

DOCKET NUMBER
PROPOSED RULE PR 26
 (67FR 07093)

DOCKETED
 USNRC

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September 23, 2002 (4:47PM)

OFFICE OF SECRETARY
 RULEMAKINGS AND
 ADJUDICATIONS STAFF

Fitness for Duty Comment Number 1
September 11, 2002

Purpose: To provide general comments on Sections A and B of the draft FFD rule.

Issue: The following general changes to Sections A and B are recommended. Additional comments and changes will be provided in specific topical areas

Proposed Text:

Subpart A - Administrative Provisions

§26.1 Purpose.

This part prescribes requirements and standards for the establishment and maintenance of fitness-for-duty (FFD) programs

§26.3 Scope.

- (a) The regulations in this part apply to licensees authorized to operate a nuclear power reactor.
- (b) The regulations in this part apply to licensees authorized to possess, use, or transport formula quantities of strategic special nuclear material (SSNM) under part 73 of this chapter.
- (c) The regulations in this part apply to a Corporation that obtains a certificate of compliance or an approved compliance plan under part 76 of this chapter only if the Corporation elects to engage in activities involving formula quantities of SSNM. When applicable, the requirements apply only to the Corporation and personnel specified in §26.25(a)(3)
- (d) Each combined operating permit holder, construction permit holder, and the licensees listed in this paragraph, shall comply with §§26.23, 26.27, 26.31(c) and (d), 26.35, 26.37, 26.39, 26.71, 26.181 and 26.189 of this part --
- (1) Combined operating permit and construction permit holders with a plant under active construction,
 - (2) Decommissioning nuclear power plants that have submitted a certification of permanent shutdown and removal of fuel from the reactor vessel under Part 50.82 of this chapter and continue to store irradiated nuclear fuel;
 - (3) Licensees authorized to conduct activities under part 72 of this chapter.

§26.5 Definitions.

Adulterated specimen means a urine specimen containing a substance that is not a normal constituent or containing an endogenous substance at a concentration that is not a normal physiological concentration.

Aliquot means a portion of a specimen used for testing. It is taken as a sample representing the whole specimen.

Blood Alcohol Concentration (BAC) means the mass of alcohol in a volume of blood, as measured by an evidential-grade breath alcohol analysis device or an alcohol saliva analysis device.

Calibrator means a solution of known concentration used to calibrate a measurement procedure or to compare the response obtained with the response of a test specimen/sample. The concentration of the analyte of interest in the calibrator is known within limits ascertained during its preparation. Calibrators may be used to establish a calibration curve over a range of interest.

Category IA Material means SSNM directly usable in the manufacture of a nuclear explosive device, except if.

- (1) The dimensions are large enough (at least 2 meters in one dimension, greater than 1 meter in each of two dimensions, or greater than 25 cm in each of three dimensions) to preclude hiding the item on an individual,
- (2) The total weight of 5 formula kilograms of SSNM plus its matrix (at least 50 kilograms) cannot be carried inconspicuously by one person, or
- (3) The quantity of SSNM (less than 0.05 formula kilogram) in each container requires protracted diversions in order to accumulate 5 formula kilograms

Chain of custody means procedures to account for the integrity of each specimen by tracking its handling and storage from point of specimen collection to final disposition of the specimen "Chain of custody" and "custody and control" are synonymous and may be used interchangeably.

Collection site means a place where individuals present themselves for the purpose of providing a specimen of their urine, oral fluids, and/or breath to be analyzed for the presence of drugs or alcohol.

Collector means a person who instructs and assists individuals at a collection site and who receives and makes an initial examination of the specimen(s) provided by those individuals.

Commission means the U S. Nuclear Regulatory Commission or its duly authorized representatives.

Confirmatory drug or alcohol test means a second analytical procedure to identify the presence of alcohol or a specific drug or drug metabolite in a specimen The purpose of a confirmatory test is to ensure the reliability and accuracy of an initial test result.

Confirmatory validity test means a second test performed on a different aliquot of the original urine specimen to further support a validity test result.

Confirmed positive test result means a non-negative test result that has been determined to be a violation of a FFD policy. For drugs other than alcohol, a confirmed positive test result is determined by the Medical Review Officer (MRO) after evaluation. For alcohol, a confirmed positive test result is determined without an MRO evaluation, based upon confirmatory test results from an evidential-grade breath alcohol analysis device.

Contractor/vendor (C/V) means any company, or an individual not employed by a licensee, that is providing work or services as described in § 26.251 of this part, either by contract, purchase order, verbal agreement, or other arrangement.

Control means a sample used to monitor the status of an analysis to maintain its performance within desired limits.

Cutoff level means the value set for designating a test result as non-negative.

Dilute specimen means a urine specimen with creatinine and specific gravity values that are lower than expected for human urine.

Donor means the individual from whom a specimen is collected.

Employment action means a change in job responsibilities or removal from a job, or the mandated implementation of a plan for substance abuse treatment in order to avoid a change in or removal from a job, in response to an employer's concern about the individual's use of drugs or alcohol.

Fuel handling means any activities involving the movement of irradiated nuclear fuel.

¹ § 26.25 is the operative section of who is covered in this part The scope may be construed as being too broad

HHS-certified laboratory means a laboratory that is certified to perform urine drug testing under the Department of Health and Human Services Mandatory Guidelines for Federal Workplace Drug Testing Programs (59 FR 29908, June 9, 1994), and all future revisions thereto.

Illegal drugs means those drugs included in Schedules I through V of the Controlled Substances Act, but not when used in accordance with a valid prescription or when used as otherwise authorized by law.

Initial drug test (also known as a screening test) means a test to eliminate "negative" specimens from further consideration and to identify the presumptively positive specimens that require confirmation or further testing.

Initial validity test means the first test used to determine if a specimen is adulterated, diluted, or substituted

Invalid result means the result reported by a HHS-certified laboratory for a specimen that contains an unidentified adulterant, contains an unidentified interfering substance, has an abnormal physical characteristic, or has an endogenous substance at an abnormal concentration that prevents the laboratory from completing testing or obtaining a valid drug test result

Legal action means a formal action taken by a recognized law enforcement authority, including, but not limited to, an arrest, charges, conviction, or the mandated implementation of a plan for substance abuse treatment in order to avoid a permanent record of an arrest or conviction, in response to --

- (1) the use, sale, or possession of illegal drugs,
- (2) the abuse of legal drugs, including alcohol, or
- (3) the refusal to take a drug or alcohol test

Licensee's testing facility means a drug testing facility operated by a licensee or one of its C/Vs to perform onsite initial tests of urine specimens.

Limit of detection (LOD) means the lowest concentration of an analyte that an analytical procedure can reliably detect, which should be significantly lower than the established cut-off levels

Limit of quantitation (LOQ) means the lowest concentration of an analyte at which the concentration of the analyte can be accurately determined under defined conditions.

Medical Review Officer (MRO) means a licensed physician responsible for receiving laboratory results generated by an employer's drug testing program who has knowledge of substance abuse disorders and has appropriate medical training to interpret and evaluate an individual's positive test result together with his or her medical history and any other relevant biomedical information.

Nominal 12-month frequency means the item is conducted on an annual basis or more frequently if appropriate but is allowed up to a 3-month extension beyond the specified 12-month (or annual) period to provide flexibility as long as the extension does not exceed 3-months over a 3-year period.²

Non-negative test result means a report by the HHS-certified laboratory that a specimen is adulterated, substituted, diluted, or positive for a drug or drug metabolite.

Oxidizing adulterant means a substance that acts alone or in combination with other substances to oxidize drugs or drug metabolites to prevent the detection of the drugs or drug metabolites, or affects the reagents in either the screening or confirmatory drug test. Examples of these agents include, but are not limited to, nitrites, pyridinium chlorochromate, chromium (VI)/chromates, bleach, iodine/iodide, halogens, peroxidase, and peroxide.

Potentially disqualifying FFD information means information demonstrating that an individual has,³

² Nominal used in §§26.29(b)(2) and 26.41(c) without adequate definition

³ Additional words/explanation may make the requirements clearer for the reader to understand.

- (1) violated a licensee or C/V FFD policy;
- (2) had authorization denied⁴ or terminated unfavorably 26.X here, and 26 X, 26.X in Subpart D - insert sections numbers when final] of this part;
- (3) used, sold, or possessed illegal drugs;
- (4) abused legal drugs;
- (5) subverted or attempted to subvert a drug or alcohol testing program;
- (6) refused to take a drug or alcohol test;
- (7) been subjected to a plan for substance abuse treatment (except for self-referral); or
- (8) had legal action or employment action, as defined herein, taken for alcohol or drug use.

Presumptive positive test result means the result of an initial test for alcohol indicating a BAC of 0.02 percent or higher, or the result of an initial test for drugs and drug metabolites that indicates the presence of some drug or drug metabolite and that could be confirmed through gas chromatography/mass spectrometry testing by an HHS-certified laboratory as a laboratory confirmed positive test result.

Protected area means an area encompassed by physical barriers and to which access is controlled, as defined in §73.2 of this chapter.

Quality control sample means a sample used to evaluate whether or not the analytical procedure is operating within predefined tolerance limits. Calibrators, controls, negative samples, and blind samples are collectively referred to as "quality control samples" and each as a "sample."

Reviewing official means the designated licensee or C/V employee who is responsible for reviewing and evaluating any potentially disqualifying FFD information obtained about an individual, including but not limited to the results of a determination of fitness, as defined in subpart C herein, in order to determine whether the individual may be granted and maintain authorization to perform activities within the scope of this part

Standard means a reference material of known purity or a solution containing a reference material at a known concentration

Strategic Special Nuclear Material (SSNM) means uranium-235 (contained in uranium enriched to 20 percent or more in the U-235 isotope), uranium-233, or plutonium 6

Substance abuse means the use, sale, or possession of illegal drugs, or the abuse of prescription and over-the-counter drugs, and alcohol.

Subversion and subvert the testing process mean an act to avoid being tested or to bring about an inaccurate drug or alcohol test result for oneself or others at any stage of the testing process, including selection and notification of individuals for testing, specimen collection, specimen analysis, test result reporting, and adding an adulterant to a specimen.

Substituted specimen means a urine specimen with creatinine and specific gravity values that are so diminished or so divergent that they are not consistent with normal human urine.

Transporter means a general licensee pursuant to 10 CFR 70.20(a), who is authorized to possess formula quantities of SSNM in the regular course of carriage for another or storage incident thereto, and includes the driver or operator of any conveyance, and the accompanying guards or escorts.

§26.7 Interpretations.

⁴ The term denied includes revoked. Revoked may mean placed on hold for administrative reasons and is not a denial of access in the rule sense of the word. Revoke should not be used anywhere in this rule when it means denied.

⁵ The term is not in definitions so may be confusing as not spelled out until later in the document.

⁶ What will the situation be with MOX (mixed oxide) nuclear fuel?

Except as specifically authorized by the Commission in writing, no interpretation of the meaning of the regulations in this part by any officer or employee of the Commission other than a written interpretation by the General Counsel will be recognized to be binding upon the Commission

§26.9 Exemptions.

The Commission may, upon application of any interested person or upon its own initiative, grant such exemptions from the requirements of the regulations in this part as it determines are authorized by law and will not endanger life, property, or the common defense and security, and are otherwise in the public interest. Any exemptions submitted under this part must meet the provisions of 10.12 or §70.14, as applicable.

§ 26.11 Communications.

Except where otherwise specified in this part, all communications and reports concerning the regulations in this part must be addressed to the NRC Document Control Desk, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001. Copies of all communications must be sent to the appropriate regional office and resident inspector. Communications and reports may be delivered in person at the Commission's offices at 11555 Rockville Pike, One White Flint North, Rockville, Maryland, or at the Commission's Public Document Room located at One White Flint North, 11555 Rockville Pike (first floor), Rockville, MD.

§26.13 Information collection requirements: OMB approval.

(a) The Nuclear Regulatory Commission has submitted the information collection requirements contained in this part to the Office of Management and Budget (OMB) for approval as required by the Paperwork Reduction Act (44 U.S.C. 3501 et seq.). The NRC may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. OMB has approved the information collection requirements contained in this part under control number (update for proposed rule).

(b) The approved information collection requirements contained in this part appear in 26.X (insert when section numbers are determined.)

§ 26.15 Future revisions.

Changes to this part that are necessary to conform to the Department of Health and Human Services "Mandatory Guidelines for Federal Workplace Drug Testing Programs," (59 FR 29908, June 9, 1994), and all future revisions thereto, do not require a backfit analysis⁷ pursuant to §50.109 of this chapter, [in accordance with (insert recent FR notice regarding combined backfit/regulatory analysis guidance) the NRC's rulemaking process.] Changes to this part that depart from the provisions of the "Mandatory Guidelines for Federal Workplace Drug Testing Programs," and all future revisions thereto, are subject to the provisions of §50.109 of this chapter.

⁷ This seems to be a blank check. When FFD technical or process improvements are authorized by HHS they should be passed on to the industry by ensuring the wording in this rule is not exclusionary. However, if HHS adopts some provision that would be troublesome for the industry, the backfit rule is the industry's only official means of objection.

Subpart B - Program Elements

§26.21 FFD program.

Each licensee subject to this part shall establish and implement a FFD program that complies with the applicable requirements in this part.

§26.23 Performance objectives.

Fitness-for-duty programs must --

- (a) Provide high assurance that individuals subject to this part are trustworthy and reliable from a fitness-for-duty standpoint 89;
- (b) Provide reasonable assurance that individual subject to this part are not under the influence of any substance, legal or illegal, or mentally or physically impaired from any cause, which in any way adversely affects their ability to safely and competently perform their duties;
- (c) Provide reasonable measures for the early detection of persons who are not fit to perform activities within the scope of this part, and
- (d) Have a goal of achieving a workplace free of illegal drugs and alcohol¹⁰, and the effects of such substances

§26.25 Individuals subject to the FFD program.

(a) The following individuals shall be subject to the FFD program --

- (1) All persons granted unescorted access to protected areas;
- (2) All persons required by the licensee to physically report to a licensee's Technical Support Center (TSC) or Emergency Operations Facility (EOF), in accordance with licensee emergency plans and procedures,
- (3) SSNM licensee and transporter personnel who --
 - (i) Are granted unescorted access to Category IA Material,
 - (ii) Create or have access to procedures or records for safeguarding SSNM;
 - (iii) Measure Category IA Material,
 - (iv) Transport or escort Category IA Material; or
 - (v) Guard Category IA Material
- (4) All FFD program personnel involved in the day-to-day operations of the program as defined by the licensee or C/V that --¹¹
 - (i) Can link test results with the individual who was tested before a FFD policy violation determination is made;
 - (ii) Make determinations of fitness;
 - (iii) Make authorization decisions;
 - (iv) Are involved in the selection or notification of individuals for testing; or
 - (v) Are involved in the collection or onsite testing of specimens.

⁸ Phrase inserted to avoid infringement on the access authorization requirements

⁹ This is not the purpose of this rulemaking

¹⁰ How will and inspector/auditor evaluate whether this has been achieved? Will a positive random test result obviate achieving the goal? Then what?

¹¹ The subject can be interpreted too broadly. By licensee or C/V specifying who these people are and their expected duties in appropriate procedures necessary structure would be provided while minimizing subjectivity

(5) All persons who --

- (i) Are responsible for handling irradiated fuel or SSNM movement control center,
- (ii) Have unescorted access to areas containing irradiated fuel.

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(b) The following individuals are not subject to the FFD program --

(1) Persons who are not employed by the FFD program, who do not routinely provide FFD program services, and whose normal workplace is not at the licensee's facility, but who may be called upon to provide a FFD program service, including, but not limited to, collecting specimens for drug and alcohol testing, performing behavioral observation, or providing input to a determination of fitness. Such persons may include, but are not limited to, hospital, employee assistance program (EAP), or substance abuse treatment facility personnel, or other medical professionals,

(2) NRC employees, law enforcement personnel, or offsite emergency fire and medical response personnel while responding onsite;

(3) SSNM transporter personnel who are subject to U.S. Department of Transportation drug or alcohol fitness programs that require random testing for drugs and alcohol

§26.27 Written policy and procedures.

(a) General. Each licensee subject to this part, and each C/V with a licensee-approved FFD program, shall establish, implement, and maintain written policies and procedures designed to meet the general performance objectives and applicable requirements of this part.

(b) Policy. Licensees and C/Vs shall prepare a clear and concise FFD policy statement and make a copy of the most current revision of this statement readily available to all individuals subject to the policy. Methods of making the statement readily available include, but are not limited to, posting the policy in multiple work areas, providing individuals with brochures, or allowing individuals to print out the policy from a computer. The policy statement must be written in sufficient detail to provide affected individuals with information on what is expected of them and what consequences may result from lack of adherence to the policy. At a minimum, the written statement shall --

(1) Describe the consequences of the use, sale, or possession of illegal drugs on or off site, and the abuse of legal drugs, including alcohol,

(2) Describe the expectation that individuals who are notified that they have been selected for random testing will report to the collection site as soon as reasonably practicable;

(3) Describe the consequences of refusals to provide a specimen for testing and subversion of the testing process;

(4) Prohibit the consumption of alcohol, at a minimum:

(i) Within an abstinence period of 5 hours preceding any scheduled working tour; and

(ii) During the period of any working tour.

¹² These categories of people all are required to have UAA/UA to the PA and should not be singled out here. The intent should be on those individuals who have the ability to influence the outcome or are a potential threat (in a practical sense) to program viability

(5) Describe Fitness-for-duty requirements for licensee personnel required to physically report to a licensee's Technical Support Center (TSC) or Emergency Operations Facility (EOF), in accordance with the licensee's emergency plans and procedures; 13

(6) Convey that abstinence from alcohol for the five hours preceding any scheduled working tour is considered to be a minimum that is necessary but may not be sufficient to ensure the individual is fit for duty;

(7) Address other factors that could affect fitness for duty such as mental stress, fatigue, illness, and the use of prescription and over-the-counter medications that could cause impairment,

(8) Provide a description of programs that are available to personnel desiring assistance in dealing with drug, alcohol, or other problems that could adversely affect the performance of activities within the scope of this part;

(8) Describe the consequences of violating the policy; and

(9) Describe the individual's responsibility to report any legal actions.

(c) Procedures. The licensee and C/V shall prepare written procedures that describe the methods to be used in implementing the FFD policy and the requirements of this part. The procedures shall --

(1) Describe the methods and techniques to be used in testing for drugs and alcohol, including procedures for protecting the individual providing a specimen and the integrity of the specimen, and the quality controls used to ensure the test results are valid and attributable to the correct individual.

(2) Describe immediate and follow-up actions that will be taken, and the procedures to be used, in those cases where individuals subject to this part are determined to have -

- (i) Been involved in the use, sale or possession of illegal drugs,
- (ii) Consumed alcohol during the mandatory pre-work abstinence period, while on duty, or to excess before reporting to duty, as demonstrated with a test that can be used to determine BAC;
- (iii) Attempted to subvert the testing process by adulterating or diluting specimens (in vivo or in vitro), substituting specimens, or by any other means;
- (iv) Refused to provide a specimen for analysis; or
- (v) Had legal action taken on a drug- or alcohol-related charge.

(3) Describe the process to ensure that persons called in to perform an unscheduled working tour are fit for duty. Consumption of alcohol during the abstinence period shall not by itself preclude a licensee from using individuals needed to respond to an emergency. At a minimum --

(i) The procedure must require a statement to be made by a called-in person as to whether the individual considers himself or herself fit for duty and whether the individual has consumed alcohol within the pre-duty abstinence period stated in the policy;

(ii) If alcohol has been consumed within this period and the person is called in, the procedure must --

(A) Require a determination of fitness by breath alcohol analysis or other means, and

(B) Require the establishment of controls and conditions under which the individual who has been called-in can perform work, if necessary.

(iii) If the individual reports that he or she considers himself or herself unfit for duty for other reasons, including illness, fatigue, or other potentially impairing conditions, and the person is called in, the procedure must require the establishment of controls and conditions under which the individual can perform work, if necessary.

(4) Describe the process to be followed if an individual's behavior raises a concern regarding possible possession, use or sale of illegal drugs, possession of alcohol on-site, or impairment of any kind that may constitute a risk to the health and safety of the public. The procedure must require that persons who have a concern about another individual's behavior contact the appropriate designated 14personnel to report the concern. The procedure also must

13 The TSC/EOF should not be under (4) so (iii) has been deleted and reworded as (5)

14 There are multiple avenues to get concerns into the system and the licensee designates who and how to report. It is not necessarily to FFD program personnel -- it is usually the individual's supervisor

state that the decision to conduct a determination of fitness of an individual who may be impaired, which may include, but is not limited to testing for drugs or alcohol, shall be made by appropriate designated personnel ¹⁵

§26.29 Training.

(a) Content of training. Licensees and C/Vs must ensure that individuals subject to this part have the knowledge, skills and abilities (KSAs) required to implement their responsibilities under the FFD policy. This is demonstrated by passing a comprehensive examination that includes an understanding of the following KSAs:¹⁶

- (1) Knowledge of the policy and procedures that apply to the individual and the consequences of a lack of adherence to the policy;
- (2) Knowledge of the individual's role and responsibilities under the FFD program, including the responsibility to report fitness concerns;
- (3) Knowledge of the roles and responsibilities of others, such as the MRO, and the human resources, FFD and EAP staffs;
- (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, including alcohol,
- (6) Knowledge of the effects of prescription and over-the-counter drugs and dietary conditions that have the potential to affect job performance;
- (7) Knowledge of prescription and over-the-counter drugs and dietary conditions that have the potential to affect drug and alcohol test results,
- (8) Ability to recognize drugs and indications of the use, sale, or possession of drugs;
- (9) Ability to observe and detect performance degradation, indications of impairment, or behavioral changes; and

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(b) Training administration. Licensees and C/Vs shall ensure that individuals performing activities under this part are trained, as follows --

- (1) Training for all personnel must be completed prior to an initial assignment of duties within the scope of this part.
- (2) Refresher training must be completed on a nominal 12-month frequency (as defined in Subpart A)¹⁸ Individuals who demonstrate an understanding of the training objectives by passing a comprehensive annual examination may forgo the refresher training
- (3) Successful completion of initial or refresher training requires demonstration an understanding of the KSAs in paragraph (a) of this section. The examination must include a comprehensive random sampling of all KSAs with

¹⁵ There will be additional comments concerning this paragraph

¹⁶ Mastery is a term that would ensure unintended consequences without extensive definition. The rewording serves the same purpose

¹⁷ Redundant to (2) above—if more is needed it should be included there

¹⁸ The definition is the better way to convey this concept

questions that test each KSA, including at least one item for each KSA. The examination must be administered under the supervision of a proctor¹⁹. The minimum passing score required shall be 80%. Remedial training and testing is required for individuals who fail to answer correctly at least 80% of the test questions

(4) Initial and refresher training may be delivered using a variety of media, including, but not limited to, classroom lectures, required reading, video, or computer-based training systems. The licensee or C/V must monitor that the training occurs and provide a qualified instructor who is able to answer questions in the course of completion.

(5) Licensees may accept training of individuals who have been subject to a part 26 program and who have had initial or refresher training, or successfully demonstrated an understanding of the required KSAs, within the prior 12 months

§26.31 Drug and alcohol testing.

(a) General. To provide a means to deter and detect substance abuse, licensees shall implement drug and alcohol testing programs for persons subject to this part

(b) FFD program personnel. Licensees and C/Vs shall carefully select and monitor FFD program personnel, as defined in 26.25(a)(4) of this subpart, based upon the highest standards for honesty and integrity, and shall implement measures to ensure that these standards are maintained. These measures must ensure that the honesty and integrity of such persons is not compromised or subject to influence attempts due to personal relationships with any individuals subject to testing, an undetected or untreated substance abuse problem, or other factors. At a minimum,

(1) Supervisors, co-workers within the same work group, and relatives of the individual being tested shall not perform any collection, assessment, or evaluation procedures unless monitored in accordance with licensee or C/V procedures. ²⁰

(2) Appropriate background investigations, ²¹ and psychological evaluations of the FFD program personnel must be completed before assignment to tasks directly associated with administration of the FFD program and periodically updated, and

(3) FFD program personnel shall be subject to a behavioral observation program designed to assure that they continue to meet the highest standards for honesty and integrity.

(c) Conditions for testing. Licensees shall administer drug and alcohol tests under the following conditions²² --

(1) Within 30 days before the assignment to activities within the scope of this part, unless the individual meets the conditions for an exemption described in §§26.XX and 26.XX of this part,

(2) In response to a for-cause²³ situation of observed behavior or physical condition that creates a reasonable suspicion of possible substance abuse,

(3) As soon as practical after an event involving a failure in individual performance that resulted in --

(i) a personal injury, such as an injury that requires medical treatment that is recordable under USDOL OSHA

¹⁹ Proctor is adequate as defined by Webster. The proctor is only there to prevent cheating and maintain such things as time requirements.

²⁰ The procedure covers this to avoid unintended consequences of lack of clarity of specific requirements.

²¹ FFD program personnel are required to be covered by UAA/UA under the AA program specified in § 26.25(a)(1)

²² Current reporting is done by category: pre-access, for-cause (post-accident or observed behavior), random, follow-up, and other. This section is not conducive to continuing these categories.

We recommend that reporting for NRC tracking be continued in the same categories that have worked for over a decade—requires reorganization of this section for implementation clarity.

²³ Of the three conditions, this one has traditionally been titled "for-cause" as well as (3) but not (1).

²⁴ Per NRC at August Meeting

standards contained in 29 CFR § 1904.7²⁴ and subsequent amendments thereto and results in lost work time,
 (ii) a radiation exposure or release of radioactivity in excess of regulatory limits, or
 (iii) actual or potential substantial degradations of the level of safety of the plant;
 (4) After receiving credible information that an individual is abusing drugs or alcohol;
 (5) Before an individual's authorization is reinstated following a violation of the substance abuse provisions of the FFD policy;

(6) As part of a follow-up plan to verify continued abstinence from substance abuse; and

(7) On a statistically random and unannounced basis so that all persons in the population subject to testing have an equal probability of being selected and tested.

(d) General requirements for conducting drug and alcohol testing.

(1) Random testing.

(i) Random testing must include testing during all types of work periods, including weekends, backshifts, and holidays
 (ii) At a minimum, random tests must be administered by the FFD program on a nominal weekly frequency and at various times during the day.
 (iii) Individuals selected for random testing must be required to report to the collection site as soon as reasonably practicable after notification
 (iv) Reasonable efforts must be made to test persons selected for random testing. Persons offsite when selected for testing, and not reasonably available for testing when selected, must be tested as soon as reasonably practicable, that is within a reasonable period of time in accordance with the licensee's or C/V's testing program procedures,²⁵ and without notification to the individual until immediately before he or she reports for the test.
 (v) A person completing a test shall be immediately eligible for another unannounced test
 (vi) The sampling process used to select individuals for random testing shall ensure that the number of random tests performed annually is equal to at least 50% of the workforce population that is subject to the FFD program

(2) Cutoff levels. Licensees must, at a minimum, apply the cutoff levels published in the HHS Guidelines for both initial and confirmatory validity²⁶ drug testing. Licensees, at their discretion, may implement programs with lower cutoff levels. If a licensee implements lower cutoff levels than those published in the HHS Guidelines, and an individual is determined to have a confirmed positive test result using the licensee's more stringent cutoff levels, the individual must be subject to all management actions and sanctions required by the licensee's policy and this part, as if the individual had a confirmed positive test result using the HHS Guidelines' cutoff levels.

(3) Substances tested. Licensees shall, at a minimum, test for alcohol and the panel of drugs specified in the HHS Guidelines, and any future revisions thereto

(i) In addition, licensees may consult with local law enforcement authorities, hospitals, and drug counseling services to determine whether other substances with abuse potential are being used in the geographical locale of the facility and by the local workforce that may not be detected in the HHS panel.

(A) When appropriate, other substances so identified may be added to the panel of substances for testing

(B) Appropriate cutoff limits must be established by the licensee for these substances.

(C) The licensee shall establish rigorous testing procedures for these substances that are consistent with the intent of this part, so that the appropriateness of the use of these substances can be evaluated by the MRO.

(ii) Licensees may also test for any illegal drugs or any other substances suspected of having been abused by an individual and may consider any detected drugs or metabolites when determining appropriate action under Subpart D of this part. Any detected drugs or metabolites may be considered in the analysis of any specimen suspected of being

²⁴ Per NRC at August Meeting

²⁵ Puts the specifics of what "reasonably practicable" means in procedures—unless defined must be consistent throughout—add to §26.27(b)(2), etc. Note highlighted in yellow where appearing

²⁶ Wording was not clear—believe reference is to validity tests only

adulterated, diluted (in vivo or in vitro), substituted, or tampered with by any other means.

(4) Drug testing.

(i) Urine specimens must be forwarded to a laboratory certified by HHS, except that licensees may conduct initial validity and drug tests of urine aliquots to determine which specimens are valid and negative and need no further testing, provided the licensee's staff possesses the necessary training and skills for the tasks assigned, the staff's qualifications are documented, and adequate quality controls for the testing are implemented.

(ii) Testing of urine specimens for drugs, except initial tests performed by licensees under paragraph (i), must be performed in a laboratory certified by HHS for that purpose consistent with its standards and procedures for certification. Except for suspect specimens submitted for special processing, specimens sent to HHS-certified laboratories must be subject to initial validity and drug testing by the laboratory. Specimens screened as non-negative must be subject to confirmatory testing by the laboratory in accordance with the requirements of the HHS Guidelines. Licensees shall ensure that all specimens of at least 1527 milliliters (mL) are tested and that laboratories report results for all specimens sent for testing, including blind performance test specimens.

(5) Alcohol testing. Initial tests for alcohol must be administered by breath or oral fluids analysis using alcohol analysis devices meeting the requirements described in 26 XX of Subpart E of this part. If the initial test shows a BAC of 0.02 percent or greater, a confirmatory test for alcohol must be performed. The confirmatory test must be performed with a breath alcohol analysis device meeting the evidential standards described in §26.XX. A confirmatory test result for alcohol must be declared positive at the following BACs --

(i) 0.04 percent BAC at any time, or

(ii) 0.03 percent BAC or greater, if the individual has been in a work status for at least one hour (including any breaks for rest, lunch, dental/doctor appointments, etc.); or

(iii) 0.02 percent BAC or greater, if the individual has been in a work status for at least two hours (including any breaks for rest, lunch, dental/doctor appointments, etc.)

(6) If an individual has a medical condition that makes collection of breath, oral fluids, or urine specimens difficult or hazardous, the MRO may authorize an alternative evaluation process, tailored to the individual case, for determining whether a violation of the FFD policy has occurred, provided this process includes measures to prevent subversion and can achieve results comparable to those produced by urinalysis for illegal drugs and breath analysis for alcohol.

(7) Specimens collected under NRC regulations may only be designated or approved for testing as described in this part and shall not be used to conduct any other analysis or test without the permission of the tested individual.

(e) Use of specimen collection for drug- and alcohol-testing services at a local hospital or other organization that meet the requirements of 49 CFR 40, "Procedures for Department of Transportation Workplace Drug and Alcohol Testing Programs" (65 FR 41944, August 9, 2001) is acceptable for the following individuals -

(1) FFD program personnel listed in 26.25(a)(4) of this part, and

(2) Personnel listed in 26.25(a)(5) of this part

§26.33 Behavioral Observation

Licensees and C/Vs with approved FFD programs must assure that individuals performing activities under this part are subject to behavioral observation by observers trained to detect behaviors that may indicate possible possession, use or sales of illegal drugs, possession of alcohol on-site, or impairment that, if left unattended, may constitute a risk to the health and safety of the public. Individuals assigned to perform activities within the scope of

²⁷ It is not clear whether a second specimen of minimum 27 mL is also required. Which is the official specimen, etc.? Text throughout (see 26.107) needs to be clear on this.

²⁸ The report is usually made to the supervisor who is probably not a FFD program person but would arrange for the determination of fitness test with that group. A previous section has already told them how to do this.

this part must report fitness concerns in accordance with the appropriate licensee or C/V program. 28. The MRO is excluded from this requirement.²⁹

§26.35 Employee assistance programs

Each licensee subject to this part, and each C/V with a licensee-approved FFD program, shall maintain an employee assistance program (EAP) to strengthen the FFD program by offering assessment, short-term counseling, referral services, and treatment monitoring to its employees with problems that could adversely affect the performance of activities within the scope of this part. Licensees are not required to provide EAP services to C/V employees. Employee assistance programs must be designed to achieve early intervention and provide for confidential assistance. The EAP staff shall inform licensee or C/V management, as appropriate, when a determination has been made that any individual's condition constitutes a hazard to himself or herself or others, including those who have self-referred.

§26.37 Protection of information.

(a) Each licensee subject to this part, and any C/V upon which a licensee relies, that collects personal information on an individual for the purpose of complying with this part, shall establish and maintain a system of files and procedures for the protection of the personal information. Records shall be maintained and used with the highest regard for individual privacy by limiting access to those individuals listed in (b)(1) through (b)(9) of this section

(b) Licensees and C/Vs must obtain a signed consent from the subject individual that authorizes the disclosure of the personal information collected and maintained to persons other than -

- (1) assigned MROs;
- (2) other licensees and C/Vs or their authorized representatives, legitimately seeking the information as required by this part for unescorted access decisions and who have obtained a release from the subject individual,
- (3) NRC representatives;
- (4) appropriate law enforcement officials under court order;
- (5) the subject individual or his or her representative, as designated in writing by the individual for specified FFD matters;
- (6) licensee and C/V representatives who have a need to have access to the information in performing assigned duties, including determinations of fitness, audits of licensee or C/V FFD programs, and human resources or personnel functions;
- (7) the presiding officer in a judicial or administrative proceeding initiated by the subject individual,
- (8) persons deciding matters on review or appeal; and
- (9) other persons pursuant to court order.

(c) Upon receipt of a written request by the subject individual, the licensee, C/V, or HHS-certified laboratory possessing such records shall promptly provide copies of all records pertaining to the determination of a violation of the FFD policy, including test results, MRO reviews, and management actions pertaining to the subject individual. Records relating to the results of any relevant laboratory certification review or revocation of certification

²⁸ The report is usually made to the supervisor who is probably not a FFD program person but would arrange for the determination of fitness test with that group. A previous section has already told them how to do this.

²⁹ The MRO must be excluded based upon professionalism. An MRO would be included if in a licensee's UAA/UA program.

proceeding must be obtained from the relevant laboratory and provided to the subject individual upon request

(d) Licensee and C/V contracts with HHS-certified laboratories and procedures for a licensee's testing facility shall require that test records be maintained in confidence, except as provided in paragraphs (b) and (c) of this section.

(e) This section does not authorize the licensee or C/V to withhold evidence of criminal conduct from law enforcement officials

§26.39 Review Process for FFD Policy Violations.

Each licensee subject to this part, and C/Vs with approved FFD programs, shall establish a procedure for their respective employees, and applicants for unescorted access, for the review of a determination that the individual has violated the FFD policy. The procedure must provide notice to the individual of the grounds for the determination that the individual has violated the FFD policy, and must provide an opportunity to respond and to submit additional relevant information. The procedure must provide for an objective and impartial review of the facts relating to the determination that the individual has violated the FFD policy. The review must be conducted by persons not associated with the administration of the FFD program, as described in §26.XX, and may include internal management. If the review finds in favor of the individual, the relevant records must be corrected. A licensee review procedure need not be provided to employees of C/Vs when the C/V is administering a drug and alcohol testing program for its applicants and employees.

§26.41 Audits and Corrective Action.

(a) General. Each licensee subject to this part is responsible for the continuing effectiveness of the FFD program, including FFD program elements that are provided by C/Vs, the FFD programs of any C/Vs that are accepted by the licensee, and the programs of the HHS-certified laboratories relied upon by a licensee and its C/Vs. Each licensee shall ensure that audits of these programs are conducted and that corrective actions are taken to resolve any problems identified.

(b) FFD program. Each licensee subject to this part, and C/Vs with approved FFD programs, shall ensure that the complete FFD program is audited as needed but no less frequently than every 36 months. Licensees and C/Vs are responsible for determining the appropriate frequency, scope, and depth of additional auditing activities within the 3-year period based on review of program performance indicators such as the frequency, nature, and severity of discovered problems, testing errors, personnel or procedural changes, previous audit findings, and "lessons learned."

(c) C/Vs and HHS-certified laboratories. Licensees' FFD program elements that are implemented by C/Vs, FFD services provided to the licensee by personnel who are off site or not under the direct daily supervision or observation of licensee personnel, and HHS-certified laboratories used by the licensee or C/V for drug testing and/or collection site services shall be audited nominally every 12 months. Organizations and professionals that provide FFD program services, but who are not routinely involved in providing services to a licensee's or C/V's FFD program under §26.X of this part, are exempt from this requirement. There is no requirement to audit program aspects of the HHS-certified laboratory that are covered by the HHS biennial audit program. Only licensee- or C/V-unique program aspects, (i.e., different cutoff levels or special testing requirements) must be audited.³⁰

(d) Contracts. Licensee's contracts with C/Vs and HHS-certified laboratories must reserve the right to audit the C/V, the C/V's subcontractors providing FFD program services, and the HHS-certified laboratories at any time, including at unannounced times, and to obtain all information and documentation reasonably relevant to the audits. Licensee contracts with C/Vs and HHS-certified laboratories must also provide the licensee with the ability to obtain copies of

³⁰ This is what we previously discussed but not rule text was found to reference this audit requirement. Whatever audit is expected, there needs to be a process to determine the date that the one year period (annual) begins for the conduct of Lab audits. Would it be from the effective date of the rule or the date a site completes implementation? This affects scheduling of the joint audits and will impact any site that has not performed such an audit. When does the first round of other routine audits need to be completed—can the current audit schedule continue as is?

any documents, including reviews and inspections pertaining to a laboratory's certification by HHS, and any other data that may be needed to assure that the C/V, its subcontractors, or the HHS-certified laboratory are performing their functions properly and that staff and procedures meet applicable requirements. In addition, before the award of a contract, the licensee shall ensure completion of pre-award inspections and/or audits of the procedural aspects of the C/V's or the HHS-laboratory's operations.

(e) Conduct of audits. Audits must focus on the effectiveness of the program and be conducted by individuals qualified in the subject(s) being audited, and independent of both FFD program management and personnel directly responsible for implementation of the FFD program.

(f) Audit results. The result of the audits, along with recommendations, if any, must be documented and reported to senior corporate and site management. C/Vs with licensee-approved FFD programs must also provide the licensees they serve with copies of the audit report. Each audit report must identify conditions adverse to the proper performance of the FFD program, the cause of the condition(s) and, when appropriate, recommend corrective actions. Management shall review the audit findings and take corrective actions, including re-audit of the deficient areas where indicated, to preclude, within reason, repetition of the condition. The resolution of the audit findings and corrective actions must be documented.

(g) Sharing of audits. Licensees may jointly conduct audits, or accept audits of C/Vs and HHS-certified laboratories that were conducted by other licensees subject to this part, when the services provided to the sharing licensees by the C/Vs and HHS-certified laboratories are the same.

(1) Licensees shall review audit records and reports to identify the areas not covered by the shared or accepted audit.

(2) Sharing licensees need not re-audit the same C/V or HHS-certified laboratory for the same period of time, except to audit program elements and services used by the licensee that were not addressed in the shared audit.

(3) Annual licensee inspections and audits of HHS-certified laboratories need not duplicate areas inspected in the most recent HHS certification inspection. However, licensees must review the HHS certification inspection records and reports to identify any areas in which the licensee uses services that were not addressed by the HHS certification inspection. Any additional areas identified by licensees must be audited.³¹

(4) Each sharing licensee and C/V shall maintain a copy of the shared audit and HHS certification inspection records and reports, to include findings, recommendations and corrective actions.

(5) If an HHS-certified laboratory loses its certification, in whole or in part, a licensee or C/V is permitted to immediately use another HHS-certified laboratory that has been audited within the previous 12 months by another NRC licensee having the same drug panel and cut-off levels. The licensee or C/V must ensure completion of an audit of any areas not audited by another licensee or C/V within 3 months of the change.

³¹ Is this really a sharing issue. It is more appropriate in (c) above.

Fitness for Duty Comments Number 2
Performance Objectives
September 11, 2002

Purpose: To discuss proposed changes to section 26.23, Performance Objectives, NRC footnote 203.

Issue: Early in the rule review process there was significant discussion on the performance objectives. There has been extensive discussion on the difference between "reasonable" and "high" and the intent of "achieving a workplace free of illegal drugs and alcohol."

We are concerned with the addition of the objective "are not vulnerable to coercion or influence attempts related to substance abuse" this late in the review process. In reviewing the rest of the draft rule we find no items that address the issue of coercion.

There is concern that "trustworthy and reliable" is primarily the providence of the Access Authorization rule. The proposed addition would make it clear that this rule is only looking at the fitness-for-duty aspects of this

Proposed Text:

§26.23 Performance objectives.

Fitness-for-duty programs must --

(a) Provide high assurance that individuals subject to this part are trustworthy and reliable from a fitness-for-duty standpoint ;

Fitness for Duty Comments Number 3
Training
September 16, 2002

Purpose: To discuss proposed changes to section 26.29, Training.

Issue: When introduced into the training section the term "knowledge, skills and abilities" was not fully integrated into the training section. Under a training program, the first step would be a job-task analysis (JTA) to determine the knowledge, skills and abilities (KSAs) required to perform the function. In this case the JTA has apparently been completed by the NRC and the items listed under (a) represent the set of KSAs needed to perform the function. Note that knowledge or ability is the first word of each set. No skill is apparently required. Each KSA should stand alone and should not need amplification if the JTA has been performed properly.

The examination is mentioned multiple times. Section (a) should focus on content and (b) on administration—that is at least what the words say. The exam is not content it is administration and does not belong in (a).

Having introduced KSAs, "training objectives" becomes an unneeded term.

Item (a)(10) does not seem to be an ability, and repeats program requirements described elsewhere in the rule. It is recommended this item be deleted and the knowledge part be included under (2). NRC footnote 219 is a program issue, not a training issue and does not need to be repeated here.

There are some minor issues of form here. For example, if an individual can forgo refresher training, how do we track it? When is it due again? It takes three extra lines to talk about credit at other facilities. It should be changed so that the individual has completed refresher training by taking the exam.

Proposed Text:(Line-in/out not used so you can see what it says)

§26.29 Training.

(a) Content of training. Licensees and C/Vs must ensure that individuals subject to this part have the knowledge, skills and abilities (KSAs) required to implement their responsibilities under the FFD policy. Training will, as a minimum, include the following KSAs:

- (1) Knowledge of the policy and procedures that apply to the individual and the consequences of a lack of adherence to the policy;
- (2) Knowledge of the individual's role and responsibilities under the FFD program, including the responsibility to report fitness concerns;
- (3) Knowledge of the roles and responsibilities of others, such as the MRO, and the human resources, FFD and EAP staffs;
- (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, including alcohol;
- (6) Knowledge of the effects of prescription and over-the-counter drugs and dietary conditions that have the potential to affect job performance;
- (7) Knowledge of prescription and over-the-counter drugs and dietary conditions that have the potential to affect drug and alcohol test results;

- (8) Ability to recognize drugs and indications of the use, sale, or possession of drugs;
- (9) Ability to observe and detect performance degradation, indications of impairment, or behavioral changes;
- (b) Training administration. Licensees and C/Vs shall ensure that individuals performing activities under this part are trained, as follows --
- (1) Training for all personnel must be completed prior to an initial assignment of duties within the scope of this part.
- (2) Refresher training must be completed on a nominal 12-month frequency. Individuals who demonstrate they have the knowledge, skills and abilities of paragraph (a) of this section by passing a comprehensive examination may be considered to have completing the refresher training.
- (3) Successful completion of initial or refresher training requires that an individual pass a comprehensive examination demonstrating they have the knowledge, skills and abilities of paragraph (a) of this section. The examination must include a comprehensive random sampling of all KSAs with questions that test each KSA, including at least one item for each KSA. The examination must be administered under the supervision of a proctor. The minimum passing score required shall be 80%. Remedial training and testing is required for individuals who fail to answer correctly at least 80% of the test questions.
- (4) Initial and refresher training may be delivered using a variety of media, including, but not limited to, classroom lectures, required reading, video, or computer-based training systems. The licensee or C/V must monitor that the training occurs and provide a qualified instructor who is able to answer questions in the course of completion.
- (5) Licensees may accept training of individuals who have been subject to a part 26 program and who have had initial or refresher training, within the prior 12 months.

Fitness for Duty Comments Number 4
Suitable Inquiry
September 16, 2002

Purpose: To discuss proposed changes to affecting suitable inquiry. This topic is complicated because it spans several portions of the rule. The related sections have been drawn together in this paper.

Issue: It appears that there is relatively close agreement on what is required to complete the suitable inquiry. A major difficult is trying to address the different SI requirements if there is potentially disqualifying information. The issue is complicated by repetition of requirements in various sections of Section C and Section D.

Section 26.49(b)(1) is a classic example of adding requirements where they are not needed and the issues that resulted in the Affirmed Rule. The requirement to "Obtain a self-disclosure and verify that no potentially disqualifying FFD information was disclosed" is inconsistent with the information collection and review process discussed in the rest of the rule. What if there is potentially disqualifying information? Now do we verify none exists? It does! The verify statement needs to be deleted or all the material from the preceding section added.

Looking logically at what needs to be done:

1. You need information from the individual on past events and work history sufficient to support the SI and evaluations. The self-disclosure is not an evaluation, it is a collection of information
2. You need to conduct a suitable inquiry with employers. There are three basic cases or initial, update, or reinstatement. The SI is not an evaluation, it is a collection of information
3. If potentially disqualifying information is developed or reported a management review is required. To do this.
 - a. The items to be considered must be defined—A Section D issue.
 - b. Those elements that are not available must be completed or collected—this is a Section C issue, but it must directly support the required review.

Definitions become important to this section—if we remember the definition, there is no need to repeat. I see one exception to this—In 26.55(b) the list of self-disclosure items is so important that it needs to be repeated here. It also needs to stay consistent with our definition

26.53(c) is repeated three times in the document as written below. It is left in because it has no real impact on the problem that is being solved. If this concept is accepted, this section should be rewritten to provide a "general requirement" related to what the self-disclosure, SI and management review are intended to do.

Proposed Text: (line-in/out used where possible, but not everywhere so clarity of the issue can be maintained.)(Some of the 26.xx numbers may be off by 10?)

§26.5 Definitions.

Potentially disqualifying FFD information means information demonstrating that an individual has, during a specified period.

- (1) violated a licensee or C/V FFD policy,
- (2) had authorization denied or terminated unfavorably 26.X here, and 26.X, 26 X in Subpart D – [insert sections numbers when final] of this part;
- (3) used, sold, or possessed illegal drugs;

- (4) abused legal drugs;
- (5) subverted or attempted to subvert a drug or alcohol testing program;
- (6) refused to take a drug or alcohol test;
- (7) been subjected to a plan for substance abuse treatment (except for self-referral), or
- (8) had legal action or employment action taken for alcohol or drug use

Reviewing official means the designated licensee or C/V employee who is responsible for reviewing and evaluating any potentially disqualifying FFD information obtained about an individual, including but not limited to the results of a determination of fitness, in order to determine whether the individual may be granted and maintain authorization to perform activities within the scope of this part.

§26.53 General Provisions.

(c) If, in the past five years, potentially disqualifying FFD information regarding a candidate for authorization is obtained through a self-disclosure, suitable inquiry, or other means, including, but not limited to, the background investigation and criminal history check conducted under part 73, and a determination of fitness has not been made by a previous licensee or C/V, authorization shall not be granted except in accordance with 26 XX.

26.55 Self-disclosure.

(a) Before granting authorization, except as described in 26 53(a) of this section, the licensee shall obtain a written self-disclosure from the individual

(b) The written self-disclosure from the individual must state whether the individual, since his or her eighteenth birthday, or since last access if terminated favorably within the last three years, has:

- (1) violated a licensee or C/V FFD policy;
- (2) had authorization denied or terminated unfavorably under 26 X here, and 26 X, 26.X in Subpart D of this part,
- (3) used, sold, or possessed illegal drugs;
- (4) abused legal drugs;
- (5) subverted or attempted to subvert a drug or alcohol testing program;
- (6) refused to take a drug or alcohol test;
- (7) been subject to a plan for substance abuse treatment (except for self-referral); or
- (8) had legal action or employment action taken for alcohol or drug use.

(c) The self-disclosure statement must also address the specific type, duration, and resolution of any matter disclosed.

(d) The individual must provide a list of all employments, with dates of employment for shortest period of

- (1) the last three years,
- (2) since the eighteenth birthday, or
- (3) since last authorization if terminated favorably within the last three years.

(e) Falsification of the self-disclosure statement or failure by an individual to disclose and list reasons in the self-disclosure for a denial, revocation, or unfavorable termination of authorization under this part is sufficient cause for denial of authorization to perform activities within the scope of this part.

§ 26.57 Suitable Inquiry.

(a) A suitable inquiry shall be conducted to verify self-disclosed information and to determine if any potentially disqualifying FFD information exists.

(b) For candidates for initial authorization, who have either never held authorization or have not held authorization within the past three years, the period of the suitable inquire shall be the past three years, or since the individual's eighteenth birthday, whichever is shorter.

(i) For the one-year period immediately preceding the application for authorization, the licensee or C/V shall contact every employer regardless of the length of employment

- (ii) For the remaining two-year period, the licensee or C/V shall contact at least one employer for each 30-day period when employed. .
- (c) For a candidate for update or reinstate authorization, where the individual held authorization within the past three years but not in the past 30 days, the licensee or C/V shall conduct a suitable inquiry with at least one employer, if employed, for each 30-day period since the individual last held authorization
- (d) For individuals who held authorization within the last 30-day period, a suitable inquiry is not required if review of the self-disclosure shows no potentially disqualifying FFD information.
- (e) A management review under Section 26.57 is required if an individual's self-disclosure, the suitable inquiry, or other sources indicate potentially disqualifying FFD information within the past five years. A review is not required for reinstatements and updates if all potentially disqualifying information had been reviewed as part of a previous authorization. The following additional suitable inquiry will be conducted to support this management review:
 - (1) A suitable inquiry will be completed for all employers within the suitable inquiry period specified in 26.57(a), (b), or (c) as applicable.
 - (2) For reinstatements and updates, records must be obtained and reviewed for any potentially disqualifying FFD information developed within the past 5 years as part of a suitable inquiry for authorization under this part.
- (f) The SI shall be conducted by questioning present and former employers as follows:
 - (1) For claimed employment periods as specified, the suitable inquiry will ascertain, on a best-effort basis, if there is potentially disqualifying FFD information that could reflect on the individual's fitness to perform activities within the scope of this part.
 - (2) If the claimed employment was military service, the suitable inquiry will request a characterization of service, reason for separation, and any disciplinary actions related to potentially disqualifying FFD information
 - (3) For claimed periods of education in lieu of employment or periods of self-employment, potentially disqualifying FFD information must be verified through any reasonable method, including contacts with relatives or references
- (c) In conducting a suitable inquiry, the licensee or C/V may use:
 - (1) Information received over the telephone if a record of the contents of the telephone call is made and retained; and
 - (2) Information received by electronic means, including, but not limited to, facsimile or e-mail, if the document or electronic file is retained
- (d) When presented with a signed release authorizing disclosure of information, licensees and C/Vs shall disclose whether or not the subject individual's authorization was denied, or terminated unfavorably due to a violation of a FFD policy. The circumstances for the denial, or unfavorable termination, including test results, must be made available in response to a licensee's or C/V's inquiry. Failure by an individual to authorize the release of information is sufficient cause for the denial of authorization to perform activities within the scope of this part.

§ 26.59 Initial Authorization.

- (a) This section defines requirements for granting authorization to individuals who have not held authorization within

the past 3 years

(b) Before granting authorization, the licensee shall--

- (1) Obtain a self-disclosure
- (2) Complete a suitable inquiry
- (3) Complete management review of any potentially disqualifying information.
- (4) Verify that drug and alcohol test results were negative; and
- (5) Ensure that initial FFD training was successfully completed

{ Similar changes are required to 26 51 and 26 53 }

Subpart D - Management actions and sanctions to be imposed.

26.73 Management actions in response to potentially disqualifying information.

(a) This section defines management actions to be taken before an individual is granted authorization when new potentially disqualifying FFD information has been identified by any means, including, but not limited to, the individual's self-disclosure, the suitable inquiry, a self-report of a legal action, or the administration of a licensee's or C/V's FFD program. If there were no potentially disqualifying FFD information developed since the individual last held authorization no further review is required.

(d) Authorization with new information. If an individual's self-disclosure, the suitable inquiry, other sources of information, or administration of the FFD program indicate the existence of potentially disqualifying FFD information within the past five years that was not addressed and resolved by a previous FFD program review, the granting and maintaining of authorization must be based upon a review of the circumstances associated with the information. This review must be completed by the designated reviewing official and must take into account, as a minimum, all potentially disqualifying FFD information for the past five years and the recommendations from a determination of fitness. The receiving FFD program must implement recommendations for treatment and follow-up testing, if the reviewing official determines that authorization is warranted.

Open Issues:

1. There is still some concern with what "verify self-disclosure information" means in 26.57. It appears the intent is to, where possible, confirm during the SI that the self-disclosure is accurate and fully discloses the magnitude of the issue. But what happens if there is no confirmatory information? For example, an employer refuses to discuss the issue. If the issue is a DUI, there would not be a lot to verify. Can this be restated to what the intent is?
2. 26.53(c), 26 57(e), 26 73(a), and 26.73(d) all repeat much of the same information. Once the basic flow of Subpart C and D are settled, it may be worth another look at these four areas to make sure they support each other correctly.

Fitness for Duty Comment Number 5 September 16, 2002

Purpose: To provide general comments on Sections C and D of the draft FFD rule.

Issue: The following general changes to Sections C and D are provided based on the general discussion at the August 28, 2002 meeting. Additional comments and changes will be provided in specific topical areas. Note that the changes recommended by FFD 4 have not been included in the following text.

Proposed Text:

Subpart C - Granting and Maintaining Authorization

§ 26.51 Purpose.

This subpart defines FFD requirements for granting and maintaining authorization for unescorted access to protected areas in nuclear power plants and for assignment to perform activities described in §26.XX of this part, hereinafter referred to as authorization.

§26.53 General Provisions.

(a) Licensees seeking to grant authorization to an individual covered by another FFD program that complies with this part may rely on that other FFD program to satisfy requirements of this part. Authorization may be maintained if that individual continues to be subject to either the receiving FFD program or the transferring FFD program, or a combination of elements from both programs that collectively satisfy the requirements of this part.

(b) If an authorized individual is not subject to a licensee-approved FFD program that meets the requirements of this part for more than 30 days, then the individual's authorization must be terminated and the individual must meet the applicable requirements in this subpart to regain reinstatement authorization.

(c) If, in the past year, potentially disqualifying FFD information regarding a candidate for authorization is obtained through a self-disclosure, suitable inquiry, or other means, including, but not limited to, the background investigation and criminal history check conducted under part 73, and a determination of fitness had not been made by a previous licensee or C/V, authorization shall not be granted except in accordance with 26 XX.

26.55 Self-disclosure.

(a) Before granting authorization, except as described in 26.43(a) of this section, the licensee shall obtain a written self-disclosure from the individual.

(b) The written self-disclosure from the individual must state whether the individual, since his or her eighteenth birthday, or since last access if terminated favorably within the last three years, has:

- (1) violated a licensee or C/V FFD policy,
- (2) had authorization denied or terminated unfavorably under 26.X here, and 26.X, 26 X in Subpart D of this part;
- (3) used, sold, or possessed illegal drugs;
- (4) abused legal drugs;
- (5) subverted or attempted to subvert a drug or alcohol testing program;
- (6) refused to take a drug or alcohol test,
- (7) been subject to a plan for substance abuse treatment (except for self-referral); or
- (8) had legal action or employment action taken for alcohol or drug use.

(c) The self-disclosure statement must also address the specific type, duration, and resolution of any matter disclosed.

- (d) The individual must provide a list of all employments, with dates of employment for shortest period of
- (1) the last three years,
 - (2) since the eighteenth birthday, or
 - (3) since last authorization if terminated favorably within the last three years.
- (e) Falsification of the self-disclosure statement or failure by an individual to disclose and list reasons in the self-disclosure for a denial, revocation, or unfavorable termination of authorization under this part is sufficient cause for denial of authorization to perform activities within the scope of this part

§ 26.57 Suitable Inquiry.1

- (a) A suitable inquiry shall be conducted to verify self-disclosed information and to determine if any potentially disqualifying FFD information exists
- (b) For candidates for initial authorization, who have either never held authorization or have not held authorization within the past three years, the period of the suitable inquiry shall be the past three years, or since the individual's eighteenth birthday, whichever is shorter.
- (i) For the one-year period immediately preceding the application for authorization, the licensee or C/V shall contact every employer regardless of the length of employment.
 - (ii) For the remaining two-year period, the licensee or C/V shall contact at least one employer for each 30-day period when employed.
- (c) For a candidate for update or reinstate authorization, where the individual held authorization within the past three years but not in the past 30 days, the licensee or C/V shall conduct a suitable inquiry with at least one employer, if employed, for each 30-day period since the individual last held authorization
- (d) For individuals who held authorization within the last 30-day period, a suitable inquiry is not required if review of the self-disclosure shows no potentially disqualifying FFD information
- (e) A management review under Section 26.57 is required if an individual's self-disclosure, the suitable inquiry, or other sources indicate potentially disqualifying FFD information within the past five years. A review is not required for reinstatements and updates if all potentially disqualifying information had been reviewed as part of a previous authorization. The following additional suitable inquiry will be conducted to support this management review:
- (1) A suitable inquiry will be completed for all employers within the suitable inquiry period specified in 26.57(a), (b), or (c) as applicable.
 - (2) For reinstatements and updates, records must be obtained and reviewed for any potentially disqualifying FFD information developed within the past 5 years as part of a suitable inquiry for authorization under this part
- (f) The SI shall be conducted by questioning present and former employers as follows:
- (1) For claimed employment periods as specified, the suitable inquiry will ascertain, on a best-effort basis, if there is potentially disqualifying FFD information that could reflect on the individual's fitness to perform activities within the scope of this part
 - (2) If the claimed employment was military service, the suitable inquiry will request a characterization of service, reason for separation, and any disciplinary actions related to potentially disqualifying FFD

¹ This section has been rewritten. It was too complicated and did not easily track for the user. Duplications with AA were also eliminated. This piece has also been provided separately to the staff in a white paper.

information.

- (3) For claimed periods of education in lieu of employment or periods of self-employment, potentially disqualifying FFD information must be verified through any reasonable method, including contacts with relatives or references.

(c) In conducting a suitable inquiry, the licensee or C/V may use:

- (1) Information received over the telephone if a record of the contents of the telephone call is made and retained; and
- (2) Information received by electronic means, including, but not limited to, facsimile or e-mail, if the document or electronic file is retained.

(d) When presented with a signed release authorizing disclosure of information, licensees and C/Vs shall disclose whether or not the subject individual's authorization was denied, or terminated unfavorably due to a violation of a FFD policy. The circumstances for the denial, or unfavorable termination, including test results, must be made available in response to a licensee's or C/V's inquiry. Failure by an individual to authorize the release of information is sufficient cause for the denial of authorization to perform activities within the scope of this part.

§ 26.59 Initial Authorization.

(a) This section defines requirements for granting authorization to individuals who have not held authorization within the past 3 years.

(b) Before granting authorization, the licensee shall--

- (1) Obtain a self-disclosure;
- (2) Complete a suitable inquiry;
- (3) Complete a management review of any potentially disqualifying FFD information and take action in accordance with § 26.73 of subpart D 2
- (4) Verify that drug and alcohol test results were negative; and
- (5) Ensure that initial FFD training was successfully completed

§ 26.61 Authorization Updates.

(a) This section defines requirements for updating authorization for individuals whose authorization has been interrupted for more than 365 days but less than 3 years and whose previous authorization was terminated favorably.

(b) Before granting authorization, the licensee shall--

- (1) Obtain a self-disclosure and verify that no potentially disqualifying FFD information was disclosed. No self-disclosure is required if the individual was subject to a licensee-approved behavioral observation and arrest-reporting program throughout the period of interruption;
- (2) Complete a suitable inquiry and verify that no potentially disqualifying FFD information was discovered,
- (3) Verify that drug and alcohol test results were negative. No drug and alcohol test is required if the individual

² This insertion and those in the two subsequent sections are necessary to explain what happens if the is PDI and the action is the same per subpart D , which is referenced.

was subject to a licensee-approved random drug and alcohol testing program throughout the period of interruption or had negative test results from a drug and alcohol test performed within the last 30 days; and

- (4) Ensure that the individual has met initial or refresher FFD training requirements, as appropriate.
- (c) If potentially disqualifying information is disclosed or discovered, before granting authorization the reviewing official shall complete a management review and take action in accordance with § 26 73 of subpart D.

§ 26.63 Authorization Reinstatements.

(a) This section defines requirements for reinstating authorization for individuals whose authorization has been interrupted for 365 days or less and whose previous authorization was terminated favorably.

(b) For an individual whose authorization has been interrupted for 30 days or less, before reinstating authorization, the licensee shall obtain a self-disclosure and verify that no potentially disqualifying FFD information was disclosed. No self-disclosure is required if the individual was subject to a licensee-approved behavioral observation and arrest-reporting program throughout the period of interruption,

(c) For an individual whose authorization has been interrupted for more than 30 days but not more than 365 days, in order to reinstate authorization, the licensee shall -

(1) Obtain a self-disclosure and verify that no potentially disqualifying FFD information was disclosed before reinstating authorization. No self-disclosure is required if the individual was subject to a licensee-approved behavioral observation and arrest-reporting program throughout the period of interruption;

(2) Within 5 business days of reinstating authorization, complete a suitable inquiry and verify that no potentially disqualifying FFD information was discovered. No suitable inquiry is required if the individual was subject to a licensee-approved behavioral observation and arrest-reporting program throughout the period of interruption. If the suitable inquiry is not completed within 5 business days and the licensee is aware of no potentially disqualifying information regarding the individual from the past five years, then the individual's authorization may be maintained until the suitable inquiry is completed or until the licensee determines that a best effort has been achieved.

(3) Verify that results of an alcohol test are negative and collect a specimen for drug testing before reinstating authorization. Verify that drug test results are negative within 5 business days of specimen collection. No drug and alcohol test is required if the individual was subject to a licensee-approved random drug and alcohol testing program throughout the period of interruption or had negative test results from a drug and alcohol test performed within the last 30 days. If drug test results are not available within 5 business days and the licensee is aware of no potentially disqualifying information regarding the individual from the past five years, then the individual's authorization may be maintained until the drug test results are available.

(d) If potentially disqualifying information is disclosed or discovered, before granting authorization the reviewing official shall complete a management review and take action in accordance with § 26 73 of subpart D.

(e) FFD training requirements must be met before authorization is reinstated.

§ 26.65 Maintaining Authorization.

Individuals may maintain authorization under the following conditions --

(a) The individual complies with the licensee's or CV's FFD policies to which they are subject, including the responsibility to report any legal actions;

(b) The individual remains subject to a drug and alcohol testing program that complies with the requirements of this part;

(c) The individual remains subject to an approved behavioral observation program that complies with the requirements of this part; and

(d) The individual successfully completes required FFD training, on the schedule specified in §26.XX of this part.

Subpart D - Management actions and sanctions to be imposed.

26.71 Sanctions.

(a) This section defines the minimum sanctions to be imposed when an individual has violated the FFD policy. The requirements of this section do not prohibit the licensee or C/V from taking more stringent action, except as specified in paragraph (g)

(b) Any act or attempted act to subvert the testing process, including refusal to provide a specimen for testing and the provision of a diluted, substituted, or adulterated specimen, must result in permanent revocation of authorization.

(c) Any individual determined to have been involved in the sale, use, or possession of illegal drugs or the use of alcohol when performing activities subject to this part must immediately have his or her authorization denied for a minimum of five years from the date of revocation

(d) An individual who resigns before authorization is terminated for violation of the drug and alcohol provisions of the FFD policy must immediately have his or her authorization denied for a minimum of five years from the date of revocation

(e) Lacking any other evidence to indicate the use, sale, or possession of illegal drugs or use of alcohol on site, a confirmed positive test result must be presumed to be an indication of offsite drug or alcohol use in violation of the FFD policy.

(1) The first violation of the FFD policy involving a confirmed positive drug or alcohol test result must, at a minimum, result in the immediate unfavorable termination of the individual's authorization for at least 14 days.

(2) A subsequent violation of any licensee's or C/V's FFD policy³, including during an assessment or treatment period, must result in unfavorable termination of authorization for a minimum of five years from that date.

(f) Paragraph (e) of this section does not apply to the misuse of valid prescription and over-the-counter drugs, unless the MRO determines that use of the prescription or over-the-counter drug represents substance abuse. Sanctions for misuse of valid prescription and over-the-counter drugs must be sufficient to deter abuse of legally obtainable substances.

(g) For individuals who have had their authorization to perform activities within the scope of this part denied for five years under paragraphs (c), (d) or (e) of this section, any subsequent violation of the drug and alcohol provisions of a FFD policy must immediately result in permanent revocation of authorization to perform activities under this part

(h) An individual's authorization may not be terminated and the individual may not be subjected to other administrative action based solely on a non-negative initial test result from any validity or drug test, other than for marijuana or cocaine metabolites, unless other evidence, including information obtained under the process set forth in §[insert correct reference when known] indicates that the individual is impaired or might otherwise pose a safety hazard. With respect to onsite initial drug tests for marijuana and cocaine metabolites, licensee management may be informed, and licensees may temporarily terminate authorization or take lesser administrative actions against the individual based on a non-negative initial drug test result provided the licensee complies with the following conditions --

(1) For the drug for which action will be taken, at least 85 percent of the specimens which were determined to be non-negative as a result of onsite initial drug tests during the last 12-month data reporting period submitted to the Commission under § 26.71(d) were subsequently reported as positive by the HHS-certified laboratory as the result of a gas chromatography/mass spectroscopy (GC/MS) confirmatory test.

³ It is not clear what happens between year 3 and year five. The industry has been using a second offence as out for five years whenever occurring

(2) There is no loss of compensation or benefits to the tested person during the period of temporary administrative action

(3) Immediately upon receipt of a negative report from the HHS-certified laboratory, any matter which could link the individual to the temporary administrative action is eliminated from the tested individual's personnel record and other records.

(4) No disclosure of the temporary administrative action against an individual whose test is not subsequently confirmed as a violation of FFD policy may be made in response to a suitable inquiry conducted under the provisions of § 26 XX, a background investigation conducted under the provisions of §73.56, or to any other inquiry or investigation. For the purpose of assuring that no records have been retained, access to the system of files and records must be provided to licensee personnel conducting reviews, inquiries into an allegation, or audits under the provisions of §26.XX, or to an NRC inspector or other Federal officials. The tested individual must be provided a statement that the records specified in 26.XX of this section have not been retained and must be informed in writing that the temporary administrative action that was taken will not be disclosed and need not be disclosed by the individual in response to requests for self-disclosure of potentially disqualifying FFD information.

26.73 Management actions in response to potentially disqualifying information.

(a) This section defines management actions to be taken before an individual is granted authorization when new potentially disqualifying FFD information has been identified by any means, including, but not limited to, the individual's self-disclosure, the suitable inquiry, a self-report of a legal action, or the administration of a licensee's or C/V's FFD program. If there were no FFD events since the individual last held authorization no further review is required.

(b) Re-authorization after a first violation. The requirements in this paragraph apply to an individual whose authorization was suspended⁴ for a first violation of the FFD policy involving a confirmed positive drug or alcohol test result.

(1) Before the individual's authorization may be updated or reinstated by a licensee, the licensee must --

(i) Verify that, during the 14-day suspension period, the individual was assessed by a substance abuse professional, as defined in 26 XX of this part, and that plans for treatment and follow-up testing were developed

(ii) Verify that the individual is in compliance with, or has successfully completed, the treatment plans;

(iii) Verify that a determination of fitness has indicated that the individual is fit to safely and competently perform his or her duties, and

(iv) Verify that the results of an alcohol test were negative, that the results of an observed drug test performed within five working days⁵ before re-authorization indicated no further drug use since the original confirmed positive test result, and that the results of any other drug and alcohol tests conducted since authorization was terminated indicated no further drug use since the original confirmed positive test result;

(v) Ensure that the individual is subject to unannounced drug and alcohol testing for a period of three years from the date authorization was terminated at a frequency of no less than once every 30 days, for four months after re-authorization, and at least once every 90 days for the next two years and eight months. Licensees and C/Vs may accept follow-up testing that was conducted in accordance with this part by another licensee or C/V.

(2) If the individual leaves the FFD program under which the violation occurred and is authorized to perform

⁴ To be consistent with (b)(1)(i)—it could be a suspension and not a termination such that the process does not have to revert to the requirements of an initial authorization but can be reinstated with specific considerations.

⁵ There needs to be some flexibility for holiday weekends etc.

activities within the scope of this part by another licensee with a different FFD program, the receiving licensee must ensure that the treatment and follow-up testing requirements are met with accountability assumed by the receiving FFD program. If the previous licensee determined that any required treatment and follow-up testing were completed successfully by the individual, and the individual's authorization was terminated favorably, the receiving licensee may accept the previous licensee's determination of fitness.

(c) Re-authorization following a revocation or denial of authorization. Individuals whose authorization was denied for five years or denied under the provisions of this part may be granted authorization under the following conditions

(1) The licensee determines that the individual has not used illegal drugs or abused legal drugs, including alcohol, for at least three years;

(2) A determination of fitness indicates that the individual is fit to safely and competently perform activities within the scope of this part;

(3) The individual has obtained a negative test result on an alcohol test and an observed drug test performed within five working days prior to authorization, and

(4) A clinically appropriate plan for unannounced drug and alcohol testing is initiated

(d) Authorization with new information. If an individual's self-disclosure, the suitable inquiry, other sources of information, or administration of the FFD program indicate the existence of potentially disqualifying FFD information, within the past 5 years, that was not addressed and resolved by a previous FFD program, the granting and maintaining of authorization must be based upon a review of the circumstances associated with the information. This review must be completed by the designated reviewing official and must take into account, as a minimum, all potentially disqualifying FFD information for the past five years and must take into account the recommendations from a determination of fitness. The receiving FFD program must implement recommendations for treatment and follow-up testing, if the reviewing official determines that authorization is warranted.

26.75 Management actions regarding possible impairment.

(a) This section defines management actions to be taken when an individual subject to this part shows indications that he or she may not be fit to perform activities within the scope of this part.

(b) If an individual subject to this part is impaired or the individual's fitness is questionable, the licensee shall take immediate action to prevent the individual from performing activities within the scope of this part. If an observed behavior or physical condition creates a reasonable suspicion of possible substance abuse, the licensee must perform a drug and alcohol test and the results must be negative before the individual is returned to performing activities within the scope of this part. The licensee may return the individual to performing activities within the scope of this part only after impairing or questionable conditions are resolved and a determination of fitness indicates that the individual is fit to safely and competently perform activities within the scope of this part.

(c) If a licensee has a reasonable belief that an NRC employee or NRC contractor may be under the influence of any substance, or otherwise unfit for duty, the licensee may not deny access but shall escort the individual. In any instance of this occurrence, the appropriate Regional Administrator must be notified immediately by telephone, followed by written notification (e.g., e-mail or fax) to document the notification. During other than normal working hours, the NRC Operations Center must be notified.

⁶ This needs to be consistent with the re-authorization of (b)(4) above

Fitness for Duty Comment Number 6 September 16, 2002

Purpose: To provide general comments on Sections E and I of the draft FFD rule.

Issue: The following general changes to Sections E and I are provided based on the discussion at the August 28, 2002 public meeting. Additional comments and changes will be provided in specific topical areas.

Proposed Text:

Subpart E - Collecting Specimens for Testing

§26.81 Purpose.

This subpart defines requirements for collecting specimens for drug and alcohol testing.

§26.83 Specimens to be collected.

- (a) Either breath or oral fluids may be collected for initial tests for alcohol but only breath for confirmatory testing ¹
- (b) Until testing of other specimens (i.e., oral fluids, sweat, hair) is approved by HHS, only urine may be collected for initial and confirmatory tests for drugs.

§26.85 Collector qualifications and responsibilities².

- (a) A collector shall have successfully completed training to carry out this function.
- (b) Urine Collector Qualifications.

(1) Basic information Urine collectors must be knowledgeable about this part, the FFD policy and procedures of the licensees and C/Vs for whom collections are performed, and must keep current on any changes to urine collection procedures..

(2) Qualification training Collectors must receive qualification training meeting the requirements of the licensee or C/V program. [this paragraph At a minimum, qualification training must provide instruction on the following subjects --

(i) All steps necessary to complete a collection correctly and the proper completion and transmission of the custody-and-control form;

(ii) Methods to address "problem" collections, including, but not limited to, collections involving "shy bladder" and attempts to tamper with a specimen;

(iii) How to correct problems in collections; and

(iv) The collector's responsibility for maintaining the integrity of the specimen collection and transfer process, carefully ensuring the modesty and privacy of the individual tested, and avoiding any conduct or remarks that might

¹ Words needed for clarification

² It is considered totally inappropriate to include the collectors training manual information in the FFD rule. If such is necessary, reference it — although it hasn't been necessary for the past 12 years in the nuclear power industry. No other NRC rule is so unnecessarily prescriptive. It is considered insufficient justification that HHS & DOT do this—is this in their regulations. Where does regulation stop?

be construed as accusatorial or otherwise offensive or inappropriate.

(3) Initial Proficiency Demonstration. Following completion of qualification training under paragraph (2) of this section, candidate collectors must demonstrate proficiency in collections by completing, at a minimum, five consecutive error-free mock collections.

(i) The five required mock collections must include two uneventful collection scenarios, one insufficient quantity of urine scenario, one temperature out-of-range scenario, and one scenario in which the donor refuses to sign the custody-and-control form and initial the specimen bottle tamper-evident seal.

(ii) An instructor shall monitor and evaluate the candidate collector's performance in person or by a means that provides real-time observation and interaction between the instructor and candidate, and attest in writing that the mock collections are "error-free." The instructor must be a qualified collector who has demonstrated necessary knowledge, skills, and abilities to serve as an instructor by --

- (A) Regularly conducting drug test collections for a period of at least a year, and either
- (B) Conducting collector training for a year, or
- (C) Successfully completing a "train the trainer" course

(4) Refresher training. No less frequently than every five years from the date on which a collector has completed the requirements of paragraphs (b)(2) and (3) of this section, the collector must again pass a proficiency examination as described in paragraph (b)(3) of this section. If the collector fails the proficiency examination, remedial training that meets all the requirements of paragraph (b)(2) of section must be provided until he or she is able to pass the examination]

(c) Alcohol collector qualifications

(1) Basic information. Alcohol collectors must be knowledgeable about this part, the FFD policy and procedures of the licensees and C/Vs for whom collections are performed, and must keep current on any changes to alcohol collection procedures.

(2) Qualification training. Alcohol collectors must receive qualification training meeting the requirements of the licensee or C/V program. [this paragraph.

(i) Qualification training must include training to proficiency in using the alcohol testing procedures of this part and in the operation of the particular alcohol testing device(s) (i.e., the alcohol saliva devices (ASDs) or evidential-grade breath alcohol testing devices (EBTs)) to be used, consistent with the manufacturers' instructions.

(ii) The training must emphasize that the collector is responsible for maintaining the integrity of the testing process, ensuring the privacy of donors being tested, and avoiding conduct or statements that could be viewed as offensive or inappropriate.

(iii) The instructor must be a qualified collector who has demonstrated necessary knowledge, skills, and abilities by --

- (A) Regularly conducting alcohol test collections for a period of at least a year, and either
- (B) Conducting collector training for a year, or
- (C) Successfully completing a "train the trainer" course.

(3) Initial Proficiency Demonstration. Following completion of qualification training under paragraph (c)(2) of this section, alcohol collector candidates must demonstrate proficiency in alcohol testing under this part by completing, at a minimum, five consecutive error-free mock tests for each device for which the candidate has received training

(i) An instructor shall monitor and evaluate the candidate collector's performance in person or by a means that

provides real-time observation and interaction between the instructor and candidate, and attest in writing that the mock collections are "error-free." The instructor must be an individual who meets the requirements of paragraph (c)(2)(iii) of this section.

(ii) These tests must use the alcohol testing devices (e.g., EBT(s) or ASD(s)) that will be used by the alcohol collector.

(iii) If the candidate collector will be using an ASD that indicates readings by changes, contrasts, or other readings in color, the candidate must demonstrate as part of the mock test that he or she is able to discern changes, contrasts, or readings correctly

(iv) The five mock collections for each device that will be used by the collector must include, at a minimum, one uneventful collection scenario; one insufficient quantity of breath or oral fluids scenario, as appropriate; two malfunctioning equipment scenarios; and one scenario in which the donor refuses to be tested.

(4) Refresher training. No less frequently than every five years from the date on which an alcohol collector satisfactorily completes the requirements of paragraphs (c)(2) and (3) of this section, the collector must again pass a proficiency examination as described in paragraph (c)(3) of this section. If the collector fails the proficiency examination, remedial training that meets all the requirements of paragraph (c)(2) of section must be provided until he or she is able to pass the examination.]

(d) Urine and alcohol collectors who meet the collector training and proficiency requirements under 49 CFR 40.33 and 40.213 may conduct specimen collections under this part.

(e) A medical professional, technologist, or technician licensed or otherwise approved to practice in the jurisdiction in which collection occurs may serve as a collector if that person is provided appropriate instructions and performs collections in accordance with those instructions.

§26.87 Collection sites.

(a) Each FFD program shall have one or more designated collection sites that have all necessary personnel, materials, equipment, facilities, and supervision to collect specimens for drug testing and to perform alcohol testing. Each collection site shall provide for the collection, security, temporary storage, and shipping or transportation of urine specimens to a drug testing laboratory, and for the collection and security of alcohol testing devices and test results. A properly equipped mobile facility that meets the requirements of this part is an acceptable collection site.

(b) Contracts for collection site services must permit the NRC and the licensee or C/V to conduct unannounced inspections and audits and to obtain all information and documentation reasonably relevant to the inspections and audits.

(c) Measures shall be provided to prevent unauthorized access to the collection site that could compromise the integrity of the collection process or the specimens. No unauthorized personnel shall be permitted in any part of the designated collection site where specimens are collected or stored. Security procedures shall provide for the designated collection site to be secure. Methods of assuring security may include physical measures to control access such as locked doors, alarms, or 3visual monitoring of the collection site when it is not occupied. If a collection site facility cannot be dedicated solely to drug and alcohol testing, the portion of the facility used for specimen collection shall be secured and, during use, a sign must be posted to indicate that access is allowed only for authorized personnel.

(d) To deter the dilution of urine specimens at the collection site, agents that color the water in the toilet bowl any color other than yellow, must be placed in toilet tanks wherever possible, so the reservoir of water in the toilet bowl

³ Wording changes offered for better clarity

is neither yellow nor colorless. 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. The collector shall have instructed the donor to not flush the toilet. The collector will flush after inspecting to ensure nothing untoward was involved that would be flushed down the toilet.⁴

(e) In the exceptional event that a designated collection site is inaccessible and there is an immediate requirement for urine specimen collection, including but not limited to an accident investigation, a public rest room, on-site rest room, or hospital examining room, may be used according to the following procedures --

(1) The facility must be secured by visual inspection to ensure other persons are not present, and that undetected access (e.g., through a rear door not in the view of the collector) is impossible. Security during 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 to the donor and distraction of the collector.

(2) If practicable, a water-coloring agent must be placed in the toilet bowl to be used by the donor and any accessible toilet tank. The collector shall instruct the donor not to flush the toilet. The collector will flush after inspecting to ensure nothing untoward was involved that would be flushed down the toilet.⁵

(3) A collector of the same gender as the donor shall accompany the donor into the area that will be used for specimen collection. If a collector of the same gender is not available, the licensee shall select a same gender person to accompany the donor. This person shall be briefed on relevant collection procedures.

(4) The collector shall remain in the rest room, but outside the stall, until the specimen is collected. After the collector has possession of the specimen, the collector shall flush the toilet. The collector shall instruct the donor to participate with the collector in completing the chain-of-custody procedures.

(f) If it is impractical to maintain continuous physical security of a collection site from the time a urine specimen is presented until the sealed container is transferred for shipment, the specimen shall remain under the direct control of an authorized individual.⁶

(g) The shipping container shall be immediately shipped, maintained in secure storage, or remain under the personal control of an authorized individual until shipped. These minimum procedures shall apply to the shipping of specimens to licensee testing facilities from collection sites (except where co-located) as well as to the shipping of specimens to HHS-certified laboratories. As an option, licensees and C/Vs with approved FFD programs may ship several specimens via courier in a locked or sealed shipping container.

(h) The collection site shall provide for the visual privacy of a donor who is submitting oral fluids or a breath specimen. No unauthorized personnel shall be present for the specimen collection.

§26.89 Preparing to collect specimens for testing.

(a) When an individual has been notified of testing and does not appear at the collection site within the time allowed 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 failure to appear for testing or undue tardiness is a FFD policy violation.

(b) Donors must provide positive identification before testing.

(1) Acceptable identification includes photo-identification issued by a licensee subject to this part or by a

⁴ It should be clear that only the collector will flush the toilet after determining that inspection of the area does not reveal any attempt to subvert the process.

⁵ The individual is going to be told not to flush, whether there is coloring agent or not.

⁶ The collector may be doing other things—another authorized individual can maintain control of the specimen.

licensee-approved C/V, or by the federal, state or local government. Faxes or photocopies of identification are not acceptable.

(2) If the donor cannot produce positive identification, the collector shall proceed with the test and immediately inform FFD program management that the donor did not present positive identification. FFD program management will ensure that the donor is positively identified and that the necessary steps are taken to determine whether the lack of identification was an attempt to subvert the testing process.

(3) For first time donors the collector shall explain the testing procedure to the donor, including showing the donor the form(s) to be used, and ask the donor to sign a consent-to-testing form. The donor shall not be required to list prescription medications or over-the-counter preparations that he or she can remember using recently.

(c) When the donor enters the collection site, testing must begin without undue delay.

(d) To the greatest extent practicable, alcohol testing must be completed before collecting urine for drug testing.

(e) If an individual requires medical attention, including, but not limited to the case of an injured worker in an emergency medical facility who is required to have a post-accident test, treatment shall not be delayed to conduct drug and alcohol testing.

§26.91 Acceptable devices for conducting initial and confirmatory tests for alcohol and methods of use.

(a) Alcohol breath analysis equipment must be an evidential-grade breath alcohol analysis device (EBT) of a brand and model that conforms to National Highway Traffic Safety Administration (NHTSA) standards and is on the most current version of NHTSA's Conforming Products List (CPL)⁸. Calibration units used to calibrate alcohol breath analysis equipment must be of a brand and type that conform to NHTSA standards and are on the most current version of NHTSA's CPL for such devices. The manufacturer-required performance tests of the breath analysis equipment used by the FFD program must be conducted as set forth in the manufacturer's specifications.

(b) EBTs on the NHTSA CPL for evidential devices that have the following capabilities are the preferred devices, but are not required, for conducting initial and confirmatory alcohol tests under this part --

- (1) Provides a printed result of each breath test;
- (2) Assigns a unique number to each completed test, which the collector and individual tested can read before each test and which is printed on each copy of the result,
- (3) Prints, on each copy of the 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) Performs an external calibration check.

(c) If a preferred EBT is used, the initial and confirmatory tests for alcohol may be performed using the same or different EBT. One breath specimen shall be collected for the initial test, and, if necessary, a second breath specimen shall be collected for the confirmatory test using the same [could it be different?] preferred EBT.

⁷ No explanation should be required for veteran donors, doing so would result in delaying the process which may influence the result. Licensees have instructions/expectations that the donor can review before the collection on a not-to-delay testing basis.

⁸ Apparently there are four types—must be more specific.

(d) If EBTs that meet the requirements in paragraph (a) of this section are used for alcohol testing, but they are not the preferred devices, then the initial test and the confirmatory test shall be performed using two different EBTs. If one breath specimen is collected for the initial test using a non-preferred EBT, then, if necessary, the second breath specimen for the confirmatory test shall be collected using a second EBT.

(e) Alcohol saliva analysis devices (ASDs) must be approved by the NHTSA and placed on the CPL for such devices. An alcohol saliva analysis device that is on the NHTSA CPL may be used for initial alcohol tests only if there are instructions for its use in this part. An alcohol saliva analysis device must be used only for initial tests for alcohol, and may not be used for confirmatory tests, which must be performed using an EBT that meets the requirements of paragraph (a) of this section.

§26.93 Conducting an initial test for alcohol using a breath specimen.

(a) To perform the initial test, the collector shall --

- (1) Select, or allow the donor to select, an individually wrapped or sealed mouthpiece from the testing materials.
- (2) Open the individually wrapped or sealed mouthpiece in view of the donor and insert it into the device in accordance with the manufacturer's instructions.
- (3) Instruct the donor to blow steadily and forcefully into the mouthpiece for at least six seconds or until the device indicates that an adequate amount of breath has been obtained.
- (4) Show the donor the displayed test result.
- (5) Ensure that the test result record can be associated with the donor and is maintained secure.

(b) Unless there are problems in administering the breath test that require an additional collection, only one breath specimen is required for the initial test.

§26.95 Conducting an initial test for alcohol using a specimen of oral fluids.

(a) To perform the initial test, the collector shall -

- (1) Check the expiration date on the device and show it to the donor. The device may not be used after its expiration date.
- (2) Open an individually wrapped or sealed package containing the device in the presence of the donor.
- (3) Offer the donor the opportunity to use the device. If the donor uses it, instruct the donor to insert it into his or her mouth and use it in the manner described by the device's manufacturer.
- (4) If the donor chooses not to use the device, or in all cases in which a new test is necessary because the device did not activate, insert the device into the donor's mouth and gather oral fluids in the manner described by the device's manufacturer. Wear single-use examination or similar gloves while doing so and change them following each test.
- (5) When the device is removed from the donor's mouth, follow the manufacturer's instructions regarding necessary next steps in ensuring that the device has activated.

(b) If the steps in paragraph (a) of this section could not be completed successfully (e.g., the device breaks, the device is dropped on the floor), the collector shall --

- (1) Discard the device and conduct a new test using a new device. The new device must be one that has been under the collector's control before the test.

(2) Record the reason for the new test on the custody-and-control form.

(3) Offer the donor the choice of using the device or having the collector use it unless the donor, in the opinion of the collector, was responsible for the new test needing to be conducted

(4) Repeat the procedures in paragraph (b) of this section

(c) If the second collection attempt in paragraph (b) of this section could not be completed, the collector shall -

(1) End the collection and document the reasons the collection could not be completed

(2) Immediately conduct another initial test using an evidential-grade breath alcohol analysis device.

(d) The collector shall read the result displayed on the device no sooner than the device's manufacturer instructs. In all cases the result displayed must be read within 15 minutes of the test. The collector must then show the device and its reading to the individual, record the result, and record that an alcohol saliva device was used

(e) Devices, swabs, gloves, or other materials used in collecting oral fluids may not be re-used

§26.97 Determining the need for a confirmatory test for alcohol.

(a) If the initial test result is an alcohol concentration of less than 0.02, the collector shall declare the test result as negative.

(b) If the initial test result is 0.02 or greater, the collector shall ensure that the time at which the test result was concluded (i.e., the time at which the test result was known) is recorded and inform the individual that a confirmatory test for alcohol is required.

§26.99 Conducting a confirmatory test for alcohol.

(a) As soon as the determination has been made that a confirmatory test for alcohol is required, the collector shall advise the donor not to eat, drink, or put anything, including, but not limited to a cigarette, chewing gum, into his or her mouth.

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(b) The confirmatory test must begin as soon as possible, but not more than 30 minutes after the conclusion of the initial test.

(c) To complete the confirmatory test using a preferred EBT, the collector shall -

⁹ There is no need for any waiting period except as may be technically necessary to reset the EBT. The individual is aware that no alcohol can be consumed within 5 hours of reporting to work. Steps (2) - (6) need to be deleted.

(1) In the presence of the employee, conduct an air blank on the EBT before beginning the confirmatory test and show the result to the individual,

(2) Verify that the reading is 0.00. If the reading is 0.00, the test may proceed. If not, then conduct another air blank;

(3) 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.

(4) Open an individually wrapped or sealed mouthpiece in view of the individual and insert it into the device in accordance with the manufacturer's instructions

(5) Ensure that the collector and the donor read the unique test number displayed on the EBT.

(6) Instruct the donor to blow steadily and forcefully into the mouthpiece for at least six seconds or until the device indicates that an adequate amount of breath has been obtained.

(7) Show the donor the result displayed on the EBT, record it, and document the time at which the confirmatory test result was known

(d) To complete a confirmatory test using an EBT that is not a preferred EBT, the collector shall -

(1) Conduct the confirmatory test in accordance with the manufacturer's instructions;

(2) Show the test result to the donor, record it, and document the time at which the confirmatory test result was known

§26.101 Determining a confirmed positive test result for alcohol.

A confirmed positive test result for alcohol shall be declared under the following conditions --

(a) When the result of the confirmatory test for alcohol is 0.04 or higher;

(b) If the result of the confirmatory test for alcohol is 0.03 or higher and the donor had been in a work status for at least one hour at the time the initial test was concluded (including any breaks for rest, lunch, dental/doctor appointments, etc.), or

(c) If the result of the confirmatory test for alcohol is 0.02 or higher and the donor had been in a work status for at least two hours at the time the initial test was concluded (including any breaks for rest, lunch, dental/doctor appointments, etc.).

§26.103 Preparing for urine collection.

(a) The collector shall ask the donor to remove any unnecessary outer garments such as a coat or jacket that might conceal items or substances that could be used to tamper with or adulterate the individual's urine specimen. The collector shall ensure that all personal belongings such as a purse or briefcase remain with the outer garments outside of the room in which the urine specimen is collected. The donor may retain his or her wallet.

(b) The collector shall also ask the donor to empty his or her pockets and display the items in them to ensure that no items are present which could be used to adulterate the specimen. Individuals subject to testing shall allow the collector to make this observation.

(1) If the collector identifies nothing that can be used to adulterate a specimen, the donor may place the items back into his or her pockets.

(2) If the collector finds any material that could be used to tamper with a specimen, the collector shall --

(i) Assess whether the material appears to be inadvertently brought to the collection site, and, if so, secure and maintain it until the collection process is completed and conduct an unobserved collection; or

(ii) Assess whether the donor has no explicable purpose to have the material other than to tamper with a specimen, and, if so, the collector shall contact the appropriate FFD program manager to determine the need for a directly observed collection, as described in §26 XX). The FFD program manager may determine that the presence of the material indicates an attempt to subvert the testing process and that no additional urine collection is required.

(c) The donor shall be instructed to wash and dry his or her hands prior to urination

(d) After washing hands prior to urination, the donor shall remain in the presence of the collector and shall not have access to any water fountain, faucet, soap dispenser, cleaning agent or any other materials that could be used to adulterate the urine specimen.

(e) Select, or allow the donor to select, an individually wrapped or sealed collection container from collection kit materials. Either the collector or the donor, with both present, shall unwrap or break the seal of the collection container. The donor shall not be allowed to take anything from the collection kit into the room used for urination except the collection container.

§26.105 Collecting a urine specimen.

(a) The collector shall direct the donor to go into the room used for urination, provide a specimen of at least 45 mL, not flush the toilet, and return with the specimen as soon as the donor has completed the void.

(1) Except in the case of an observed collection as described in §26.XX, no-one may go into the room with the donor.

(2) The collector may set a reasonable time limit for voiding.

(b) The donor may provide his or her urine specimen in the privacy of a stall or otherwise partitioned areas that allows for individual privacy.

(c) The collector shall pay careful attention to the donor during the entire collection process to note any conduct that clearly indicates an attempt to tamper with a specimen (e.g., substitute urine in plain view or an attempt to bring into the collection site an adulterant or urine substitute). If any such conduct is detected, the collector shall contact FFD program management to determine whether an observed collection is required, as described in §26.XX of this subpart.

(d) After the urine specimen has been provided and submitted to the collector, the donor shall be allowed to wash his or her hands. The collector shall flush the toilet.

§26.107 Urine specimen quantity.

(a) The specimen must include at least 27 milliliters (mL) for the testing at the HHS-certified laboratory plus an appropriate additional quantity if the licensee tests for additional drugs. Where collected specimens are to be split under the provisions of this part, the specimen must include an additional 15 mL¹⁰. If initial validity and drug tests will be performed at the licensee testing facility, the specimen must include the necessary additional amount. The

¹⁰ The plethora of specimen quantity is confusing. This must be clarified in one place.

total minimum specimen quantity is called the predetermined quantity.

(b) Upon receiving a urine specimen from the donor, the collector shall determine whether it contains the predetermined quantity of urine sufficient to meet specific testing program requirements. This quantity must take into account all analyses and re-analyses provided for in the licensee's FFD policy.

(c) If there is less than the quantity of urine in the container required for HHS-certified laboratory testing (less than 27mL), additional specimen(s) must be collected in separate container(s). Because low volume specimens are not routinely provided, one or more additional specimens shall be collected to ensure a sufficient testing quantity. In order to be able to provide more urine, the individual may be encouraged to drink a reasonable amount of liquid (normally, an 8 oz. glass of water every 30 minutes, but not to exceed a maximum of 24 oz.) until a specimen containing sufficient urine has been collected. Each successive void must be collected in a separate container. If the donor provides a quantity of urine sufficient for testing at the HHS-certified laboratory, no sanctions shall be applied if the donor declines to drink additional fluid to obtain enough for initial tests at the licensee test facility. All specimens of 15mL or more shall be forwarded to the HHS laboratory for testing.

(d) In cases where the specimen volume is insufficient to fulfill all analysis and reanalysis requirements as predetermined by the licensee, the specimen should be used to the extent possible to meet those requirements in the following order of priority: testing of the specimen at the HHS-certified laboratory, provision for a split specimen, and initial validity and drug tests at the licensee testing facility. Partial specimens (less than 27mL but greater than 15mL) should be retained and sent with any subsequently collected specimen(s) for testing at the HHS-certified laboratory. Specimens of less than 15mL must be discarded. Specimens may not be combined. 11

§26.109 Splitting the urine specimen.

(a) Licensees may, but are not required to, use split specimen methods of collection.

(b) If the urine specimen is split into two specimen bottles, hereinafter referred to as Bottle A and Bottle B, the following procedure must be followed --

(1) The donor shall urinate into either a specimen bottle or a specimen container. The collector, in the presence of the donor, after determining specimen temperature as described in 26.XX of this subpart, shall pour the urine into two specimen bottles that are sequentially labeled "Bottle A" and "Bottle B." If Bottle A was used to collect the specimen, the collector will pour a minimum of 15 mL into Bottle B. If there is no additional urine available for the second specimen bottle (Bottle B), the first specimen bottle (Bottle A) shall nevertheless be processed for testing.

(2) The urine in Bottle A is to be used for the validity tests described in 26 XX and for drug testing.

(3) The collector shall request the donor to observe the splitting of the urine specimen and to maintain visual contact with the specimen bottles until they are both prepared for secure storage or shipping.

(c) The specimen contained in Bottle A shall be used for validity and drug testing. Bottle B shall be stored in a secure manner until all processing of Bottle A has been completed. If the specimen in Bottle A is free of any evidence of subversion and drug test results are negative, the specimen contained in Bottle B may be discarded.

§26.111 Checking the validity of the urine specimen.

(a) Immediately after a urine specimen is collected, including specimens of less than the predetermined quantity, 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 must not exceed 4 minutes, and may need to be less because of the ambient temperature.

11 How report multiple collections for the same reason? Which one is the reportable result, etc.? More guidance on NRC expectations is necessary. Some method to work with the laboratory to have a minimum single specimen vice this multiple situation is necessary.

(b) If the temperature of a urine specimen is outside the range of 90°F to 100°F, that is sufficient reason to believe that the individual may have altered or substituted the specimen. The collector shall inform the donor that he or she may volunteer to have his or her oral temperature taken to provide evidence to counter the reason to believe the donor may have altered or substituted the specimen caused by the specimen temperature falling outside the prescribed range.

(c) If there is reason to believe the individual may have diluted, substituted, or adulterated the specimen based upon specimen temperature, the collector shall contact the designated FFD program manager who may consult with the MRO to determine whether the donor has attempted to subvert the testing process 12

(d) Immediately after a urine specimen is collected, the collector shall also inspect the specimen to determine its color and clarity and look for any signs of contaminants or adulteration. Any unusual findings must be noted on the custody-and-control form.

(e) Any specimen of 15mL or more that is suspected of having been diluted, substituted, or adulterated shall be sent directly to the HHS-certified laboratory for further processing.

(f) Devices used to determine the temperature of the specimen must be accurate and not contaminate the specimen

(g) As much of the specimen as possible must be preserved for possible future testing.

(h) A specimen that is acceptable for further processing is free of any contaminants, meets the required quantity of at least 27mL and is within the acceptable temperature range.

§26.113 Collecting a urine specimen under direct observation.

(a) Procedures for collecting urine specimens must allow individual privacy unless there is reason to believe that a particular donor may alter or substitute the specimen to be provided. For purposes of this part, the following circumstances are the exclusive grounds constituting a reason to believe that the donor may alter or substitute a urine specimen --

(1) The donor has presented, at this or any previous collection, a urine specimen that the HHS-certified laboratory reported as being invalid to the MRO and the MRO reports to the licensee or C/V that there is no adequate medical explanation for the result;

(2) The donor has presented a urine specimen that falls outside the normal temperature range, and

(i) the donor declines to provide a measurement of oral body temperature by sterile thermometer, or

(ii) the donor's oral temperature varies by more than 1EC/1.8EF from the temperature of the specimen,

(3) The collector observes conduct clearly and unequivocally indicating an attempt to dilute, substitute, or adulterate the specimen;

(b) Urine specimens must also be collected under direct observation as required in §§26.63(b)(1)(iv) and 26.63(c)(3) in Subpart D of this part.

(c) Agreement of the MRO, other designated medical professional, or a higher level supervisor of the collector must be obtained in advance of each decision to obtain a urine specimen under the direct observation of a same gender collector based on a reason to believe that the individual may alter or substitute the specimen to be provided as specified herein. After agreement has been obtained, the collector shall ensure that a specimen is collected under

¹² It is not clear what is expected. Using may and deletions

direct observation as soon as reasonably practicable.

(d) The collector shall explain to the donor the reason, if known, for a directly observed collection under paragraphs (a) and (b) of this section.

(e) A new custody-and-control form shall be completed for the specimen obtained from the directly observed collection. The fact that the collection was observed and the reasons for the observed collection must be recorded on the form.

(f) The collector shall ensure that the observer is the same gender as the individual. 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. (h) If someone other than the collector is to observe the collection, the collector shall verbally instruct that person to follow the procedures in this paragraph. If the collector is the observer, these procedures must be followed --

(1) 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.

(2) If the observer is not the collector, the observer shall not take the collection container from the donor, but shall observe the specimen as the donor takes it to the collector.

(3) If someone else has acted as the observer, the collector must include the observer's name in the "Remarks" line of the custody-and-control form.

(g) If a donor declines to allow a directly observed collection required or permitted under this section to occur, this is a refusal to test.

(h) If a collector learns that a directly observed collection should have been collected but was not, the collector shall inform the FFD program manager, or his or her designee, to direct that the donor to have an immediate recollection under direct observation.

(i) The same measurements¹³ must be performed on specimens collected under direct observation as required for specimens collected unobserved, and any specimens collected under direct observation must be forwarded to the HHS-laboratory for testing.

§26.115 Preparing urine specimens for storage and shipping.

(a) Both the donor and the collector shall keep urine specimens in view at all times before the specimens are sealed and labeled. If any specimen is transferred to a second container, the collector shall request the donor to observe the transfer and sealing of the specimen with the tamper-evident seal.

(b) The collector and the donor shall be present at the same time during procedures outlined in this section.

(c) The collector shall place securely on each container an identification label that contains the date, the donor's specimen number, and any other identification information provided or required by the drug-testing program. If separate from the labels, tamper-evident seals shall also be applied. The specimen bottles must be securely sealed to prevent undetected tampering.

(d) The donor shall initial the identification labels on the specimen bottles for the purpose of certifying that it is the specimen collected from him or her. The donor must also be asked to read and sign a statement on the custody-and-control form certifying that the specimens identified as having been collected from him or her are in fact the specimens that he or she provided.

¹³ Which measurements are these? Must be clear to user

(e) The collector shall complete the custody-and-control forms for both Bottle A and Bottle B, if collected, and shall certify proper completion of the collection

(f) The specimens and chain-of-custody forms shall be packaged for transfer to the HHS-laboratory or the licensee's testing facility. If the specimens are not immediately prepared for shipment, they shall be appropriately safeguarded during temporary storage.

(g) While any part of the above chain-of-custody procedures is being performed it is essential that the specimens and custody documents be under the control of the involved collector. The collector must not leave the collection site in the interval between presentation of the specimen by the donor and securing of the specimens with identifying labels bearing the donor's specimen identification numbers and seals initialed by the donor. If the involved collector leaves his or her workstation momentarily, the sealed specimens and chain-of-custody forms must be taken with him or her or must be secured. If the collector is leaving for an extended period of time, the specimens must be packaged for transfer to the laboratory or licensee testing facility and secured before he or she leaves the collection site.

(h) Collection site personnel shall arrange to transfer the collected specimens to the HHS laboratory or licensee testing facility. Licensees shall take appropriate and prudent actions to minimize false negative results from specimen degradation. Specimens must be sent to the HHS-certified laboratory as soon as reasonably possible but, except under unusual circumstances, the time between specimen shipment and receipt of the specimen at the HHS-certified laboratory should not exceed 48 hours, or the time between shipment and the initial test at the HHS-certified laboratory must be¹⁴ within 7 days.

(i) The collection site personnel shall ensure that a custody-and-control form is packaged with its associated urine specimen bottle. Sealed and labeled specimen bottles, with their associated custody-and-control forms, being transferred from the collection site to the drug testing laboratory must be placed in a second, tamper-evident shipping container which must be designed to minimize the possibility of damage to the specimen during shipment (e.g., specimen boxes, 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.

(j) Because chain-of-custody documentation for each urine specimen must be attached to the specimen bottle¹⁵ and the specimen bottles must be placed in a sealed, tamper-evident shipping container for shipment to the HHS laboratory or licensee testing facility, couriers, express carriers, and postal service personnel do not have access to the custody-and-control forms. Therefore, there is no requirement that such personnel document chain of custody on the custody-and-control forms during transit. Custody accountability of the shipping containers during shipment must be maintained by a tracking system provided by the courier, express carrier, or postal service. Every effort must be made to minimize the number of persons handling the specimens.

¹⁴ We expect the new NRC investigation will clarify the expectation that specimen degradation is not a short term concern.

¹⁵ The form is not attached to the specimen bottle.

Subpart F - Licensee Testing Facilities¹⁶

§ 26.121 Purpose.

This subpart defines requirements for on-site testing laboratories operated by licensees to perform initial tests of urine specimens for validity, drugs, and drug metabolites.

§ 26.123 Testing facility capabilities.

Each licensee testing facility shall have the capability, at the same premises, of performing initial validity tests and initial drug tests for each drug and drug metabolite for which testing is conducted. Initial and confirmatory tests for alcohol may be performed at the collection site.

§ 26.125 Licensee testing facility personnel.

(a) Each licensee testing facility shall have an individual to be responsible for day-to-day operations and to supervise the testing technicians. This individual(s) shall have at least a bachelor's degree in the chemical or biological sciences or medical technology or equivalent. He or she shall have training and experience in the theory and practice of the procedures used in the licensee testing facility, resulting in his or her thorough understanding of quality control practices and procedures; the review, interpretation, and reporting of test results; and proper remedial actions to be taken in response to detecting abnormal test or quality control results.

(b) Other technicians or non-technical staff shall have the necessary training and skills for the tasks assigned.

(c) Licensee testing facility personnel files shall include: resume of training and experience; certification or license, if any; references; job descriptions; records of performance evaluation and advancement; incident reports, results of tests which establish employee competency for the position he or she holds, such as a test for color blindness, if appropriate; and appropriate data to support determinations of honesty and integrity conducted in accordance with this part.

§ 26.127 Procedures.

(a) Licensee testing facilities must develop and maintain clear and well-documented procedures for collection, shipment, testing, and accession of urine specimens.

(b) Chain-of-custody procedures must describe the methods to be used to maintain control and accountability of specimens from receipt through completion of testing, reporting of results, during storage, and continuing until final disposition of specimens. These procedures shall require that --

(1) The HHS custody-and-control form, or a similar custody-and-control form, is used that allows for identification of the donor, and documentation of information about the testing process and transfers of custody of the specimen;

(2) Each time a specimen is handled or transferred, the date and purpose shall be documented on the custody-and-control form and every individual in the chain shall be identified, except for couriers, express carriers, and postal service personnel, as described in 26.XX.

(3) Authorized technicians are responsible for each urine specimen or aliquot in their possession and shall sign and complete custody-and-control forms for those specimens or aliquots as they are received.

(4) The original custody-and-control form shall accompany the specimen to the HHS-certified laboratory. A copy

¹⁶ Subpart E is for Collection — Subpart F is for Testing. Using the Edit find there are multiple references to Collection in the Testing section that seem to be redundant. The text needs to be groomed and streamlined.

shall accompany any split sample.

(5) A tamper-evident sealing system is used that is designed so that the specimen container can be sealed against undetected opening, the container can be identified with a unique identifying number identical to that appearing on the custody-and-control form, and space has been provided to initial the container affirming its identity. For purposes of clarity, this requirement assumes use of a system made up of one or more pre-printed labels and seals (or a unitary label/seal), but use of other, equally effective technologies is authorized.

(6) Shipping containers may be used in which one or more specimens and associated paperwork may be transferred and which can be sealed and initialed to prevent undetected tampering

(c) Each licensee testing facility shall have a standard operating procedure manual. The manual must include, but is not limited to, a detailed description of --

- (1) the principles of each test;
- (2) preparation of reagents, standards and controls;
- (3) calibration procedures;
- (4) derivation of results,
- (5) linearity of the methods;
- (6) sensitivity of the methods;
- (7) cutoff values,
- (8) mechanisms for reporting results;
- (9) controls;
- (10) criteria for unacceptable specimens and results;
- (11) remedial actions to be taken when the test systems are outside of acceptable limits;
- (12) reagents and expiration dates; and
- (13) references.

(d) There shall be written procedures for the remedial actions to be taken when systems are out of acceptable limits or errors are detected. There shall be documentation that these procedures are followed and that all necessary corrective actions are taken. There shall also be in place systems to verify all stages of testing and reporting, and documentation that these procedures are followed

(e) There shall be written procedures for instrument set-up and normal operation, a schedule for checking critical operating characteristics for all instruments, tolerance limits for acceptable function checks, and instructions for major troubleshooting and repair.

(f) Procedures governing licensee testing facility calibrators and controls must require that the calibrators and controls be prepared using pure drug reference materials, stock standard solutions obtained from other laboratories, or standard solutions obtained from commercial manufacturers that are properly labeled as to content and concentration. The standards and controls must be labeled with the following dates: when received; when prepared or opened; when placed in service; and expiration date.

§ 26.129 Cutoff levels for initial validity tests and for drugs and drug metabolites.

(a) Each urine specimen must be initially tested for creatinine, pH, and one or more oxidizing adulterants, and must include nitrite. If tests or observations indicate one or more of the following, there is reason to believe the individual may have diluted, substituted, or adulterated the specimen, and the specimen shall be forwarded to the HHS laboratory for additional testing --

- (1) Creatinine--less than 20 milligrams(mg) per deciliter (dL) 17;
- (2) pH--less than 3.0 or equal to or greater than 11.0,
- (3) Nitrite concentration--equal to or greater than 200 micrograms (mcg) per milliliter (mL); or
- (4) If there is evidence of adulterants, including, but not limited to -
 - (i) Abnormal physical characteristics;
 - (ii) Reactions or responses characteristic of an adulterant obtained during the initial test; or
 - (iii) Possible unidentified interfering substance or adulterant.

(b) Licensees may specify more stringent cutoff levels than those in the table below and report initial test results for only the more stringent cutoff levels in such cases. Otherwise, the following cutoff levels shall be used for initial testing of urine specimens to determine whether they are negative for the indicated substances --

Initial test cutoff levels for drugs and drug metabolites (ng/ml)

Substance	Cutoff level (ng/ml)
Marijuana metabolites	50
Cocaine metabolites	300
Opiate metabolites ¹	2000
Phencyclidine	25
Amphetamines	1000

¹25 ng/ml is immunoassay specific for free morphine.

§26.131 Requirements for performing initial validity tests.

(a) Non-instrumented devices may be used for the test to determine specimen validity.

(b) Creatinine concentration shall be measured to one decimal place.

(1) The initial creatinine test shall have a calibrator at either 5 mg/dL or at 20 mg/dL.

(2) The initial creatinine test shall have a control in the range of 2 mg/dL to 4 mg/dL, a control in the range of 5 mg/dL to 20 mg/dL, and a control in the range of 21 mg/dL to 25 mg/dL.

(c) Dipsticks, pH paper, and spectrophotometric/colorimetric tests that have a narrow dynamic range and lack the accuracy necessary to support the specified program cutoffs may be used only to determine if the specimen must be forwarded to the HHS laboratory for further testing. These pH tests shall have the following controls -

- (1) One control in the range of 3 to 4.3;
- (2) One control in the range of 9.2 to 11; and

¹⁷ For diluted specimens it may be clearer if this advised that Sp Gr is useful only if creatinine is out of specification.

(3) One control in the range of 4.5 to 9

(d) Testing for one or more oxidizing adulterants may be achieved using either a general oxidizing adulterant test or one or more specific oxidizing adulterant tests.

(1) When a general oxidizing adulterant test is used, the test shall be able to detect at least the activity equivalent of 200 mcg/mL of nitrite.

(2) Each analytical run of specimens shall include a control without the compound of interest (i.e., a certified negative control) and at least one control with one of the compounds of interest at a measurable concentration.

(e) Dipsticks may be used to determine the presence of nitrite at a concentration sufficient to require further testing by the HHS laboratory. A dipstick test shall have a control without nitrite (i.e., a certified negative control) and one control in the range of 500 mcg/mL to 625 mcg/mL.

§ 26.133 Requirements for performing tests for drugs and drug metabolites.

(a) Pending HHS (SAMSHA) review and approval of non-instrumented immunoassay testing devices, such devices shall not be used to test for drugs of abuse in part 26 FFD programs. Until such devices are approved, initial testing of urine specimens for drugs and drug metabolites performed by a licensee testing facility must use an immunoassay which meets the requirements of the Food and Drug Administration for commercial distribution

(b) A negative specimen shall be discarded or may be pooled for use in the laboratory's internal quality control program unless validity test results indicate that the specimen may not be a valid specimen.

(c) Multiple initial drug tests for the same drug or drug class may be performed provided that all tests meet the cutoffs and quality control requirements of this part. Multiple testing may include, but is not limited to, performing a test by immunoassay technique "A" for all drugs using the cutoff levels, but presumptive positive amphetamines are then tested using immunoassay technique "B" to eliminate any possible presumptive positives due to structural analogues

§ 26.135 Quality assurance program.

(a) The licensee's testing facility shall have a quality assurance program that encompasses all aspects of the testing process including but not limited to specimen acquisition, chain of custody, security, reporting of results, initial validity and drug testing, and validation of analytical procedures. Quality assurance procedures must be designed, implemented, and reviewed to monitor the conduct of each step of the process of validity testing and testing for drugs.

(b) Quality assurance requirements for initial drug tests.

(1) Licensee testing facilities are not required to assess their false positive testing rates for drugs, because all specimens that have tested as presumptive positive on the initial tests for drugs and drug metabolites must be forwarded to an HHS-certified laboratory for initial and confirmatory testing.

(2) To ensure that the rate of false negative drug tests is kept to the minimum that the immunoassay technology supports, licensees shall perform an immunoassay test on all blind performance test specimens and submit these test specimens and a sampling of specimens screened as negative from every test run to the HHS-certified laboratory.

(3) Quality control specimens for each analytical run of specimens to be initially tested for drugs by the licensee must include:

- (i) Urine specimens certified to contain no drug;
- (ii) Urine specimens fortified with known standards; and

(iii) Positive controls with the drug or metabolite at or near the threshold (cut-off).

(4) A minimum of 10 percent of all urine specimens in each analytical run must be quality control specimens. One percent of each run, with a minimum of at least one sample, must be blind performance test specimens that appear as normal samples to the laboratory technicians. Licensee testing facility quality control specimens, fortified with known standards and positive controls with the drug or metabolite at or near the cutoff levels must be included in the run and should appear as normal specimens to laboratory analysts 18

(5) With each batch of urine specimens a sufficient number of standards must be included to ensure and document the linearity of the assay method over time in the concentration area of the cutoff. After acceptable values are obtained for the known standards, those values will be used to calculate specimen data. Implementation of procedures to ensure that carryover does not contaminate the testing of a donor's specimen must be documented.

(c) Quality assurance requirements for initial validity tests.

(1) Each initial validity test result shall be based on performing an initial validity test on one aliquot of a urine specimen.

(2) The performance characteristics (e.g., accuracy, precision, limit of detection, limit of quantitation, linearity, specificity) shall be documented for each validity test used, as appropriate.

(3) Each analytical run of specimens for which an initial validity test is being performed shall include the appropriate calibrators and controls, as defined in §§ 26 XX, XX of this subpart.

(d) The licensee shall investigate any testing errors or unsatisfactory performance discovered in blind performance testing and testing of other quality control specimens, in the testing of actual specimens, or through the processing of management reviews and/or MRO reviews, as well as any other errors or matters that could reflect adversely on the licensee's testing process. The investigation must determine relevant facts and identify the root cause(s) of the testing or process error when possible. The licensee shall take action to correct the cause(s) of any error or the unsatisfactory performance that are within the licensee's control. A record of the investigative findings and the corrective actions taken, where applicable, must be dated and signed by the individuals responsible for the day-to-day management of the licensee testing facility. The licensee and the NRC may require an on-site review of the laboratory that may be conducted unannounced during any hours of operation of the laboratory. Based on information provided by the NRC, HHS has the option of revoking or suspending the laboratory's certification or recommending that no further action be taken if the case is one of less serious error in which corrective action has already been taken, thus reasonably assuring that the error will not occur again.

(e) Volumetric pipettes and measuring devices shall be certified for accuracy or be checked by gravimetric, colorimetric or other verification procedure. Automatic pipettes and dilutors shall be checked for accuracy and reproducibility before being placed in service and checked periodically thereafter.

(f) The NRC reserves the right to inspect a licensee's testing facility at any time, pursuant to 10 CFR 50.70.

(g) Licensees will only use blind quality control materials that have been certified by immunoassay and GC/MS; and have stability data that verify performance of those materials over time.

§ 26.137 Receiving and processing specimens.

(a) When specimens are received, licensee testing facility personnel shall inspect each package for evidence of possible tampering and compare information on specimen containers within each package to the information on the accompanying custody-and-control forms. Indications of tampering with specimens at a collection site, in transit, or at a testing facility operated by a licensee must be reported to senior licensee management as soon as practicable, but

¹⁸ Some licensees have a continuous run vice this batch system. This needs further consideration because it doesn't make sense for everyone's process

no later than 8 hours after the indications are identified. An investigation shall be initiated to determine whether tampering has occurred. If it is determined that tampering has occurred, corrective actions shall be taken

(b) Specimen containers will normally be retained within the testing facility's accession area until all analyses have been completed. Specimens and aliquots may be discarded as soon as practicable after initial validity tests have demonstrated that the specimen was valid and initial test results for drugs and drug metabolites were negative.

(c) Specimen aliquots and the custody-and-control forms shall be used by testing facility personnel for conducting initial tests, as appropriate.

(d) Urine specimens and any associated split specimens, identified as presumptive positive or as questionable for adulteration, substitution, or dilution by a licensee's testing facility must be shipped to an HHS-certified laboratory for testing. Special processing may be conducted by the HHS-certified laboratory to analyze specimens suspected of being adulterated, substituted, or diluted (including hydration) Any evidence of substitution, adulteration, or dilution must be reported to the MRO.

(e) Each licensee testing facility shall be secure at all times. The facility shall have in place sufficient security measures to control access to the premises and to ensure that no unauthorized personnel handle specimens or gain access to the laboratory processes or to areas where records are stored Access to these secured areas shall be limited to specifically authorized individuals whose authorization is documented. All authorized visitors and maintenance and service personnel shall be escorted at all times in the licensee's testing facility.

§ 26.139 Split specimens.

(a) Urine specimens may be split, at the licensee's discretion, into two parts at the collection site, as described in 26.XX of this part.

(b) The specimen contained in Bottle A shall be analyzed by the licensee's testing facility for the licensee's purposes as described in this part. The specimen contained in Bottle B shall be stored in a secure manner until processing of the specimen contained in Bottle A by the licensee has been completed. If the specimen contained in Bottle A is determined to be negative and free of any evidence of subversion, Bottle B may be destroyed. If the initial test result of the specimen in Bottle A is positive for drugs or drug metabolites, or if the specimen in Bottle A was determined to have possibly been subject to substitution, dilution, or adulteration, or other means of subversion, Bottle A shall be forwarded to the HHS laboratory for testing and Bottle B shall be retained in secure storage by the licensee.

(c) Upon notification of a non-negative test result from the HHS laboratory, the donor may request in a timely manner (as established by the licensee) that the split specimen in Bottle B be tested by another HHS-certified laboratory. The donor must be informed of this option, and the split specimen may be tested only at the request of donor. The licensee shall forward Bottle B to another HHS-certified laboratory that did not test the specimen contained in Bottle A as soon as practicable, but in no case, no more than 3 business days (Monday to Friday, not including holidays) following the day of the request by the donor to have Bottle B tested

(d) The testing procedures to which the specimen in Bottle B is subject must be the same as those used to test the specimen in Bottle A and must meet the requirements of the HHS Guidelines for retesting specimens. The quantitative results of testing Bottle B shall be made available to the MRO and to the donor.

(e) Upon determination by the MRO that the specimen in Bottle A is non-negative, the licensee shall transfer Bottle B into long-term frozen storage until the specimen may be destroyed

§ 26.141 Reporting initial validity and drug test results.

(a) The licensee testing facility shall report as negative all valid specimens that are negative on the initial tests for drugs and drug metabolites. Except as provided in this part, presumptive positive drug test results from initial tests at the licensee's testing facility will not be reported to licensee management.

(b) Access to the results of initial tests must be limited to the licensee's testing staff, the MRO and the MRO's staff, the FFD Program Manager, the reviewing official, and, when appropriate, EAP staff, except as provided in §26.37.

(c) The licensee's testing facility shall provide qualified personnel when required to testify in an administrative or disciplinary proceeding against an individual when that proceeding is based on 56alcohol test results reported by the licensee's testing facility.

(d) The licensee's testing facility shall prepare the information for the annual report to the NRC as specified in Section I, § 26.187.57

(e) The data shall be presented for the cutoff levels in this part or any more stringent cutoff levels that licensees may specify. If the licensee tests for drugs and drug metabolites not included in the HHS panel of drugs, the summary must also include the number of presumptive positive specimens for those drugs and drug metabolites.

(f) The designed FFD program official shall use the available licensee information in conjunction with the monthly summary from the HHS Laboratory to evaluate continued testing program effectiveness as well as to detect any local trends in drugs of abuse which may require management action or FFD program adjustments, which may include, but are not limited to, training enhancements, procedure changes, the addition of substances to be tested to the FFD program's drug panel, or changes in the types of validity and drug tests used.

⁵⁶ The licensee only does drug test screening. Any disciplinary action would only be based upon the HHS Laboratory confirmation. The alcohol test is totally under the purview of the licensee.

⁵⁷ The way this is written — as a monthly report from one licensee entity to another — is unnecessary and distracting. This is a small group of people in the same place, not a big empire that needs to send reports to each other. Each licensee has been providing the NRC with semi-annual reports for over a decade without using this specific report process. The licensee will continue to provide required data to the NRC annually. The specifics of §26.187 is all that should be necessary.

Subpart G - HHS-Certified Laboratories⁵⁸

§ 26.151 Purpose.

This subpart provides requirements for the HHS-certified laboratories used by licensees and C/Vs to perform testing for drugs and drug metabolites.

§ 26.153 Using HHS-certified laboratories for testing urine specimens.

(a) Licensees and C/Vs subject to this part shall use only laboratories certified under the HHS "Mandatory Guidelines for Federal Workplace Drug Testing Programs", Subpart C - "Certification of Laboratories Engaged in Urine Drug Testing for Federal Agencies," (June 1994, 59 FR 29908, 29925-2929), and subsequent amendments thereto, for initial and confirmatory tests for drugs and drug metabolites, and for specimen validity testing, except for initial validity and drug tests that are authorized to be conducted at a licensee's testing facility. Information concerning the current certification status of laboratories is available from: The Division of Workplace Programs, Center for Substance Abuse Prevention, Substance Abuse and Mental Health Services Administration, Room 815, 5600 Fishers Lane, Rockwall 2 Bldg, Rockville, Maryland 20857.

(b) The HHS-certified laboratory shall not subcontract and shall perform all work with its own personnel and equipment unless otherwise authorized by the licensee or C/V. The laboratory must be capable of initial and confirmatory validity testing and testing for the required panel of drugs, drug metabolites, and any other substances required by the licensee or C/V, in accordance with the methods required by the HHS Guidelines.

(c) Licensees and C/Vs shall only use HHS-certified laboratories that agree to follow the same rigorous chemical testing, quality control, and chain-of-custody procedures when testing for more stringent cut-off levels as may be specified by licensees and C/Vs for the classes of drugs identified in this part, and for any other substances included in licensees' or C/V's drug panels. Because the HHS national laboratory certification process does not address practices outside the HHS Guidelines, such as using more stringent cutoff levels than set forth in the HHS Guidelines or testing for additional substances, licensees and C/Vs that choose to follow practices outside the HHS Guidelines must ensure that the HHS laboratory takes measures that are consistent with this part to assure that the reported test results are valid and defensible.

(d) If an HHS-certified laboratory loses its certification, in whole or in part, a licensee or C/V is permitted to immediately use an HHS-certified laboratory being used by another licensee or C/V having the same drug panel and cut-off levels

§26.155 Contracting with HHS-certified laboratories.

(a) All contracts between licensees and HHS-certified laboratories and between C/Vs and HHS-certified laboratories, must require implementation of all obligations of this part applicable to HHS-certified laboratories.

(b) Before the award of a contract to a HHS-certified laboratory, the licensee or C/V shall ensure that pre-award inspections and evaluation of the procedural aspects of the laboratory's drug testing operation are conducted by qualified personnel.

(c) At a minimum, licensee and C/V contracts with HHS-certified laboratory shall require the following --

- (1) The laboratory shall comply with applicable provisions of any State licensure requirements;
- (2) The laboratory shall make available qualified personnel to testify at proceedings in an administrative or

⁵⁸ NEI TF does not have the expertise to comment on most of the technical detail appearing in this section. It is not clear why much of this is included. The licensee needs to know those things that can be changed, options that are under its control, etc. Information associated with the licensee interaction with the lab is appropriate but not the details of internal processing. If those are needed the MRO will work directly with the laboratory personnel.

disciplinary proceeding against an individual when that proceeding is based on urinalysis results reported by the HHS-certified laboratory.

(3) The laboratory shall employ personnel with the necessary qualifications and skills to satisfactorily perform the roles and responsibilities delineated in the HHS Mandatory Guidelines and under this part.

(4) The laboratory shall develop, implement and maintain procedures for remedial actions to be taken when systems are out of acceptable limits or errors are detected. There shall be documentation that these procedures are followed and that all necessary corrective actions are taken. There shall also be in place systems to verify all stages of testing and reporting and documentation that these procedures are followed.

(5) The laboratory shall not enter into any relationship with the licensee's or C/V's MRO that may be construed as a potential conflict of interest or derive any financial benefit by having a licensee or C/V use a specific MRO.

(6) Licensees and C/Vs shall reserve the right to inspect or audit the laboratory at any time. Licensee contracts with HHS-certified laboratories for validity and drug testing, must permit the NRC and the licensee or C/V to conduct unannounced inspections and audits and to obtain all information and documentation reasonably relevant to the inspections and audits. Licensee and C/V contracts with HHS-certified laboratories must also provide the licensee, C/V and the NRC with the ability to obtain copies of any documents, including reviews and inspections pertaining to the laboratory's certification by HHS, and any other data that may be needed to assure that the laboratory is performing its testing and quality control functions properly and that laboratory staff and procedures meet applicable requirements.

§26.157 Assuring specimen security and chain-of-custody.

(a) The HHS-certified laboratories performing services under this part shall be secure at all times. There must be in place sufficient security measures to control access to the premises and to ensure that no unauthorized personnel handle specimens or gain access to the laboratory processes or to areas where records are stored. Access to these secured areas shall be limited to specially authorized individuals whose authorization is documented. With the exception of personnel authorized to conduct inspections on behalf of licensees, C/Vs, the NRC, and emergency personnel, including but not limited to firefighters and medical rescue teams, all authorized visitors and maintenance and service personnel shall be escorted at all times.

(b) The HHS-certified laboratories performing services under this part shall develop and maintain clear and well-documented procedures to maintain control and accountability of specimens from receipt through completion of testing, reporting of results, during storage, and continuing until final disposition of specimens.

(c) At a minimum, chain-of-custody procedures shall require that --

(1) The HHS custody-and-control form, or a similar custody-and-control form, is used that allows for identification of the donor, and documentation of information about the testing process and transfers of custody of the specimen;

(2) Each time a specimen is handled or transferred, the date and purpose shall be documented on the custody-and-control form and every individual in the chain shall be identified, except for couriers, express carriers, and postal service personnel, as described in 26 XX.

(3) Authorized technicians are responsible for each urine specimen or aliquot in their possession and shall sign and complete custody-and-control forms for those specimens or aliquots as they are received.

(4) The original custody-and-control form shall accompany the specimen to the HHS-certified laboratory. A copy shall accompany any split sample.

(5) A tamper-evident sealing system is used that is designed so that the specimen container can be sealed against undetected opening, the container can be identified with a unique identifying number identical to that appearing on

the custody-and-control form, and space has been provided to initial the container affirming its identity. For purposes of clarity, this requirement assumes use of a system made up of one or more pre-printed labels and seals (or a unitary label/seal), but use of other, equally effective technologies is authorized.

(6) Shipping containers may be used in which one or more specimens and associated paperwork may be transferred and which can be sealed and initialed to prevent undetected tampering.

(d) When a shipment of specimens is received, laboratory personnel shall inspect each package for evidence of possible tampering and compare information on specimen bottles within each package to the information on the accompanying custody-and-control forms. Any direct evidence of tampering or discrepancies in the information on the specimen bottles and the custody-and-control forms attached to the shipment shall be immediately report to the licensee or C/V and shall be noted on the custody-and-control forms.

(e) Specimen bottles will normally be retained within the laboratory's accession area until all analyses have been completed. Aliquots and laboratory custody-and-control forms shall be used by laboratory personnel for conducting initial and confirmatory tests while the original specimen and the custody-and-control form remain in secure storage.

(f) Specimens that do not receive an initial test within 7 days of arrival at the laboratory shall be placed in secure refrigeration units. Temperatures shall not exceed 6°C. The laboratory shall have the capability to ensure proper storage conditions in the event of a prolonged power failure.

§26.159 Testing urine specimens.

(a) All urine specimens submitted to the HHS-certified laboratory must be tested for validity, drugs and drug metabolites in the manner that is consistent with the laboratory's standards and procedures for certification.

(b) A specimen that tests negative on initial or confirmatory drug tests shall be discarded or may be pooled for use in the laboratory's internal quality control program unless validity test results indicate that the specimen may not be valid.

(c) Non-instrumented devices may be used for specimen validity testing.

(d) Initial validity testing. Each specimen shall be tested by the laboratory as follows --

(1) Determine the creatinine concentration;

(2) Determine the specific gravity on every specimen for which the creatinine concentration is less than 20 mg/dL;

(3) Determine the pH,

(4) Perform one or more initial validity tests for oxidizing adulterants, and

(5) Perform additional validity tests, the choice of which is dependent upon the observed indicators or characteristics below, when the following conditions are observed --

(i) Abnormal physical characteristics;

(ii) Reactions or responses characteristic of an adulterant obtained during initial or confirmatory drug tests (e.g., non-recovery of internal standards, unusual response), or

(iii) Possible unidentified interfering substance or adulterant.

(e) Initial drug testing. For the analysis of urine specimens, any initial test performed by a HHS-certified laboratory must use an immunoassay that meets the requirements of the Food and Drug Administration for commercial distribution. Pending HHS (SAMSHA) review and approval of non-instrumented immunoassay testing devices, such devices shall not be used for initial drug testing under this part.

(1) The following cutoff levels shall be used for initial testing of specimens to determine whether they are negative for the indicated substances --

Initial test cutoff levels for drugs and drug metabolites (ng/ml)

Substance	Cutoff level (ng/ml)
Marijuana metabolites	50
Cocaine metabolites	300
Opiate metabolites ¹	2000
Phencyclidine	25
Amphetamines	1000

¹25 ng/ml is immunoassay specific for free morphine.

(2) If licensees or C/Vs specify more stringent cutoff levels, only the more stringent tests need be conducted by the laboratory and the results of the initial tests be reported for only the more stringent cutoff levels

(3) Multiple initial drug tests for the same drug or drug class may be performed provided that all tests meet the cutoffs and quality control requirements of this part. Multiple testing may include, but is not limited to, performing a test by immunoassay technique "A" for all drugs using the cutoff levels, but presumptive positive amphetamines are then tested using immunoassay technique "B" to eliminate any possible presumptive positives due to structural analogues, or immunoassay technique "B" is used because a valid analytical result cannot be obtained using immunoassay technique "A "

(f) Confirmatory drug testing A specimen identified as positive on an initial drug test shall be confirmed for the class(es) of drugs for which the specimen initially tested positive using gas chromatography/mass spectrometry (GC/MS) at the cutoff levels specified in this paragraph, except if the licensee or C/V has required more stringent cutoff levels --

Confirmatory drug test cutoff levels (ng/ml)

Marijuana metabolite ¹	15
Cocaine metabolite ²	150
Opiates:	
Morphine	2000
Codeine	2000
6-Acetylmorphine ³	10
Phencyclidine	25
Amphetamines	
Amphetamine	500
Methamphetamine ⁴	500

¹Delta-9-tetrahydrocannabinol-9-carboxylic acid.

²Benzoylcegonine.

³Test for 6-AM when the confirmatory test shows a morphine concentration exceeding 2,000 ng/ml.

⁴Specimen must also contain amphetamine at a concentration \geq 200 ng/ml.

(1) Each confirmatory drug test shall provide a quantitative result. When the concentration of a drug or metabolite exceeds the linear region of the standard curve the laboratory may record the result as "exceeds the linear range of the test" or may dilute the specimen to obtain an accurate quantitative result when the concentration is above the upper limit of the linear range.

(2) If licensees or C/Vs specify more stringent cutoff levels, only tests at the more stringent cutoff levels need be conducted by the laboratory and the results of the confirmatory tests shall be reported for only the more stringent cutoff levels.

(g) Long-term storage Long-term frozen storage (-20°C or less) ensures that positive adulterated, substituted, and diluted urine specimens will be available for any necessary retest. Unless otherwise authorized in writing by the licensee or C/V, laboratories shall retain and place in properly secured long-term frozen storage all specimens reported positive, adulterated, substituted, or diluted. Specimens shall be stored for a minimum of one year. Within this one-year period, a licensee or C/V may request the laboratory to retain the specimen for an additional period of time. If no such request is received, the laboratory may discard the specimen after the end of one year, except that the laboratory shall be required to maintain any specimens under legal challenge for an indefinite period.

(h) Split specimens. If, at the licensee's or C/V's discretion, a specimen has been split into Bottle A and Bottle B at the collection site, then Bottle A must be analyzed by the HHS-certified laboratory. At the licensee's or C/V's discretion, Bottle B may also be forwarded to the laboratory or maintained in secure storage by the licensee or C/V. If the specimen in Bottle A is free of any evidence of drugs, drug metabolites, and subversion, then the specimen in Bottle B may be discarded. If initial and confirmatory drug tests of the specimen in Bottle A are positive, or, if validity testing shows the specimen has been subject to adulteration, dilution, substitution, or other means of subversion, the laboratory shall notify the MRO, and the donor may request in a timely manner (as established by the licensee or C/V) that the specimen in Bottle B be tested. The donor must be informed of this option and the specimen in Bottle B may be tested only at the donor's request. The specimen in Bottle B shall be forwarded to a second HHS-certified laboratory that did not test the specimen in Bottle A as soon as reasonably practicable, but in no case more than three business days following the day of the donor's request. The quantitative results of testing the specimen in Bottle B shall be made available to the MRO and the MRO shall provide them to the donor.

(i) Retesting a specimen for drugs. At a licensee's or C/V's request, the laboratory may be asked to forward an aliquot of a single specimen or Bottle B of a split specimen to a second HHS-certified laboratory for testing.

(1) The second laboratory shall use its confirmatory drug test when retesting an aliquot of a single specimen or testing Bottle B of a split specimen for the drug or drug metabolite that was reported positive by the first laboratory.

(2) Because some drugs or drug metabolites may deteriorate during storage, the retest by the second laboratory is not subject to a specific drug cutoff level, but must provide data sufficient to confirm the presence of the drug or drug metabolite.

(3) If the second laboratory fails to reconfirm the presence of the drug or drug metabolite that was reported by the first laboratory, the second laboratory shall attempt to determine the reason for not reconfirming the first laboratory's findings by conducting specimen validity tests. The second laboratory shall conduct the same specimen validity tests it would conduct on a single specimen or the specimen in Bottle A of a split specimen

(4) The second laboratory shall report all results to the licensee's or C/V's MRO

(i) Retesting a specimen for adulterants. A second laboratory may only conduct the confirmatory validity test(s) necessary to reconfirm the presence of an adulterant in a specimen reported by the first laboratory. The second laboratory shall use one of the following criteria to reconfirm an adulterated result when retesting an aliquot of a single specimen or testing the specimen in Bottle B of a split specimen -

(1) pH shall be measured using the laboratory's confirmatory pH test with the appropriate cutoff (i.e., either less than 3 or greater than or equal to 11);

(2) Nitrite shall be measured using the laboratory's confirmatory nitrite test with a cutoff concentration of greater than or equal to 500 mcg/mL; or

(3) For adulterants without a specified cutoff (e.g., glutaraldehyde, surfactant, chromium(VI), halogens, bleach, peroxidase, peroxide, and other oxidizing agents), the laboratory shall use its confirmatory validity test to reconfirm the presence of an adulterant.

(j) Retesting a specimen for substitution. A second laboratory may only conduct confirmatory validity test(s)

necessary to reconfirm substitution of a specimen reported by the first laboratory. The second laboratory shall use the following criteria to reconfirm a substituted result when retesting an aliquot of a single specimen or testing the specimen in Bottle B of a split specimen -

(1) The creatinine shall be measured using the laboratory's confirmatory creatinine test with a cutoff concentration of less than 5 mg/dL; and

(2) The specific gravity shall be measured using the laboratory's confirmatory specific gravity test with the specified cutoffs of less than 1.002 or greater than or equal to 1.020.

(k) Quality assurance and quality control of validity and drug testing. HHS-certified laboratories shall have a quality assurance program that encompasses all aspects of the testing process, including, but not limited to, specimen accessioning, chain of custody, security and reporting of results, initial and confirmatory testing, certification of calibrators and controls, and validation of analytical procedures. Validation of procedures shall document that carryover does not affect the donor's specimen results. Periodic verification of analytical procedures is required. Quality assurance procedures shall be designed, implemented, and reviewed to monitor the conduct of each step of the testing process to include the quality control requirements specified in the HHS Mandatory Guidelines, and subsequent amendments thereto, for -

- (1) initial drug tests;
- (2) confirmatory drug tests;
- (3) specimen validity tests, including --
 - (i) creatinine tests;
 - (ii) specific gravity tests;
 - (iii) pH tests;
 - (iv) oxidizing adulterant tests;
 - (v) nitrite tests; and
 - (vi) other adulterant tests

§ 26.161 Reporting results

(a) The HHS-certified laboratory shall report test results to the licensee's or C/V's MRO within an average of 5 business days after receipt of the specimen by the laboratory. Before any test result is reported, it must be certified as correct by the laboratory's certifying scientist. The report must identify the substances tested for, the results of the validity and drug tests, the cutoff levels for each, the specimen number assigned by the licensee or C/V, any indications of tampering, adulteration, substitution, or dilution that may be present, and the laboratory's specimen identification number.

(b) A urine specimen from a single specimen collection, or the primary (Bottle A) specimen from a split specimen collection, must be reported --

(1) negative when each specimen validity test result indicates that the specimen is a valid urine specimen, and either --

- (i) each initial drug test is negative, or
- (ii) confirmatory drug test results are negative.

(2) positive for a specific drug when the initial drug test is positive and the confirmatory drug test is positive

(3) adulterated when --

- (i) The nitrite concentration is greater than or equal to 500 mcg/mL using an initial nitrite test on the first

aliquot and a different confirmatory nitrite test on the second aliquot;

(ii) The pH is less than 3 or greater than or equal to 11 using a pH meter for the initial test on the first aliquot and a pH meter for the confirmatory test on the second aliquot or using a colorimetric pH initial test on the first aliquot and a pH meter for the confirmatory test on the second aliquot;

(iii) The presence of an exogenous substance (i.e., a substance which is not a normal constituent of urine) is documented using an initial test on the first aliquot and a different confirmatory test on the second aliquot; or

(iv) The presence of an endogenous substance at a concentration greater than what is considered a normal physiological concentration is documented using an initial test on the first aliquot and a different confirmatory test on the second aliquot.

(4) substituted when both the initial and confirmatory creatinine tests and initial and confirmatory specific gravity tests have the following results --

(i) The creatinine concentration is less than 5 mg/dL; and

(ii) The specific gravity is less than 1.002 or greater than or equal to 1.020

(5) dilute when the initial or confirmatory tests for creatinine and specific gravity have the following results --

(i) The creatinine concentration is less than 20 mg/dL;

(ii) The specific gravity is less than 1.003; and

(iii) The creatinine and specific gravity results do not satisfy the criteria for a substituted specimen or the incongruent criteria described in paragraph (g)(1) below

(6) invalid result when --

(i) Inconsistent creatinine and specific gravity results are obtained (e.g., a creatinine less than 5 mg/dL on both the initial and confirmatory tests and a specific gravity greater than or equal to 1.002 and less than 1.020 on either the initial or confirmatory tests, a creatinine less than 5 mg/dL on both the initial and confirmatory tests and a specific gravity greater than or equal to 1.0011 and less than 1.0020 on either the initial or confirmatory tests when using a refractometer that measures specific gravity to four decimal places, or a specific gravity of 1.000 on both the initial and confirmatory tests and a creatinine greater than or equal to 5 mg/dL on either the initial or confirmatory tests;

(ii) The pH is greater than or equal to 3 and less than 4.5 or greater than or equal to 9 and less than 11 on two separate aliquots;

(iii) The nitrite concentration is greater than or equal to 200 and less than 500 mcg/mL on two separate aliquots;

(iv) The same general oxidant test is used for the initial validity test on one aliquot and for the confirmatory validity test on a second aliquot to identify the presence of an oxidant ;

(v) The odor of a specimen is used as the initial test to detect the presence of a halogen followed by a confirmatory halogen colorimetric test;

(vi) Interference occurs on the immunoassay drug tests on two separate aliquots (i.e., valid immunoassay drug test results cannot be obtained);

(vii) The same surfactant test is used for the initial test on one aliquot and for the confirmatory test on the second aliquot or a visual foam/shake test is used as an initial test for a possible surfactant followed by the confirmatory surfactant test; or

(viii) Interference with the GC/MS drug confirmation assay occurs on at least two separate aliquots of the specimen and the laboratory is unable to identify the interfering substance.

(c) The laboratory may report more than one test result for a specimen. For example, a specimen can be positive for a specific drug and invalid for another drug.

(d) The laboratory shall provide numerical values for confirmed drug positive, adulterated, diluted, and substituted test results to the MRO when the MRO requests such information. The MRO's request may either be a general request covering all such results or on a specific case by case request. When the concentration of a drug or metabolite exceeds the linear region of the standard curve, the laboratory may report to the MRO that the

quantitative value "exceeds the linear range of the test" or report an accurate quantitative value above the upper limit of the linear range that was obtained by diluting the specimen. The MRO shall not disclose quantitative drug test results to the licensee or C/V, but shall report only whether the specimen was drug positive or negative. This restriction does not preclude the provision of program performance data. Quantitation of negative tests for urine specimens must not be disclosed, except where deemed appropriate by the MRO for proper disposition of the results of tests of suspect specimens

(e) The laboratory shall provide quantitative values for confirmed opiate results for morphine or codeine that are greater than or equal to 15,000 ng/mL, even if the MRO has not requested quantitative values for the test result.

(f) The laboratory may transmit results to the MRO by various electronic means (for example, teleprinters, facsimile, or computer) in a manner designed to ensure confidentiality of the information. Results may not be provided verbally by telephone. The licensee or C/V, directly or through the HHS-certified laboratory, must ensure the security of the data transmission and ensure only authorized access to any data transmission, storage, and retrieval system.

(g) For a specimen that has a non-negative result, the laboratory shall retain the original custody-and-control form and send to the MRO a copy of the original custody-and-control form signed by a certifying scientist.

(h) The HHS-certified laboratory shall provide to the licensee official responsible for coordination of the FFD program an annual statistical summary of urinalysis testing and shall not include in the summary any personal identifying information. The summary report shall include test results that are reported within the year period. Normally, the summary report is sent within 14 calendar days after the end of the one-year period covered by the report. The statistics shall be presented for the cutoff levels in these guidelines or any more stringent cut-off levels that licensees or C/Vs may specify. The HHS-certified laboratory shall make available quantitative results for all samples tested when requested by the NRC, licensee or C/V for which the laboratory is performing drug-testing services. The summary report must contain the following information --

- (1) Total number of specimens received
- (2) Number of specimens reported as
 - (i) negative
 - (ii) negative and dilute
- (3) Number of specimens reported as positive by drug
 - (i) marijuana metabolite
 - (ii) cocaine metabolite
 - (iii) opiates (total)
 - (A) codeine
 - (B) morphine
 - (C) 6-AM
 - (iv) phencyclidine
 - (v) amphetamines (total)
 - (A) amphetamine
 - (B) methamphetamine
- (4) Total number reported as adulterated.
- (5) Total number reported as substituted
- (6) Total number reported as invalid

§ 26.163 Blind specimen procedures and errors in testing.

- (a) Licensees and C/Vs shall have a blind specimen procedure that meets the requirements of this part.
- (b) Each licensee and C/V shall submit blind performance test specimens to the laboratory. During the initial 90-day period of any contract with a HHS-certified laboratory (not including rewritten or renewed contracts), the number of blind performance test specimens submitted to the laboratory shall be at least 20 percent of the total number of specimens submitted (up to a maximum of 100 blind performance specimens) or 30 blind performance test specimens, whichever is greater. Following the initial 90-day period, the number of blind performance test specimens submitted per quarter must be a minimum of 3 percent of all specimens (up to a maximum of 25 percent) or 10 blind performance test specimens, whichever is greater. Licensees and C/Vs should attempt to submit blind performance test specimens, both during the initial 90-day period and quarterly thereafter, at a frequency that corresponds to the submission frequency for other specimens.
- (c) Approximately 50 percent of the blind performance test specimens must be blank (i.e., certified to contain no drug) and the remaining specimens must be positive for one or more drugs per specimen in a distribution so that all the drugs for which the licensee is testing are included in approximately equal frequencies of challenge. The positive specimens must be spiked only with those drugs for which the licensee is testing.
- (d) In addition, 10 percent of the positive blind specimens must be appropriately adulterated or diluted and spiked to between 60 percent and 80 percent of the initial cutoff values for drugs established herein, or of any lower cut-off values established by the licensee or C/V, to challenge the laboratory's ability to determine specimen validity and perform special processing, as required by this part.
- (e) Licensees and C/Vs will only use blind quality control materials that have been certified by immunoassay and GC/MS; and have stability data that verify performance of those materials over time.
- (f) Any testing errors or unsatisfactory performance discovered in blind performance testing, in the testing of actual specimens, or through the processing of appeals and MRO reviews, as well as any other errors or matters that could reflect adversely on the testing process shall be investigated by the licensee or C/V.
- (1) The investigation must determine relevant facts and identify the root cause(s) of the testing or process error when possible. The licensee or C/V, and the laboratory, shall take action to correct the cause(s) of any error or the unsatisfactory performance that are within their control
 - (2) Should a false positive error occur on a blind performance test specimen or on a regular specimen, the licensee or C/V shall require the laboratory to take corrective action to minimize the occurrence of the particular error in the future. If there is reason to believe the error could have been systematic, the licensee may also require review and reanalysis of previously run specimens
 - (3) Should a false positive error be determined to be technical or methodological, the licensee or C/V shall instruct the laboratory to provide all quality control data from the batch of specimens that included a false positive specimen. In addition, the licensee or C/V shall require the laboratory to retest all specimens analyzed positive for that drug or metabolite from the time of final resolution of the error back to the time of the last satisfactory performance test cycle. This retesting must be documented by a statement signed by the laboratory's certifying scientist. The licensee or C/V and the NRC may require an on-site review of the laboratory that may be conducted unannounced during any hours of operation of the laboratory. Based on information provided by the NRC, HHS has the option of revoking or suspending the laboratory's certification or recommending that no further action be taken if the case is one of less serious error in which corrective action has already been taken, thus reasonably assuring that the error will not occur again.

Subpart H - Determining FFD Policy Violations and Determining Fitness²²**§26.171 Purpose.**

This subpart part defines requirements for determining that a FFD policy violation has occurred and for making a determination of fitness

§26.173 Medical Review Officer (MRO)

(a) **Qualifications.** The MRO shall be a licensed physician holding either a Doctor of Medicine or Doctor of Osteopathy degree and must 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. The MRO shall also be knowledgeable of the FFD policies of the licensees or C/Vs for whom the MRO is providing services. At a minimum, the MRO must be trained in, and the examination must address, the following topics -

- (1) collection procedures for each type of specimen;
- (2) chain of custody, recordkeeping and reporting;
- (3) the interpretation of test results, and
- (4) the requirements of this part.

(b) **Relationships.** The MRO may be a licensee, C/V, or contract employee. However, the MRO shall not be an employee or agent of or have any financial interest in a laboratory or a contracted operator of a licensee testing facility whose drug testing results the MRO is reviewing for the licensee or C/V. Additionally, the MRO shall not derive any financial benefit by having the licensee or C/V use a specific drug testing laboratory or licensee testing facility operating contractor or have any agreement with such parties that may be construed as a potential conflict of interest.

(c) **MRO staff.** The MRO's staff may perform routine administrative support functions, including receipt of test results, review of negative test results, and scheduling interviews for the MRO

(1) Staff under the direct, personal supervision of the MRO may review and report a negative test results to the licensee's or C/V's designated representative.

(2) Staff reviews of negative drug test results must be limited to reviews of the custody-and-control form to determine if there are any errors that may require the MRO to initiate corrective action and to ensure that it is consistent with the information on the MRO's copy;

(3) The MRO is responsible for assuring the quality of the staff's work.

(4) The MRO shall personally review at least 5 percent of all custody-and-control forms reviewed by the staff on a quarterly basis, up to a total of 500 negative results in any quarter. The MRO review must include, at a minimum --

- (i) all results that required a corrective action;
- (ii) the custody-and-control form;
- (iii) the negative laboratory test result and any accompanying corrective documents; and
- (iv) the report provided to the licensee or C/V.

²² This section has not had adequate review by NEI TF members. Comments will be provided when available

(5) The MRO must correct and document any errors that are discovered and take action as necessary to ensure compliance by the MRO staff with this part. The MRO shall attest to the quality assurance review by initialing the custody-and-control forms that the MRO reviews.

(6) The staff may not conduct verification interviews with donors

(7) The designation of staff to perform MRO functions under MRO direction must be limited and not used as a subterfuge to circumvent confidentiality and other requirements of this part. The MRO is responsible for assuring that staff operate under controls sufficient to ensure that the independence and confidentiality of the MRO process are not compromised.

(c) Responsibilities. The role of the MRO is to review and interpret non-negative test results obtained through the licensee's or C/V's testing program and to identify evidence of subversion of the testing process. The MRO is also responsible for identifying issues associated with the collection and testing of specimens, and advising and assisting management in the planning and oversight of the overall FFD program. In carrying out this responsibility, the MRO shall examine alternate medical explanations for any non-negative test result. This action may include, but is not limited to, conducting a medical interview with the donor, review of the donor's medical history, or review of any other relevant biomedical factors. The MRO shall review all medical records made available by the donor when a non-negative test could have resulted from responsible use of legally prescribed medication. The MRO shall not consider the results of tests that are not obtained or processed in accordance with this part, although he or she may consider the results of tests on split specimens in making his or her determination, as long as those split specimens have been stored and tested in accordance with the procedures described herein.

(d) Verification of FFD policy violations. A non-negative test result does not automatically identify an individual as having used substances in violation of the NRC's regulations or the licensee's or C/V's FFD policy or as having attempted to subvert the testing process. An individual with a detailed knowledge of possible alternate medical explanations is essential to the review of the results. This review must be performed by the MRO before the transmission of results to licensee or C/V management officials.

(1) Before making a final decision to verify a non-negative test result, the MRO shall give the donor an opportunity to discuss the test result or other occurrence with the MRO. Following verification of a non-negative test result or other occurrence as a violation of FFD policy, the MRO shall, as provided in the licensee's or C/V's FFD policy, immediately notify the licensee's or C/V's management official empowered to recommend or take administrative action (or the official's designated agent).

(2) Presumptive positive initial test results must not be reported except as provided by 26.XX.

(3) The MRO may verify a non-negative test result, or otherwise make a determination of an FFD policy violation, without having discussed the test result or other occurrence directly with the donor in the following three circumstances --

(i) The MRO contacts the donor, the donor expressly declines the opportunity to discuss the test result or other occurrence that may constitute an FFD policy violation;

(ii) The MRO, after making all reasonable efforts, has been unable to contact the donor within 14 days of the date on which the MRO receives notice of the non-negative test result; evidence of subversion of the testing process, or other activity that would constitute an FFD policy violation;

(iii) A licensee representative has successfully made and documented contact with the donor and has instructed him or her to contact the MRO and more than 5 business days have passed since the date the donor was successfully contacted by the licensee representative.

(4) If the MRO determines that the FFD policy has been violated, the donor may present to the MRO information documenting the circumstances, including, but not limited to serious illness or injury, that unavoidably prevented the

donor from being contacted by the MRO or licensee representative or from contacting the MRO in a timely manner. The MRO, on the basis of this information, may reopen the procedure for determination of an FFD policy violation and allow the individual to present information relating to the issue. The MRO may modify the initial determination based on an evaluation of the information provided.

(e) **Verification for opiates.** Before the MRO verifies a non-negative test result as a violation of FFD policy and the licensee takes action for opiates, the MRO shall determine that there is reasonable and substantial clinical evidence, in addition to the non-negative test results, of unauthorized use of any opium, opiate, or opium derivative (e.g., morphine/codeine). Clinical signs of abuse include recent needle tracks or test results that are inconsistent with the ingestion of food or medication including prescription medications containing opiates (e.g., 6-AM test). Clinical signs of abuse also include, but are not limited to, behavioral and psychological signs of acute opiate intoxication or withdrawal, or admission of non-prescribed opiate use. This requirement does not apply if the GC/MS confirmation testing for opiates confirms the presence of 6-AM since the presence of this metabolite is proof of heroin use.

(f) **Reanalysis authorized.** Should any question arise as to the accuracy or validity of a laboratory confirmed positive test result, only the MRO is authorized to order a reanalysis of the original specimen and these retests are authorized only at laboratories certified by HHS. The MRO shall authorize a reanalysis of the original aliquot on timely request (as established by the licensee or C/V) by the donor tested, and shall also authorize an analysis of any split specimen stored by or for the licensee under the provisions of this part.

(g) **Results consistent with responsible substance use.** If the MRO determines that there is a legitimate medical explanation for the non-negative test result, and that the use of a substance 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 there has not been a violation of licensee's or C/V's FFD policy. The MRO shall report the test result to the licensee as negative. The MRO shall further evaluate the non-negative test result and medical explanation to determine if there is a potential risk to public health and safety of the individual being impaired on duty from the substance or from the medical condition. If the MRO determines that such a risk exists, he or she shall ensure that a determination of fitness is performed.

(h) **Result scientifically insufficient.** Additionally, the MRO based on review of inspection reports, quality control data, multiple specimens, and other pertinent results, may determine that the result is scientifically insufficient for further action and declare the test specimen negative. In this situation, the MRO may request reanalysis of the original specimen before making this decision. 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 an alternate laboratory which is certified in accordance with the HHS Guidelines. 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's testing facility, of 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 licensee.

(i) **Re-authorization after a first violation.** The MRO is also responsible for reviewing drug test results from an individual whose authorization was terminated for a first violation of the FFD policy involving a confirmed positive drug test result and who is being considered for re-authorization, as described in §26.63(b)(1)(iv). In order to determine whether subsequent non-negative 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 laboratory, and the laboratory shall provide, quantitation of test results and other information necessary to make the determination. If the drug for which the individual first tested positive was marijuana and the results of an immunoassay test, conducted prior to reinstatement of authorization, are below either 50ng/mL or the licensee's or C/V's initial cutoff level for marijuana, then the MRO may after evaluation declare the test result as negative and the specimen shall not be forwarded to the HHS laboratory for confirmatory testing.

§26.175 Substance abuse professional²³.

²³ This is beyond necessary for NPPs. It may be needed for DOT's spread out and not tightly controlled facilities.

(a) Credentials. A substance abuse professional (SAP) shall have at least one of the following credentials --

- (1) a licensed physician,
- (2) a licensed or certified social worker,
- (3) a licensed or certified psychologist,
- (4) a licensed or certified employee assistance professional; or

(5) an alcohol and drug abuse counselor certified by the National Association of Alcoholism and Drug Abuse Counselors Certification Commission (NAADAC) or by the International Certification Reciprocity Consortium/Alcohol and Other Drug Abuse (ICRC).

(b) Basic knowledge. A SAP shall be knowledgeable in the following areas --

- (1) Knowledge of and clinical experience in the diagnosis and treatment of alcohol and controlled substances-related disorders;
- (2) Knowledge of the SAP function as it relates to the public's interests in activities performed within the scope of this part.
- (3) Knowledge of this part and any changes thereto.

(c) Qualification training. SAPs must receive qualification training on the following subjects --

- (i) Background, rationale, and scope of this part;
- (ii) Key drug testing requirements of this part, including specimen collections, laboratory testing, MRO review, and problems in drug testing,
- (iii) Key alcohol testing requirements of this part, including specimen collections, the testing process, and problems in alcohol tests;
- (iv) SAP qualifications and prohibitions;
- (v) The role of the SAP in making determinations of fitness and the return-to-duty process, including the initial employee evaluation, referrals for education and/or treatment, the follow-up evaluation, continuing treatment recommendations, and the follow-up testing plan;
- (vi) Procedures for SAP consultation and communication with licensees or C/Vs, MROs, and treatment providers;
- (vii) Reporting and recordkeeping requirements of this part,
- (ix) Issues that SAPs confront in carrying out their duties under this part.

(d) Continuing education. During each three-year period following completion of initial qualification training, the SAP shall complete continuing education consisting of at least 12 continuing professional education hours relevant to performing SAP functions.

(1) This continuing education must include material concerning new technologies, interpretations, recent guidance, rule changes, and other information about developments in SAP practice pertaining to this part, since the time the SAP met the qualification training requirements of this section.

(2) Continuing education activities must include documented assessment tools to assist in determining that the material has been learned.

(e) Documentation The SAP must maintain documentation showing that the SAP currently meets all requirements of this section. This documentation must be provided on request to NRC representatives, licensees, or C/Vs who are using or contemplating using the SAP's services.

(f) Responsibilities. A SAP may be authorized to make determinations of fitness when potentially disqualifying FFD information has been identified regarding a candidate for authorization to perform activities under this part and for individuals who have violated the substance abuse provisions of a licensee's or C/V's FFD policy. The SAP evaluates individuals who have violated the substance abuse provisions of a FFD policy and makes recommendations concerning education, treatment, return to duty, follow-up drug and alcohol testing, and aftercare.

§26.177 Determination of fitness.

(a) A determination of fitness is the process whereby it is determined whether there are indications that an individual may be in violation of the licensee's FFD policy or is otherwise unable to safely and competently perform duties. A determination of fitness shall be made by a licensed or certified professional who is appropriately qualified and has the necessary clinical expertise, as verified by the licensee, to evaluate the specific fitness issues presented by the individual. Professionals called upon by the licensee or C/V may not perform a determination of fitness regarding specific fitness issues that are outside of their specific areas of expertise. The types of professionals and the fitness issues for which they are qualified to make a determination of fitness include, but are not limited to --

(1) A SAP who meets the requirements of §26.175 of this part may determine the fitness of an individual who may have engaged in substance abuse, but would 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 SAP has additional qualifications for addressing those fitness issues;

(2) A clinical psychologist 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, but would not be qualified to assess the fitness of an individual who may have a substance abuse problem, unless the psychologist is also a SAP;

(3) A psychiatrist may determine the fitness of an individual who is taking psychoactive medications in accordance with a valid prescription(s), but may not be qualified to assess potential impairment due to substance abuse, unless the psychiatrist has had specific training to diagnose and treat substance abuse;

(4) A physician may determine the fitness of an individual who may be ill, injured, fatigued, taking medications in accordance with a valid prescription(s) or using over-the-counter medications, but may not be qualified to assess the fitness of an individual who may have a substance abuse problem, unless the physician is also a SAP;

(5) The MRO may determine the fitness of an individual who may have engaged in substance abuse, who may be ill, injured, fatigued, taking medications in accordance with valid prescription(s) and/or using over-the-counter medications, but may not be qualified to evaluate potential impairment due to mental illness, unless the MRO has had specific training to diagnose and treat these illnesses.

(b) A determination of fitness, must be performed in at least the following circumstances --

(i) When there is an alternative medical explanation for a non-negative test result but there is a basis for believing impairment on duty could exist;

(ii) Before making return-to-duty recommendations subsequent to an individual's removal from duty in accordance with the licensee's FFD policy;

(iii) Before an individual is granted authorization to perform activities within the scope of this part when potentially disqualifying FFD information is identified and has not been previously evaluated by another licensee, and

(iv) If potentially disqualifying FFD information is otherwise identified.

(c) A determination of fitness may not be conducted through electronic means. Face-to-face interaction between the subject individual and the professional performing the determination is required.

(d) If there is neither conclusive evidence of a FFD policy violation nor a significant basis for concern that the individual may be impaired while on duty, then the individual shall be determined to be fit for duty.

(e) If there is no conclusive evidence of a FFD policy violation but that there is a significant basis for concern that the individual may be impaired while on duty, then the subject individual shall be determined to be unfit for duty. These results do not constitute a violation of this part or of the licensee's FFD policy, and no sanctions under the rule or the FFD policy shall be applied. However, the professional who made the determination of fitness shall consult with licensee management personnel to identify the actions required to ensure that any possible limiting condition does not represent a threat to workplace or public health and safety. Licensee management personnel shall implement the actions required. When appropriate, the subject individual may also be referred to the EAP.

(f) Licensee and C/V personnel may not 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 C/V. After the initial determination of fitness has been made, the evaluation and recommendations may be modified based on new or additional information from other sources, including, but not limited to, the subject individual, other licensee or C/V personnel, or staff of an education or treatment program. Unless the professional who made the initial determination of fitness is no longer employed by nor under contract to the licensee or C/V, only that professional is authorized to modify the evaluation and recommendations. When reasonably practicable, licensees and C/Vs shall assist in arranging for consultation between the new professional and the professional who is no longer available, to ensure continuity and consistency in the recommendations and their implementation.

Subpart I - Recordkeeping and Reporting Requirements

§26.181 General provisions.

(a) Each licensee subject to this part, and C/Vs with approved FFD programs, shall maintain records and submit certain reports to the NRC.

(b) All records may be stored and archived electronically, if the method used to create the electronic records:

- (1) provides an accurate representation of the original records;
- (2) prevents the alteration of any archived information and/or data once it has been committed to storage; and
- (3) allows easy retrieval and re-creation of the original records.

§26.183 Recordkeeping requirements for licensees and C/Vs.

(a) Each licensee subject to this part, and C/Vs with approved FFD programs shall retain the following records for at least five years or until the completion of all related legal proceedings, whichever is later--

- (1) Records of self-disclosures and suitable inquiries conducted under §26.45 and 26.47 that result in the granting of authorization;
- (2) Records pertaining to a denial of authorization under this part;
- (3) Records pertaining to the determination of a violation of the FFD policy and related management actions;
- (4) Records pertaining to a resignation before authorization is terminated for violation of the drug and alcohol provisions of the company's FFD policy

(b) Each licensee subject to this part, and C/Vs with approved FFD programs, shall retain the following records for at least three years or until the completion of all related legal proceedings, whichever is later -

- (1) Records of FFD training and examinations conducted under 26.XX of this part; and
- (2) Records of audits, audit findings, and corrective actions taken under 26.XX of this part

(c) Licensees and C/Vs shall ensure the retention and availability of records pertaining to a permanent revocation of authorization under §26.X and 26.X of this part for at least 40 years or until, upon application, the Commission determines that the records are no longer needed.

(d) Until, upon application, the Commission determines that the records are no longer needed, licensees and C/Vs shall retain the written FFD policy and procedures required under 26.XX. If any portion of the policy and procedures were superseded, the superseded material must be retained for at least five years or until completion of all legal proceedings related to a FFD violation that may have occurred under the superseded version, whichever is later.

(e) Written agreements for the provision of services under this part shall be retained for the life of the agreement or until completion of all legal proceedings related to a FFD violation that involved those services, whichever is later.

§26.185 Recordkeeping requirements for collection sites, licensee testing facilities and HHS-certified laboratories.

(a) Collection sites providing services to licensees and C/Vs, HHS-certified laboratories and licensee testing facilities shall maintain and make available documentation of all aspects of the testing process for at least two years

or until the completion of all legal proceedings related to a determination of a FFD violation, whichever is later. This two-year period may be extended upon written notification by the NRC or by any licensee or C/V for which services are being provided

(b) Documentation that must be retained includes, but is not limited to --

- (1) personnel files on all individuals authorized to have access to specimens;
- (2) chain of custody documents other than forms recording specimens with negative test results and no FFD violations or anomalies, which may be destroyed after appropriate summary information has been recorded for program administration purposes;
- (3) quality assurance/quality control records;
- (4) current and superceded procedure manuals,
- (5) all test data (including calibration curves and any calculations used in determining test results),
- (6) test reports;
- (7) performance records on performance testing,
- (8) records pertaining to the investigation of testing errors or unsatisfactory performance discovered in blind performance testing, in the testing of actual specimens, or through the processing of appeals and MRO reviews, as well as any other errors or matters that could reflect adversely on the integrity of the testing process, investigation findings and corrective actions taken, where applicable,
- (9) performance records on certification inspections;
- (10) records of preventative maintenance on licensee testing facility instruments;
- (11) records that summarize any negative test results based on scientific insufficiency;
- (12) either printed or electronic copies of computer generated data; and
- (13) records of individuals accessing secured areas in licensee testing facilities and HHS-certified laboratories, including dates and times of entry, and purpose of entry

§26.187 FFD program performance data.

(a) Each FFD program subject to this part shall collect and compile FFD program performance data

(b) The FFD program performance data must include --

- (1) the random testing rate;
- (2) drugs tested for and cutoff levels, including results of tests using lower cutoff levels and tests for drugs not included in the HHS panel;
- (3) workforce populations tested (i e., permanent licensee employees, C/Vs);
- (4) numbers of tests administered and results of those tests sorted by workforce population tested (i e., permanent licensee employee, C/Vs);
- (5) conditions under which the tests were performed, as defined in 26 31(b);

- (6) substances identified,
- (7) number of subversion attempts by type, and
- (8) summary of management actions.

(c) The data must be analyzed at least annually and appropriate actions taken to correct program weaknesses. Records of the data, analysis, and corrective actions taken must be retained for at least three years or until the completion of any related legal proceedings, whichever is later.

(d) Any licensee that terminates an individual's authorization or takes administrative action on the basis of the results of a non-negative initial test for marijuana (THC) or cocaine shall also report these test results in the annual summary by processing stage (i.e., onsite screening, laboratory screening, confirmatory tests, and MRO determinations). The report shall also include the number of terminations and administrative actions taken against individuals for the reporting period.

(e) The FFD program performance data must be submitted to the Commission annually (January through December), before March 1 of the following year.

(f) The FFD program performance data may be submitted in a consolidated report as long as the data are reported separately for each site.

(g) Each C/V that maintains an approved drug and alcohol testing program is subject to the reporting requirements of this section and shall submit the information required either directly to the NRC or through the licensee to which the C/V provided services during the year. Licensees and C/Vs shall share information to ensure that the information is reported completely and is not duplicated in reports submitted to the NRC.

§26.189 Reporting requirements.

(a) Each licensee subject to this part, and C/Vs with approved FFD programs, shall inform the Commission of significant violations of the FFD policy, significant FFD program failures, FFD authorization events, and errors in drug and alcohol testing. These events shall be reported under this section rather than reported under the provisions of 10 CFR 73.71.

(b) Significant FFD policy violations The following significant FFD policy violations must be reported to the NRC Operations Center by telephone within 24 hours of discovery of the violation by a licensee --

(1) The sale, distribution, use, possession, or presence of illegal drugs, or the use or presence of alcohol within a protected area or by an individual while performing activities subject to this part;

(2) Any acts by any person licensed under 10 CFR part 55 to operate a power reactor, by individuals responsible for moving irradiated fuel, by SSNM transporters, by the security personnel defined in 26.XX(5) in Subpart B, or by any supervisory personnel assigned to perform activities within the scope of this part that --

(i) Involve the sale, use, or possession of a controlled substance,

(ii) Results in a determination that the individual has violated the licensee's FFD policy including subversion as defined in §26.5; or

(iii) Involve use of alcohol within a protected area or while performing activities within the scope of this part.

²⁴ This section must comport to the RROP as it is used in the performance indicator process. This is too subjective. Someone needs to identify what is really significant and list those--no open

(c) Significant FFD program failures pursuant to the Revised Regulatory Oversight Process²⁴ Significant FFD program failures must be reported to the NRC Operations Center within 24 hours of the determination that the failure is reportable. Significant FFD program failures that must be reported include, but are not limited to --

- (1) An intention act that would cast doubt on the integrity of the FFD program;
- (2) An act or event that casts doubt on the honesty and integrity of FFD program personnel specified in §26.XX (Subpart B),
- (3) A program failure preventing an individual from being selected and subsequently tested in a random testing program while that individual was assigned to perform duties within the scope of this part;
- (d) FFD authorization events.

(1) Significant authorization events must be reported to the NRC Operations Center within 24 hours of the determination that the event is reportable²⁵. Significant authorization events that must be reported include, but are not limited to --

(i) An instance in which potentially disqualifying information from any source is obtained about an individual granted authorization under 26.53(c) more than five business days after authorization is granted that results in the termination of authorization; and

(ii) An instance in which an individual who has been granted authorization under 26.53(c) receives a confirmed positive drug test result that results in termination of authorization

(2) Authorization events that must be logged include, but are not limited to -

(i) Any instance in which the suitable inquiry required under 26.XX in Subpart C of this part is not completed within five business days after authorization is granted; and

(ii) Any instance in which drug test results are not available within five business days after authorization is granted under 26.XX in Subpart C.

(e) Drug and alcohol testing errors

(1) Within 30 days of completing an investigation of any testing errors or unsatisfactory performance discovered in blind performance testing at either a licensee testing facility or an HHS-certified laboratory, in the testing of actual specimens, or through the processing of appeals and MRO reviews, as well as any other errors or matters that could reflect adversely on the integrity of the testing process, the licensee or C/V shall submit to the NRC a report of the incident and corrective actions taken or planned. If the error involves a HHS-certified laboratory, the NRC shall ensure notification of the finding to HHS.

(2) Should a false positive error occur on a blind performance test specimen or on a regular specimen, the licensee or C/V shall notify the NRC within 24 hours of knowledge of the error.

²⁴ ended "any" There is a PRA being done by one licensee to put the random testing program in perspective

²⁵ These are not significant events and should continue to be only loggable—not reportable General comment - delete and determine what is really significant and worthy of NRC immediate attention.

Fitness for Duty Comments Number 7
Qualifications
September 17, 2002

Purpose: To discuss proposed changes proposed increases in qualification requirements for the MRO, Substance abuse professional and collectors.

Issue: The August draft unexpectedly expanded the qualification requirements. The proposed changes do not recognize the differences in management and control between FFD programs at a licensee facility and DOT sponsored programs.

- 1 MRO requirements—There was little difference between the current and affirmed rule.
 - a. Current rule--(b) "Medical Review Officer-qualifications and responsibilities." The Medical Review Officer shall be a licensed physician with knowledge of substance abuse disorders and may be a licensee or contract employee.
 - b. Affirmed rule--(b) Medical Review Officer--qualifications and responsibilities. The MRO shall be a licensed physician with knowledge of substance abuse disorders. The MRO may be a licensee or contract employee
 - c. The expanded requirements in 26 173 should be removed
- 2 Section 26 175 is a new section addressing Substance Abuse Professionals.
 - a. The training and qualification requirements do not fit with the expected duties. (b)(1) seems to define the core of the duties, that is Knowledge of and clinical experience in the diagnosis and treatment of alcohol and controlled substance-related disorders
 - b. It is unclear what (b)(2) means—it should be deleted
 - c. The SAP is not the MRO—why does the SAP have to be trained on all the details of Part 26 as required in (b)(3) and several parts of (c). Laboratory testing is not within the SAP purview. Many of the items in (c) should be deleted.
 - d. Continuing education in (d) should be deleted. The licensing and certification process should be relied on to provide the basic skills needed.
- 3 Section 26.85 addresses collectors
 - a. Current rule-- "Collection site person." A person who instructs and assists individuals at a collection site and who receives and makes an initial examination of the specimen(s) provided by those individuals. A collection site person shall have successfully completed training to carry out this function or shall be a licensed medical professional or technician who is provided instructions for collection under this part and certifies completion as required herein.
 - (d) Written procedures, instructions, and training shall be provided as follows:
 - (1) Licensee collection site procedures and training of collection site personnel shall clearly emphasize that the collection site person is responsible for maintaining the integrity of the specimen collection and transfer process, carefully ensuring the modesty and privacy of the individual tested, and is to avoid any conduct or remarks that might be construed as accusatorial or otherwise offensive or inappropriate.
 - (2) A non-medical collection site person shall receive training in compliance with this appendix and shall demonstrate proficiency in the application of this appendix prior to serving as a collection site person. A medical professional, technologist, or technician licensed or otherwise approved to practice in the jurisdiction in which collection occurs may serve as a collection site person if that person is provided the instruction described in 2 2(3) and performs collections 1 in accordance with those instructions

- b. Affirmed rule--Collection site person. A person who instructs and assists individuals at a collection site and who receives and makes an initial examination of the specimen(s) provided by those individuals. A collection site person shall have successfully completed training to carry out this function or shall be a licensed medical professional or technician who is provided instructions for collection under this part and certifies completion as required herein
 - (d) Written procedures, instructions, and training must be provided as follows:
 - (1) Licensee collection site procedures and training of collection site personnel shall clearly emphasize that the collection site person is responsible for maintaining the integrity of the specimen collection and transfer process, carefully ensuring the modesty and privacy of the individual tested, and is to avoid any conduct or remarks that might be construed as accusatorial or otherwise offensive or inappropriate.
 - (2) A non-medical collection site person shall receive training in compliance with this appendix and shall demonstrate proficiency in the application of this appendix before serving as a collection site person. A medical professional, technologist, or technician licensed or otherwise approved to practice in the jurisdiction in which collection occurs may serve as a collection site person if that person is provided the instructions described in § 2.2(d)(3) of this appendix and performs collections in accordance with those instructions.
- c. The requirement that licensee provide detailed procedures and training are adequate.
- d. Delete 26 85 (b), (c)

Proposed Text:

Go back about two revisions, as discussed above.

**'Fitness for Duty Comments Number 8
Use of HSS guidelines
September 18, 2002**

Purpose: Subpart G of the draft FFD rule provides guidelines for testing by HHS certified laboratories. This paper provides some general comments about that section

Issue: In review of Subpart G it is unclear when we rely on HHS guidelines, replicate HHS guidelines in the rule, or provide requirements above those of the guidelines. Some of the duplication does not seem necessary.

1. In early discussions the industry asked that this section clearly delineate the licensee's responsibility and not repeat requirements that are part of the labs certification process.
2. 26.153(a) requires use of laboratories certified under HHS guidelines. 26.155(a) says the contract will require complying with part 26. 26.155(c)(1) says that State licensure requirements must be followed, but it is unclear what this adds to the process. 26.159(a) requires validity and drug testing consistent with the procedures for certification.
 - a. Does this all mean that the lab must follow the HHS guidelines under which they were certified? If not which part of the guidelines apply and which ones do not?
 - b. Is the testing to be done to the standards for Federal Workplace Drug Testing Programs for Federal Agencies?
3. 26.155(c)(3) seems to go in the right direction by referring to HHS guidelines for laboratory employee qualifications. It is presumed that this is here because the NRC has concern that the certification process does not adequately cover employee qualification.
4. 26.157 provides extensive guidance on chain-of-custody. Which of these requirements are not part of the certification process? Clearly the licensee needs to understand that it must send the form to the lab as stated in 26.157(c)(4) but it repeats 26.115 requirements. Since licensee custody control and shipping is covered in 26.115, are the requirements of 26.157(c) intended only for handling within the HHS lab?
5. The problem of unnecessarily repeating HHS guidelines can be seen in 26.157(f) which provides explicit guidance on handling samples that are not analyzed upon receipt. Footnote 703 talks about HHS guidelines, 1 day in the affirmed rule, 7 days in draft HHS guidelines, and the possibility of change. Can we rely on the certification process to ensure new samples are properly handled? We have been working on this rule for eleven years. In the future, as the Part 26 requirements differ from certification guidelines, the cost to the licensee goes up and the areas requiring audit increase.

Proposed Text:

None until the intent of Subpart G is better understood

Fitness for Duty Comments Number 9
Testing for PH
September 18, 2002

Purpose: Subpart G of the draft FFD rule provides guidelines for testing by HHS certified laboratories. This paper provides looks at PH and the differences in the testing requirements of Subpart G.

Issue: All testing requirements for PH in Subpart G have been pulled together and evaluated for consistency. The requirement to measure PH becomes increasingly difficult as the section progresses, and adds testing requirements in unexpected places. PH was picked because it seems like a simple measurement that should be fairly easy. Although not analyzed, we believe that similar problems can be seen in other areas.

1. The requirements from Subpart G, Rev 3 2, dated August 20, 2002.
 - a 26 159(d)Initial validity Testing.(3) Determine the pH;
 - b 26 159(i) Retest for adulterants.(A second lab) (1) pH shall be measured using the laboratory's confirmatory pH test with the appropriate cutoff (i e., either less than 3 or greater than or equal to 11)
 - c. 26.161 Reporting (b)(3) adulterated when--(ii) The pH is less than 3 or greater than or equal to 11 using a pH meter for the initial test on the first aliquot and a pH meter for the confirmatory test on the second aliquot or using a colorimetric pH initial test on the first aliquot and a pH meter for the confirmatory test on the second aliquot
 - d. 26 161 Reporting (b)(6) invalid when--(ii) The pH is greater than or equal to 3 and less than 4.5 or greater than or equal to 9 and less than 11 on two separate aliquots;
2. Why are testing requirements listed under reporting, instead of testing? The first requirement is to "Determine the PH", but the rule does not tell you what to do with it. Since it is a validity test, it would seem that laboratory procedures would provide appropriate cutoff levels and required confirmatory PH testing if the PH was outside the range.
 - a If this is the case then we do not need the test requirements in the reporting section
 - b. Do HHS guidelines require a PH meter for all confirmatory tests? If they do, why repeat the requirement. If not, why do we add this requirement.
 - c. If it is not the case then we need the validity requirements in 26.159)(d).
 - d. Is the discussion of equipment in 26.161 significant to the intial testing?
 - e In 26.161 the statement "appropriate cutoff" and parenthetical limits are redundant. One should be eliminated.
3. It takes a lot of effort to figure out that a valid sample has a PH in the range 4.5 to 8.99.

Proposed Text:

None. This section is not ready for line by line comment.

Fitness for Duty Comment Number 10
Reporting related to random samples
September 19, 2002

Purpose: The draft rule requires that the random sampling program be structured to ultimately test personnel with authorization even if they are not available at the time selected. Section 26.189(c)(3) adds a reporting requirement for significant program failures related to the random sampling program.

Issue. "Any condition" is too broad a term and will require reporting conditions that are not significant FFD program failures. Here are some examples of reports that would be required even though it was not a program failure.

1. There will be some difference in the time the various lists are updated. An individual receives authorization at 8:00 am. At 8:30 am a random draw is conducted. At 9:00 am the individual is added to the pool list. This violates the any condition.
2. An individual's name is drawn at 8:30 from the pool testing later in the day. At 10:00 the individual is terminated favorably before he or his supervisor are notified. Now what?
3. A transient worker's name is drawn at 8:30 from the pool for testing. He is not available during the test period and designated for the next testing period. His access is terminated favorably before the next testing period. Now what?
4. None of these examples would be considered program failures.

Proposed Text: 26.189(c)(3) A program failure preventing an individual from being selected and subsequently tested in a random testing program while that individual was assigned to perform duties within the scope of this part;