exists in the random testing program, request a list of a random tests conducted during the period of inspection review. The information should include: name, testing date, and test times.
2. Consider using graphical analyses of random testing information to evaluate predictability over a relatively long period of time (e.g., 12 months).
- b. Evaluate if it is possible for individuals to determine that random testing will be conducted prior to notification for testing. For example:
 1. Does the arrival of the mobile collector onsite to conduct testing notify staff that testing will be conducted during the day?
 2. Is the location where testing is conducted only occupied on days when testing is performed (e.g., office is closed, and no staff are present when no testing is performed)?
 3. Is backshift testing only conducted by a certain security supervisor?
- c. The inspector(s) should evaluate the method(s) used by the licensee to determine the frequency and timing of testing:
 1. Number of days per week (testing is required at least on a nominal weekly basis).
 2. Number of days per month.
 3. Coverage across days of the week (is testing conducted on each day of the week, including weekends and holidays?). For example, if weekend testing is only conducted during outages, that would be predictable.
 4. Time of the day of testing events (including backshifts).
- d. The inspector(s) should obtain information on how the collection site(s) operate (hours of service, how is off peak testing conducted?).
- e. Does the licensee test a large number of staff each time testing is conducted (i.e., a limited number of testing days and a lot of tests conducted on each testing day)?
5. The inspector(s) should verify time limit(s) established by the FFD policy statement for individuals to report to the collection site for random testing once notified.
 - (a) The inspector(s) should ensure that upon notification, individuals appear for testing at the earliest reasonable and practicable opportunity, as described in licensee procedures. If no legitimate work, travel, or other demands would prevent an individual from immediately reporting for testing, the individual is to report as soon as they are notified.

- (b) The licensee may not notify an individual for testing until they can proceed for testing (e.g., notifying an individual at the start of a shift to appear for testing at the end of the shift is not appropriate; notifying an individual to appear for testing the next day is not appropriate).
 - (c) The inspector(s) should evaluate if the established time period to report for random testing is reasonable. For example, if it takes a person 25 minutes to get to the collection site from inside the PA, an individual should not be reporting 45 minutes later.
 - (d) The inspector(s) should ascertain how the licensee ensures that persons reporting for random drug testing meet the “earliest reasonable and practicable opportunity” requirement. For example, does the licensee document the time of notification and time of arrival at the collection site? The inspector(s) should review the documentation on notification and arrival times and follow-up actions to see if individuals who report late for testing are held responsible and ascertain whether corrective actions were taken. Are reviews conducted?
6. Verify that the licensee is meeting the minimum annual random testing rate of 50 percent of the population subject to testing.
- (a) The annual random testing rate is reported for each calendar year in the FFD performance report (i.e., the ARF) submitted to NRC. Evaluate the method that the licensee uses to ensure that the annual testing rate is accurate (i.e., verify the calculation of the value).
 - (b) Evaluate how the licensee tracks in the current year of testing progress in meeting the 50 percent testing rate. What method(s) does the licensee use to ensure that the annual random testing rate is met?

02.12 Recordkeeping and Reporting

- a. Verify that the licensee has developed, implemented, or is prepared to implement a records retention program for the time periods specified in Subpart N of 10 CFR Part 26. (10 CFR 26.711(a), 10 CFR 26.713)**

Specific Guidance

The inspector(s) should ensure that the FFD procedures require records to be retained as follows:

- 1. For at least 5 years after the licensee terminates or denies an individual's authorization, or until the completion of all related legal proceedings, whichever is later:
 - (a) Records of self-disclosures, employment histories, and suitable inquiries that result in the granting of an authorization;
 - (b) Records pertaining to the determination of a violation of the FFD policy and related management actions;
 - (c) Documentation of the granting and termination of an authorization;

- (d) Records of any determinations of fitness, including any recommendations for treatment and follow-up testing plans; and
 - (e) Superseded versions of the FFD policy statement and FFD procedures.
- 2. For at least 3 years, or until the completion of all related legal proceedings, whichever is later:
 - (a) Records of FFD training and examinations;
 - (b) Records of audits, audit findings, and corrective actions taken; and
 - (c) Fatigue-related records for security officers.
- 3. For at least 40 years or until, on application, the NRC determines that the records are no longer needed:
 - (a) Records pertaining to any 5-year denial of authorization and any permanent denial of authorization.
- 4. For the life of the agreement, or until completion of all legal proceedings, whichever is later:
 - (a) Written agreements for the provision of services under 10 CFR Part 26.
- 5. For the length of the individual's employment or contractual relationship with the licensee, or until the completion of all related legal proceedings, whichever is later:
 - (a) Records of the background investigations, credit and criminal history checks, and psychological assessments of FFD program personnel.
- 6. For the time the FFD program follows these practices, or until the completion of all related legal proceedings, whichever is later:
 - (a) If the licensee tests for drugs in addition to the ones required by 10 CFR Part 26 or uses more stringent cutoff levels, documentation certifying the scientific and technical suitability of the assays and cutoff levels used.
- b. Verify, if a licensee maintains records electronically, that the electronic records:**
 - 1. Provide an accurate representation of the original record;**
 - 2. Prevent alteration of any archived information and/or data once it has been committed to storage; and**
 - 3. Permit easy retrieval and recreation of the original record. (10 CFR 26.711(b)).**

Specific Guidance

The inspector(s) should review a sample of employee records that are maintained electronically. The inspector(s) should assess the accuracy, permanence, and ease of access associated with the records.

c. Verify, as applicable, that the licensee is submitting the following reports to the NRC:

- 1. Annual FFD program performance report that includes information on the licensee's drug and alcohol testing program for the full site and the fatigue program for security officers. (10 CFR 26.717(b)(1)-(8) and 10 CFR 26.203(e))**
- 2. Twenty-four hour Event Reports on significant FFD policy violations and programmatic failures. (10 CFR 26.719(b)(1)-(4))**
- 3. Thirty-day Event Reports on drug and alcohol testing errors. (10 CFR 26.719(c))**

Specific Guidance

The inspector(s) should request to see all documentation associated with licensee reports to the NRC relating to:

1. Meeting the annual FFD performance report requirement that includes information on the drug and alcohol testing program and fatigue program for security officers. Confirmation can be made through contacting NRC staff who maintain the FFD performance reporting data collection system and/or through review of licensee's files completed during the inspection. Evaluate issues included in the annual FFD performance reports related to:

Drug and alcohol testing program. Review positive test rates, testing refusals, and adulterated and substituted specimens. A comparison to previous reports will permit an evaluation of trends. Adulterated and substituted specimens indicate that individuals have subverted the collection process, and their action was detected during the testing process. A spike in positive rates for a specific employee category or for a particular substance may indicate a program deficiency or new trend. Discuss with FFD management apparent changes in trends.

- (a) Drug and alcohol testing program. Programmatic issues with the testing laboratories, implementation of program policies and procedures, and program and system management.
 - (b) Performance reporting categories describe deviations from established procedures and protocols. Ensure that the licensee is adequately addressing all deficiencies reported.
 - (c) Fatigue reporting program for site security force. Evaluate the waivers issued and ensure that the licensee is adequately addressing staffing issues, when necessary. Were a large number of waivers issued to site security? Were specific individuals issued a large number of waivers?
2. Reporting cases of significant FFD policy violations and programmatic failures including the discovery of any intentional act(s) that cast doubt on the integrity of the FFD program and any programmatic failure, degradation, or discovered vulnerability of the FFD program that may permit undetected drug or alcohol use or abuse. The inspector(s) should verify through the licensee's internal documentation and through discussions with relevant staff that each report was made to the NRC within 24 hours

of discovery. Inspector(s) should ensure that the licensee is adequately addressing all deficiencies and follow up on corrective actions implemented, as appropriate.

3. Drug and alcohol testing errors. Review the reports provided on any errors related to the unsatisfactory performance of the licensee's testing facility (as applicable), the HHS-certified laboratory, and any other errors that could adversely affect the integrity of the testing program. The inspector(s) should verify through the licensee's internal documentation and through discussions with relevant staff that each report was made to the NRC within 30 days of completing the investigation of any testing error or program performance issue. Inspector(s) should ensure that the licensee is adequately addressing all deficiencies and follow up on corrective actions, as appropriate.
 4. If available, consult the annual summary report published by the NRC on FFD program performance, which includes information on all 24-hour and 30-day Event Reports received by the NRC under 10 CFR 26.719, including a summary of each event and associated NRC Event Notice number (for 24-hour Event Reports) and ADAMS Accession Number (for 30-day Event Reports).
- d. Verify that the licensee has a process in place to retain fatigue-related records for security officers for at least 3 years, or until the completion of all related legal proceedings, whichever is later. (10 CFR 26.203(d))**

Specific Guidance

No inspection guidance.

- e. Verify that the licensee establishes, uses, and maintains a system of files and procedures that protects the individual's privacy. (10 CFR 26.37)**

Specific Guidance

The inspector(s) should review the licensee's written procedure to verify that provisions exist to protect personal information. The inspector(s) should evaluate the adequacy and implementation of the provisions by visually observing the file and recordkeeping system(s).

1. Verify who is permitted to access FFD program records and personnel files.
2. Request to see where FFD administration records and personal files (e.g., test results, Federal CCFs, consent forms, appeal records) are maintained and stored. The inspector(s) should verify that the system(s) restricts access to individuals not authorized to access the information.
3. Request a sample of records to review while at the facility and observe the retrieval of the information from the storage location to verify that the personnel information is stored in accordance with the licensee's or other entity's procedures to protect personal information.

02.13 Managing Fatigue – Security Force Work Hours

- a. **Verify, as applicable, that security officers do not exceed work hour limits. (10 CFR 26.205)**

Specific Guidance

The inspector(s) should examine the work hour records for a sample of security officers. These work hour records should not be work schedules; rather, the records should represent actual hours worked by security officers during the period of inspection. The inspector(s) should ensure that the work hours do not exceed the work hour requirements in 10 CFR 26.205.

- b. **Verify, as applicable, that the waivers issued from work hour limits were authorized and documented in accordance with the rule requirements. (10 CFR 26.207)**

Specific Guidance

1. The inspector(s) should examine a sample of waivers from the work hour limits that were issued to security officers during the period of inspection. The inspector(s) should ensure that the waivers were authorized and documented in accordance with 10 CFR 26.207.
 2. The inspector(s) can evaluate if a licensee has issued any waivers to work hour limits for the security force by reviewing the Annual Fatigue Reporting Form (NRC Form 892) submitted to the NRC under 10 CFR 26.203(e).
- c. **Verify that the licensee developed or augmented procedures to describe the process to be followed if a security officer:**
1. **Declares that, due to fatigue, they are unable to perform their duties safely and competently.**
 2. **Requires a fatigue assessment. (10 CFR 26.209, 10 CFR 26.211)**

Specific Guidance

No inspection guidance.

02.14 FFD Events and Log Review

Events and Logs. Review and evaluate licensee event reports under 10 CFR 26.719, and safeguards log entries for the previous 12 months or since the last NRC inspection that are associated with the FFD program and follow up, if appropriate.

Security Program Review. Verify that the licensee developed, implemented, or is prepared to implement security program reviews in accordance with 10 CFR 26.41 and that the licensee's FFD program is included in the security program reviews, as required by the regulation. (10 CFR 73.55(b)(1), 10 CFR 73.55(b)(9)(ii), 10 CFR 73.55(m); 10 CFR 26.41(b); and Security Plans)

Identification and Resolution of Problems. Verify that the licensee is identifying issues related to its FFD program at an appropriate threshold and entering them into the corrective action program. Verify that the licensee has appropriately resolved the issues regarding regulatory requirements for a selected sample of problems associated with its FFD program.
(10 CFR 73.55(b)(10), 10 CFR 26.41(f), and 10 CFR 26.719(d))

Specific Guidance

As applicable, the inspector(s) should review the documented results of the security program reviews or audits performed by the licensee to ensure the continued effectiveness of its FFD program. The inspector(s) should ensure that the reviews have been conducted in accordance with the requirements of 10 CFR 73.55(m). The inspector(s) should also request a copy of the report that was developed and provided to licensee management for review. The inspector(s) should review the report to identify any findings of the review or audit and ensure that the findings were entered in the licensee's corrective action program.

81000.08-03 PROCEDURE COMPLETION

Inspection of all 50 inspection requirements will constitute the completion of this IP.

81000.08-04 RESOURCE ESTIMATE

The resource estimate for the completion of this procedure consists of approximately 33 hours of direct inspection effort onsite. The sample size for this procedure is 50.

81000.08-05 REFERENCES

10 CFR Part 26 Final Rule, *Federal Register*, Volume 87, No. 224, November 22, 2022, is available at: <https://www.govinfo.gov/content/pkg/FR-2022-11-22/pdf/2022-24903.pdf>

10 CFR Part 26 Final Rule, *Federal Register*, Volume 73, No. 62, March 31, 2008, is available at: <https://www.govinfo.gov/content/pkg/FR-2008-03-31/pdf/E8-4998.pdf>

10 CFR Part 26 is available at the Electronic Code of Federal Regulations (eCFR) Website: <https://www.ecfr.gov/current/title-10/chapter-I/part-26>

A current list of controlled substances (Schedules I to V of section 202 of the Controlled Substances Act [21 U.S.C. 812]) is available at: <https://www.dea.gov/drug-information/drug-scheduling>

A current list of HHS-certified laboratories (urine and oral fluid) is published each month in the *Federal Register* and is available at: <https://www.samhsa.gov/workplace/drug-testing-resources/certified-lab-list>

National Highway Traffic Safety (NHTSA) Conforming Products List (CPL) for evidential breath testing devices (67 FR 62091; October 3, 2002, and subsequent amendments). A current list of approved devices is available at: <https://www.transportation.gov/odapc/approved-evidential-breath-testing-devices>

Nuclear Energy Institute (NEI) 03-01, Nuclear Power Plant Access Authorization Program,
Revision 3, May 2009 (non-public)

Regulatory Guide (RG) 5.89, "Fitness-For-Duty Programs for Commercial Power Reactor and
Category I Special Nuclear Material Licensees," Revision 0, November 2022
(ML20143A034)

The annual summary reports published by the NRC on 10 CFR 26.717 FFD program
performance data are available at the NRC Web Site: [https://www.nrc.gov/reactors/
operating/ops-experience/fitness-for-duty-programs/performance-reports.html](https://www.nrc.gov/reactors/operating/ops-experience/fitness-for-duty-programs/performance-reports.html).

END

Attachments:

- Attachment 1: Urine Collection Questionnaire
- Attachment 2: Breath Collection Questionnaire
- Attachment 3: Medical Review Officer Questionnaire
- Attachment 4: Substance Abuse Expert Questionnaire
- Attachment 5: Blind Performance Test Sample Submissions
- Attachment 6: Revision History for IP 81000.08

Attachment 1: Urine Collection Questionnaire

10 CFR Part 26
URINE COLLECTION QUESTIONNAIRE

Licensee	
Contact Person	
Inspection Date	
Inspector	

This Urine Collection questionnaire may be used by the U.S. Nuclear Regulatory Commission (NRC) inspector when evaluating the urine collection procedures at a licensee's or other entity's specimen collection site. Each question is accompanied by potential answers and the relevant requirement(s) in 10 CFR Part 26, Subpart E.

INSTRUCTIONS:

The Urine Collector questionnaire is divided into three sections.

- Section A (Observing the Collector – Mock Collection) is to be completed by the inspector during a mock specimen collection. The inspector is to direct the collector to treat the inspector as an employee who has just arrived for a test. At the point in the collection when the collector requests the inspector to provide a specimen, the inspector will direct the collector to fill the specimen collection cup with water and assume the “specimen” is acceptable (in appearance and temperature). The full specimen collection process must be observed by the inspector. The inspector must also enter the private collection area to assess security measures.
- Section B (Knowledge of Collection Procedures) is to be completed after the mock collection. The inspector will ask the collector questions about the procedures to be followed during typical and atypical collections.
- Section C (Observing the Facility) consists of questions to be completed by the inspector based on observations made regarding the specimen collection facility.

Table of Contents

Section	Question Numbers
A. Observing the Collector (Mock Collection)	A1 – A28
B. Knowledge of Collection Procedures	B1 – B29
C. Observing the Facility	C 1 – C8

A. Urine Collection, Observing the Collector (Mock Collection)			
Num.	Question	Answer	NRC Regulation(s)
A1	Did the collector positively identify the donor [or the inspector] by photo identification before beginning the collection process?	<ul style="list-style-type: none">• Yes.• No.• Other:	§ 26.89(b)(1) states: “Acceptable identification includes photo-identification issued by a licensee or other entity who is subject to his part, or by the Federal, State, or local government. Licensees and other entities may not accept faxes or photocopies of identification.”
A2	Did the collector require the donor to sign a consent form?	<ul style="list-style-type: none">• Yes.• No.• Other:	§ 26.89(b)(4) states: “The collector shall ask the donor to sign a consent-to-testing form.”

A. Urine Collection, Observing the Collector (Mock Collection)			
Num.	Question	Answer	NRC Regulation(s)
A3	Did the collector explain the collection process to the donor and show the donor the form(s) to be used?	<ul style="list-style-type: none"> • Yes. • No. • Other: 	§ 26.89(b)(4) states: “The collector shall explain the testing procedure to the donor, show the donor the form(s) to be used.”
A4	Did the collector require the donor to list all prescription and over-the-counter medications recently used?	<ul style="list-style-type: none"> • No. • Yes. • Other: 	§ 26.89(b)(4) states: “The donor may not be required to list prescription medications or over-the-counter preparations that he or she has recently used.”
A5	Did the collector direct the donor to remove any outer garments (e.g., jacket, coat, or hat) and to leave personal belongings such as purses and briefcases with the outer garments?	<ul style="list-style-type: none"> • Yes. • No. • Other: 	§ 26.105(a) states: “The collector shall... ask the donor to remove any unnecessary outer garments, such as a coat or jacket, which might conceal items or substances that the donor could use to tamper with or adulterate his or her specimen. The collector shall ensure that all personal belongings such as a purse or briefcase remain with the outer garments outside of the room or stall in which the specimen is collected.”
A6	Did the collector direct the donor to empty his or her pockets and display the items in them to ensure that there are no items present that could be used to adulterate the specimen?	<ul style="list-style-type: none"> • Yes. • No. • Other: 	§ 26.105(b) states: “The collector shall also ask the donor to empty his or her pockets and display the items in them to enable the collector to identify items that the donor could use to adulterate or substitute his or her urine specimen. The donor shall permit the collector to make this observation.”
A7	If the collector identifies nothing that the donor could use to adulterate or substitute the specimen, is the donor allowed to place the items back into his or her pockets?	<ul style="list-style-type: none"> • Yes. • No. • Other: 	§ 26.105(b) states: “If the collector identifies nothing that the donor could use to adulterate or substitute the specimen, the donor may place the items back into his or her pockets.”

A. Urine Collection, Observing the Collector (Mock Collection)			
Num.	Question	Answer	NRC Regulation(s)
A8	Did the collector allow the donor to keep his/her wallet?	<ul style="list-style-type: none"> • Yes. • No. • Other: 	§ 26.105(a) states: “The donor may retain his or her wallet.”
A9	After the donor has removed any outer clothing and displayed the contents of his or her pockets, did the collector instruct the donor to wash and dry his/her hands?	<ul style="list-style-type: none"> • Yes. • No. • Other: 	§ 26.105(c) states: “The collector shall instruct the donor to wash and dry his or her hands before providing a specimen.”
A10	Are collection containers sealed, and did the donor or collector remove the sealed wrapper in the presence of both?	<ul style="list-style-type: none"> • Yes. • No. • Other: 	§ 26.105(e) states: “The collector may select, or allow the donor to select, an individually wrapped or sealed urine specimen collection container from the collection kit materials or an oral fluid specimen collection device. Either the collector or the donor, with both present, shall unwrap or break the seal of the urine specimen collection container.”
A11	Did the collector assure that the donor takes nothing from the collection kit into the room used for urination except the collection container?	<ul style="list-style-type: none"> • Yes. • No. • Other: 	§ 26.105(e) states: “With the exception of the collection container, the donor may not take anything from the collection kit into the room or stall used for urination.”

A. Urine Collection, Observing the Collector (Mock Collection)			
Num.	Question	Answer	NRC Regulation(s)
A12	Was the donor then required to remain in the presence of the collector (with no access to water, soap, or other adulterating agents) until entering the privacy enclosure to provide the specimen?	<ul style="list-style-type: none"> • Yes. • No. • Other: 	<p>§ 26.105(d) states:</p> <p>“After washing his or her hands, the donor shall remain in the presence of the collector and may not have access to any water fountain, faucet, soap dispenser, cleaning agent, or other materials that he or she could use to adulterate the specimen.”</p>
A13	Did the collector ensure that the privacy enclosure was secure for use: (1) All sources of clear water were eliminated and or secured, (2) Possible specimen contaminants were removed (e.g., aerosol cans; cleaning agents, etc.); and (3) All places where paraphernalia could be hidden were secured or removed (e.g., garbage cans, cabinets)?	<ul style="list-style-type: none"> • Yes. • No, the privacy enclosure was not properly secured. • Other: 	<p>§ 26.87(e) states:</p> <p>“The following steps must be taken to deter the dilution and adulteration of urine specimens at the collection site:</p> <p>(1) Agents that color any source of standing water in the stall or room in which the donor will provide a specimen, including, but not limited to, the toilet bowl or tank, must be placed in the source of standing water, so that the reservoirs of water are neither yellow nor colorless;</p> <p>(2) There must be no other source of water (e.g., no shower or sink) in the enclosure where urination occurs, or the source of water must be rendered unusable; and</p> <p>(3) Chemicals or products that could be used to contaminate or otherwise alter the specimen must be removed from the collection site or secured. The collector shall inspect the enclosure in which urination will occur before each collection to ensure that no materials are available that could be used to subvert the testing process.”</p>

A. Urine Collection, Observing the Collector (Mock Collection)			
Num.	Question	Answer	NRC Regulation(s)
A14	Did the water in the toilet (and any other source of standing water, including the toilet tank if it is not secured) contain an agent that ensures the water is neither yellow nor colorless?	<ul style="list-style-type: none"> • Yes. • No. • Other: 	<p>§ 26.87(e) states:</p> <p>“The following steps must be taken to deter the dilution and adulteration of urine specimens at the collection site:</p> <p>(1) Agents that color any source of standing water in the stall or room in which the donor will provide a specimen, including, but not limited to, the toilet bowl or tank, must be placed in the source of standing water, so that the reservoirs of water are neither yellow nor colorless.”</p>
A15	After the donor provided the urine specimen to the collector, did the collector inspect the toilet bowl and collection area and then flush the toilet?	<ul style="list-style-type: none"> • Yes. • No. • Other: 	<p>§ 26.107(c) states:</p> <p>“After the donor has provided the urine specimen and submitted it to the collector, the donor shall be permitted to wash his or her hands. The collector shall inspect the toilet bowl and room or stall in which the donor voided to identify any evidence of a subversion attempt, and then flush the toilet.”</p>

A. Urine Collection, Observing the Collector (Mock Collection)			
Num.	Question	Answer	NRC Regulation(s)
A16	Once the donor provided the urine specimen to the collector, did the collector verify that the minimum quantity of urine was provided (at least 30 mL for a single collection; or at least 45 mL for a split specimen)?	<ul style="list-style-type: none"> • Yes. • No. • Other: 	<p>§ 26.109(a) states:</p> <p>“Licensees and other entities who are subject to this subpart shall establish a predetermined quantity of urine that donors are requested to provide when submitting a specimen. At a minimum, the predetermined quantity must include 30 milliliters (mL) to ensure that a sufficient quantity of urine is available for initial and confirmatory validity and drug tests at an HHS-certified laboratory, and for retesting of an aliquot of the specimen if requested by the donor under § 26.165(b). The licensee’s or other entity’s predetermined quantity may include more than 30 mL, if the testing program follows split specimen procedures, tests for additional drugs, or performs initial testing at a licensee testing facility. Where collected specimens are to be split under the provisions of this subpart, the predetermined quantity must include an additional 15 mL.”</p>
A17	Did the collector, within 4 minutes of receiving the specimen, measure the specimen temperature (using the temperature strip attached to the collection container <u>or</u> by another temperature measuring device that did not contaminate the specimen)?	<ul style="list-style-type: none"> • Yes. • No. • Other: 	<p>§ 26.111(a) states:</p> <p>“Immediately after the donor provides the urine specimen to the collector, including specimens of less than 30 mL but equal to or greater than 15 mL, the collector shall measure the temperature of the specimen. The temperature-measuring device used must accurately reflect the temperature of the specimen and not contaminate the specimen. The time from urination to temperature measurement may not exceed 4 minutes. If the temperature of a urine specimen is outside the range of 90°F to 100°F (32°C to 38°C), that is a reason to believe the donor may have altered (e.g., adulterated or diluted) or substituted the specimen.”</p>

A. Urine Collection, Observing the Collector (Mock Collection)			
Num.	Question	Answer	NRC Regulation(s)
A18	Did the collector determine if the color or clarity of the urine specimen was unusual?	<ul style="list-style-type: none"> • Yes. • No. • Other: 	<p>§ 26.111(b) states:</p> <p>“Immediately after the donor provides a urine specimen, including specimens of less than 30 mL but equal to or greater than 15 mL, the collector shall also inspect the specimen to determine its color and clarity and look for any signs of contaminants or adulteration. The collector shall note any unusual findings on the Federal CCF or through another documentation method consistent with the collection procedures of the licensee or other entity.”</p>
A19	<p><u>For split specimen collections.</u></p> <p>What quantity of urine was poured into Bottle A and Bottle B by the collector?</p>	<ul style="list-style-type: none"> • At least 30 mL into Bottle A, and at least 15 mL into Bottle B. • Less than the minimum required amount(s). • Other: 	<p>§ 26.113(b)(2) states:</p> <p>“The collector, in the presence of the donor and after determining specimen temperature as described in § 26.111(a), shall split the urine specimen. The collector shall pour 30 mL of urine into Bottle A and a minimum of 15 mL of urine into Bottle B. If the quantity of urine available for Bottle B is less than 15 mL, the collector shall pour the remaining urine into Bottle B and forward the specimens in Bottles A and B to the HHS-certified laboratory for drug and validity testing.”</p>
A20	Did the collector securely place tamper-evident seals on each container?	<ul style="list-style-type: none"> • Yes. • No. • Other: 	<p>§ 26.117(c) states:</p> <p>“The collector shall place an identification label securely on each container. The label must contain the date, the donor’s specimen number, and any other identifying information provided or required by the FFD program. The collector shall also apply a tamper-evident seal on each container if it is separate from the label. The specimen bottle must be securely sealed to prevent undetected tampering.”</p>

A. Urine Collection, Observing the Collector (Mock Collection)			
Num.	Question	Answer	NRC Regulation(s)
A21	Did the collector then apply an identification label with the date, the donor's specimen number, and any other identifying information provided or required by the FFD program over each specimen container?	<ul style="list-style-type: none"> • Yes. • No, the donor wrote some or all of the information on the labels before the collector applied the label(s) to the container(s). • No, all information was not included on the labels. • Other: 	<p>§ 26.117(c) states:</p> <p>"The collector shall place an identification label securely on each container. The label must contain the date, the donor's specimen number, and any other identifying information provided or required by the FFD program. The collector shall also apply a tamper-evident seal on each container if it is separate from the label. The specimen bottle must be securely sealed to prevent undetected tampering."</p>
A22	Did the collector instruct the donor to initial each specimen container label <u>only after</u> the seal(s) were affixed to the bottle(s) and label(s) were dated by the collector?	<ul style="list-style-type: none"> • Yes. • No. • Other: 	<p>§ 26.117(d) states:</p> <p>"The donor shall initial the identification label(s) on the specimen bottle(s) for the purpose of certifying that the specimen was collected from him or her."</p>
A23	Did the collector keep the donor's collection container within his/her view from the point when the urine specimen was received from the donor to the time the specimen container was sealed?	<ul style="list-style-type: none"> • Yes. • No. • Other: 	<p>§ 26.117(a) states:</p> <p>"Once the collector is presented with the specimen from the donor, both the donor and the collector shall keep the donor's specimen(s) in view at all times before the specimen(s) are sealed and labeled. If any specimen or aliquot is transferred to another container, the collector shall ask the donor to observe the transfer and sealing of the container with a tamper-evident seal."</p>

A. Urine Collection, Observing the Collector (Mock Collection)			
Num.	Question	Answer	NRC Regulation(s)
A24	After the specimen container labels are initialed by the donor, did the collector direct the donor to read and sign the statement on the Federal custody and control form (Federal CCF) certifying that the specimen(s) identified as having been collected from the donor is, in fact, the specimen(s) that he or she provided?	<ul style="list-style-type: none"> • Yes. • No. • Other: 	<p>§ 26.117(d) states:</p> <p>“The donor shall initial the identification label(s) on the specimen bottle(s) for the purpose of certifying that the specimen was collected from him or her. The collector shall also ask the donor to read and sign a statement on the Federal CCF certifying that the specimen(s) identified as having been collected from the donor is, in fact, the specimen(s) that he or she provided.”</p>
A25	After the donor signed the certification statement, did the collector complete the Federal CCF and certify proper completion of the collection?	<ul style="list-style-type: none"> • Yes. • No. • Other: 	<p>§ 26.117(e) states:</p> <p>“The collector shall complete the Federal CCF(s) and shall certify proper completion of the collection.”</p>
A26	After completing the Federal CCF, did the collector package the sealed specimen container(s) with the Federal CCF?	<ul style="list-style-type: none"> • Yes. • No. • Other: 	<p>§ 26.117(i) states:</p> <p>“Collection site personnel shall ensure that a Federal CCF is packaged with its associated specimen bottle.”</p>

A. Urine Collection, Observing the Collector (Mock Collection)			
Num.	Question	Answer	NRC Regulation(s)
A27	<p><u>Only applies if using a licensee testing facility.</u></p> <p>If the collection site and licensee testing facility are not co-located, did the collector place the sealed and labeled specimen bottles with the associated Federal CCF in a tamper-evident container, designed to minimize the possibility of damage to the specimen during shipment?</p>	<ul style="list-style-type: none"> • Yes. • No. The shipping container was not acceptable. • Other: 	<p>§ 26.117(i) states:</p> <p>“Unless a collection site and a licensee testing facility are co-located, the sealed and labeled specimen bottles, with their associated Federal CCFs that are being transferred from the collection site to the drug-testing laboratory must be placed in a second, tamper-evident shipping container. The second container must be designed to minimize the possibility of damage to the specimen during shipment (e.g., specimen boxes, shipping bags, padded mailers, or bulk insulated shipping containers with that capability), so that the contents of the shipping containers are no longer accessible without breaking a tamper-evident seal.”</p>

A. Urine Collection, Observing the Collector (Mock Collection)			
Num.	Question	Answer	NRC Regulation(s)
A28	Did the collector have only one donor under his/her supervision at one time until the collection process was completed (i.e., specimen was collected, the urine specimen container was sealed and initialed, the Federal CCF was completed, and the donor departed the collection site)?	<ul style="list-style-type: none"> • Yes. • No, the donor was unable to provide a specimen of sufficient quantity on the initial attempt, and a hydration monitor was used during the hydration process. • Other: 	<p>§ 26.89(d) states: “In order to promote the security of specimens, avoid distraction of the collector, and ensure against any confusion in the identification of specimens, a collector shall conduct only one collection procedure at any given time, except as described in § 26.109(b)(1). For the collection of specimen(s) for drug testing, the collection procedure is complete when the specimen container has been sealed with a tamper-evident seal, the seal has been dated and initialed, and the Federal CCF has been completed or when a refusal to test has been determined.”</p> <p>§ 26.109(b)(1) states: “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 on the Federal CCF; and (iii) May perform other collections while the donor is in the hydration process.”</p> <p>Note: Regulatory Guide 5.89 includes guidance in section C.1., “Monitoring a donor during the hydration process.”</p>
[This concludes the mock collection section of the questionnaire]			

B. Urine Collection, Knowledge of Collection Procedures			
Num.	Question	Answer	NRC Regulation(s)
B1	What actions must you take if a donor does not arrive for a scheduled test?	<ul style="list-style-type: none"> • I notify FFD program management. • No action is taken on my part, it's the responsibility of someone else. • I don't know. • Other: 	<p>§ 26.89(a) states:</p> <p>"When an individual has been notified of a requirement for testing and does not appear at the collection site within the time period specified by FFD program procedures, the collector shall inform FFD program management that the individual has not reported for testing. FFD program management shall ensure that the necessary steps are taken to determine whether the individual's undue tardiness or failure to appear for testing constitutes a violation of the licensee's or other entity's FFD policy. If FFD program management determines that the undue tardiness or failure to report for testing represents an attempt to subvert the testing process, the licensee or other entity shall impose on the individual the sanctions in § 26.75(b). If FFD program management determines that the undue tardiness or failure to report does not represent a subversion attempt, the licensee or other entity may not impose sanctions but shall ensure that the individual is tested at the earliest reasonable and practical opportunity after locating the individual."</p>

B. Urine Collection, Knowledge of Collection Procedures			
Num.	Question	Answer	NRC Regulation(s)
B2	What steps are taken if a donor arrives without a photo ID?	<ul style="list-style-type: none"> • <u>Other than for a pre-access test</u>, (1) proceed with the collection; and then (2) contact FFD program management, and do not allow the donor to leave the collection site until his or her identity has been established. • Continue with the testing process. • We take a digital photograph of the donor and email it to the FFD program manager for confirmation. • I don't know. • Other: 	<p>§ 26.89(b)(2) states: "If the donor cannot produce acceptable identification before any testing that is required under this part other than pre-access testing, the collector shall proceed with the test and immediately inform FFD program management that the donor did not present acceptable identification. When so informed, FFD program management shall contact the individual's supervisor to verify in-person the individual's identity, or, if the supervisor is not available, take other steps to establish the individual's identity and determine whether the lack of identification was an attempt to subvert the testing process. The donor may not leave the collection site except under supervision until his or her identity has been established."</p>
B3	For a donor without a photo ID, can another licensee employee verify the identity of the donor?	<ul style="list-style-type: none"> • Yes, but only the supervisor of the donor. • Yes, the collection site will accept verification of identity from any other employee (i.e., a non-supervisor) of the licensee. • I don't know. • Other: 	

B. Urine Collection, Knowledge of Collection Procedures			
Num.	Question	Answer	NRC Regulation(s)
B4	During the collection process when a donor is directed to display the items in his or her pockets – what steps are taken if you identify a material that could be used to tamper with a specimen?	<ul style="list-style-type: none"> • If it appears to have been brought with the intent to subvert the test, contact the MRO or FFD program manager. If not, secure the item and continue with the normal collection procedure. • Notify FFD program management. • Secure the items until after the collection. • I don't know. • Other: 	<p>§ 26.105(b) states:</p> <p>“The collector shall also ask the donor to empty his or her pockets and display the items in them to enable the collector to identify items that the donor could use to adulterate or substitute his or her urine specimen. The donor shall permit the collector to make this observation. If the donor refuses to show the collector the items in his or her pockets, this is considered a refusal to test. If an item is found that appears to have been brought to the collection site with the intent to adulterate or substitute the specimen, the collector shall contact the MRO or FFD program manager to determine whether a directly observed collection is required. If the item appears to have been inadvertently brought to the collection site, the collector shall secure the item and continue with the normal collection procedure. If the collector identifies nothing that the donor could use to adulterate or substitute the specimen, the donor may place the items back into his or her pockets.”</p>

B. Urine Collection, Knowledge of Collection Procedures			
Num.	Question	Answer	NRC Regulation(s)
B5	If a donor refuses to cooperate with the collection process, what do you do?	<ul style="list-style-type: none"> • Contact FFD program management for direction. • The collector described all five steps if the donor refuses to cooperate <u>AND</u> the FFD program management determines the donor refused the test: <ol style="list-style-type: none"> (1) Inform the donor a refusal to test has been determined; (2) Terminate the collection process; (3) Describe the donor's actions on the Federal CCF (OR through another documentation method consistent with collection procedures); (4) Discard any specimen(s) provided unless the specimen is for a post-event test; and • (5) Immediately inform the FFD program manager. • I don't know. • Other: 	<p>§ 26.89(c) states: "If the donor refuses to cooperate in the collection procedures, the collector shall inform FFD program management to obtain guidance on the actions to be taken."</p> <p>§ 26.107(d) states: "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 or through another documentation method consistent with the collection procedures of the licensee or other entity; (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."</p>

B. Urine Collection, Knowledge of Collection Procedures			
Num.	Question	Answer	NRC Regulation(s)
B6	How is the collection site secured to prevent a donor from tampering with or adulterating a specimen?	<ul style="list-style-type: none"> • Secure water sources and other potential adulterants, add coloring agent to the toilet water and other standing water sources. • There is nothing special that needs to be done. • I don't know. • Other: 	<p>§ 26.87(e) states: "The following steps must be taken to deter the dilution and adulteration of urine specimens at the collection site: (1) Agents that color any source of standing water in the stall or room in which the donor will provide a specimen, including, but not limited to, the toilet bowl or tank, must be placed in the source of standing water, so that the reservoirs of water are neither yellow nor colorless; (2) There must be no other source of water (e.g., no shower or sink) in the enclosure where urination occurs, or the source of water must be rendered unusable; and (3) Chemicals or products that could be used to contaminate or otherwise alter the specimen must be removed from the collection site or secured. The collector shall inspect the enclosure in which urination will occur before each collection to ensure that no materials are available that could be used to subvert the testing process."</p>

B. Urine Collection, Knowledge of Collection Procedures			
Num.	Question	Answer	NRC Regulation(s)
B7	If donor conduct indicates an attempt to subvert the testing process, what steps do you take?	<ul style="list-style-type: none"> Document a description of the observed conduct on the Federal CCF (<u>OR</u> through another documentation method consistent with collection procedures) <u>AND</u> contact FFD program management for direction on whether a directly observed collection is required. Conduct a directly observed collection without contacting FFD management. I don't know. Other: 	<p>§ 26.107(b)(1) states:</p> <p>"The collector shall pay careful attention to the donor during the entire collection process, except as provided in § 26.109(b)(1), to observe any conduct that indicates an attempt to subvert the testing process (e.g., tampering with a specimen; having a substitute urine specimen in plain view; attempting to bring an adulterant, urine substitute, heating element, and/or temperature measurement device into the room, stall, or private area used for urination). If any such conduct is detected, the collector shall document a description of the conduct on the Federal CCF or through another documentation method consistent with the collection procedures of the licensee or other entity, and contact FFD program management to determine whether a directly observed collection is required, as described in § 26.115."</p>
B8	If a donor provides a specimen that appears adulterated (e.g., altered color, odor of bleach), what do you do with the specimen?	<ul style="list-style-type: none"> Send the specimen to the HHS-certified laboratory for testing. Contact FFD program management for direction. Discard the specimen. I don't know. Other: 	<p>§ 26.111(d) states:</p> <p>"Any specimen of 15 mL or more that the collector suspects has been diluted, substituted, or adulterated, and any specimen of 15 mL or more that has been collected under direct observation under paragraph (c) of this section, must be sent directly to the HHS-certified laboratory for initial and, if required, confirmatory testing, and may not be subject to initial testing at a licensee testing facility."</p>

B. Urine Collection, Knowledge of Collection Procedures			
Num.	Question	Answer	NRC Regulation(s)
B9	If the temperature of a urine specimen is outside the acceptable range, what do you do with the specimen?	<ul style="list-style-type: none"> • Send the specimen to the HHS-certified laboratory for testing. • Contact FFD program management for direction. • Discard the specimen. • Continue with the collection. • I don't know. • Other: 	<p>§ 26.111(a) states: "Immediately after the donor provides the urine specimen to the collector, including specimens of less than 30 mL but equal to or greater than 15 mL, the collector shall measure the temperature of the specimen. The temperature-measuring device used must accurately reflect the temperature of the specimen and not contaminate the specimen. The time from urination to temperature measurement may not exceed 4 minutes. If the temperature of a urine specimen is outside the range of 90 F to 100 F (32 C to 38 C), that is a reason to believe the donor may have altered (e.g., adulterated or diluted) or substituted the specimen."</p> <p>§ 26.111(d) states: "Any specimen of 15 mL or more that the collector suspects has been diluted, substituted, or adulterated, and any specimen of 15 mL or more that has been collected under direct observation under paragraph (c) of this section, must be sent directly to the HHS-certified laboratory for initial and, if required, confirmatory testing, and may not be subject to initial testing at a licensee testing facility."</p>

B. Urine Collection, Knowledge of Collection Procedures			
Num.	Question	Answer	NRC Regulation(s)
B10	If the color or clarity of a urine specimen is unusual, what do you do?	<ul style="list-style-type: none"> • Note the observations on the remarks line of the Federal CCF(OR through another documentation method consistent with collection procedures) <u>and</u> send the specimen to the HHS-certified laboratory for testing. • Contact FFD program management for direction. • Discard the specimen. • Continue with the collection. • I don't know. • Other: 	<p>§ 26.111(b) states: "Immediately after the donor provides a urine specimen, including specimens of less than 30 mL but equal to or greater than 15 mL, the collector shall also inspect the specimen to determine its color and clarity and look for any signs of contaminants or adulteration. The collector shall note any unusual findings on the Federal CCF or through another documentation method consistent with the collection procedures of the licensee or other entity."</p> <p>§ 26.111(d) states: "Any specimen of 15 mL or more that the collector suspects have been diluted, substituted, or adulterated, and any specimen of 15 mL or more that has been collected under direct observation under paragraph (c) of this section, must be sent directly to the HHS-certified laboratory for initial and, if required, confirmatory testing, and may not be subject to initial testing at a licensee testing facility."</p>

B. Urine Collection, Knowledge of Collection Procedures			
Num.	Question	Answer	NRC Regulation(s)
B11	If the individual's behavior clearly indicates an attempt to dilute, substitute, or adulterate the specimen, is a direct observation collection required?	<ul style="list-style-type: none"> • Yes, but only after receiving direction from FFD management. • No, if sufficient information on a subversion attempt is obtained (e.g., subversion paraphernalia), the FFD program manager could stop the collection process. • I don't know. • Other: 	<p>§ 26.111(c) states: "If there is reason to believe that the donor may have attempted to dilute, substitute, or adulterate the specimen based on specimen temperature or other observations made during the collection, the collector shall contact the FFD program manager, who may consult with the MRO, to determine whether the donor has attempted to subvert the testing process."</p> <p>§ 26.115(a) states: "The following circumstances constitute the exclusive grounds for performing a directly observed collection: (3) The collector, or the hydration monitor if one is used as permitted in § 26.109(b)(1), observes conduct by the donor indicating an attempt to subvert the testing process."</p>
B12	Can a donor voluntarily submit a second specimen under direct observation if the collector suspects the first specimen was altered (e.g., unusual appearance, odor, etc.)?	<ul style="list-style-type: none"> • Yes. • No. • I don't know. • Other: 	<p>§ 26.111(c) states: "If there is reason to believe that the donor may have attempted to dilute, substitute, or adulterate the specimen based on specimen temperature or other observations made during the collection, the collector shall contact the FFD program manager, who may consult with the MRO, to determine whether the donor has attempted to subvert the testing process or whether other circumstances may explain the observations. The FFD program manager or MRO may require the donor to provide a second specimen as soon as possible under direct observation. In addition, the collector shall inform the donor that he or she may volunteer to submit a second specimen under direct observation to counter the reason to believe the donor may have altered (e.g., adulterated or diluted) or substituted the specimen."</p>

B. Urine Collection, Knowledge of Collection Procedures			
Num.	Question	Answer	NRC Regulation(s)
B13	What steps must be taken prior to initiating an observed collection?	<ul style="list-style-type: none"> • Receive approval from FFD program manager or MRO. • Proceed with the collection without any contact with the FFD program manager or MRO. • Contact FFD program management for direction. • I don't know. • Other: 	<p>§ 26.115(b) states: "Before collecting a urine specimen under direct observation, the collector shall obtain the agreement of the FFD program manager or MRO to obtain a urine specimen under direct observation. After obtaining agreement, the collector shall ensure that a specimen is collected under direct observation as soon as reasonably practicable."</p>
B14	When conducting a directly observed collection, is it sufficient for you to see the donor's back or side?	<ul style="list-style-type: none"> • No, the collector must watch the urine exit from the donor's body directly into the collection container. • Yes. • I don't know. <p>Other:</p>	<p>§ 26.115(f)(2) states: "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."</p>
B15	When conducting a directly observed collection, can the collector use a mirror to assist in observing the provision of a specimen?	<ul style="list-style-type: none"> • No. • Yes, we have the option if we cannot directly observe the provision of a urine specimen based on the configuration of the room, stall, or private area used for the collection. • I don't know. • Other: 	<p>§ 26.115(f)(2) states: "A reflective mirror may be used to assist in observing the provision of the specimen <u>only if the physical configuration of the room, stall, or private area used for urination is not sufficient to meet this direct observation requirement</u>; the use of a video camera to assist in the observation process is not permitted."</p> <p><u>Note:</u> Regulatory Guide 5.89 also includes guidance in section C.2, "Using mirrors during specimen collections under direct observation."</p>

B. Urine Collection, Knowledge of Collection Procedures			
Num.	Question	Answer	NRC Regulation(s)
B16	If the donor refuses to allow a required directly observed collection, what five steps must you complete?	<ul style="list-style-type: none"> The collector described all five steps: <ol style="list-style-type: none"> (1) Inform the donor a refusal to test has been determined; (2) Terminate the collection process; (3) Describe the donor's actions on the Federal CCF (<u>OR</u> through another documentation method consistent with collection procedures); (4) Discard any specimen(s) provided unless the specimen is for a post-event test; and (5) Immediately inform the FFD program manager. Contact FFD program management for direction. I don't know. <p>Other:</p>	<p>§ 26.115(g) states: "If a donor declines to allow a directly observed collection that is required or permitted under this section, the donor's refusal constitutes an act to subvert the testing process, and the collector shall follow the procedures in § 26.107(d)."</p> <p>§ 26.107(d) states: "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 or through another documentation method consistent with the collection procedures of the licensee or other entity; (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."</p>
B17	What should you do if you learn that a directly observed collection should have been performed, but was not?	<ul style="list-style-type: none"> Notify FFD program management. I don't know. Other: 	<p>§ 26.115(h) states: "If a collector learns that a directly observed collection should have been performed but was not, the collector shall inform the FFD program manager, or his or her designee. The FFD program manager or designee shall ensure that a directly observed collection is immediately performed."</p>

B. Urine Collection, Knowledge of Collection Procedures			
Num.	Question	Answer	NRC Regulation(s)
B18	If the donor is unable to provide a specimen of at least 30 milliliters (mL), what is done?	<ul style="list-style-type: none"> • The collector offers the donor up to 40 ounces of fluid over 3 hours or until a specimen is collected. • We typically use a hydration monitor to provide the donor with up to 40 ounces of fluid over a 3-hour time period. • Contact FFD program management. • I don't know. • Other: 	<p>§ 26.109(b)(1) states:</p> <p>"The collector shall encourage the donor to drink a reasonable amount of liquid (normally, 8 ounces of water every 30 minutes, but not to exceed a maximum of 40 ounces over 3 hours) until the donor provides a specimen of at least 30 mL. 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. 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 on the Federal CCF; and (iii) May perform other collections while the donor is in the hydration process."</p>

B. Urine Collection, Knowledge of Collection Procedures			
Num.	Question	Answer	NRC Regulation(s)
B19	How does the collector (or hydration monitor if one is used) measure the amount of fluid provided to the donor?	<ul style="list-style-type: none"> • We keep a log of the amount of water provided and the time provided. For example, we provide the donor with 8 oz. bottles of water. • We provide the donor with a cup and permit them to fill it at the water cooler, but we do not measure how much water is consumed. • We allow a donor to consume a beverage that they brought to the collection site, but do not measure the amount consumed. • Other: 	<p>§ 26.109(b)(1) states: “The collector shall encourage the donor to drink a reasonable amount of liquid (normally, 8 ounces of water every 30 minutes, but not to exceed a maximum of 40 ounces over 3 hours) until the donor provides a specimen of at least 30 mL. 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. If another collector or hydration monitor is used, the collector:</p> <ul style="list-style-type: none"> (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 on the Federal CCF; and (iii) May perform other collections while the donor is in the hydration process.” <p><u>Note</u>: Regulatory Guide 5.89 also includes guidance in section C.1.C, “Providing liquid for hydration.”</p>

B. Urine Collection, Knowledge of Collection Procedures			
Num.	Question	Answer	NRC Regulation(s)
B20	After providing a specimen of less than 30 mL, if the donor refuses to provide a new specimen, or leaves the collection site before the process is complete, what do you do?	<ul style="list-style-type: none"> The collector described the five steps (as applicable): <ol style="list-style-type: none"> (1) Inform the donor a refusal to test has been determined; (2) Terminate the collection process; (3) Describe the donor's action(s) on the Federal CCF (OR through another documentation method consistent with collection procedures); (4) Discard any specimen(s) provided unless the specimen is for a post-event test; and <ol style="list-style-type: none"> (5) Contact FFD program management. Contact FFD program management for direction. I don't know. Other: 	<p>§ 26.89(c) states: "If the donor refuses to cooperate in the collection procedures, the collector shall inform FFD program management to obtain guidance on the actions to be taken."</p> <p>§ 26.107(d) states: "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 or through another documentation method consistent with the collection procedures of the licensee or other entity; (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."</p>
B21	If the donor cannot provide a sufficient specimen within 3 hours of the first unsuccessful attempt, what do you do?	<ul style="list-style-type: none"> Terminate the collection process, document on the Federal CCF the situation and notify the FFD program manager or MRO. Contact FFD program management for direction. I don't know. Other: 	<p>§ 26.109(b)(3) states: "If the donor has not provided a specimen of at least 30 mL within 3 hours of the first unsuccessful attempt to provide a specimen of the predetermined quantity, the collector shall discontinue the collection and notify the FFD program manager or MRO to initiate the "shy bladder" procedures in § 26.119."</p>

B. Urine Collection, Knowledge of Collection Procedures			
Num.	Question	Answer	NRC Regulation(s)
B22	What do you do with a specimen that has not been shipped to the HHS-certified laboratory or the licensee testing facility within 24 hours of specimen collection?	<ul style="list-style-type: none"> • We place the specimen in the refrigerator until shipped, so the temperature does not rise above 6°C or 42.8°F. • We refrigerate all specimens until shipment to the laboratory. • I don't know. • Other: 	<p>§ 26.117(j) states: "Urine specimens that have not 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...."</p>
B23	If the initial specimen is out of temperature range, and a second specimen is collected under direct observation, which specimen(s) are sent to the lab?	<ul style="list-style-type: none"> • Both specimens. • Only the second, observed specimen. • Only the first, out of temperature range specimen. • Contact FFD program management for direction. • I don't know. • Other: 	<p>§ 26.111(d) states: "Any specimen of 15 mL or more that the collector suspects has been diluted, substituted, or adulterated, and any specimen of 15 mL or more that has been collected under direct observation under paragraph (c) of this section, must be sent directly to the HHS-certified laboratory for initial and, if required, confirmatory testing, and may not be subject to initial testing at a licensee testing facility."</p>
B24	If you believe that the donor has tampered with the initial specimen, and a second specimen is collected under direct observation, which specimens are sent to the lab?	<ul style="list-style-type: none"> • Both specimens. • Only the second specimen (i.e., the observed specimen). • Only the initial specimen (i.e., the tampered-with specimen). • Contact FFD program manager for direction. • I don't know. • Other: 	<p>§ 26.111(d) states: "Any specimen of 15 mL or more that the collector suspects has been diluted, substituted, or adulterated, and any specimen of 15 mL or more that has been collected under direct observation under paragraph (c) of this section, must be sent directly to the HHS-certified laboratory for initial and, if required, confirmatory testing, and may not be subject to initial testing at a licensee testing facility."</p>

B. Urine Collection, Knowledge of Collection Procedures			
Num.	Question	Answer	NRC Regulation(s)
B25	What do you do with a specimen of insufficient quantity (less than 30 mL)?	<ul style="list-style-type: none"> • Discard it, unless the specimen shows signs of tampering, adulteration, or the temperature or color was out of range. If so, contact FFD program management and send the sample to the HHS-certified laboratory. • Discard it. • Send it to the lab. • Contact FFD program management for direction. • I don't know. • Other: 	<p>§ 26.109(b)(4) states:</p> <p>"Neither the donor nor the collector may combine specimens. The collector shall discard specimens of less than 30 mL, except if there is reason to believe that the donor has diluted, adulterated, substituted, or otherwise tampered with the specimen, based on the collector's observations of the donor's behavior during the collection process or the specimen's characteristics, as specified in § 26.111. If the collector has a reason to believe that a specimen that is 15 mL or more, but less than 30 mL, has been diluted, adulterated, substituted, or altered, the collector shall prepare the suspect specimen for shipping to the HHS-certified laboratory and contact FFD program management to determine whether a directly observed collection is required, as described in § 26.115."</p>
B26	If a specimen has been collected but not yet packaged for transfer, and you momentarily have to leave your workstation, what do you do with the sealed specimen(s) and Federal CCF(s)?	<ul style="list-style-type: none"> • Take both the specimen(s) and Federal CCF(s) with me or secure them. • Leave the specimen(s) with another authorized collector. • I don't know. • Other: 	<p>§ 26.117(g) states:</p> <p>"If the involved collector momentarily leaves his or her workstation, the sealed specimens and Federal CCFs must be secured or taken with him or her."</p>

B. Urine Collection, Knowledge of Collection Procedures			
Num.	Question	Answer	NRC Regulation(s)
B27	<p>In the exceptional event that a non-dedicated facility (public restroom or hospital examining room) is used for a collection (e.g., post-event test):</p> <p>How do you secure the location used for testing?</p>	<ul style="list-style-type: none"> • Visually inspect the facility, add a coloring agent to the water in the toilet, assure that undetected access is prevented, and post limited access signs or assign an individual to ensure no unauthorized personnel are present during the collection process. • I don't know, I've never conducted a collection under these circumstances. • Other: 	<p>§ 26.87(f) states: "In the exceptional event that a designated collection site is inaccessible and there is an immediate requirement to collect a specimen for drug testing, including, but not limited to, an event investigation, then the licensee or other entity may use a public rest room, onsite rest room, or hospital examining room according to the following procedures:</p> <p>(1) The facility must be secured by visual inspection to ensure that no unauthorized persons are present, and that undetected access (e.g., through a rear door not in the view of the collector) is impossible. Security during the collection may be maintained by restricting access to collection materials and specimens. In the case of a public rest room, a sign must be posted or an individual assigned to ensure that no unauthorized personnel are present during the entire collection procedure to avoid embarrassment of the donor and distraction of the collector."</p>
B28	<p>In the exceptional event that a non-dedicated facility (public restroom or hospital examining room) is used for a collection (e.g., post-event test):</p> <p>Where do you (or a different collector of the same gender as the donor) go while the donor is in a multi-unit stall or single restroom?</p>	<ul style="list-style-type: none"> • Stand directly outside the stall (if multi-stall restroom) or outside the door to the room (if a single restroom). • Stand inside the stall or restroom. • I don't know, I've never conducted a collection under these circumstances. • Other: 	<p>§ 26.87(f)(3) states:</p> <p>"A collector of the same gender as the donor shall accompany the donor into the area that will be used for a urine specimen collection, but remain outside of the stall, if it is a multi-stalled rest room, or outside of the door to the room, if it is a single rest room, in which the donor will provide the specimen. If a collector of the same gender is not available, the collector shall select a same-gender person to accompany the donor. This person shall be instructed on the collection procedures specified in this subpart and his or her identity must be documented on the Federal CCF."</p>

B. Urine Collection, Knowledge of Collection Procedures			
Num.	Question	Answer	NRC Regulation(s)
B29	<p>In the exceptional event that a non-dedicated facility (public restroom or hospital examining room) is used for collections (e.g., post-event test):</p> <p>What do you do after the collection?</p>	<ul style="list-style-type: none"> • Inspect the toilet bowl and area and then flush the toilet. • Inspect the toilet bowl and area. • Flush the toilet. • I don't know, I've never conducted a collection under these circumstances. • Other: 	<p>§ 26.87(f)(4) states:</p> <p>"Once the collector has possession of the specimen, if the specimen is urine, the collector shall inspect the toilet bowl and area to ensure that there is no evidence of a subversion attempt and shall then flush the toilet, and for any specimen collected for drug testing, the collector shall instruct the donor to participate with the collector in completing the chain of custody procedures."</p>

C. Urine Collection, Observing the Facility			
Num.	Question	Answer	NRC Regulation(s)
C1	Was the urine collection site prepared for the inspection team, and did the vendor cooperate with the inspection team and facilitate the inspection process, including producing the required records?	<ul style="list-style-type: none"> • Yes. • No. Staff at the collection site were unable to produce all required records. • No. Staff at the collection site provided the requested records but did not participate in a mock collection. • Other: 	<p>§ 26.87(c) states:</p> <p>“Contracts for collection site services must permit representatives of the NRC, licensee, or other entity to conduct unannounced inspections and audits and to obtain all information and documentation that is reasonably relevant to the inspections and audits.”</p>
C2	Is the designated collection site securely maintained at all times?	<ul style="list-style-type: none"> • Yes. • No. • Other: 	<p>§ 26.87(d) states:</p> <p>“Licensees and other entities shall take the following measures to prevent unauthorized access to the collection site that could compromise the integrity of the collection process or the specimens:</p> <p>(2) A designated collection site must be secure. If a collection site is dedicated solely to specimen collection, it must be secure at all times. Methods of assuring security may include, but are not limited to, physical measures to control access, such as locked doors, alarms, or visual monitoring of the collection site when it is not occupied.”</p>
C3	Are only authorized personnel permitted in any area of the designated collection site where urine specimens are collected and stored?	<ul style="list-style-type: none"> • Yes. • No. • Other: 	<p>§ 26.87(d) states:</p> <p>“Licensees and other entities shall take the following measures to prevent unauthorized access to the collection site that could compromise the integrity of the collection process or the specimens. (1) Unauthorized personnel may not be permitted in any part of the designated collection site where specimens are collected or stored.”</p>

C. Urine Collection, Observing the Facility			
Num.	Question	Answer	NRC Regulation(s)
C4	Is security of the collection materials and completed specimens within the collection site maintained at all times?	<ul style="list-style-type: none"> • Yes. • No. • Other: 	<p>§ 26.87(d)(2) states:</p> <p>“A designated collection site must be secure. If a collection site is dedicated solely to specimen collection, it must be secure at all times. Methods of assuring security may include, but are not limited to, physical measures to control access, such as locked doors, alarms, or visual monitoring of the collection site when it is not occupied.”</p>
C5	Does the collection site provide for donor privacy?	<ul style="list-style-type: none"> • Yes. • No. • Other: 	<p>§ 26.87(b) states:</p> <p>“Visual privacy must be provided to the donor and collector when viewing alcohol test results and during the collection of an oral fluid specimen for drug testing. The donor must be provided with individual privacy while submitting a urine specimen, except if a directly observed urine specimen collection is required. Unauthorized personnel may not be present for the specimen collection.”</p>

C. Urine Collection, Observing the Facility			
Num.	Question	Answer	NRC Regulation(s)
C6	Does this collection site have procedures in place to ensure that a same-gender collector is available for observed collections?	<ul style="list-style-type: none"> • Yes, if a qualified same-gender collector is not available, the collector instructs a same-gender observer on the collection procedures. • Yes, we collect an oral fluid specimen for most observed collection conditions so the same-gender collector requirement is not an issue. • No, there are a few times when the collection site could not conduct an observed collection. • No, this collection site cannot collect a urine specimen under direct observation procedures. • Other: 	<p>§ 26.115(e) states: “The collector shall ensure that the observer is the same gender as the donor. A person of the opposite gender may not act as the observer under any conditions. The observer may be a different person from the collector and need not be a qualified collector. If the observer is not a qualified collector, the collector shall, in the presence of the donor, instruct the observer on the collection procedures in paragraph (f) of this section before proceeding with the directly observed collection.”</p> <p>§ 26.115(f) states: “The individual who observes the collection shall follow these procedures: (1) The observer shall instruct the donor to adjust his or her clothing to ensure that the area of the donor's body between the waist and knees is exposed; (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; (3) If the observer is not the collector, the observer may not touch or handle the collection container but shall maintain visual contact with the specimen until the donor hands the collection container to the collector; and</p>

C. Urine Collection, Observing the Facility			
Num.	Question	Answer	NRC Regulation(s)
C6 Cont'd			<p>(4) If the observer is not the collector, the collector shall record the observer's name on the Federal CCF."</p> <p>§ 26.83, "Specimens to be collected" states: "(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."</p>

C. Urine Collection, Observing the Facility			
Num.	Question	Answer	NRC Regulation(s)
C7	<p>Have each of the urine collectors received training in accordance with 10 CFR 26.85(a)?</p> <p>[Examine training records].</p>	<ul style="list-style-type: none"> • Adequate training was conducted, and records were produced. • Training was not conducted. • Training was conducted, but certificates were not found for all collectors. • Other: 	<p>§ 26.85(a) states:</p> <p><i>“Collector qualifications.</i> Each collector 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 the collection procedures for each specimen the individual is qualified to collect under this part. Each collector 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. At a minimum, qualification training must provide instruction on the following subjects:</p> <p>(1) All steps necessary to complete a collection correctly and the proper completion and transmission of the Federal CCF;</p> <p>(2) Methods to address “problem” collections, including, but not limited to:</p> <p>(i) Inability to provide a specimen (e.g., “shy bladder” for a urine specimen, “shy lung” for a breath specimen, dry mouth for an oral fluid specimen); and</p> <p>(ii) Attempts to tamper with a specimen;</p> <p>(3) Operation of the particular specimen collection or alcohol testing device(s) [e.g., alcohol screening device (ASD), EBT, oral fluid] to be used, consistent with the most recent version of the manufacturers’ instructions;</p> <p>(4) How to correct problems in collections; and</p> <p>(5) The collector’s responsibility for maintaining the integrity of the specimen collection process, carefully ensuring the modesty and privacy of the donor, and avoiding any conduct or remarks that might be construed as accusatorial or otherwise offensive or inappropriate, and the specimen transfer process, if applicable.”</p>

C. Urine Collection, Observing the Facility			
Num.	Question	Answer	NRC Regulation(s)
C8	Were the personnel files for the urine collectors complete?	<ul style="list-style-type: none"> • Yes. • No, some required information was missing. • Other: 	<p>§ 26.85(e) states:</p> <p><i>“Files.</i> Collection site personnel files must include each individual’s resume of training and experience; certification or license, if any; references; job descriptions; records of performance evaluations and advancement; incident reports, if any; results of tests to establish employee competency for the position he or she holds, including, but not limited to, certification that collectors are proficient in administering alcohol tests consistent with the most recent manufacturer’s instructions for the instruments and devices used; and appropriate data to support determinations of honesty and integrity conducted under § 26.31(b).”</p>
THAT WAS THE LAST QUESTION. THANK YOU FOR YOUR TIME AND INPUT.			

Attachment 2: Breath Collection Questionnaire

10 CFR Part 26
BREATH COLLECTION QUESTIONNAIRE

Licensee	
Contact Person	
Inspection Date	
Inspector	

This Breath Collection questionnaire may be used by the U.S. Nuclear Regulatory Commission (NRC) inspector when evaluating the breath alcohol testing procedures at a licensee's or other entity's specimen collection site. Each question is accompanied by potential answers and the relevant requirement(s) in 10 CFR Part 26, Subpart E.

INSTRUCTIONS:

The Breath Collection questionnaire is divided into four sections.

- Section A (Observing the Collector – Initial Breath Test (Mock Collection)) is to be completed by the inspector during a mock breath collection. The inspector is to direct the collector to treat the inspector as an employee who has arrived for both a urine and breath alcohol test. The inspector is to participate in the complete collection process for the initial alcohol test (including providing a breath specimen).
- Section B (Knowledge of Collection Procedures – Confirmatory Alcohol Testing and External Calibration Checks) is a question and answer segment of the inspection to evaluate the collector's knowledge on conducting confirmatory alcohol testing. In this section, the inspector will ask the collector questions. An evaluation of the evidential breath testing device (EBT) external calibration capabilities (i.e., a verification that the EBT is functioning correctly) also will be assessed.
- Section C (Knowledge of Collection Procedures – Non-Typical Specimen Collections) is a question and answer segment of the inspection to evaluate the collector's knowledge of how to address non-typical situations that might arise during a breath alcohol test.
- Section D (Observing the Facility) consists of questions to be completed by the inspector based on observations made regarding the specimen collection facility, a records review, and some questions that may require speaking to the collection site manager.

Table of Contents

Section	Question Numbers
A. Observing the Collector – Initial Breath Test (Mock Collection)	A1 – A14
B. Knowledge of Collection Procedures – Confirmatory Alcohol Testing and External Calibration Checks	B1 – B21
C. Knowledge of Collection Procedures – Non-Typical Specimen Collections	C1 – C7
D. Observing the Facility	D1 – D4

A. Breath Collection, Observing the Collector – Initial Breath Test (Mock Collection)			
Num.	Question	Answer	NRC Regulation(s)
A1	Did the collector positively identify the donor [or the inspector] by photo identification before beginning the collection process?	<ul style="list-style-type: none"> • Yes. • No. • Other: 	§ 26.89(b)(1) states: “Acceptable identification includes photo-identification issued by a licensee or other entity who is subject to this part, or by the Federal, State, or local government. Licensees and other entities may not accept faxes or photocopies of identification.”
A2	Did the collector require the donor to sign a consent form?	<ul style="list-style-type: none"> • Yes. • No. • Other: 	§ 26.89(b)(4) states: “The collector shall... ask the donor to sign a consent-to-testing form.”
A3	Did the collector explain the collection process to the donor and show the donor the form(s) to be used?	<ul style="list-style-type: none"> • Yes. • No. • Other: 	§ 26.89(b)(4) states: “The collector shall explain the testing procedure to the donor, show the donor the form(s) to be used...”
A4	Immediately before collecting a breath specimen, did the collector ask the donor if he or she ate, drank, belched, or put anything into their mouth?	<ul style="list-style-type: none"> • Yes. • No. • Other: 	§ 26.93(a) states: “Immediately before collecting a specimen for alcohol testing, the collector shall — (1) Ask the donor whether he or she, in the past 15 minutes, has had anything to eat or drink, belched, or put anything into his or her mouth (including, but not limited to, a cigarette, breath mint, or chewing gum), and instruct the donor that he or she should avoid these activities during the collection process.”

A. Breath Collection, Observing the Collector – Initial Breath Test (Mock Collection)			
Num.	Question	Answer	NRC Regulation(s)
A5	<p>Did the collector then instruct the donor that eating, drinking, belching, or putting anything into their mouth during the collection process should be avoided?</p> <p>and,</p> <p>Did the collector document on the custody and control form that these instructions were provided to the donor?</p>	<ul style="list-style-type: none"> • Yes. • Directions provided to the donor, but the collector did not document that the directions were provided to the donor. • Other: 	<p>§ 26.93(a) states:</p> <p>“Immediately before collecting a specimen for alcohol testing, the collector shall —</p> <p>(1) Ask the donor whether he or she, in the past 15 minutes, has had anything to eat or drink, belched, or put anything into his or her mouth (including, but not limited to, a cigarette, breath mint, or chewing gum), and instruct the donor that he or she should avoid these activities during the collection process;</p> <p>(2) Explain that it is to the donor’s benefit to avoid the activities listed in paragraph (a)(1) of this section during the collection process;</p> <p>(3) Document that the instructions were communicated to the donor.”</p>
A6	After the donor states that he or she has not engaged in any of the activities requiring a waiting period, when does the collector perform the test?	<ul style="list-style-type: none"> • As soon as possible. • Other: 	<p>§ 26.95(a) states:</p> <p>“The collector shall perform the initial breath test as soon as practical after the donor indicates that he or she has not engaged in the activities listed in § 26.93(a)(1) or after the 15-minute waiting period has elapsed, if required.”</p>
A7	Did the collector select, or allow the donor to select, an individually wrapped or sealed mouthpiece from the testing materials?	<ul style="list-style-type: none"> • Yes. • No. • Other: 	<p>§ 26.95(b)(1) states:</p> <p>“Select, or allow the donor to select, an individually wrapped or sealed mouthpiece from the testing materials.”</p>
A8	Did the collector then open the individually wrapped or sealed mouthpiece in view of the donor and insert it into the EBT?	<ul style="list-style-type: none"> • Yes. • No. • Other: 	<p>§ 26.95(b)(2) states:</p> <p>“Open the individually wrapped or sealed mouthpiece in view of the donor and insert it into the device as required by the manufacturer’s instructions.”</p>

A. Breath Collection, Observing the Collector – Initial Breath Test (Mock Collection)			
Num.	Question	Answer	NRC Regulation(s)
A9	Did the collector then instruct the donor to blow steadily and forcefully into the mouthpiece for at least 6 seconds or until the EBT indicated that an adequate amount of breath had been obtained?	<ul style="list-style-type: none"> • Yes. • The collector only instructed the donor to blow into the mouthpiece. • Other: 	<p>§ 26.95(b)(3) states: “Instruct the donor to blow steadily and forcefully into the mouthpiece for at least 6 seconds or until the device indicates that an adequate amount of breath has been obtained.”</p>
A10	Did the collector then show the donor the displayed or printed test result?	<ul style="list-style-type: none"> • Yes. • No. • Other: 	<p>§ 26.95(b)(4) states: “Show the donor the displayed or printed test result.”</p>
A11	Did the collection site provide for the donor’s visual privacy while the donor and the collector were viewing the test result?	<ul style="list-style-type: none"> • Yes. • No. • Other: 	<p>§ 26.87(b) states: “Visual privacy must be provided to the donor and collector when viewing alcohol test results.... Unauthorized personnel may not be present for the specimen collection.”</p>
A12	Did the collector then ensure that the test result record was associated with the donor and maintained securely?	<ul style="list-style-type: none"> • Yes. • No. • Other: 	<p>§ 26.95(b)(5) states: “Ensure that the test result record can be associated with the donor and is maintained secure.”</p> <p>[Guidance: Some EBTs print the result directly onto the custody and control form; other EBTs print the result onto a small “receipt” type piece of paper and the collector will affix it to the custody and control form with tamper-evident tape or by some other means.]</p> <p>[Guidance: If an ASD or screening EBT is used (i.e., doesn’t print a result), the collector will write the result onto the custody and control form.]</p>

A. Breath Collection, Observing the Collector – Initial Breath Test (Mock Collection)			
Num.	Question	Answer	NRC Regulation(s)
A13	Did the collector have only one donor under his or her supervision until the collection process was completed?	<ul style="list-style-type: none"> • Yes. • No, but a hydration monitor was assigned to the donor during the shy-bladder hydration process. • Other: 	<p>§ 26.89(d) states:</p> <p>“In order to promote the security of specimens, avoid distraction of the collector, and ensure against any confusion in the identification of specimens, a collector shall conduct only one collection procedure at any given time, except as described in § 26.109(b)(1).”</p>
A14	<p>Was the EBT used for the initial test listed on the NHTSA Conforming Product List (CPL) of alcohol screening devices?</p> <p>Record the EBT information here and verify:</p> <hr/> <hr/>	<ul style="list-style-type: none"> • Yes. • No. • Other: 	<p>§ 26.91(a) states:</p> <p>“Alcohol screening devices (ASDs), including devices that test specimens of oral fluids or breath must be approved by the National Highway Traffic Safety Administration (NHTSA) and listed in the most current version of NHTSA’s Conforming Products List (CPL) for such devices. An ASD that is listed in the NHTSA CPL may be used only for initial tests for alcohol, and may not be used for confirmatory tests.”</p> <p>§26.91(b) states:</p> <p>“Evidential breath testing devices listed in the NHTSA CPL for evidential devices that meet the requirements of paragraph (c) of this section must be used to conduct confirmatory alcohol tests, and may be used to conduct initial alcohol tests.”</p>

B. Breath Collection, Knowledge of the Collection Procedures – Confirmatory Alcohol Testing and External Calibration Checks			
Num.	Question	Answer	NRC Regulation(s)
B1	<p>Did the collection site have an EBT compliant with 26.91(b) for use for confirmatory alcohol testing?</p> <p>Record the EBT information here and verify:</p> <hr/> <hr/>	<ul style="list-style-type: none"> • Yes, all EBTs used at the collection site can be used for confirmatory testing. • Yes, we have a separate EBT that we use for confirmatory testing. • No, we must transport the donor to another location to conduct confirmatory testing. • No. • Other: 	<p>§ 26.91(b) states: “Evidential breath testing devices listed in the NHTSA CPL for evidential devices that meet the requirements of paragraph (c) of this section must be used to conduct confirmatory alcohol tests, and may be used to conduct initial alcohol tests. Note that, among the devices listed in the CPL for EBTs, only those devices listed without an asterisk (*) may be used for confirmatory alcohol testing under this subpart.”</p> <p>§ 26.91(c) states: “An EBT that is listed in the NHTSA CPL for evidential devices that has the following capabilities may be used for conducting initial alcohol tests and must be used for confirmatory alcohol tests under this subpart: (1) Provides a printed result of each breath test; (2) Assigns a unique number to each completed test, which the collector and donor can read before each test and which is printed on each copy of the test result; (3) Prints, on each copy of the test result, the manufacturer’s name for the device, its serial number, and the time of the test; (4) Distinguishes alcohol from acetone at the 0.02 alcohol concentration level; (5) Tests an air blank; and (6) Permits performance of an external calibration check.”</p>

B. Breath Collection, Knowledge of the Collection Procedures – Confirmatory Alcohol Testing and External Calibration Checks			
Num.	Question	Answer	NRC Regulation(s)
B2	What initial alcohol test result requires confirmatory testing to be conducted?	<ul style="list-style-type: none"> • 0.02 % blood alcohol concentration (BAC) or greater. • Any BAC greater than 0.00. • Other: 	<p>§ 26.99 states:</p> <p>(a) "If the initial test result is less than 0.02 percent BAC, the collector shall declare the test result as negative.</p> <p>(b) If the initial test result is 0.02 percent BAC or higher, the collector shall ensure that the time at which the test was concluded (i.e., the time at which the test result was known) is recorded and inform the donor that a confirmatory test for alcohol is required."</p>
B3	What do you do immediately after an initial positive result registers on the EBT?	<ul style="list-style-type: none"> • Record the time the initial test result was known and inform the donor that confirmatory testing will be conducted. • Other: 	<p>§ 26.99(b) states:</p> <p>"If the initial test result is 0.02 percent BAC or higher, the collector shall ensure that the time at which the test was concluded (i.e., the time at which the test result was known) is recorded and inform the donor that a confirmatory test for alcohol is required."</p>
B4	How soon after receiving an initial positive test result is confirmatory testing conducted on the donor?	<ul style="list-style-type: none"> • As soon as possible, but no more than 30 minutes after the conclusion of the initial test. • It doesn't matter. • I don't know. • Other: 	<p>§ 26.101(a) states:</p> <p>"The confirmatory test must begin as soon as possible, but no more than 30 minutes after the conclusion of the initial test."</p>
B5	Can the same EBT used for the initial breath test also be used for the confirmatory test?	<ul style="list-style-type: none"> • Yes, if the EBT is on the NHTSA CPL for confirmatory testing. • No. • I don't know. • Other: 	<p>§ 26.101(d) states:</p> <p>"If an EBT that meets the requirements of § 26.91(b) and (c) was used for the initial alcohol test, the same EBT may be used for confirmatory testing."</p>
B6	Before a confirmatory test is conducted, is an air blank required to be run on the EBT?	<ul style="list-style-type: none"> • Yes. • No. • Other: 	<p>§ 26.101(b)(1) states:</p> <p>"In the presence of the donor, conduct an air blank on the EBT before beginning the confirmatory test and show the result to the donor."</p>

B. Breath Collection, Knowledge of the Collection Procedures – Confirmatory Alcohol Testing and External Calibration Checks			
Num.	Question	Answer	NRC Regulation(s)
B7	Is it required that the collector show the air blank result to the donor?	<ul style="list-style-type: none"> • Yes. • No. • Other: 	§ 26.101(b)(1) states: “In the presence of the donor, conduct an air blank on the EBT before beginning the confirmatory test and show the result to the donor.”
B8	What reading must result from an air blank to proceed with a confirmatory test?	<ul style="list-style-type: none"> • 0.00 % BAC. • I don't know. • Other: 	§ 26.101(b)(2) states: “Verify that the reading is 0.00. If the reading is 0.00, the test may proceed.”
B9	If the EBT does not display a 0.00 result after two consecutive air blanks, what do you do?	<ul style="list-style-type: none"> • Take the EBT out of service and proceed with the collection using another EBT. • Cancel the test and notify the FFD program manager. • I don't know. • Other: 	§ 26.101(b)(3) states: “If the reading on the second air blank is 0.00, the test may proceed. If the reading is greater than 0.00, take the EBT out of service and proceed with the test using another EBT. If an EBT is taken out of service for this reason, the EBT may not be used for further testing until it is found to be within tolerance limits on an external check of calibration.”
B10	If the same EBT is used for confirmatory testing that was used for initial testing, is a new mouthpiece used?	<ul style="list-style-type: none"> • Yes, a new mouthpiece is used for each breath alcohol collection. • No. • Other: 	§ 26.101(b)(4) states: “Open an individually wrapped or sealed mouthpiece in view of the donor and insert it into the device as required by the manufacturer's instructions.”
B11	After the mouthpiece is inserted into the EBT, what do you do before collecting the specimen?	<ul style="list-style-type: none"> • Read the unique test number displayed on the EBT, and ensure the donor reads the same number. • Read the unique test number displayed on the EBT. • I don't know. • Other: 	§ 26.101(b)(5) states: “Read the unique test number displayed on the EBT, and ensure that the donor reads the same number.”

B. Breath Collection, Knowledge of the Collection Procedures – Confirmatory Alcohol Testing and External Calibration Checks			
Num.	Question	Answer	NRC Regulation(s)
B12	After the test result is displayed on the EBT, what is the next step?	<ul style="list-style-type: none"> • Show the donor the result, record the result, and document the time the result was known. • Mentioned one or two of the three required actions. • I don't know. • Other: 	§ 26.101(b)(7) states: "Show the donor the result displayed on or printed by the EBT, record the result, and document the time at which the confirmatory test result was known."
B13	What BAC level for a confirmatory alcohol test is considered a positive result?	<ul style="list-style-type: none"> • Any result that is 0.04% BAC or greater is a positive result. A positive test result also may be determined based on the hours that that donor has been in work status for results less than 0.04% BAC. The FFD program manager determines in these cases if an individual is positive. • Any result that is 0.04% BAC or greater. • The collector notifies the FFD program manager of all confirmatory alcohol test results. • I don't know. • Other: 	§ 26.103(a) states: "A confirmed positive test result for alcohol must be declared under any of the following conditions: (1) When the result of the confirmatory test for alcohol is 0.04 percent BAC or higher; (2) When the result of the confirmatory test for alcohol is 0.03 percent BAC or higher and the donor had been in a work status for at least 1 hour at the time the initial test was concluded (including any breaks for rest, lunch, dental/doctor appointments, etc.); or (3) When the result of the confirmatory test for alcohol is 0.02 percent BAC or higher and the donor had been in a work status for at least 2 hours at the time the initial test was concluded (including any breaks for rest, lunch, dental/doctor appointments, etc.)."

B. Breath Collection, Knowledge of the Collection Procedures – Confirmatory Alcohol Testing and External Calibration Checks			
Num.	Question	Answer	NRC Regulation(s)
B14	After a confirmed positive alcohol test result, does the collection site perform an external calibration check on the EBT in the presence of the donor?	<ul style="list-style-type: none"> • Yes. • No, we only conduct external calibration checks at the interval specified by the EBT manufacturer quality assurance plan (QAP). • Other: 	<p>§ 26.91(e)(4) states: “In order to ensure that confirmed positive alcohol test results are derived from an EBT that is calibrated, the licensee or other entity shall implement <u>one of the following procedures</u>:</p> <p>(i) If an EBT fails any external check of calibration, cancel every confirmed positive test result that was obtained using the EBT from any tests that were conducted after the EBT passed the last external calibration check; or</p> <p>(ii) After every confirmed positive test result obtained from using an EBT, conduct an external check of calibration of the EBT in the presence of the donor. If the EBT fails the external calibration check, cancel the donor’s test result and conduct another initial and confirmatory test on a different EBT as soon as practicable.”</p>
B15	<p><u>If the answer to question B14 is NO, skip this question.</u></p> <p>What action is taken if an EBT fails an external calibration check performed immediately after a confirmed positive test result?</p>	<ul style="list-style-type: none"> • Take the EBT out of service and, as soon as practicable, conduct another initial and confirmatory test on a different EBT. • Take the EBT out of service. • Contact FFD program management. • I don’t know. • Other: 	
B16	What do you do if an EBT fails an external calibration check?	<ul style="list-style-type: none"> • Take the EBT out of service, contact the FFD program manager to cancel every confirmed test result that was obtained using the EBT after the EBT passed its last external calibration check. • Take the EBT out of service. • Contact FFD program management. • I don’t know. • Other: 	<p>§ 26.91(e)(3) states: “If an EBT fails an external check of calibration, the licensee or other entity shall take the EBT out of service. The EBT may not be used again for alcohol testing under this subpart until it is repaired and passes an external calibration check.”</p>

B. Breath Collection, Knowledge of the Collection Procedures – Confirmatory Alcohol Testing and External Calibration Checks			
Num.	Question	Answer	NRC Regulation(s)
B17	Who is qualified to do calibration checks at the collection site?	Record the individual name(s), verify when evaluating the external calibration check log, and confirm when reviewing training records.	§ 26.91(e)(5) states: “Inspection, maintenance, and calibration of the EBT must be performed by its manufacturer or a maintenance representative or other individual who is certified either by the manufacturer or by a State health agency or other appropriate State agency.”
B18	Does the collection site use the most current QAP for the EBT? Verify that the collection site has a copy of the QAP. Record the EBT model and QAP version:	<ul style="list-style-type: none"> • Yes, and adequate records were produced. • Unable to verify because the collection site could not present a copy of the QAP for review. • No, the QAP is not the most current version submitted to NHTSA by the EBT manufacturer. • Other: 	§ 26.91(e)(1) states: “Licensees and other entities shall implement the most recent version of the manufacturer’s instructions for the use and care of the EBT consistently with the quality assurance plan submitted to NHTSA for the EBT, including performing external calibration checks no less frequently than at the intervals specified in the manufacturer’s instructions.”
B19	Is the external calibration device used for calibration listed on the NHTSA CPL for “Calibrating Units for Breath and Alcohol Tests?” [Make sure that the calibration device is not expired (gas cylinders list an expiration date).]	<ul style="list-style-type: none"> • Yes. • No. • Other: 	§ 26.91(e)(2) states: “When conducting external calibration checks, licensees and other entities shall use only calibration devices appearing on NHTSA’s CPL for ‘Calibrating Units for Breath Alcohol Tests.’”

B. Breath Collection, Knowledge of the Collection Procedures – Confirmatory Alcohol Testing and External Calibration Checks			
Num.	Question	Answer	NRC Regulation(s)
B20	<p>Is the collection site performing the calibration checks at the specified interval in the QAP?</p> <p>[Evaluate the records of the external calibration checks performed on the EBT used for the alcohol test.]</p>	<ul style="list-style-type: none"> • Yes, EBT calibration is conducted in accordance with the manufacturer QAP. • No, the calibration records demonstrate that the collection site has not calibrated the EBT in accordance with the manufacturer QAP. 	<p>§ 26.91(e)(1) states:</p> <p>“Licensees and other entities shall implement the most recent version of the manufacturer’s instructions for the use and care of the EBT consistently with the quality assurance plan submitted to NHTSA for the EBT, including performing external calibration checks no less frequently than at the intervals specified in the manufacturer’s instructions.”</p>
B21	<p>Are inspection, maintenance, and calibration of EBTs performed by manufacturer, maintenance representative, or other individual who is certified either by the manufacturer or by a State health agency or other appropriate State agency?</p> <p>[Verify with the collection site management and through a records review]</p>	<ul style="list-style-type: none"> • Yes. • No. • Other: 	<p>§ 26.91(e)(5) states:</p> <p>“Inspection, maintenance, and calibration of the EBT must be performed by its manufacturer or a maintenance representative or other individual who is certified either by the manufacturer or by a State health agency or other appropriate State agency.”</p>

C. Breath Collection, Knowledge of Collection Procedures – Non-Typical Collection Situations			
Num.	Question	Answer	NRC Regulation(s)
C1	What actions must you take if a donor does not arrive to take a scheduled test?	<ul style="list-style-type: none"> • I notify the FFD program management. • We are not notified of when a donor may arrive for a test. • Other: 	<p>§ 26.89(a) states:</p> <p>“When an individual has been notified of a requirement for testing and does not appear at the collection site within the time period specified by FFD program procedures, the collector shall inform FFD program management that the individual has not reported for testing. FFD program management shall ensure that the necessary steps are taken to determine whether the individual’s undue tardiness or failure to appear for testing constitutes a violation of the licensee’s or other entity’s FFD policy. If FFD program management determines that the undue tardiness or failure to report for testing represents an attempt to subvert the testing process, the licensee or other entity shall impose on the individual the sanctions in § 26.75(b). If FFD program management determines that the undue tardiness or failure to report does not represent a subversion attempt, the licensee or other entity may not impose sanctions but shall ensure that the individual is tested at the earliest reasonable and practical opportunity after locating the individual.”</p>

C. Breath Collection, Knowledge of Collection Procedures – Non-Typical Collection Situations			
Num.	Question	Answer	NRC Regulation(s)
C2	What steps are taken if a donor arrives without a photo ID?	<ul style="list-style-type: none"> • (1) Other than for a pre-access test I proceed with the collection; • (2) then I contact FFD program management and do not allow the donor to leave the collection site until his or her identity has been established. • Continue with the testing process. • We take a digital photograph of the donor and email it to the FFD program manager for confirmation. • I don't know. • Other: 	<p>§ 26.89(b)(2) states: “If the donor cannot produce acceptable identification before any testing that is required under this part other than pre-access testing, the collector shall proceed with the test and immediately inform FFD program management that the donor did not present acceptable identification. When so informed, FFD program management shall contact the individual's supervisor to verify in-person the individual's identity, or, if the supervisor is not available, take other steps to establish the individual's identity and determine whether the lack of identification was an attempt to subvert the testing process. The donor may not leave the collection site except under supervision until his or her identity has been established.”</p>
C3	For a donor without a photo ID, can another licensee employee verify the identity of the donor?	<ul style="list-style-type: none"> • Yes, but only the supervisor of the donor. • Yes, the collection site will accept verification of identity from any other employee (i.e., a non-supervisor) of the licensee. • I don't know. • Other: 	
C4	If a donor refuses to cooperate with the collection process, what do you do?	<ul style="list-style-type: none"> • Document the action on the custody and control form and contact FFD program management. • Contact FFD management and receive guidance on actions to take. • Other: 	<p>§ 26.89(c) states: “If the donor refuses to cooperate in the collection procedures, the collector shall inform FFD program management to obtain guidance on the actions to be taken.”</p>

C. Breath Collection, Knowledge of Collection Procedures – Non-Typical Collection Situations			
Num.	Question	Answer	NRC Regulation(s)
C5	If for-cause drug and alcohol testing is being conducted, which test is performed first?	<ul style="list-style-type: none"> • We always conduct alcohol testing first when a drug and alcohol tests are to be performed. • Drug test. • Either or is fine. • Other: 	<p>§ 26.93(b) states: “With the exception of the 15-minute waiting period, if necessary, the collector shall begin for-cause alcohol and/or drug testing as soon as reasonably practical after the decision is made that for-cause testing is required. When for-cause alcohol testing is required, alcohol testing may not be delayed by collecting a specimen for drug testing.”</p>
C6	What steps must be taken if a donor states that he or she had eaten, drank, belched, or put anything into his or her mouth, 15 minutes prior to the initial breath test?	<ul style="list-style-type: none"> • Implement a 15-minute waiting period and explain that the initial and, if needed, confirmatory tests, will be conducted at the end of the period. • Implement a waiting period of uncertain length. • I don’t know. • Other: 	<p>§ 26.93(a) states: “(3) If the donor states that he or she has engaged in any of the activities listed in paragraph (a)(1) of this section, inform the donor that a 15-minute waiting period is necessary to prevent an accumulation of mouth alcohol from leading to an artificially high reading... (5) Explain that the initial and confirmatory tests, if a confirmatory test is necessary, will be conducted at the end of the waiting period, even if the donor has not followed the instructions.”</p>

C. Breath Collection, Knowledge of Collection Procedures – Non-Typical Collection Situations			
Num.	Question	Answer	NRC Regulation(s)
C7	If problems occur while administering a breath test that requires an additional collection(s), which is the valid test result?	<ul style="list-style-type: none"> • The first successful collection. • I don't know. • Other: 	<p>§ 26.95(c) states: “Unless problems in administering the breath test require an additional collection, only one breath specimen may be collected for the initial test. If an additional collection(s) is required, the collector shall rely on the test result from the first successful collection to determine the need for confirmatory testing.”</p> <p>§ 26.101(c) states: “Unless there are problems in administering the breath test that require an additional collection, the collector shall collect only one breath specimen for the confirmatory test. If an additional collection(s) is required because of problems in administering the breath test, the collector shall rely on the breath specimen from the first successful collection to determine the confirmatory test result. Collection procedures may not require collectors to calculate an average or otherwise combine results from two or more breath specimens to determine the confirmatory test result.”</p>

D. Breath Collection, Observing the Facility			
Num.	Question	Answer	NRC Regulation(s)
D1	Is the facility used for breath collections secure at all times?	<ul style="list-style-type: none"> • Yes, only authorized collection site staff are permitted in the areas where specimen collections are conducted, and equipment and materials are stored. All other persons are escorted when entering secure areas in the collection site. • No, unauthorized staff have access to the collection area, equipment, and/or materials at times during the day. • Other: 	<p>§ 26.87(d) states:</p> <p>“Licensees and other entities shall take the following measures to prevent unauthorized access to the collection site that could compromise the integrity of the collection process or the specimens.</p> <p>(1) Unauthorized personnel may not be permitted in any part of the designated collection site where specimens are collected or stored;</p> <p>(2) A designated collection site must be secure. If a collection site is dedicated solely to specimen collection, it must be secure at all times. Methods of assuring security may include, but are not limited to, physical measures to control access, such as locked doors, alarms, or visual monitoring of the collection site when it is not occupied; and</p> <p>(3) If a collection site cannot be dedicated solely to collecting specimens, the portion of the facility that is used for specimen collection must be secured and, during the time period during which a specimen is being collected, a sign must be posted to indicate that access is permitted only for authorized personnel.”</p>

D. Breath Collection, Observing the Facility			
Num.	Question	Answer	NRC Regulation(s)
D2	<p>Has each breath collector received training in accordance with 10 CFR 26.85?</p> <p>[Examine training records]</p>	<ul style="list-style-type: none"> • Adequate training was conducted, and records were produced. • Training was not conducted. • Training was conducted, but certificates were not found for all collectors. • Other: 	<p>§ 26.85(a) states:</p> <p><i>“Collector qualifications.</i> Each collector 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 the collection procedures for each specimen the individual is qualified to collect under this part. Each collector 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. At a minimum, qualification training must provide instruction on the following subjects:</p> <p>(1) All steps necessary to complete a collection correctly and the proper completion and transmission of the Federal CCF;</p> <p>(2) Methods to address “problem” collections, including, but not limited to:</p> <p>(i) Inability to provide a specimen (e.g., “shy bladder” for a urine specimen, “shy lung” for a breath specimen, dry mouth for an oral fluid specimen); and</p> <p>(ii) Attempts to tamper with a specimen;</p> <p>(3) Operation of the particular specimen collection or alcohol testing device(s) [e.g., alcohol screening device (ASD), EBT, oral fluid] to be used, consistent with the most recent version of the manufacturers’ instructions;</p> <p>(4) How to correct problems in collections; and</p> <p>(5) The collector’s responsibility for maintaining the integrity of the specimen collection process, carefully ensuring the privacy of the donor, and avoiding any conduct or remarks that might be construed as accusatorial or otherwise offensive or inappropriate, and the specimen transfer process, if applicable.”</p>

D. Breath Collection, Observing the Facility			
Num.	Question	Answer	NRC Regulation(s)
D3	<p>Were the personnel files for the breath collectors complete?</p> <p>[Examine collector personnel files]</p>	<ul style="list-style-type: none"> • Yes. • Some required information was missing. • Other: 	<p>§ 26.85(d) states: “<i>Files</i>. Collection site personnel files must include each individual’s resume of training and experience; certification or license, if any; references; job descriptions; records of performance evaluations and advancement; incident reports, if any; results of tests to establish employee competency for the position he or she holds, including, but not limited to, certification that collectors are proficient in administering alcohol tests consistent with the most recent manufacturer’s instructions for the instruments and devices used; and appropriate data to support determinations of honesty and integrity conducted under § 26.31(b).”</p>
D4	<p>Were the collection site personnel prepared for the inspection team, and did they facilitate the inspection process, and produce the required records?</p>	<ul style="list-style-type: none"> • Yes. • No, the collection site was not prepared for the inspection but cooperated with the inspection team and produced all required records. • No, the collection site was unable to produce all requested records. • No, the collection site staff did not cooperate with the inspection process. • Other: 	<p>§ 26.87(c) states: “Contracts for collection site services must permit representatives of the NRC, licensee, or other entity to conduct unannounced inspections and audits and to obtain all information and documentation that is reasonably relevant to the inspections and audits.”</p>
THAT WAS THE LAST QUESTION. THANK YOU FOR YOUR TIME AND INPUT.			

Attachment 3: Medical Review Officer Questionnaire

10 CFR Part 26
Medical Review Officer Questionnaire

Licensee	
Contact Person	
Date	
Inspector	

This questionnaire may be used by the U.S. Nuclear Regulatory Commission (NRC) inspector when evaluating the Medical Review Officer (MRO) supporting a licensee's or other entity's fitness-for-duty (FFD) program. Each question is accompanied by potential answers and the relevant requirements in 10 CFR Part 26, Subpart H. This questionnaire is divided into the following five sections:

Section	Question Numbers
A. MRO Qualifications, Knowledge, and Affiliations	A1 – A6
B. MRO Responsibilities and Test Results Review	B1 – B11
C. MRO Staff Oversight and Activities	C1 – C6
D. MRO Activities Associated with Test Results Reviews (Invalid, Adulterated, Substituted, Dilute, Medications	D1 – D19
E. Retesting an Aliquot of a Single Specimen or Split-Specimen Testing	E1 – E5

A. MRO Qualifications, Knowledge, and Affiliations			
Num.	Question	Answer	NRC Regulation(s)
A1	<p>Please describe your qualifications to serve as an MRO for an NRC-regulated licensee under 10 CFR Part 26.</p> <p>[Request a copy of the medical license from the MRO or the licensee or other entity]</p>	<ul style="list-style-type: none"> • Medical Doctor (MD) licensed in the U.S. • Doctor of Osteopathy (DO) licensed in the U.S. • Other: 	<p>§ 26.183(a) states:</p> <p>"The MRO shall 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."</p>
A2	<p>Have you 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?</p> <p>[Request a copy of the training certificate]</p>	<ul style="list-style-type: none"> • Yes. • No. • Other: 	<p>§ 26.183(a) states:</p> <p>"The MRO shall 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."</p>

A. MRO Qualifications, Knowledge, and Affiliations			
Num.	Question	Answer	NRC Regulation(s)
A3	How do you keep up to date on the NRC drug and alcohol testing regulations in 10 CFR Part 26?	<ul style="list-style-type: none"> • I regularly review the NRC FFD website for information on the regulation. • I receive a newsletter that informs me of changes in the NRC's drug and alcohol testing regulations. • I have a copy of 10 CFR Part 26. • The licensee's or other entity's staff provides me with any updates on the rule. • Other: 	§ 26.183(a) states: "The MRO shall be knowledgeable of this part and of the FFD policies of the licensees and other entities for whom the MRO provides services."
A4	Do you have a copy of the licensee's or other entity's FFD program policy?	<ul style="list-style-type: none"> • Yes. • No. • Other: 	
A5	How do you keep up to date on any changes to the FFD program policy?	<ul style="list-style-type: none"> • I receive information from the FFD program manager if any changes are implemented. • I rely upon the policy that is provided to me by the FFD program. • Other: 	

A. MRO Qualifications, Knowledge, and Affiliations			
Num.	Question	Answer	NRC Regulation(s)
A6	Are you an employee, agent of, or do you have a financial interest in the contracted operator of the licensee testing facility (LTF) – if applicable, and/or the HHS-certified laboratories used by the FFD program?	<ul style="list-style-type: none"> • No, I have no professional or financial relationship with the contracted operator of the LTF or the HHS-certified laboratories. • Yes, I have a financial interest, or I am an employee or agent of the contracted operator of the LTF or one of the HHS-certified laboratories. • Other: 	<p>§ 26.183(b) states: <i>“Relationships</i> ...the MRO may not be an employee or agent of, or have any financial interest in, an HHS-certified laboratory or a contracted operator of a licensee testing facility for whom the MRO reviews drug test results. Additionally, the MRO may not derive any financial benefit by having the licensee or other entity use a specific drug-testing laboratory or licensee testing facility operating contractor and may not have an agreement with such parties that may be construed as a potential conflict of interest. Examples of relationships between laboratories and MROs that create conflicts of interest, or the appearance of such conflicts, include, but are not limited to –</p> <p>(1) The laboratory employs an MRO who reviews test results produced by the laboratory;</p> <p>(2) The laboratory has a contract or retainer with the MRO for the review of the results produced by the laboratory;</p> <p>(3) The laboratory designates which MRO the licensee or other entity is to use, gives the licensee or other entity a slate of MROs from which to choose, or recommends certain MROs;</p> <p>(4) The laboratory gives the licensee or other entity a discount or other incentive to use a particular MRO;</p> <p>(5) The laboratory has its place of business co-located with that of an MRO or MRO staff who review test results produced by the laboratory; or</p> <p>(6) The laboratory permits an MRO, or an MRO’s organization, to have a financial interest in the laboratory.”</p>

B. MRO Responsibilities and Test Results Review			
Num.	Question	Answer	NRC Regulation(s)
B1	Describe your responsibilities as an MRO for an NRC licensee?	<ul style="list-style-type: none"> • Review and interpret drug and validity test results received from the licensee testing facility and/or the HHS-certified laboratory. • Conduct donor interviews for positive, adulterated, substituted, and invalid test results received from the HHS-certified laboratory. • Advise the licensee or other entity on collection site issues related to possible subversion attempts [§ 26.111(c)]. • Assist in shy-bladder situations [§26.119]. • Advise the collector regarding a decision to proceed with an observed specimen collection [§ 26.115(b)] • All of the above. • Other: 	<p>§ 26.183(c) states: “The primary role of the MRO is to review and interpret positive, adulterated, substituted, invalid, and dilute test results obtained through the licensee’s or other entity’s testing program and to identify any evidence of subversion of the testing process.”</p> <p>§ 26.111(c) states: “If there is reason to believe that the donor may have attempted to dilute, substitute, or adulterate the specimen based on specimen temperature or other observations made during the collection, the collector shall contact the FFD program manager, who may consult with the MRO, to determine whether the donor has attempted to subvert the testing process or whether other circumstances may explain the observations. The FFD program manager or MRO may require the donor to provide a second specimen as soon as possible under direct observation...”</p> <p>§ 26.119 “<i>Determining “shy” bladder</i>” states: “(a) When a donor has not provided a specimen of at least 30 mL within the 3 hours permitted for urine collection, FFD program personnel shall direct the donor to obtain, within 5 business days, an evaluation from a licensed physician who is acceptable to the MRO and has expertise in the medical issues raised by the donor’s failure to provide a sufficient specimen. The MRO may perform this evaluation if the MRO has the appropriate expertise.”</p>
B1 Cont’d			<p>§ 26.115(b) states: “Before collecting a urine specimen under direct observation, the collector shall obtain the agreement of the FFD program manager or MRO to obtain a urine specimen under direct observation. After obtaining agreement, the collector shall ensure that a specimen is collected under direct observation as soon as reasonably practicable.”</p>

B. MRO Responsibilities and Test Results Review			
Num.	Question	Answer	NRC Regulation(s)
B2	What steps do you take as the MRO a confirmatory positive, adulterated, substituted, dilute, or invalid test result is received from the HHS-certified laboratory?	<ul style="list-style-type: none"> The MRO stated the following three steps: <ol style="list-style-type: none"> 1) Review the Federal CCF and laboratory test results. 2) Contact the donor to discuss the test results and evaluate if a legitimate medical explanation exists to explain the result. 3) Immediately notify the licensee's or other entity's designated representative once an FFD policy violation is determined. Other: 	<p>§ 26.185(a) states: "<i>MRO review required</i>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 before reporting the results to the licensee's or other entity's designated representative."</p> <p>§ 26.185(c) states: "<i>Discussion with the donor</i>. Before determining that a positive, adulterated, substituted, dilute, or invalid test result or other occurrence is an FFD policy violation and reporting it to the licensee or other entity, the MRO shall give the donor an opportunity to discuss the test result or other occurrence with the MRO, except as described in paragraph (d) of this section. After this discussion, if the MRO determines that a positive, adulterated, substituted, dilute, or invalid test result or other occurrence is an FFD policy violation, the MRO shall immediately notify the licensee's or other entity's designated representative."</p>

B. MRO Responsibilities and Test Results Review			
Num.	Question	Answer	NRC Regulation(s)
B3	As the MRO, are you permitted to report initial test results received from the HHS-certified laboratory to the licensee or other entity?	<ul style="list-style-type: none"> • No. • Yes. • Other: 	<p>§ 26.185(b) states:</p> <p><i>“Reporting of initial test results prohibited.</i> Neither the MRO nor MRO staff may report positive, adulterated, substituted, dilute, or invalid initial test results that are received from the HHS-certified laboratory to the licensee or other entity.”</p>
B4	For confirmatory positive, adulterated, substituted, and invalid test results, what method(s) do you use to examine alternate medical explanations?	<ul style="list-style-type: none"> • Conduct a medical interview with the donor. • Review the donor’s medical history, including any records that they might provide to me. • Review any other relevant biomedical factors. • All of the above • Other: 	<p>§ 26.183(c)(1) states:</p> <p>“In carrying out these responsibilities, the MRO 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. The MRO shall review all medical records that the 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.”</p>

B. MRO Responsibilities and Test Results Review			
Num.	Question	Answer	NRC Regulation(s)
B5	Can you consider test results for specimens that have <u>not</u> been collected and processed under 10 CFR Part 26?	<ul style="list-style-type: none"> • No. • Yes. • Other: 	§ 26.183(c)(2) states: “The MRO may only consider the results of tests of specimens that are collected and processed under this part [10 CFR Part 26], including the results of testing split specimens, in making his or her determination, as long as those split specimens have been stored and tested under the procedures described in this part.”
B6	When attempting to speak to a donor about a positive, adulterated, substituted, or invalid test result, at a minimum, what is considered a “reasonable effort” to contact the individual?	<ul style="list-style-type: none"> • Three attempts using the day and evening telephone numbers reasonably spread out over a 24-hour period. • Fewer than three attempts in a 24-hour period of time. • Other: 	§ 26.185(d)(3) states: “Reasonable efforts include, at a minimum, three attempts, spaced reasonably over a 24-hour period, to reach the donor at the day and evening telephone numbers listed on the Federal CCF.”
B7	Under what three circumstances may you verify that a positive, adulterated, substituted, dilute, or invalid test result is an FFD policy violation without discussing the test result directly with the donor?	<ul style="list-style-type: none"> • The MRO stated the three circumstances: <ol style="list-style-type: none"> 1) I made and documented contact with the donor and the donor expressly declined to discuss the test result. 2) My staff or a licensee representative successfully made and documented contact with the donor and instructed the donor to contact me [the MRO], and more than 1 business day has elapsed. 3) After making all reasonable efforts and 	§ 26.185(d) states: “ <i>Donor unavailability.</i> The MRO may determine that a positive, adulterated, substituted, dilute, or invalid test result or other occurrence is an FFD policy violation without having discussed the test result or other occurrence directly with the donor in the following three circumstances: (1) The MRO has made and documented contact with the donor and the donor expressly declined the opportunity to discuss the test result or other occurrence that may constitute an FFD policy violation; (2) A representative of the licensee or other entity, or an MRO staff member, has successfully made and documented contact with the donor and has instructed him or her to contact the MRO, and more than 1 business day has elapsed since the date on which the licensee’s representative or MRO’s staff member successfully contact the donor; or

B. MRO Responsibilities and Test Results Review			
Num.	Question	Answer	NRC Regulation(s)
		<p>documenting the dates and time of those efforts, I have been unable to contact the donor.</p> <ul style="list-style-type: none"> • I refer to 10 CFR Part 26 for non-typical circumstances to ensure that I follow the correct procedures. • Other: 	(3) The MRO, after making all reasonable efforts and documenting the dates and time of those efforts, has been unable to contact the donor."
B8	Can you as the MRO modify your initial determination of an FFD policy violation for instances where a donor interview was unable to be conducted?	<ul style="list-style-type: none"> • Yes, but only if the donor presents information within 30 days of my initial confirmed result that documents a legitimate reason that the donor was unable to contact me in a timely manner. • Yes, at any point in the future. • No. • Other: 	<p>§ 26.185(e) states:</p> <p><i>"Additional opportunity for discussion.</i> If the MRO determines that the donor has violated the FFD policy without having discussed the positive, adulterated, substituted, dilute, or invalid test result or other occurrence directly with the donor, the donor may, on subsequent notification of the MRO determination and within 30 days of that notification, present to the MRO information documenting the circumstances, including, but not limited to, serious illness or injury, which unavoidably prevented the donor from being contacted by the MRO or a representative of the licensee of other entity, or from contacting the MRO in a timely manner. On the basis of this information, the MRO may reopen the procedure for determining whether the donor's test result or other occurrence is an FFD policy violation and permit the individual to present information related to the issue. The MRO may modify the initial determination based on an evaluation of the information provided."</p>

B. MRO Responsibilities and Test Results Review			
Num.	Question	Answer	NRC Regulation(s)
B9	How many days does 10 CFR Part 26 permit you as the MRO to complete the review of a positive, adulterated, substituted, or invalid specimen test result?	<ul style="list-style-type: none"> • Within 10 business days of receiving the result from the HHS-certified laboratory. • Any time period less than 10 business days. • Other: 	<p>§ 26.185(p) states:</p> <p><i>“Time to complete MRO review.</i> The MRO shall complete his or her review of positive, adulterated, substituted, and invalid test results and, in instances when the MRO determines that there is no legitimate medical explanation for the test result(s), notify the licensee’s or other entity’s designated representative within 10 business days of an initial positive, adulterated, substituted, or invalid test result.”</p>

B. MRO Responsibilities and Test Results Review			
Num.	Question	Answer	NRC Regulation(s)
B10	After completing your review of positive, adulterated, substituted, and invalid test results, what communication method do you use to transmit the test result to the licensee or other entity?	<ul style="list-style-type: none"> • I or my staff notifies the licensee's or other entity's designated representative of the results in writing and by telephone (using a dedicated telephone number for the contact). • I or my staff transmits the results in a manner designed to ensure the confidentiality of the information (using a secure fax, secure website, contact via cell phone or dedicated telephone number) • Other: 	§ 26.185(p) states: "The MRO shall notify the licensee or other entity of the results of his or her review in writing and in a manner designed to ensure the confidentiality of the information."

B. MRO Responsibilities and Test Results Review			
Num.	Question	Answer	NRC Regulation(s)
B11	What procedures must you follow when reviewing drug test results from an individual whose authorization was terminated or denied for a first violation of the FFD policy involving a confirmed positive drug test result and who is being considered for re-authorization?	<ul style="list-style-type: none"> Request from the HHS-certified laboratory the quantitation of the test results and other information necessary to determine whether subsequent positive confirmatory drug test results represent new drug use or remaining metabolites from the drug use that initially resulted in the FFD policy violation. Other: 	<p>§ 26.185(o) states: <i>“Re-authorization after a first violation for a positive test result.</i> The MRO is responsible for reviewing drug test results from an individual whose authorization was terminated or denied for a first violation of the FFD policy involving a confirmed positive drug test result and who is being considered for re-authorization. In order to determine whether subsequent positive confirmatory drug test results represent new drug use or remaining metabolites from the drug use that initially resulted in the FFD policy violation, the MRO shall request from the HHS-certified laboratory, and the laboratory shall provide, quantitation of the test results and other information necessary to make the determination. If the drug for which the individual first tested positive was marijuana and the confirmatory assay for delta-9-tetrahydrocannabinol-9-carboxylic acid yields a positive result, the MRO shall determine whether the confirmatory test result indicates further marijuana use since the first positive test result, or whether the test result is consistent with the level of delta-9-tetrahydrocannabinol-9-carboxylic acid that would be expected if no further marijuana use had occurred. If the test result indicates that no further marijuana use has occurred since the first positive test result, then the MRO shall declare the drug test result as negative.”</p>
<p>Does the MRO use MRO staff to assist in performing administrative functions? If NO, skip the next section of questions (C1–C6) on “MRO Staff Oversight Activities.”</p>			

C. MRO Staff Oversight and Activities			
Num.	Question	Answer	NRC Regulation(s)
C1	Who is responsible for overseeing the individual(s) performing MRO staff functions?	<ul style="list-style-type: none"> • The MRO is directly responsible. • The licensee is directly responsible. • The staff is responsible for their own actions. • Other: 	<p>§ 26.183(d)(1) states: “MROs shall be directly responsible for all administrative, technical, and professional activities of individuals who are serving MRO staff functions while they are performing those functions, and those functions must be under the MRO’s direction.”</p>
C2	What steps must the MRO’s staff take to protect the privacy of donor testing information and records?	<ul style="list-style-type: none"> • Assure that procedures being performed by MRO staff meet NRC regulations and HHS and professional standards of practice. • Assure that data transmission is secure (only between authorized staff using a dedicated telephone number; secure fax line, secure electronic communication). • Assure that records and other donor personal information are maintained confidential by MRO staff and are not released to other individuals or entities (restricted access to hardcopy and electronic files). • Assure that drug test results are reported to the licensee’s or other entity’s designated reviewing official only. • All of the above. • Other: 	<p>§ 26.183 (d)(1)(ii) states: “An MRO’s responsibilities for directing MRO staff must include, but are not limited to, ensuring that— (A) The procedures being performed by MRO staff meet NRC regulations and HHS’ and professional standards of practice; (B) Records and other donor personal information are maintained confidential by MRO staff and are not released to other individuals or entities, except as permitted under this part; (C) Data transmission is secure; and (D) Drug test results are reported to the licensee’s or other entity’s designated reviewing official only as required by this part.”</p>

C. MRO Staff Oversight and Activities			
Num.	Question	Answer	NRC Regulation(s)
C3	Does the MRO's staff receive, review, and report negative drug test results to the licensee's or other entity's designated representative?	<ul style="list-style-type: none"> • Yes. • No. • Other: 	<p>§ 26.183(d)(2) states: "MRO staff may perform routine administrative support functions, including receiving test results, reviewing negative test results, and scheduling interviews for the MRO. (i) The staff under the direction of the MRO may receive, review, and report negative test results to the licensee's or other entity's designated representative."</p>
C4	<p>Does the MRO's staff review positive, adulterated, substituted, and invalid, test results?</p> <p><u>If yes</u>, what specifically do they do?</p>	<ul style="list-style-type: none"> • No. • Yes, but my staff only reviews the Federal CCFs for errors. • Other: 	<p>§ 26.183(d)(2)(ii) states: "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 require corrective action and to ensure that it is consistent with the information on the MRO's copy. The staff may resolve errors in Federal CCFs that require corrective action(s), but shall forward the Federal CCFs to the MRO for review and approval of the resolution."</p>
C5	Does the MRO's staff conduct interviews with donors to discuss positive, adulterated, substituted, and invalid test results and/or to request medical information?	<ul style="list-style-type: none"> • No. • Yes. • Other: 	<p>§ 26.183(d)(2)(iii) states: "The staff may not conduct interviews with donors to discuss positive, adulterated, substituted, invalid, or dilute test results nor request medical information from a donor. Only the MRO may request and review medical information related to a positive, adulterated, substituted, or invalid test result or other matter from a donor."</p>

C. MRO Staff Oversight and Activities			
Num.	Question	Answer	NRC Regulation(s)
C6	With whom is the MRO's staff permitted to discuss confirmed positive, adulterated, substituted, invalid, and dilute test results?	<ul style="list-style-type: none"> • Licensee FFD program personnel. • MRO staff only can speak with authorized FFD program personnel, but they cannot review quantitative test results or donor medical information that the MRO collected as part of the test result review process. • Other: 	<p>§ 26.183 (d)(2)(iv) states:</p> <p>"Any MRO staff discussions of confirmed positive, adulterated, substituted, invalid, or dilute test results must be limited to discussions only with the licensee's or other entity's FFD program personnel and may not reveal quantitative test results or any personal medical information about the donor that the MRO may have obtained in the course of reviewing confirmatory test results from the HHS-certified laboratory."</p>

D. MRO Activities Associated with Test Result Reviews (Invalid, Adulterated, Substituted, Dilute, Medications)			
Num.	Question	Answer	NRC Regulation(s)
D1	Describe the three steps the MRO must take when an HHS-certified laboratory reports an <u>invalid</u> result for a donor's specimen.	<ul style="list-style-type: none"> The MRO described the three steps: <ol style="list-style-type: none"> Consult with the laboratory and determine if additional testing at another HHS-certified laboratory may be useful to identify an adulterant or to obtain a positive result. Contact the donor and determine if an acceptable medical explanation exists for the invalid result. If no additional testing is conducted and no legitimate medical explanation exists for the invalid test result, require that a second specimen be collected as soon as practical under direct observation. I refer to 10 CFR Part 26 for non-typical circumstances to ensure that I follow the correct procedures. Other: 	<p>§ 26.185(f) states: <i>"Review of invalid specimens"</i></p> <p>(1) If the HHS-certified laboratory reports an invalid result, the MRO shall consult with the laboratory to determine whether additional testing by another HHS-certified laboratory may be useful in determining and reporting a positive or adulterated test result. If the MRO and the laboratory agree that further testing would be useful, the HHS-certified laboratory shall forward the specimen to a second laboratory for additional testing.</p> <p>(2) If the MRO and the laboratory agree that further testing would not be useful and there is no technical explanation for the result, the MRO shall contact the donor and determine whether there is an acceptable medical explanation for the invalid result. If there is an acceptable medical explanation, the MRO shall report to the licensee or other entity that the test result is not an FFD policy violation, but that a negative test result was not obtained. If the medical reason for the invalid result is, in the opinion of the MRO, a temporary condition, the licensee or other entity shall collect a second urine specimen from the donor as soon as reasonably practical and rely on the MRO's review of the test results from the second collection. The second specimen collected for the purposes of this paragraph may not be collected under direct observation. If the medical reason for the invalid result would similarly affect the testing of another urine specimen, the MRO may authorize an alternative method for drug testing. Licensees and other entities may not impose sanctions for an invalid test result due to a medical condition...</p>

D. MRO Activities Associated with Test Result Reviews (Invalid, Adulterated, Substituted, Dilute, Medications)			
Num.	Question	Answer	NRC Regulation(s)
D1 cont'd			(3) If the MRO and the laboratory agree that further testing would not be useful and there is no legitimate technical or medical explanation for the invalid test result, the MRO shall require that a second collection take place as soon as practical under direct observation. The licensee or other entity shall rely on the MRO's review of the test results from the directly observed collection."

D. MRO Activities Associated with Test Result Reviews (Invalid, Adulterated, Substituted, Dilute, Medications)			
Num.	Question	Answer	NRC Regulation(s)
D2	What additional steps must the MRO take if the invalid result reported by the HHS-certified laboratory is based on a pH in the range of 9.0 to 9.5?	<ul style="list-style-type: none"> Evaluate if evidence exists that elapsed time, exposure to high temperature, or both, could account for the pH value: <p><u>If evidence exists,</u></p> <ol style="list-style-type: none"> Report a cancelled test result to the licensee or other entity, Cancel the test result for the initial specimen, and Direct that a second non-observed specimen be collected as soon as reasonably practicable. <p><u>If no evidence,</u> Require a second collection take place as soon as practicable under direct observation.</p> <ul style="list-style-type: none"> I refer to 10 CFR Part 26 for non-typical circumstances to ensure that I follow the correct procedures. Other: 	<p>§ 26.185(f)(3) states:</p> <p>“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.”</p> <p><u>Note:</u> Regulatory Guide 5.89 also includes guidance in section C.3, “MRO consideration of time and temperature for urine specimens with invalid test results due to pH in the range of 9.0 to 9.5.”</p>

D. MRO Activities Associated with Test Result Reviews (Invalid, Adulterated, Substituted, Dilute, Medications)			
Num.	Question	Answer	NRC Regulation(s)
D3	What action must the MRO take for a <u>dilute</u> specimen with drug or drug metabolites detected at or above the specified cutoff level with no legitimate medical explanation?	<ul style="list-style-type: none"> • Verify the drug test result as positive and contact FFD management. • Other: 	<p>§ 26.185(g)(1) states:</p> <p>“If the HHS-certified laboratory reports that a specimen is dilute and that drugs or drug metabolites were detected in the specimen at or above the cutoff levels specified in this part or the licensee’s or other entity’s more stringent cutoff levels, and the MRO determines that there is no legitimate medical explanation for the presence of the drugs or drug metabolites in the specimen, and a clinical examination, if required under paragraph (g)(3) of this section, has been conducted, the MRO shall determine that the drug test results are positive and that the donor has violated the FFD policy.”</p>

D. MRO Activities Associated with Test Result Reviews (Invalid, Adulterated, Substituted, Dilute, Medications)			
Num.	Question	Answer	NRC Regulation(s)
D4	<p>Special analyses testing under 10 CFR 26.163(a)(2)</p> <p>What additional action must the MRO take if a donor's specimen is dilute, <u>and</u> the MRO confirms the specimen is positive for a drug or drug metabolite?</p>	<ul style="list-style-type: none"> Determine if the test result also is a refusal to test by considering if: <ol style="list-style-type: none"> The donor provided at this or a previous collection a urine specimen that an HHS-certified laboratory reported as substituted, adulterated, or invalid, and MRO review determined no adequate technical or medical explanation for the result. The donor presented a urine specimen of 30 mL or more that was outside the required temperature range. The collector observed conduct indicating an attempt to dilute the specimen. Verify the drug test result as positive and contact FFD management. Other: 	<p>§ 26.185(g)(2) states:</p> <p>"If the results of the special analysis testing required by §26.163(a)(2) are positive, the MRO determines that there is no legitimate medical explanation for the presence of the drug(s) or drug metabolite(s) in the specimen, and a clinical examination, if required... has been conducted..., the MRO shall determine whether the positive and dilute specimen is a refusal to test. If the MRO does not have sufficient reason to believe that the positive and dilute specimen is a subversion attempt, he or she shall determine that the drug test results are positive, and that the donor has violated the FFD policy. When determining whether the donor has diluted the specimen in a subversion attempt, the MRO shall also consider the following circumstances, if applicable:</p> <p>(i) The donor has presented, at this or a previous collection, a urine specimen that the HHS-certified laboratory reported as being substituted, adulterated, or invalid to the MRO and the MRO determined that there is no adequate technical or medical explanation for the result;</p> <p>(ii) The donor has presented a urine specimen of 30 mL or more that falls outside the required temperature range, even if a subsequent directly observed collection was performed; or</p> <p>(iii) The collector observed conduct indicating an attempt to dilute the specimen."</p>

D. MRO Activities Associated with Test Result Reviews (Invalid, Adulterated, Substituted, Dilute, Medications)			
Num.	Question	Answer	NRC Regulation(s)
D5	Before determining a donor violation of the FFD policy, what procedure must the MRO follow for a dilute specimen that is also positive for the opioids morphine and/or codeine, or drugs or metabolites that indicate the use of prescription or over-the-counter medications?	<ul style="list-style-type: none"> • I or a qualified designee must conduct a clinical examination for signs of abuse of the substance(s). • No clinical examination is necessary if 6-AM is detected by the laboratory. I verify the test result as positive in this case. • All of the above. • Other: 	<p>§ 26.185(g)(3) states: “If the drugs detected in a dilute specimen are opioids (i.e., morphine and/or codeine), or if the drugs or metabolites detected indicate the use of prescription or over-the-counter medications, before determining that the donor has violated the FFD policy under paragraph (a) of this section, the MRO or his/her designee, who shall also be a licensed physician with knowledge of the clinical signs of drug abuse, shall conduct the clinical examination for abuse of these substances that is required in paragraph (j) of this section. An evaluation for clinical evidence of abuse is not required if the laboratory confirms the presence of 6–AM (i.e., the presence of this metabolite is proof of heroin use) in the dilute specimen.”</p>
D6	Is an MRO review required for a dilute negative specimen result?	<ul style="list-style-type: none"> • No, my staff can review a dilute negative result. • No, but I review all drug test results. • Yes. • Other: 	<p>§ 26.183(d)(2)(i) states: “The staff under the direction of the MRO may receive, review, and report negative test results to the licensee's or other entity's designated representative.”</p> <p>§ 26.185(g)(4) states: “An MRO review is not required for specimens that the HHS-certified laboratory reports as negative and dilute. The licensee or other entity may not take any administrative actions or impose any sanctions on a donor who submits a negative and dilute specimen.”</p>

D. MRO Activities Associated with Test Result Reviews (Invalid, Adulterated, Substituted, Dilute, Medications)			
Num.	Question	Answer	NRC Regulation(s)
D7	What steps must the MRO take when a substituted or adulterated specimen test result is received from the HHS-certified laboratory?	<ul style="list-style-type: none"> The MRO stated the correct two steps: (1) Conduct an interview with the donor to evaluate if legitimate medical explanation exists for the test result; (2) Verify the test result as substituted or adulterated if no legitimate medical explanation exists. Other: 	<p><u>Substituted specimen</u> § 26.185(h)(1) states: “If the HHS-certified laboratory reports a specimen as substituted... the MRO shall contact the donor and offer the donor an opportunity to provide a legitimate medical explanation for the substituted result.”</p> <p>§ 26.185(h)(2) states: “If the MRO determines that there is no legitimate medical explanation for the substituted test result, the MRO shall report to the licensee or other entity that the specimen was substituted.”</p> <p><u>Adulterated specimen</u> § 26.185(i)(1) states: “If the HHS-certified laboratory reports a specimen as adulterated with a specific substance, the MRO shall contact the donor and offer the donor an opportunity to provide a legitimate medical explanation for the substituted result.”</p> <p>§ 26.185(i)(2) states: “If the MRO determines that there is no legitimate medical explanation for the adulterated test result, the MRO shall report to the licensee or other entity that the specimen is adulterated.”</p>

D. MRO Activities Associated with Test Result Reviews (Invalid, Adulterated, Substituted, Dilute, Medications)			
Num.	Question	Answer	NRC Regulation(s)
D8	Who has the burden of proof regarding substituted or adulterated test results (the MRO or the donor)?	<ul style="list-style-type: none"> The donor has the burden of proof and must provide legitimate medical evidence to the MRO within 5 business days of the specimen collection date. The MRO has the burden of proof. Other: 	<p>§ 26.185(h)(1) states: “The burden of proof resides solely with the donor, who must provide legitimate medical evidence within 5 business days that he or she produced the specimen for which the HHS-certified laboratory reported a <u>substituted result</u>.”</p> <p>§ 26.185(i)(1) states: “The burden of proof resides solely with the donor, who must provide legitimate medical evidence within 5 business days that he or she produced the <u>adulterated result</u>.”</p>
D9	What is the course of action if a legitimate medical explanation is verified by the MRO for a substituted or adulterated test result, and no drugs or drug metabolites were detected in the specimen?	<ul style="list-style-type: none"> Verify the test result as negative. Require a second specimen be collected under direct observation. Other: 	<p>§ 26.185(h)(3) states: “If the MRO determines that there is a legitimate medical explanation for the <u>substituted test</u> result and no drugs or drug metabolites were detected in the specimen, the MRO shall report to the licensee or other entity that no FFD policy violation has occurred.”</p> <p>§ 26.185(i)(3) states: “If the MRO determines that there is a legitimate medical explanation for the <u>adulterated test</u> result and no drugs or drug metabolites were detected in the specimen, the MRO shall report to the licensee or other entity that no FFD policy violation has occurred.”</p>
D10	Who must submit medical evidence to support a legitimate medical explanation for a substituted or adulterated specimen test result?	<ul style="list-style-type: none"> A physician experienced and qualified in the medical issues involved. The donor. Other: 	<p>§ 26.185(h)(1) and (i)(1) state: “Any medical evidence must be submitted through a physician experienced and qualified in the medical issues involved, as verified by the MRO.”</p>

D. MRO Activities Associated with Test Result Reviews (Invalid, Adulterated, Substituted, Dilute, Medications)			
Num.	Question	Answer	NRC Regulation(s)
D11	If you as the MRO determine that no legitimate medical explanation exists for a <u>confirmatory positive result for the opioids morphine and/or codeine</u> , is a clinical examination required prior to reporting a positive result?	<ul style="list-style-type: none"> • Yes, I or a qualified designee must conduct a clinical examination to determine if the donor has illegally used morphine and/or codeine. • No, a clinical examination is not necessary if 6-AM is detected, or the morphine or codeine concentration is equal to or greater than 15,000 ng/mL. • All of the above. • Other: 	<p>§ 26.185(j)(1) states:</p> <p>"If the MRO determines that there is no legitimate medical explanation for a positive confirmatory test result for opioids (i.e., morphine and/or codeine) and before the MRO determines that the test result is a violation of the FFD policy, the MRO or his/her designee, who shall also be a licensed physician with knowledge of the clinical signs of drug abuse, shall determine that there is clinical evidence, in addition to the positive confirmatory test result, that the donor has illegally used morphine and/or codeine. This requirement does not apply if the laboratory confirms the presence of 6-AM (i.e., the presence of this metabolite is proof of heroin use), or the morphine or codeine concentration is equal to or greater than 15,000 ng/mL and the donor does not present a legitimate medical explanation for the presence of morphine or codeine at or above this concentration. The MRO may not determine that the consumption of food products is a legitimate medical explanation for the presence of morphine or codeine at or above this concentration."</p>
D12	Is consumption of food products a legitimate medical explanation for the presence of <u>morphine or codeine</u> at or above 15,000 ng/mL?	<ul style="list-style-type: none"> • No. • Yes. • Other: 	
D13	Is a determination of clinical evidence of abuse needed prior to confirming a positive test result for <u>drugs other than opioids</u> that are commonly prescribed (e.g., benzodiazepines) or included in over-the-counter preparations (e.g., barbiturates)?	<ul style="list-style-type: none"> • Yes, I must determine if clinical evidence of abuse exists for the substances detected or their derivatives. • No. I can confirm the test result as positive. • Other: 	<p>§ 26.185 (j)(2) states:</p> <p>"If the MRO determines that there is no legitimate medical explanation for a positive confirmatory test result for drugs other than opioids that are commonly prescribed or included in over-the-counter preparations (e.g., benzodiazepines in the first case, barbiturates in the second) and are listed in the licensee's or other entity's panel of substances to be tested, the MRO shall determine whether there is clinical evidence, in addition to the positive confirmatory test result, of abuse of any of these substances or their derivatives."</p>

D. MRO Activities Associated with Test Result Reviews (Invalid, Adulterated, Substituted, Dilute, Medications)			
Num.	Question	Answer	NRC Regulation(s)
D14	What do you do as the MRO if you determine that a donor has used another individual's prescription medication?	<ul style="list-style-type: none"> • If clinical evidence of drug abuse is found, report to the licensee that the donor has violated the FFD policy. • If no clinical evidence of drug abuse is found, report to the licensee that the donor has misused a prescription medication. • All of the above. • Other: 	<p>§ 26.185(j)(3) states:</p> <p>"If the MRO determines that the donor has used another individual's prescription medication, including a medication containing opioids (i.e., morphine and/or codeine), and <u>no clinical evidence of drug abuse is found</u>, the MRO shall report to the licensee or other entity that the donor has misused a prescription medication. If the MRO determines that the donor has used another individual's prescription medication and <u>clinical evidence of drug abuse is found</u>, the MRO shall report to the licensee that the donor has violated the FFD policy."</p>
D15	Could the use of a medication from a foreign country support a legitimate medical explanation for a positive confirmatory test result for opioids or prescription or over-the-counter medications?	<ul style="list-style-type: none"> • Yes. • No. • Other: 	<p>§ 26.185(j)(4) states:</p> <p>"In determining whether a legitimate medical explanation exists for a positive confirmatory test result for opioids or prescription or over-the-counter medications, <u>the MRO may consider the use of a medication from a foreign country.</u>"</p>

D. MRO Activities Associated with Test Result Reviews (Invalid, Adulterated, Substituted, Dilute, Medications)			
Num.	Question	Answer	NRC Regulation(s)
D16	In determining whether a legitimate medical explanation exists for a positive confirmatory test result for opioids or prescription or over-the-counter medications, what principles should you adhere to when considering the use of a medication from a foreign country?	<ul style="list-style-type: none"> • There can be a legitimate medical explanation only with respect to a drug that is obtained legally in a foreign country. • There can be a legitimate medical explanation only with respect to a drug that has a legitimate medical use. • Use of the drug can form the basis of a legitimate medical explanation only if it is used consistently with its proper and intended medical purpose. • All of the above. • Other: 	<p>§ 26.185(j)(4) states: “The MRO shall exercise professional judgment consistently with the following principles: (i) There can be a legitimate medical explanation only with respect to a drug that is obtained legally in a foreign country; (ii) There can be a legitimate medical explanation only with respect to a drug that has a legitimate medical use. Use of a drug of abuse (e.g., heroin, PCP) or any other substance that cannot be viewed as having a legitimate medical use can never be the basis for a legitimate medical explanation, even if the drug is obtained legally in a foreign country; and (iii) Use of the drug can form the basis of a legitimate medical explanation only if it is used consistently with its proper and intended medical purpose.”</p>

D. MRO Activities Associated with Test Result Reviews (Invalid, Adulterated, Substituted, Dilute, Medications)			
Num.	Question	Answer	NRC Regulation(s)
D17	In determining whether a legitimate medical explanation exists for a positive confirmatory drug test result, may the MRO consider the consumption of food products, supplements, or other preparations containing substances that may result in the positive result?	<ul style="list-style-type: none"> • No. • Yes. • Other: 	<p>§ 26.185(j)(5) states:</p> <p>“The MRO may not consider consumption of food products, supplements, or other preparations containing substances that may result in a positive confirmatory drug test result, including, but not limited to supplements containing hemp products or coca leaf tea, as a legitimate medical explanation for the presence of drugs or drug metabolites in the urine specimen above the cutoff levels specified in § 26.163 or a licensee’s or other entity’s more stringent cutoff levels.”</p>
D18	In determining whether a legitimate medical explanation for a positive confirmatory test result exists, may the MRO consider the use of any Schedule I drug (i.e., listed in section 202 of the Controlled Substances Act [21 U.S.C. 812])?	<ul style="list-style-type: none"> • No. • Yes, if the drug was legally prescribed and used under State law. • Other: 	<p>§ 26.185(j)(6) states:</p> <p>“The MRO may not consider the use of any drug contained in Schedule I of section 202 of the Controlled Substances Act [21 U.S.C. 812] as a legitimate medical explanation for a positive confirmatory drug test result, even if the drug may be legally prescribed and used under State law.”</p>

D. MRO Activities Associated with Test Result Reviews (Invalid, Adulterated, Substituted, Dilute, Medications)			
Num.	Question	Answer	NRC Regulation(s)
D19	If you determine a legitimate medical explanation exists for a positive drug test result, what actions must you take?	<ul style="list-style-type: none"> The MRO stated the three actions: <ol style="list-style-type: none"> 1) Report to the licensee or other entity that no FFD policy violation has occurred. 2) Evaluate the positive confirmatory test result and medical explanation to determine if use of the drug and/or the medical condition poses a potential risk to public health and safety. 3) If a risk to public health exists, ensure that a determination of fitness is performed. Other: 	<p>§ 26.185(k) states:</p> <p>“Results consistent with legitimate drug use. If the MRO determines that there is a legitimate medical explanation for a positive confirmatory drug test result, and that the use of a drug identified through testing was in the manner and at the dosage prescribed, and the results do not reflect a lack of reliability or trustworthiness, then the donor has not violated the licensee’s or other entity’s FFD policy. The MRO shall report to the licensee or other entity that no FFD policy violation has occurred. The MRO shall further evaluate the positive confirmatory test result and medical explanation to determine whether use of the drug and/or the medical condition poses a potential risk to public health and safety as a result of the individual being impaired while on duty. If the MRO determines that such a risk exists, he or she shall ensure that a determination of fitness is performed.”</p>

E. Retesting an Aliquot of a Single Specimen or Split-Specimen Testing			
Num.	Question	Answer	NRC Regulation(s)
E1	Who is authorized to request the reanalysis of an aliquot of a single specimen or the analysis of the split specimen for a positive, adulterated, substituted, or invalid test result?	<ul style="list-style-type: none"> • The donor is the only individual that may request the MRO to direct such testing. • The MRO is the only individual who can request such testing. • The licensee is permitted to direct such testing. • Other: 	<p>§ 26.185(l) states: “The MRO is also the only individual who may authorize a reanalysis of an aliquot of the original specimen or an analysis of any split specimen (Bottle B) in response to a request from the donor tested.”</p>
E2	If the testing performed at the second HHS-certified laboratory <u>reconfirms</u> the initial laboratory’s test result, what action do you take as the MRO?	<ul style="list-style-type: none"> • Report an FFD policy violation to the licensee or other entity. • Other: 	<p>§ 26.185(n) states: <i>“Evaluating results from a second laboratory. After a second laboratory tests an aliquot of a single specimen or the split (Bottle B) specimen, the MRO shall take the following actions if the second laboratory reports the following results:</i> (1) If the second laboratory reconfirms any positive test results, the MRO may report an FFD policy violation to the licensee or other entity; (2) If the second laboratory reconfirms any adulterated, substituted, or invalid validity test results, the MRO may report an FFD policy violation to the licensee or other entity.”</p>

E. Retesting an Aliquot of a Single Specimen or Split-Specimen Testing			
Num.	Question	Answer	NRC Regulation(s)
E3	If the testing performed at the second HHS-certified laboratory <u>fails to reconfirm</u> the initial laboratory's test result, what action do you take as the MRO?	<ul style="list-style-type: none"> • Report that no FFD policy violation has occurred. • Report an FFD policy violation to the licensee or other entity. • Other: 	<p>§ 26.185(n) states: <i>"Evaluating results from a second laboratory.</i> After a second laboratory tests an aliquot of a single specimen or the split (Bottle B) specimen, the MRO shall take the following actions if the second laboratory reports the following results: . . . (3) If the second laboratory does not reconfirm the positive test results, the MRO shall report that no FFD policy violation has occurred; or (4) If the second laboratory does not reconfirm the adulterated, substituted, or invalid validity test results, the MRO shall report that no FFD policy violation has occurred."</p>
E4	Can you as the MRO request retesting of an aliquot of the original specimen or the analysis of the split specimen if you question the accuracy of a positive, adulterated, substituted, or invalid test result?	<p>Yes, I can request retesting at second HHS-certified laboratory. Yes, I can request retesting at the same HHS-certified laboratory. Other:</p>	<p>§ 26.185(l) states: <i>"Retesting authorized.</i> Should the MRO question the accuracy or scientific validity of a positive, adulterated, substituted, or invalid test result, only the MRO is authorized to order retesting of an aliquot of the original specimen or the analysis of any split specimen (Bottle B) in order to determine whether the FFD policy has been violated. Retesting must be performed by a second HHS-certified laboratory. The MRO is also the only individual who may authorize a reanalysis of an aliquot of the original specimen or an analysis of any split specimen (Bottle B) in response to a request from the donor tested."</p>

E. Retesting an Aliquot of a Single Specimen or Split-Specimen Testing			
Num.	Question	Answer	NRC Regulation(s)
E5	What is the appropriate course of action when you as the MRO determine that a positive, adulterated, substituted, or invalid test result is scientifically insufficient?	<ul style="list-style-type: none"> • Declare that a drug or validity test result is not an FFD policy violation, but that a negative test result was not obtained. • Request retesting of the original specimen before making this decision if warranted. • If retesting is warranted, request that the reanalysis be performed by the same laboratory, or that an aliquot of the original specimen be sent for reanalysis to another HHS-certified laboratory. • Other: 	<p>§ 26.185(m) states:</p> <p><i>“Result scientifically insufficient.</i> Based on the review of inspection and audit reports, quality control data, multiple specimens, and other pertinent results, the MRO may determine that a positive, adulterated, substituted or invalid test result is scientifically insufficient for further action and may declare that a drug or validity test result is not an FFD policy violation, but that a negative test result was not obtained. In this situation, the MRO may request retesting of the original specimen before making this decision. The MRO is neither expected nor required to request such retesting, unless in the sole opinion of the MRO, such retesting is warranted. The MRO may request that the reanalysis be performed by the same laboratory, or that an aliquot of the original specimen be sent for reanalysis to another HHS-certified laboratory. The licensee testing facility and the HHS- certified laboratory shall assist in this review process, as requested by the MRO, by making available the individual(s) responsible for day-to-day management of the licensee testing facility or the HHS-certified laboratory, or other individuals who are forensic toxicologists or who have equivalent forensic experience in urine drug testing, to provide specific consultation as required by the MRO.”</p>
THAT WAS THE LAST QUESTION. THANK YOU FOR YOUR TIME AND INPUT.			

Attachment 4: Substance Abuse Expert Questionnaire

10 CFR Part 26
Substance Abuse Expert Questionnaire

Licensee	
Contact Person	
Inspection Date	
Inspector	

This questionnaire may be used by the U.S. Nuclear Regulatory Commission (NRC) inspector when evaluating the Substance Abuse Expert (SAE) supporting a licensee's or other entity's fitness-for-duty (FFD) program. Each question is accompanied by potential answers and the relevant requirement(s) in 10 CFR Part 26, Subpart H. This questionnaire is divided into the following two sections:

Section	Question Numbers
A. SAE Qualifications and Training	A1 – A7
B. Services provided by the SAE	B1 – B14

Num.	Question	Answer	NRC Regulation(s)
A. SAE Qualifications and Training			
A1	<p>Please describe your credentials to serve as a substance abuse expert for an NRC-regulated licensee under 10 CFR Part 26.</p> <p>[Request documentation to confirm qualifications]</p>	<ul style="list-style-type: none"> • Licensed physician. • Licensed or certified social worker. • Licensed or certified psychologist. • Licensed or certified employee assistance professional (EAP). • Alcohol and drug abuse counselor certified by the National Association of Alcoholism and Drug Abuse Counselors Certification Commission. • Alcohol and drug abuse counselor certified by the International Certification Reciprocity Consortium/Alcohol and Other Drug Abuse. • The individual does not meet the SAE credential requirement in 26.187(b). 	<p>§ 26.187(b) states:</p> <p><i>“Credentials.</i> An SAE shall have at least one of the following credentials:</p> <p>(1) A licensed physician;</p> <p>(2) A licensed or certified social worker;</p> <p>(3) A licensed or certified psychologist;</p> <p>(4) A licensed or certified employee assistance professional; or</p> <p>(5) An alcohol and drug abuse counselor certified by the National Association of Alcoholism and Drug Abuse Counselors Certification Commission or by the International Certification Reciprocity Consortium/Alcohol and Other Drug Abuse.”</p>
A2	Describe your knowledge and clinical experience in diagnosing and treating alcohol and controlled substance abuse disorders?	<ul style="list-style-type: none"> • List the information provided here: 	<p>§ 26.187(c) states:</p> <p><i>“Basic Knowledge.</i> An SAE shall be knowledgeable in the following areas:</p> <p>(1) Demonstrated knowledge of and clinical experience in the diagnosis and treatment of alcohol and controlled substance abuse disorders.”</p>

Num.	Question	Answer	NRC Regulation(s)
A. SAE Qualifications and Training			
A3	How do you remain up to date on the NRC drug and alcohol testing regulations in 10 CFR Part 26?	<ul style="list-style-type: none"> • I regularly review the NRC FFD website for information on the regulation. • I receive a newsletter that informs me of changes in the NRC's drug and alcohol testing regulations. • I have a copy of 10 CFR Part 26. • The licensee or other entity's staff provides me with any updates on the rule. • Other: 	§ 26.187(c) states: <i>"Basic Knowledge.</i> An SAE shall be knowledgeable in the following areas: . . . (3) Knowledge of this part and any changes thereto."
A4	Do you have a copy of the licensee or other entity's FFD program policy?	<ul style="list-style-type: none"> • Yes. • No. • Other: 	Understanding the specific testing requirements of a licensee or other entity's FFD program is a core component of the SAE's role because the NRC permits licensees and other entities to test at more stringent cutoff levels and for drugs in addition to those required in § 26.133 and §26.163.
A5	How do you remain up to date on the FFD program policies of the licensee or other entity that you provide services?	<ul style="list-style-type: none"> • I receive information from the FFD program manager if any changes are implemented. • I rely upon the policy that is provided to me by the FFD program. • Other: 	

Num.	Question	Answer	NRC Regulation(s)
A. SAE Qualifications and Training			
A6	<p>Describe the training that you have received to comply with the qualification training requirement in § 26.187(d)?</p> <p><u>Request:</u></p> <ul style="list-style-type: none"> • The date completed qualification training. • A copy of the certificate of completion for any courses attended. • A description of training(s) attended if available (web site address, training description). 	<ul style="list-style-type: none"> • List the information provided regarding qualification training: • I have not completed qualification training. • Other: 	<p>§ 26.187(d) states: <i>"Qualification training.</i> SAEs shall receive qualification training on the following subjects: (1) Background, rationale, and scope of this part; (2) Key drug testing requirements of this part, including specimen collection, laboratory testing, MRO review, and problems in drug testing; (3) Key alcohol testing requirements of this part, including specimen collection, the testing process, and problems in alcohol tests; (4) SAE qualifications and prohibitions; (5) The role of the SAE in making determinations of fitness and the return-to-duty process, including the initial evaluation, referrals for education and/ or treatment, the follow-up evaluation, continuing treatment recommendations, and the follow-up testing plan; (6) Procedures for SAE consultation and communication with licensees or other entities, MROs, and treatment providers; (7) Reporting and recordkeeping requirements of this part; and (8) Issues that SAEs confront in carrying out their duties under this part."</p>
A7	<p>After successfully completing initial qualification training, how many professional development hours must you complete, and over what period of time?</p>	<ul style="list-style-type: none"> • 12 CPE hours over 3 years. (Ask for certificate of completion, if applicable) • I don't know but I'd look the information up in the regulations after I take my qualification training. • Other: 	<p>§ 26.187(e) states: <i>"Continuing education.</i> During each 3-year period following completion of initial qualification training, the SAE shall complete continuing education consisting of at least 12 continuing professional education hours relevant to performing SAE functions."</p>

B. Services provided by the SAE			
Num.	Question	Answer	NRC Regulation(s)
B1	What are your responsibilities as an SAE?	<ul style="list-style-type: none"> • Evaluate individuals who have violated the substance abuse policy and make appropriate education/ treatment referrals, follow-up testing, and aftercare recommendations. [§ 26.187(g)] • Make determinations of fitness for substance abuse related issues. [§ 26.189(a)] • Other: 	<p>§ 26.187(g) states: <i>"Responsibilities and prohibitions.</i> The SAE shall evaluate individuals who have violated the substance abuse provisions of an FFD policy and make recommendations concerning education, treatment, return to duty, follow-up drug and alcohol testing, and aftercare. The SAE is not an advocate for the licensee or other entity, or the individual. The SAE's function is to protect public health and safety and the common defense and security by professionally evaluating the individual and recommending appropriate education/treatment, follow-up tests, and aftercare."</p> <p>§ 26.189(a)(1) states: "An SAE who meets the requirements of § 26.187 may determine the fitness of an individual who may have engaged in substance abuse and shall determine an individual's fitness to be granted authorization following an unfavorable termination or denial of authorization under this part, but may not be qualified to assess the fitness of an individual who may have experienced mental illness, significant emotional stress, or other mental or physical conditions that may cause impairment but are unrelated to substance abuse, unless the SAE has additional qualifications for addressing those fitness issues."</p>

B. Services provided by the SAE			
Num.	Question	Answer	NRC Regulation(s)
B2	For follow-up testing, does the NRC require a minimum number of tests to be performed AND over a specific period of time?	<ul style="list-style-type: none"> • Yes, a minimum of 15 unannounced tests to be conducted at least quarterly over a period of 3 years. Random and follow-up tests count towards the 15-test minimum. • A minimum of 15 tests on an unannounced basis and at least quarterly, but I can prescribe more based on the individual case. • No. • Other: 	<p>§ 26.69(b) states: “Authorization after a first confirmed positive drug or alcohol test result or a 5-year denial of authorization.</p> <p>(6) If the individual’s authorization was denied or terminated unfavorably for a first confirmed positive drug or alcohol test result and a licensee or other entity grants authorization to the individual, ensure that the individual is subject to unannounced testing at least quarterly for three calendar years after the date the individual is granted authorization. Both random and follow-up tests, as defined in § 26.31(c), satisfy this requirement. Verify that the individual has negative test results from a minimum of 15 tests distributed over the 3-year period. . . .”</p>
B3	Under what circumstances is an SAE authorized to make a determination of fitness?	<ul style="list-style-type: none"> • The SAE stated the three circumstances in § 26.187(g)(1). <ul style="list-style-type: none"> ○ potentially disqualifying information is identified regarding an individual who has applied for authorization ○ an individual has violated the substance abuse provisions of the FFD policy ○ an individual may be impaired by alcohol, prescription or over-the-counter medications, or illegal drugs • The SAE did not state all three circumstances in § 26.187(g)(1). • Other: 	<p>§ 26.187(g)(1) states: “The SAE is authorized to make determinations of fitness in at least the following three circumstances: (i) When potentially disqualifying FFD information has been identified regarding an individual who has applied for authorization under this part; (ii) When an individual has violated the substance abuse provisions of a licensee’s or other entity’s FFD policy; and (iii) When an individual may be impaired by alcohol, prescription or over-the-counter medications, or illegal drugs.”</p>

B. Services provided by the SAE			
Num.	Question	Answer	NRC Regulation(s)
B4	<p>Are you qualified to make a determination of fitness for mental illness, emotional stress, or other mental or physical conditions that may cause impairment but are unrelated to substance abuse?</p> <p>If the answer is <u>yes</u>, assess the qualifications (MD, psychologist, etc.).</p>	<ul style="list-style-type: none"> • Yes, I am a <u>clinical psychologist</u> so I am qualified to evaluate mental illness, emotional stress, and cognitive or psychological impairment from causes unrelated to substance abuse. [see §26.189(a)(2)] • Yes, I am a <u>psychiatrist</u> so I am qualified to assess an individual taking psychoactive medications consistently with one or more valid prescription(s). [see §26.189(a)(3)] • Yes, I am a <u>physician</u> so I am qualified to determine the fitness of an individual who may be ill, injured, fatigued, taking medications in accordance with one or more valid prescriptions, or using over-the-counter medications. [see §26.189(a)(4)] • No, I am specifically trained in substance abuse related issues, but do not have appropriate training to assess mental, emotional, or physical conditions that may cause impairment. • Other: 	<p>§ 26.189(a) states:</p> <p>“A professional called on by the licensee or other entity may not perform a determination of fitness regarding fitness issues that are outside of his or her specific areas of expertise. The types of professionals and the fitness issues for which they are qualified to make determinations of fitness include, but are not limited to, the following:</p> <p>(1) <u>An SAE who meets the requirements of § 26.187</u> may determine the fitness of an individual who may have engaged in substance abuse and shall determine an individual’s fitness to be granted authorization following an unfavorable termination or denial of authorization under this part, but may not be qualified to assess the fitness of an individual who may have experienced mental illness, significant emotional stress, or other mental or physical conditions that may cause impairment but are unrelated to substance abuse, unless the SAE has additional qualifications for addressing those fitness issues;</p> <p>(2) A <u>clinical psychologist</u> may determine the fitness of an individual who may have experienced mental illness, significant emotional stress, or cognitive or psychological impairment from causes unrelated to substance abuse. . . ;</p> <p>(3) A <u>psychiatrist</u> may determine the fitness of an individual who is taking psychoactive medications consistently with one or more valid prescription(s). . . ;</p> <p>(4) A <u>physician</u> may determine the fitness of an individual who may be ill, injured, fatigued, taking medications in accordance with one or more valid prescriptions or using over-the-counter medications. . . .”</p>

B. Services provided by the SAE			
Num.	Question	Answer	NRC Regulation(s)
B5	<p>Do you make determinations of fitness for for-cause testing?</p> <p><u>If yes</u>, how do you conduct the evaluation?</p> <p><u>If no</u>, skip to next question.</p>	<p>If yes:</p> <ul style="list-style-type: none"> • A face-to-face evaluation is required. • I perform face-to-face evaluations for my work. • By telephone. • Other: 	<p>§ 26.189(c) states:</p> <p>“A determination of fitness that is conducted for cause (i.e., because of observed behavior or a physical condition) must be conducted through face-to-face interaction between the subject individual and the professional making the determination. Electronic means of communication may not be used.”</p>
B6	<p>May an individual or the licensee or other entity that you have issued a determination of fitness for seek a second determination of fitness?</p>	<ul style="list-style-type: none"> • Yes. • No. • Other: 	<p>§ 26.189(d) states:</p> <p>“Neither the individual nor licensees and other entities may seek a second determination of fitness if a determination of fitness under this part has already been performed by a qualified professional employed by or under contract to the licensee or other entity. . . . Unless the professional who made the initial determination of fitness is no longer employed by or under contract to the licensee or other entity, only that professional is authorized to modify the evaluation and recommendations. When reasonably practicable, licensees and other entities shall assist in arranging for consultation between the new professional and the professional who is no longer employed by or under contract to the licensee or other entity, to ensure continuity and consistency in the recommendations and their implementation.”</p>

B. Services provided by the SAE			
Num.	Question	Answer	NRC Regulation(s)
B7	After you have made an initial determination of fitness, can you modify your evaluation and recommendations?	<ul style="list-style-type: none"> • Yes. • No. • Other: 	§ 26.189(d) states: “After the initial determination of fitness has been made, the professional may modify his or her evaluation and recommendations based on new or additional information from other sources including, but not limited to, the subject individual, another licensee or entity, or staff of an education or treatment program.”
B8	In providing services as a SAE, can you refer an individual to your private practice?	<ul style="list-style-type: none"> • No. • Yes. • Other: 	§ 26.187(g)(2)(i) states: “To prevent the appearance of a conflict of interest, the SAE may not refer an individual requiring assistance to his or her private practice or to a person or organization from whom the SAE receives payment or in which the SAE has a financial interest. The SAE is precluded from making referrals to entities with whom the SAE is financially associated.”
B9	In providing services as a SAE, can you refer an individual to a person or organization from whom you receive payment or have a financial interest?	<ul style="list-style-type: none"> No. Yes. Other: 	

B. Services provided by the SAE			
Num.	Question	Answer	NRC Regulation(s)
B10	Are there any exceptions to the NRC conflict of interest provisions in § 26.187(g)(2)?	<ul style="list-style-type: none"> • Yes: <ul style="list-style-type: none"> ○ A public agency (e.g., treatment facility) operated by a state, county, or municipality ○ A person or organization under contract to the licensee or other entity to provide alcohol or drug treatment and/or education services ○ The sole source of therapeutically appropriate treatment under the individual's health insurance program; ○ The sole source of therapeutically appropriate treatment reasonably available to the individual (reasonably located within the general commuting area). • No. • Other: 	<p>§ 26.187(g)(2)(ii) states:</p> <p>"There are four exceptions to the prohibitions contained in the preceding paragraph. The SAE may refer an individual to any of the following providers of assistance, regardless of his or her relationship with them:</p> <p>(A) A public agency (e.g., treatment facility) operated by a state, county, or municipality;</p> <p>(B) A person or organization under contract to the licensee or other entity to provide alcohol or drug treatment and/or education services (e.g., the licensee's or other entity's contracted treatment provider);</p> <p>(C) The sole source of therapeutically appropriate treatment under the individual's health insurance program (e.g., the single substance abuse in-patient treatment program made available by the individual's insurance coverage plan); or</p> <p>(D) The sole source of therapeutically appropriate treatment reasonably available to the individual (e.g., the only treatment facility or education program reasonably located within the general commuting area)."</p>

B. Services provided by the SAE			
Num.	Question	Answer	NRC Regulation(s)
B11	Explain the maintenance and security practices for the paper and electronic records you create related to your activities as an SAE?	<ul style="list-style-type: none"> • I maintain all records in accordance with HIPAA. • I keep electronic records on a computer that is password protected and only accessible by me. • I maintain paper documents in a locked file cabinet in my office which is also locked when I'm not working. • Other: 	§ 26.37 Protection of information states: “(a) Each licensee or other entity who is subject to this subpart who collects personal information about an individual for the purpose of complying with this part, shall establish, use, and maintain a system of files and procedures that protects the individual's privacy.”
B12	<p>If an individual requests that you provide a copy of their treatment records and/or records on a determination of fitness, may you do so?</p> <p><u>If yes</u>, is there a specific process that you follow?</p>	<ul style="list-style-type: none"> • Yes, but only after I receive a written request from the individual or his or her designated representative. • Yes, but only after I receive a signed information release and then I only provide the records to the FFD program manager who then provides them to the individual. • No, the records that I create are not to be released to the individual. • Other: 	§ 26.37 Protection of information states: “(d) Upon receipt of a written request by the subject individual or his or her designated representative, the FFD program, including but not limited to, the collection site, HHS-certified laboratory, <u>substance abuse expert (SAE)</u> , or MRO, possessing such records shall promptly provide copies of all FFD records pertaining to the individual, including, but not limited to, records pertaining to a determination that the individual has violated the FFD policy, drug and alcohol test results, MRO reviews, determinations of fitness, and management actions pertaining to the subject individual.”
B13	Do you serve as an SAE for any other licensee or other entity?	<ul style="list-style-type: none"> • Yes. • No. • Other: 	It is important to collect this information in situations where the individual is not adequately qualified to serve as an SAE. Also provides information on experience level/workload.

B. Services provided by the SAE			
Num.	Question	Answer	NRC Regulation(s)
B14	Did the SAE cooperate with the inspector and facilitate the inspection process, including producing all required records?	<ul style="list-style-type: none"> • Yes. • No, the interview could not be conducted because the SAE was unavailable to be interviewed. • No, the SAE did not provide all requested documents. • Other: 	<p>§ 26.187(f) states:</p> <p><i>“Documentation.</i> The SAE shall maintain documentation showing that he or she currently meets all requirements of this section. The SAE shall provide this documentation on request to NRC representatives, licensees, or other entities who are relying on or contemplating relying on the SAE’s services, and to other individuals and entities, as required by § 26.37.”</p>
THAT WAS THE LAST QUESTION. THANK YOU FOR YOUR TIME AND INPUT.			

Attachment 5: Blind Performance Test Sample Submissions (10 CFR 26.168)

This attachment provides guidance for use by the inspector(s) when evaluating a licensee's quarterly blind performance test sample (BPTS) submissions.

The BPTS submissions are a critical component of the quality assurance/quality control program that ensures the accuracy of HHS-certified laboratory testing and MRO test result reviews.

- Positive results are infrequent events for most sites (industry positive rate for all tests is well below 1 percent so most sites are seeing less than 1 positive in every 100 people tested).
- The drug-testing panels used by NRC licensees differ from the majority of Federal workplace drug-testing programs. Therefore, NRC licensees and other entities cannot rely on the HHS-certification of laboratories and performance testing process which is a part of the HHS laboratory certification and inspection process, in part, because:
 - Testing cutoff variability - NRC cutoffs may be different than those used by other Federal workplace drug-testing programs.
 - No Federal workplace drug-testing program employs special analyses testing of specimens with dilute validity test results and specimens collected under direct observation conditions, as specified under 10 CFR 26.163(a)(2).
 - NRC licensees may test for additional substances based on local drug use trends.
- The BPTS program validates the Medical Review Officer (MRO) review and MRO staff review of non-typical specimen test results (i.e., drug positive, adulterated, substituted, and dilute).
- Many of the 30-day reportable events under 10 CFR 26.719 received each year by the NRC pertain to the testing of BPTSs.
- The annual FFD program performance reports submitted under 10 CFR 26.717 also may contain information that a licensee did not meet the quarterly submission requirement for each BPTS type (e.g., did not submit the required number of adulterated BPTSs in the fourth quarter of the calendar year).

Attachment 5 provides information for the inspector(s) to evaluate compliance with the most common 10 CFR 26.168 quarterly BPTS requirement for a site following the initial 90-day period of any HHS-certified laboratory contract.

- The number of BPTSs submitted per quarter must be a minimum of 1 percent of all specimens tested (up to a maximum of 100) or 10 per quarter, whichever is greater. (10 CFR 26.168(a)(2))
- Unless the FFD program tests more than 1,000 specimens in a quarter (rare event, maybe a three-unit operating site in outage conditions), 10 BPTSs would be submitted per quarter as follows:
 - Positive for one or more drugs or drug metabolites (10 CFR 26.168(b))
(60 percent of 10 BPTSs per quarter = 6 BPTSs per quarter).

- Include all drugs in the site's drug-testing panel in each quarter (the minimum NRC panel in 10 CFR 26.133 and 26.163 includes 14 substances: marijuana metabolite, cocaine metabolite, 4 amphetamines (AMP) (amphetamine, methamphetamine, methylenedioxyamphetamine (MDA), methylenedioxymethamphetamine (MDMA)), 7 opioids (codeine (COD), morphine, 6-acetylmorphine, hydrocodone, hydromorphone, oxycodone, oxymorphone), and phencyclidine.
- If the site submits the minimum 6 BPTSs per quarter, this means that some BPTSs must contain more than one substance. Presently, no site only submits 6 BPTSs per quarter because of how BPTS suppliers formulate specimens.
- 2 BPTSs per quarter must be for marijuana metabolite. (10 CFR 26.168(b)(1))
- In a minimum of two quarters per year, replace the PCP sample with another cocaine sample. (10 CFR 26.168(b)(2))
- False negative challenge (10 percent of BPTSs per quarter, a minimum of 1 BPTS). This is a positive specimen that is formulated with a drug concentration closer to the testing cutoff level. (10 CFR 26.168(f))
- Validity testing challenges (20 percent of BPTSs per quarter, a minimum of 3 BPTSs = 1 adulterated, 1 substituted, and 1 dilute). (10 CFR 26.168(e))
- Negative test results (10 percent of BPTSs per quarter, must not contain a measurable amount of any drug or drug metabolites)

The table on the next page provides an example BPTS submission program for a site for one calendar year. While variability among sites will exist, what may be helpful to the inspector(s) is to evaluate the framework presented to ensure that the licensee is submitting the correct number and type of BPTS each quarter to meet the 10 CFR 26.168 requirements.

The example is divided into four quarters of the calendar year (i.e., January–March; April–June; July–September, and October–December). For each quarter, the BPTSs are sequentially numbered from 01 to 14.

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, OYXM 08: Cocaine 09: PCP	01: Marijuana 02: Marijuana 03: AMP, MAMP 04: MDMA, MDA 05: COD, MOR, 6-AM 06: HYC, HYM 07: OXYC, OYXM 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, OYXM 08: Cocaine 09: PCP	01: Marijuana 02: Marijuana 03: AMP, MAMP 04: MDMA, MDA 05: COD, MOR, 6-AM 06: HYC, HYM 07: OXYC, OYXM 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; OYXM: oxymorphone

Recommendations based on the BPTS submission example above:

- While the same number sequence of each BPTS is presented in each quarter (01 through 14), it is NOT recommended that a site submit the specimens in the same order throughout the quarter (would add predictability, which could alert the laboratory that these are BPTSs).
- For False Negative BPTS, the licensee chooses the substance or substances to be included in that specimen.

Attachment 6: Revision History for IP 81000.08

Commitment Tracking Number	Accession Number Issue Date Change Notice	Description of Change	Description of Training Required and Completion Date	Comment Resolution and Closed Feedback Form Accession Number (Pre-Decisional Non-Public Information)
N/A	ML12114A080 09/07/12 CN 12-020	Researched commitments made in the last four years and found none. IP developed to support security construction inspections under IMC 2200.	Training to be covered at the July 2013 Annual NSIR Counterpart Meeting.	N/A
N/A	ML24152A229 10/29/24 CN 24-033	This document has been revised as a result of a periodic review, as well as the Palisades Restart effort. This is a major revision therefore there are no track changes. Revisions were made to the IP to coincide with IP 71130.08, as a result of the review, editorial changes to adhere to IMC 0040, as well as the addition of IMC 2562 to the program applicability.	N/A	ML24152A227