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From: Carol Gallagher
To: Evangeline Ngbea
Date: Tue, May 4, 2004 11:02 AM
Subject: Comments on Draft Rule Language - Fitness for Duty

Attached for docketing are three comments on the above noted draft rule language from James Davis, NEI, that I received via the Rulemaking website on 5/3/04.

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OFFICE OF SECRETARY
RULEMAKINGS AND
ADJUDICATIONS STAFF

CC: Garmon West; Rebecca Karas

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SECY-02

Fitness for Duty Comment Number 13
Definitions
April 30, 2004

Purpose: To provide recommended changes to definitions in Sub-Part A.

Issue: Chain of Custody. Resolve inconstancy by adding highlighted text to match HHS guideline.

Proposed Text:

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

Issue:Confirmed Positive. The definition does not address the role of the MRO in evaluating medical history. Verification would imply that based on direct personal observation an individual has. It is not clear how a MRO would verify the results of the test. The MRO reviews the certified chain of custody and the quantitative test result. In addition, the MRO evaluates this information in conjunction with the donor's medical history and other relevant information. The original evaluation wording should be restored.

Proposed Text:

Confirmed positive test result means a non-negative test result that demonstrates a violation of an FFD policy. For drugs, a confirmed positive test result is determined by the Medical Review Officer (MRO) after ~~verification~~ evaluation of the analytical result. For alcohol, a confirmed positive test result is based upon confirmatory test results from an evidential breath testing device.

Issue Dilute specimen. The HHS guideline requires creatinine and specific gravity to be lower than expected levels for the specimen to be considered a dilute. Our question is why both creatinine and specific gravity is required. We had a situation when an individual had a creatinine level of zero and the specific gravity was within normal parameters. Our MRO determine that this was not a genuine urine sample

Proposed Text:

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

Issue Substituted specimin The HHS guideline requires only the creatinine and specific gravity to be lower than expected levels for the specimen to be considered substituted. Our question is why temperature is not included. Temperature outside the acceptable range is also an example that is not consistent with normal human physiology

Proposed Text:

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

Issue Subversion and subvert the testing process The addition of the term intentional requires subjectivity in the determination. However without the term than any inadvertent act could be considered subversion such as bringing a bottle of eyewash solution to the collection facility. It is recommended to change intentional to willful to be in alignment with the terminology in 03-01 that deals will willful omission in the application process. This is a subjective term that the industry currently is familiar with.

Proposed text

Subversion and subvert the testing process mean an ~~intentional~~ willful act to avoid being tested or to bring about an inaccurate drug or alcohol test result for oneself or others at any stage of the testing process (including selection and notification of individuals for testing, specimen collection, specimen analysis, test result reporting), and adulterating, substituting, or otherwise causing a specimen to provide an inaccurate test result.

Fitness for Duty Comment Number 14
Comments on Subpart C
April 30, 2004

Purpose: Significant changes have been made to Subpart C since the last time stakeholders have had an opportunity to view it. This review is intended to eliminate some of the cross-references and improve the clarity of this section.

The industry has significant concerns with the concept of applying drug testing at the time an individual applies. An alternate approach that achieves the intent is provided.

Issue:

1. The sections on initial, update, and reinstatement should contain, not reference the conditions under which they apply. Therefore, the numbered items under 26.53 (a) are moved to the appropriate section
2. New section 26.53(b) provides a level of detail unwarranted in a rule. Although we agree that 1 plus 30 is 31, this is an implementation detail and should not be in the rule. The wording is convoluted and has to be read several times to figure out what it is trying to say.
3. In 26.57 and 26.58 it is important that the individual's authorization was terminated under favorable conditions for that section to apply. That statement has been added to the lead-in paragraph.
4. In section 26.59 it seems advisable to continue the process of going from longer periods to shorter periods. To maintain continuity with the access authorization process there need to be two, not three divisions, less that 30 and 31 to 365. This was accomplished by restructuring a through c into just two sections. In new (b)(1) the phrase "and review" was added to the self-disclosure. The intent is to make it clear that a suitable inquiry is not needed unless there is potentially disqualifying information that would drive you to 26.69. In 26.63(f)(3) a statement is added to clarify that the SI is only for reinstatements greater than 30 days.
5. In 26.59(c) The licensee is appropriately cautioned not to consider an administrative withdrawl as an unfavorable termination. However, the remainder of the section which prohibits providing this information to other licensees generates a conflict with other NRC guidance. Based on discussions with the NRC staff related to the AA Order, administrative withdrawls are entered into the industry database and available to other power reactor licensees. This entry would be updated when a final access decision is made. It is therefore recommended that the last part of that sentence be deleted.

6. 26.61 Move (e) up to be part of (a). It could also be (1) under (a) if desired, but it needs to be right there. Also there appears to only be one other case where an employment history is not required. That should be listed, not referenced. Same logic for (g) in the next section.

7. Section 26.63(c) needs have not changed significantly since the December 2002 draft; however a lot of work occurred in 2003 to harmonize the employment and suitable inquiry requirements. As written this section does not currently fit with the guidance in the NRC's January 7, 2003 order and will result in differences between AA and FFD interpretations. This could result in major expense for the industry if we are driven back to different process to meet the two rules. There are two approaches that can work: (1) delete items 1 to 3 under this section and leave the details to the implementation guidance which, after April 29, 2004, will be committed to in the licnesse security plans and endorsed by the NRC or (2) put the full details on military service, education and self-employment in the document—about another two pages. The industry believes that approach (1) would be the best approach.

8. In section 26.63(c)(2) added "best effort" to make sure it also applied to military and education checks. Does the implementation approach of use of a DD 214 meet this requirement if the unit cannot be contacted or provide the information?

9. We have a problem in section 26.63. The term "enters applicant status" does not reflect the date on the self-disclosure, but the day that the licensee takes its first action. The two will not be the same. Does the term "applies" make more sense? The draft language is splitting hairs and it is not clear that it will ever get it right at the level of detail that the staff has added.

10. 26.65(c)(2)(iii)(A) If the individual is available for the alcohol test, he is available for the drug test.

11. 26.65 (f)(2) should apply to any individual who has been continuously in a random drug and alcohol test program no matter the duration of the interruption of authorization.

12. In various places we recommend removing the phrase "while in applicant status" when referring to section 26.67, since there are different criteria that would apply.

13. 26.71(a)(2) Believe the intent is for the individual to be in a random drug and alcohol testing program.

14. In several places the term "either granted or denied authorization" is used. It would appear that the condition described, such as having the test completed within 30 days would only apply to the granting situation. If the individual is being denied, then there is little relevance of the time period. Of particular concern would be the situation where a test was taken, found to be non-negative and required a period of time to evaluate. Suddenly it is more than 30 days and the MRO finds that the test is positive. The licensee should be able to use it as a basis for denial. To grant access, another test is going to be required to meet the 30 day requirement. Changes have been made in several spots.

15. In 26.65(e) it requires that tests be completed within 30 days of granting access. This conflicts with the provisions for reinstatement that granting of access after collection of the sample. Since the collection date is the starting point, it would be conservative to state that collection must be completed 30 days prior to. In records, what the industry tracks is collection, not the date the results came back, so that would be more consistent also.

16. In 26.69(a)(1) The industry recommends adding "behavioral observation" as one of the sources of PDI. Although it could be considered to be part of other sources of information, some challenges in the past would have been easier to adjudicate if there had been an explicit reference.

17. In 26.69(b)(6) and (7) The text is too close to that for reinstatement of authorization and has misled several readers. Wording is proposed that is more explicit to make it clear that negative results must be achieved before granting authorization.

Proposed Text: with line-in line-out from March 29, 2004 draft FFD rule, Subpart C.

Subpart C – Granting and Maintaining Authorization

§26.51 Purpose.

This subpart contains FFD requirements for granting and maintaining authorization to perform the activities or have the types of access that are specified in §26.25(a) of this part.

§26.53 General provisions.

(a) In order to grant authorization to individuals, a licensee or C/V who has a licensee-approved FFD program shall meet the requirements in this

subpart for initial authorization, authorization update, or authorization reinstatement, as applicable.

~~(1) Initial authorization. In order to grant authorization to individuals who have never been authorized or whose authorization has been interrupted for a period of 3 years or more, the licensee or C/V shall meet the requirements in §26.55 of this subpart.~~

~~(2) Authorization update. In order to grant authorization to individuals whose authorization has been interrupted for a period of more than 365 days but less than 3 years the licensee or C/V shall meet the requirements in §26.57 of this subpart.~~

~~(3) Authorization reinstatement. In order to grant authorization to individuals whose authorization has been interrupted for a period of 365 days or less the licensee or C/V shall meet the requirements in §26.59 of this subpart.~~

~~(b) For individuals who have previously held authorization under this part but whose authorization has since been terminated, the licensee or C/V shall implement the requirements for either initial authorization, authorization update, or authorization reinstatement based upon the total number of days that the individual's authorization is interrupted, to include the day after the individual's last period of authorization was terminated and the intervening days until the day upon which the licensee or C/V grants or denies authorization to the individual. If, while in applicant status, the period of interruption exceeds the number of days of interruption that are permitted to grant an authorization update or any reinstatement, the licensee or C/V may not implement the authorization requirements that applied on the day that the individual entered applicant status, but shall implement the applicable authorization requirements for the total period of the interruption.~~

(c) The licensee or C/V shall ensure that an individual has met the applicable FFD training requirements that are specified in §26.29 of this part before granting authorization to the individual.

(d) Licensees or C/Vs seeking to grant authorization to an individual who is subject to another FFD program that complies with this part may rely on the transferring FFD program to satisfy the requirements of this part. The individual may maintain his or her authorization if he or she 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.

§26.55 Initial authorization.

(a) In order to grant authorization to individuals who have never been authorized or whose authorization has been interrupted for a period of 3 years or more~~Before granting authorization~~, the licensee or C/V shall —

(1) Obtain a self-disclosure in accordance with the applicable requirements of §26.61;

(2) Complete a suitable inquiry in accordance with the applicable requirements of §26.63;

(3) Ensure that the individual is subject to pre-access drug and alcohol testing in accordance with the applicable requirements of §26.65; and

(4) Ensure that the individual is subject to random drug and alcohol testing ~~while in applicant status~~ in accordance with the applicable requirements of §26.67.

(b) If potentially disqualifying FFD information is disclosed or discovered, the licensee may not grant authorization to the individual, except in accordance with §26.69.

§26.57 Authorization update.

(a) In order to grant authorization to individuals whose authorization has been terminated under favorable conditions more than 365 days but less than 3 years the licensee or C/V shall~~Before granting authorization, the licensee shall~~ —

(1) Obtain a self-disclosure in accordance with the applicable requirements of §26.61;

(2) Complete a suitable inquiry in accordance with the applicable requirements of §26.63;

(3) Ensure that the individual is subject to pre-access drug and alcohol testing in accordance with the applicable requirements of §26.65; and

(4) Ensure that the individual is subject to random drug and alcohol testing ~~while in applicant status~~ in accordance with the applicable requirements of §26.67.

(b) If potentially disqualifying FFD information is disclosed or discovered, the licensee may not grant authorization to the individual, except in accordance with §26.69.

§26.59 Authorization reinstatement.

~~(a) Before reinstating authorization for individuals whose authorization has been interrupted for a period of 5 days or less, the licensee shall obtain a self-disclosure in accordance with the applicable requirements of §26.61.~~

~~(b) In order to reinstate authorization for individuals whose authorization has been interrupted for a period of more than 5 days but not more than 30 days, the licensee shall —~~

~~(1) Obtain a self-disclosure in accordance with the applicable requirements of §26.61; and~~

~~(2) Ensure that the individual is subject to pre-access drug and alcohol testing in accordance with the applicable requirements of §26.65; and~~

~~(3) Ensure that the individual is subject to random drug and alcohol testing while in applicant status in accordance with the applicable requirements of §26.67.~~

(e<u>a</u>) In order to ~~reinstate~~ <u>grant</u> authorization for an individual whose authorization has been <u>terminated under favorable conditions</u> ~~interrupted for a period of~~ more than 30 days but not more than 365 days, the licensee shall:

(1) Obtain a self-disclosure in accordance with the applicable requirements of §26.61;

(2) Complete a suitable inquiry in accordance with the requirements of §26.63 within 5 business days of reinstating authorization. If the suitable inquiry is not completed within 5 business days due to circumstances that are outside of the licensee's control and the licensee is not aware of any potentially disqualifying information regarding the individual within the past 5 years, the licensee may maintain the individual's authorization for an additional 5 business days. If the suitable inquiry is not completed within 10 business days of reinstating authorization, the licensee shall administratively withdraw the individual's authorization until the suitable inquiry is completed;

(3) Ensure that the individual is subject to pre-access drug and alcohol testing in accordance with the applicable requirements of §26.65; and

(4) Ensure that the individual is subject to random drug and alcohol testing ~~while in applicant status~~ in accordance with the applicable requirements of §26.67.

<u>(b) In order to reinstate authorization for individuals whose authorization has been terminated under favorable conditions for not more than 30 days, the licensee shall:</u>

<u>(1) Obtain and review a self-disclosure in accordance with the applicable requirements of §26.61; and</u>

<u>(2) If authorization was interrupted more than five days, ensure that the individual is subject to pre-access drug and alcohol testing in accordance with the applicable requirements of §26.65; and</u>

<u>(3)If authorization was interrupted more than five days, ensure that the individual is subject to random drug and alcohol testing in accordance with the applicable requirements of §26.67.</u>

(c<u>d</u>) If a licensee administratively withdraws an individual's authorization under paragraph (c)(2) of this section, and until the suitable inquiry is completed, the licensee may not record the administrative action to withdraw authorization as an unfavorable termination<u>.</u> ~~and may not disclose it in response to a suitable inquiry conducted under the provisions of §26.63, a background investigation conducted under the provisions of §73.56 of this chapter, or any other inquiry or investigation.~~ The individual may not be required to disclose the administrative action in response to requests for self-disclosure of potentially disqualifying FFD information.

(de) If potentially disqualifying FFD information is disclosed or discovered, the licensee may not grant authorization to the individual, except in accordance with §26.69.

§26.61 Self-disclosure and employment history.

(a) Before granting authorization, the licensee or ~~a~~ C/V who has a licensee-approved FFD program shall obtain a written self-disclosure and employment history from the individual who is applying for authorization, except as described below~~ in paragraph (c) of this section~~.

(i) If an individual previously held authorization under this part, and the licensee or C/V has verified that the individual's last period of authorization was terminated favorably, and the individual has been subject to a licensee-approved behavioral observation and arrest-reporting program throughout the period since the individual's last authorization was terminated, the granting licensee need not obtain the self-disclosure or employment history in order to grant authorization.

(ii) An employment history is not required for reinstatements where the period of interruption is 30 days or less.

(b) The written self-disclosure must: —

(1) State whether the individual has: —

(i) Violated a licensee's or C/V's FFD policy;

(ii) Had authorization denied or terminated unfavorably under paragraphs §§26.75(b)–(d), 26.75(e)(1), or 26.75(e)(2);

(iii) Used, sold, or possessed illegal drugs;

(iv) Abused legal drugs or alcohol;

(v) Subverted or attempted to subvert a drug or alcohol testing program;

(vi) Refused to take a drug or alcohol test;

(vii) Been subject to a plan for substance abuse treatment (except for self-referral); or

(viii) Had legal action or employment action, as defined in §26.5, taken for alcohol or drug use;

(2) Address the specific type, duration, and resolution of any matter disclosed, including, but not limited to, the reason(s) for any unfavorable termination or denial of authorization; and

(3) Address the shortest of the following periods:

(i) The past 5 years;

(ii) Since the individual's eighteenth birthday; or

(iii) Since authorization was last terminated, if authorization was terminated favorably.

(c) ~~If a suitable inquiry will be conducted under §26.63, t~~The individual shall provide a list of all employers, including the current employer, if any, with dates of employment, for the shortest of the following periods:

(1) The past 3 years;

(2) Since the individual's eighteenth birthday; or

(3) Since authorization was last terminated, if authorization was terminated favorably within the past 3 years.

(d) Falsification of the self-disclosure statement or the individual's employment history required in paragraph (c) of this section is sufficient cause for denial of authorization.

~~(e) If an individual previously held authorization under this part, and the licensee or C/V has verified that the individual's last period of authorization was terminated favorably, and the individual has been subject to a licensee-approved behavioral observation and arrest-reporting program throughout the period since the individual's last authorization was terminated, the granting licensee need not obtain the self-disclosure or employment history in order to grant authorization.~~

§26.63 Suitable inquiry.

(a) The licensee or C/V who has a licensee-approved FFD program shall conduct a suitable inquiry, on a "best effort" basis, to verify the individual's self-disclosed information and to determine whether any potentially disqualifying FFD information is available~~, except as described in paragraph (g) of this section~~. If an individual previously held authorization under this part, and the licensee or C/V has verified that the individual's last period of authorization was terminated favorably, and the individual has been subject to a licensee-approved behavioral observation and arrest-reporting program throughout the period of interruption, the granting licensee need not conduct a suitable inquiry in order to grant authorization.

(b) To meet the suitable inquiry requirement, licensees and C/Vs who have a licensee-approved FFD program may rely upon the information that other licensees and C/Vs gathered for previous periods of authorization. Licensees and C/Vs may also rely upon those licensees' and C/Vs' determinations of fitness, as well as their reviews and resolutions of potentially disqualifying FFD information, for previous periods of authorization.

(c) The licensee or C/V who has a licensee-approved FFD program shall conduct the suitable inquiry on a "best effort" basis by questioning both present and former employers.

(1) For the claimed employment period, the suitable inquiry must ascertain~~, on a "best effort" basis,~~ the reason for termination, eligibility for rehire, and other information that could reflect on the individual's fitness to be granted authorization.

(2) If the claimed employment was military service, the licensee or C/V who is conducting the suitable inquiry shall request a characterization of service, reason for separation, and any disciplinary actions related to potentially disqualifying FFD information. If the individual's last duty station cannot provide this information, the licensee or C/V may accept a

hand carried copy of the DD 214 presented by the individual which on face value appears legitimate. A copy of a DD 214 provided by the custodian of military records may also be accepted.

(3) For claimed periods of education in lieu of employment ~~or periods of self-employment~~, if the educational institution will not release the requested information an alternate source may be used to verify the applicant was actively participating in the educational process. ~~the licensee or C/V shall ascertain potentially disqualifying FFD information through any reasonable method, including contacts with relatives or references.~~

(d) In response to another licensee's or C/V's inquiry and presentation of an individual's signed release authorizing the disclosure of information, a licensee or C/V shall disclose whether the subject individual's authorization was denied or terminated unfavorably as a result of a violation of an FFD policy and shall make available the information upon which the denial or unfavorable termination of authorization was based, including, but not limited to, drug or alcohol test results. The failure of an individual to authorize the release of information for the suitable inquiry is sufficient cause to deny authorization.

(e) In conducting a suitable inquiry, the licensee or C/V who has a licensee-approved FFD program may obtain information and documents by electronic means, including, but not limited to, telephone, facsimile, or email. The licensee or C/V shall make a record of the contents of the telephone call and shall retain that record, and any documents or electronic files obtained electronically, in accordance with §§26.197(a), (b), and (c), as applicable.

(f) The licensee or C/V shall conduct the suitable inquiry as follows:

(1) Initial authorization. The period of the suitable inquiry must be the past 3 years or since the individual's eighteenth birthday, whichever is shorter. For the 1-year period immediately preceding the date upon which the individual ~~enters applicant status~~applies, the licensee or C/V shall conduct the suitable inquiry with every employer, regardless of the length of employment. For the remaining 2-year period, the licensee or C/V shall conduct the suitable inquiry with the employer by whom the individual claims to have been employed the longest within each calendar month, if the individual claims employment during the given calendar month.

(2) Authorization update. The period of the suitable inquiry must be the period since authorization was terminated. For the 1-year period immediately preceding the date upon which the individual ~~enters applicant status~~applies, the licensee or C/V shall conduct the suitable inquiry with every employer, regardless of the length of employment. For the remaining period since authorization was terminated, the licensee or C/V shall conduct the suitable inquiry with the employer by whom the individual claims to have been employed the longest within each calendar month, if the individual claims employment during the given calendar month.

(3) Authorization reinstatement for periods of interruption greater than 30 days. The period of the suitable inquiry must be the period since authorization was terminated. The licensee or C/V shall conduct the suitable inquiry with the employer by whom the individual claims to have been employed the longest within the calendar month, if the individual claims employment during the given calendar month.

~~(g) If an individual previously held authorization under this part, and the licensee or C/V has verified that the individual's last period of authorization was terminated favorably, and the individual has been subject to a licensee-approved behavioral observation and arrest reporting program throughout the period of interruption, the granting licensee need not conduct a suitable inquiry in order to grant authorization.~~

§26.65 Pre-access drug and alcohol testing. (See FFD 21 for line-in line-out)

(a) Purpose. This section contains pre-access testing requirements for granting authorization to individuals who either have never held authorization or whose last period of authorization was terminated favorably and about whom no potentially disqualifying FFD information has been discovered or disclosed that was not previously reviewed and resolved by a licensee or C/V who has a licensee-approved FFD program.

(b) Initial authorization and authorization update. Before granting authorization to an individual who has never been authorized or whose authorization has been interrupted for a period of more than 365 days, except as permitted in paragraphs (b)(1) and (b)(2) of this section, the licensee shall verify that the results of pre-access drug and alcohol tests are negative.

(1) If an individual previously held authorization under this part and has been subject to both a licensee-approved drug and alcohol testing program that included random testing and a licensee-approved behavioral observation and arrest reporting program from the date upon which the individual's last authorization was terminated through the date upon which the individual is ~~is~~ granted authorization, then the granting licensee may forego pre-access testing of the individual.

(2) If an individual has negative test results from drug and alcohol tests that were performed in accordance with the requirements of this part within the 30-day period ending on the day that authorization is granted and the individual has been subject to a licensee-approved behavioral observation and arrest reporting program from the date upon which the drug and alcohol test was conducted through the date upon which the individual is granted authorization, the granting licensee may forego pre-access drug and alcohol testing of the individual.

(c) Authorization reinstatement greater than 30 days. In order to reinstate authorization to an individual whose authorization has been interrupted for a period of more than 30 days but fewer than 365 days, except

as permitted in paragraphs (c)(3) and (c)(4) of this section, the licensee shall:

(1) Verify that the individual has negative results from alcohol testing and collect a specimen for drug testing before reinstating authorization; and

(2) Verify that the drug test results are negative within 5 business days of specimen collection or administratively withdraw authorization until the drug test results are received.

(3) If an individual previously held authorization under this part and has been subject to both a licensee-approved drug and alcohol testing program that included random testing and a licensee-approved behavioral observation and arrest reporting program from the date upon which the individual's last authorization was terminated through the date upon which the individual is ~~is~~ granted authorization, then the granting licensee may forego pre-access testing of the individual.

(4) If an individual has negative test results from drug and alcohol tests that were performed in accordance with the requirements of this part within the 30-day period ending on the day that authorization is granted and the individual has been subject to a licensee-approved behavioral observation and arrest reporting program from the date upon which the drug and alcohol test was conducted through the date upon which the individual is granted authorization, the granting licensee may forego pre-access drug and alcohol testing of the individual.

(d) Reinstatement 30 days or less

(1) Pre-access testing is not required in order to reinstate authorization for an individual whose authorization has been interrupted for a period of 5 days or less.

(2) In order to reinstate authorization for an individual whose authorization has been interrupted for a period of more than 5 days but not more than 30 days, except as permitted in paragraph (d)(3) of this section, the licensee or C/V shall take the following actions:

(i) The licensee shall subject the individual to random selection for pre-access drug and alcohol testing at a one-time probability that is equal to or greater than the normal testing rate specified in §26.31(d)(2)(vi) calculated for a 30-day period.

(ii) If the individual is not selected for pre-access testing under this paragraph, the licensee need not perform pre-access drug and alcohol tests;

(iii) If the individual is selected for pre-access testing under this paragraph, the licensee shall:

(A) Verify that the individual has negative results from alcohol testing and collect a specimen for drug testing before reinstating authorization; and

(B) The licensee shall verify that the drug test results are negative within 5 business days of specimen collection or administratively withdraw authorization until drug test results are received.

(3) If an individual previously held authorization under this part and has been subject to both a licensee-approved drug and alcohol testing

program that included random testing and a licensee-approved behavioral observation and arrest reporting program from the date upon which the individual's last authorization was terminated through the date upon which the individual is granted authorization, then the granting licensee may forego pre-access testing of the individual.

(e) Time period for testing. If drug and alcohol tests are required under this section, the testing must be ~~completed~~ collected within the 30-day period that ends on the date that the licensee grants authorization to an individual.

(f) Specimen collection and testing. The licensee may rely upon drug and alcohol test results to meet the requirements for pre-access testing in this section only if the specimens were collected and tested in accordance with the requirements of this part.

(g) Administrative withdrawal of authorization. If a licensee administratively withdraws an individual's authorization under paragraphs (c)(2) or (c)(3) of this section, and until the drug test results are known, the licensee may not record the administrative action to withdraw authorization as an unfavorable termination The individual may not be required to disclose the administrative action in response to requests for self-disclosure of potentially disqualifying FFD information.

(h) If an individual has non-negative test results from any drug or alcohol tests that may be required in this section, the licensee shall, at a minimum and as appropriate:

(1) Deny authorization to the individual, in accordance with §§26.75(b), (d), (e)(2), or (g);

(2) Terminate the individual's authorization, if it has been reinstated, in accordance with §§26.75(e)(1) or (f); or

(3) Grant authorization to the individual only in accordance with the requirements of §26.69.

§26.67 Random drug and alcohol testing of individuals in applicant status.

(a) When a pre-access drug and alcohol sample is collected to meet the requirements of r §§26.55, 26.57, 26.59, or 26.69 the individual shall be placed in a random testing program in accordance with §26.31(d)(2).

(b)Where a drug and alcohol test conducted prior to application is used to meet the pre-access requirements of 26.65, the individual shall be placed in the random testing program when the licensee takes the first formal action on the application.

(c) If an individual is selected for one or more random tests after any applicable requirement for pre-access testing in §26.65 has been met, the licensee may grant authorization before random testing is completed in accordance with §26.31(d)(2), if the individual has met all other applicable requirements for authorization.

(d) If an individual has non-negative test results from any drug and alcohol testing required in this section, the licensee shall, at a minimum and as appropriate: —

(1) Deny authorization to the individual, in accordance with §§26.75(b), (d), (e)(2), or (g);

(2) Terminate the individual's authorization, if it has been granted, in accordance with §§26.75(e)(1) or (f); or

(3) Grant authorization to the individual only in accordance with the requirements of §26.69.

§26.69 Authorization with potentially disqualifying fitness-for-duty information.

(a) Purpose. This section defines the management actions that licensees or C/Vs who have licensee-approved FFD programs shall take in order to grant or maintain the authorization of an individual who is in the following circumstances:

(1) Potentially disqualifying FFD information within the past 5 years has been disclosed or discovered about the individual by any means, including, but not limited to, the individual's self-disclosure, the suitable inquiry, drug and alcohol testing, the administration of the FFD program, a self-report of a legal action, behavioral observation or other sources of information, including, but not limited to, the background investigation conducted under §73.56 of this chapter and the criminal history check conducted under §73.57 of this chapter; and

(2) The potentially disqualifying FFD information has not been reviewed and favorably resolved by a previous licensee or C/V who has a licensee-approved FFD program.

(b) Authorization after a first confirmed positive drug or alcohol test result. The requirements in this paragraph apply to an individual whose authorization was denied or terminated unfavorably for a first violation of a licensee's or C/V's FFD policy involving a confirmed positive drug or alcohol test result. In order to grant, and subsequently maintain, the individual's authorization, the licensee shall: —

(1) Verify that the individual's self-disclosure, if one is required under §§26.55, 26.57, or 26.59 as appropriate, does not contain any previously undisclosed potentially disqualifying FFD information before granting authorization;

(2) Complete a suitable inquiry with all employers by whom the individual claims to have been employed in accordance with the requirements of §26.63 and as follows before granting authorization to the individual:

(i) Conduct the suitable inquiry for the applicable period, as specified in §26.63(f) of this section; and

(ii) Obtain any records that other licensees or C/Vs may have developed related to any potentially disqualifying FFD information about the individual from the past 5 years;

(3) Ensure that a determination of fitness has indicated that the individual is fit to safely and competently perform his or her duties, and that plans for treatment and followup testing were developed before granting authorization;

(4) Verify that the individual is in compliance with, and successfully completes, the treatment plans;

~~(5) Ensure that the individual is subject to random testing while in applicant status, in accordance with the applicable requirements in §26.67, and thereafter;~~

~~(6) Perform an alcohol test within 5 business days before granting authorization;~~

(~~7~~5) Verify negative results of an alcohol test and~~Collect a specimen for~~ a drug test~~ing~~, collected under direct observation, within 5 business days before granting authorization;

(~~8~~6) Ensure that the individual is subject to followup drug and alcohol testing for a period of 3 years from the date authorization was terminated at a frequency of no less than once every 30 days for 4 months after authorization is granted, and at least once every 90 days for the next 2 years and 8 months; and

(~~9~~7) Verify that any drug and alcohol tests required in this paragraph, and any other drug and alcohol tests conducted since authorization was terminated, yield results indicating no further drug or alcohol abuse, as appropriate, since the original confirmed positive test result.

(c) Authorization following a denial of authorization. The requirements in this paragraph apply to an individual whose authorization was denied for 5 years under §§26.75(c), (d), (e)(2), or (f). In order to grant, and subsequently maintain, the individual's authorization, the licensee shall —

(1) Verify that the individual has abstained from substance abuse for at least the past 5 years;

(2) Verify that the individual's self-disclosure, if one is required under §§26.55, 26.57, or 26.59 as appropriate, does not contain any previously undisclosed potentially disqualifying FFD information before granting authorization;

(3) Complete a suitable inquiry with every employer by whom the individual claims to have been employed during the past 5 years in accordance with the applicable requirements of §26.63 and obtain any records that other licensees or C/Vs may have developed related to the denial of authorization;

(4) Ensure that a determination of fitness has indicated that the individual is fit to safely and competently perform his or her duties before granting authorization;

(5) Ensure that any recommendations for treatment and followup testing from the determination of fitness are initiated before granting authorization;

(6) Verify that the individual is in compliance with, and successfully completes, any treatment plans;

~~(7) Ensure that the individual is subject to random testing while in applicant status, in accordance with the applicable requirements of §26.67, and thereafter;~~

(8<u>7</u>) Perform an alcohol test within 5 business days before granting authorization and verify that the results are negative before granting authorization;

(9<u>8</u>) Collect a specimen for drug testing under direct observation within 5 business days before granting authorization and verify that the results are negative before granting authorization; and

(9) Verify that the results of any followup drug and alcohol testing required in this paragraph are negative.

(d) Authorization with other potentially disqualifying FFD information. The requirements in this paragraph apply to an individual who has not previously had his or her authorization terminated unfavorably or denied for 5 years under this part, who is either in applicant status or is currently authorized, and about whom potentially disqualifying FFD information has been discovered or disclosed.

(1) If the individual is in applicant status, before granting authorization, the licensee or C/V shall —

(i) Complete a suitable inquiry with every employer by whom the individual claims to have been employed in accordance with the requirements of §26.63 and as follows:

(A) Conduct a suitable inquiry for the applicable period, as specified in §26.63(f); and

(B) Obtain any records that other licensees or C/Vs may have developed with regard to potentially disqualifying FFD information about the individual from the past 5 years;

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

(iii) Ensure that the individual is in compliance with, or has completed, any plans for treatment and drug and alcohol testing from the determination of fitness.

~~(iv) Ensure that the individual is subject to random testing while in applicant status, in accordance with the applicable requirements of §26.67, and thereafter; and~~

(iv) Verify that the results of pre-access drug and alcohol tests are negative before granting authorization.

(2) If the individual is authorized when the potentially disqualifying FFD information is disclosed or discovered, in order to maintain the individual's authorization, the licensee shall —

(i) Ensure that the licensee's designated reviewing official completes a review of the circumstances associated with the information;

(ii) If the designated reviewing official determines that a determination of fitness is required, verify that the determination of fitness has indicated that the individual is fit to safely and competently perform his or her duties; and

(iii) If the reviewing official determines that maintaining the individual's authorization is warranted, implement any recommendations for treatment and followup drug and alcohol testing from the determination of fitness, and ensure that the individual successfully completes them.

(e) If an individual leaves the FFD program in which a treatment and followup testing plan was required under paragraphs (b), (c), or (d) of this section, and is granted authorization by another licensee with a different FFD program, the receiving licensee shall ensure that any treatment and followup testing requirements are met, with accountability assumed by the receiving licensee. If the previous licensee or C/V determined that the individual successfully completed any required treatment and followup testing, and the individual's authorization was terminated favorably, the receiving licensee may rely upon the previous determination of fitness and no further review or followup is required.

(f) If an individual has non-negative test results from any drug and alcohol testing required in this section, the licensee shall, at a minimum and as appropriate —

(1) Deny authorization to the individual, in accordance with §§26.75(b), (d), (e)(2), or (g); or

(2) Terminate the individual's authorization, if it has been granted, in accordance with §§26.75(e)(1) or (f).

§26.71 Maintaining authorization.

(a) Individuals may maintain authorization under the following conditions:

(1) The individual complies with the licensee's or C/V's FFD policies to which he or she is subject, including the responsibility to report any legal actions, as defined in §26.5;

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

(3) The individual remains subject to a licensee-approved behavioral observation program that complies with the requirements of this part; and

(4) The individual successfully completes required FFD training, in accordance with the schedule specified in §26.29(c).

(b) If an authorized individual is not subject to a licensee-approved FFD program for more than 30 days, then the licensee or C/V shall terminate the individual's authorization and the individual shall meet the requirements in this subpart, as applicable, to regain authorization.

Fitness for Duty Comment Number 15
Applicant Status
April 30, 2004

Purpose: The industry has significant concerns with the concept of "Applicant Status" which was introduced, for the first time, in the March 2004 draft of the Fitness-for-Duty rule. Although the industry has had to address this issue in implementation of AA and FFD requirements, applying a single concept to all situations in a rule may have significant unintended consequences.

Issue:

1. **When does an individual apply?**

   The case where an individual arrives at the site on Tuesday morning and starts the paperwork it is easy to define when he applied. But waiting until the individual arrives at a licensee facility before you do anything is not the most productive use of time and manpower. There has been a lot of attention on getting items completed in advance of arrival to speed the process. For example, over the last year, in meetings with the NRC staff, the industry has been encouraged to plan ahead and submit fingerprints early to relieve the load on the EIE submission process.

   a. There needs to be a sponsor. People cannot just apply for unescorted access, there needs to be a reason. As a result there are requests and lists that fly around as various jobs, contracts, and work is planned. In many cases AA personnel will screen these lists against the industry database to determine the level of action required; initial, update, reinstatement, is the training current, etc. Does this constitute a formal action? The industry does not think so.

   b. There needs to be paperwork. The individual will need to complete a personal history questionnaire of some sort. How does he get this? Is it provided by the licensee? Perhaps a contractor provides it. Who will process it? Is it a contractor with a licensee-approved program? The licensee may not even know the contractor is having the individual fill out the paperwork. The contactor may not have decided which job the individual will work at. There is a lot of variability in the process.

   c. The licensee needs to get the request. This may not be until after the background investigation is completed and the licensee gets a formatted request from a C/V with a licensee-approved program. In most cases when the individual arrives at the licensee site fingerprints will be taken and submitted, a pre-access drug and alcohol sample will be collected, and Plant Access training

conducted.

2. **When does the individual exit the applicant process?**

   This part is relatively easy. There are three ways to close the process: (1) Grant authorization (2) Deny authorization (an unfavorable finding), (3) The individual withdraws the request for access. Note that the proposed definition in the March 29, 2004 draft only addresses the first two of these.

   Withdrawl of the request for access occurs frequently. This is all a result of the time that it takes to process an individual an the normal flow of work. Jobs change. Work gets done. People get diverted. In some cases the individual never shows up at the licensees site.

   To be complete, there is a special case of withdrawl. An individual has the right to withdraw consent for the investigation at any time. If the individual exercises that right no further investigation elements are conducted. A withdrawl of consent is an automatic withdrawl of request for access. This issue is fully addressed in implementation procedures.

   It should also be made clear that there are two cases for "granting authorization" An individual may be granted Unescorted Access Authorization (UAA) upon completion of the investigation process and determination made by the reviewing official that the individual is trustworthy, reliable and fit-for-duty. An individual would have Unescorted Access (UA) when the individual completes Plant Access Training (PAT)(which for the purpose of this rule includes the FFD training), has been placed in a behavioral observation program, is in a random drug testing program, and has been provided the physical means of gaining access to the protected area. To complicate the issue, the criteria for maintaining UAA does not require random drug testing.

3. **When does a licensee take its first formal action?**

   The industry considers this to be when the licensee initiates one of the following:

   a. A background investigation and SI (includes developed references and credit check).

   b. A psychological evaluation.

   c. Submits fingerprints for evaluation.

   d. Conducts a pre-access drug and alcohol test at the licensee facility or makes a determination whether a sample is required (Less than 30 days)

   e. Reinstates an individual who has current UA at another licensee.

   f. Accepts a request from a C/V with a licensee-approved program

that states that some or all of the above elements have been completed.

4. **What is really important form an implementation perspective?**

   The industry has found the "clock" starts at several different places to effective support implementation, based on the situation being addressed.

   a. **Consent form signed:** Implementation procedures prohibit taking any investigation actions until after the individual has signed the consent form. This protects both the individual and allows the licensee to meet reporting and sharing requirements.

   b. **Personal History Questionnaire Signed:** Implementation procedures state that "The investigation period is through the date on which the individual applies for unescorted access documented by the date on which the personal history questionnaire is signed." There are important implementation issues related to the period of investigation, when "arrest reporting" by the individual must start and the time allowed to complete the investigation elements.

   c. **Formally Applied:** The AA Order of January 7, 2003 requires that an individual be entered in the industry accessible database when the individual "formally applies" for access. However, there is no data worth reporting until the licensee takes some action. To this end a definition of "Formal Application" has been added to the implementation guidelines

      "Formal Application—An applicant is considered to have formally applied for unescorted access authorization at the time the licensee initiates its first formal action satisfying any of the requirements for such authorization."

Proposed Text:: The industry strongly recommends that the NRC remove the definition of "Applicant Status" and all references in the rule.

- Delete 26.25(d)—We do not understand how an individual can be held accountable for a FFD program violation before they are trained on their responsibilities.
- 26.27(b)—Delete individuals in applicant status. The methods described are applicable after the individual has arrived at a licensee facility. Attempting to provide the policy and ensure that the individual understood it prior to arrival is an unreasonable burden and has not been addressed in the backfit analysis. If providing a copy of the policy is adequate, it is unclear why there is a need to conduct training before granting authorization.
- 26.39(a)—Delete individual in applicant status. It is not clear how an individual can be found to violate the fitness for duty program

prior to being trained and placed under the program.

- 26.53(b)—Change to read, "If, prior to granting authorization, the period of interruption exceeds the number of days allowed, the licensee or C/V shall implement the applicable authorization requirements of the total period of the interruption." Or even better—totally rewrite the section:

  For individuals whose previous authorization under this part has been terminated under favorable conditions, the licensee or C/V shall implement the requirements for either initial authorization, authorization update, or authorization reinstatement based upon the total number of days that the individual's authorization is interrupted, to include the day after the individual's last period of authorization was terminated to the day the licensee or C/V grants authorization to the individual.

- Other SubSection C changes are addressed in a separate industry paper.
- 26.201(b)(3) & (4)—Delete reference to applicant status.

Fitness for Duty Comment Number 16
Authorization
April 30, 2004

Purpose: The term "authorization" is used extensively throughout the document and a definition was added in the March 2004 revision. In the power reactor implementation process there are two types of authorization, Unescorted Access Authorization (UAA) and Unescorted Access (UA).

Issue: The attempt to define "authorization" generates a dilemma. Depending on the context there is a different meaning that is very important to the regulation.

- To "grant authorization" is a single point event when the reviewing official makes a determination that the individual has met all requirements for performing activities covered by the rule. The focus is on the review and approval process.
- To "hold authorization", "authorized", "maintain authorization" is time related and requires that certain continuing items occur, such as behavioral observation, arrest reporting, periodic training and random testing.

The industry has the added problem of having to integrate the separate access authorization and Fitness-for-Duty requirements into one "authorization" which meets the requirements of both rules. The use of the term "authorization" in the rule needs to support this integration process. To do this there needs to be a clear distinction between what is required for the reviewing official to grant authorization and what is required to maintain authorization once it has been granted.

Other than a few cases, being addressed in other papers, the industry believes the intent term "authorization" is clear from the context in which it is used in the rule. Where we have concerns, the proposed definition does not add clarity.

From the draft:

"Authorization means the determination that an individual is permitted to have the types of access or to perform the activities specified in §26.25." This part seems to satisfy the thought of the granting by the reviewing official.

"An individual would also be considered to be authorized if he or she has met the requirements for authorization and is subject to all elements of a Part 26 program, but has not been granted unescorted access or has not been assigned to perform activities that are subject to this part." This part does not work well. First, the individual cannot be in an authorized status unless a reviewing official has made a determination, even if the requirements are met. Second, the term UA is injected when some of the individuals covered in

26.25 do not need UA to be covered. FFD program personnel is an example for a power reactor. Third, it implies a set of rather loose conditions around what is considered authorization. Individuals have either been granted and is maintaining authorization or they are not—only two possibilities.

Proposed Text: The industry prefers the first of the following two options to solve the above Dilemma:

1. Delete the definition of Authorized which was added to the March 29 draft. In reviewing the rule text the intent appears to be clear from the context in which authorization is used.
2. Define two terms "Grant Authorization" and "Holding Authorization" and do a rigorous scrub of the rest of the rule to put the right one if for the context that is intended.

Fitness for Duty Comment Number 17
Nominal
April 30, 2004

Purpose: To suggest a slightly different approach to the concept of "nominal" as it applies to periods of audits and training.

Issue: The NRC approved template for the licensee security plan and training and qualification plan has a definition of "annual" that states

> "**Annual** – Requirements specified as "annual" should be scheduled at a nominal 12-month periodicity. Performance may be conducted up to three months before to three months after the scheduled date. The next scheduled date is 12-months from the originally scheduled date."

This approach focuses on the scheduling consistency instead of limitations over a three year period. The industry recommends that the NRC staff consider this definition for 10 CFR part 26 to be consistent with practices that will be in place in other parts of Security after April 29, 2003.

However, the industry's implementation approach can be made to work under the definition in the March draft. We will just spend a lot of time explaining why they have the same outcome.

Proposed Text:

Nominal means the limited flexibility that is permitted in meeting a scheduled date for completing a recurrent activity that is required under this part, such as the nominal 12-month frequency required for FFD refresher training in §26.29(c)(2) and the nominal 12-month frequency required for certain audits in §26.41(c)(1). Completing a recurrent-activity-at a nominal frequency means that the activity may be completed within a period that is up to 25 percent before or after the scheduled dated. The next scheduled date is calculated from the current scheduled date and may not exceed the specified scheduling frequency. The activity may performed earlier than described above, an new secheduled date would then be established based on the date the activity was performed ~~longer or shorter than the period that is established in this part, as long as the cumulative effect of any extensions, over a period that is three times the length of the required schedule, does not exceed 25 percent of the required frequency. For example, FFD refresher training must be completed on an annual basis or more frequently, if appropriate, but up to a 3 month extension is allowed to complete the refresher training, beyond the specified 12month (or annual) period, as long as the cumulative effect of any extensions does not exceed 3 months at the end of a 3year period.~~

Fitness for Duty Comment Number 18
Suitable inquiry
April 30, 2004

Purpose: The industry is concerned that the Suitable Inquiry process described in the draft rule could be interpreted differently than that that has been directed by the NRC in the January 7, 2003 Order. Interpretations during implementation that cause different approaches will significantly, and unnecessarily, drive up the cost of completing each investigation.

The industry does not understand the level of implementation detail that the Commission expects in this rule. What is the intent of adding "implementation" to the Purpose in 26.1? Does this mean that all implementation details are to be in the rule? It is unclear that this level of detail is warranted or achievable. Would it be acceptable to delete the last two sub-elements under 26.63.(c) as implementation details? The specific questions to ask could be moved up and included in (c).

At the same time there is concern that literal interpretation or some rule language, as seen with the current 10CFR Part 26, could complicate a coordinated implementation of the Access Authorization employment checks and the Fitness-for-Duty suitable inquiry. Unfortunately, it appears that we will have to opt for the details.

Issue:

1. The term "best effort" should apply to both military service and education. It would be appropriate to include it in section 26.63 (c) to be clear it applies to all 3 sub-elements.
2. Verification of military service has been a problem in the past when the last command could not be contacted. In past discussions of use of a DD 214 as verification of military service, the Department of Defense feels that it has met its obligation when it provides the individual a DD 214. The process in 26.63(c)(2) needs to allow the process described in section B.1.4.c of the Access Authorization Order.
3. The slight change in wording where education is listed in lieu of employment could be a problem and needs to be modified.
4. Self-employment should be dropped from the employment checks. None of the questions to be asked make any sense in this case. Can a person who is self-employed be terminated? How do you establish eligibility for rehire? Where is the human resources department that has records that reflect on the individuals fitness?

   Looking at the total program, including the Access Authorization requirements, there is appropriate attention in this area. The verification of periods of self-employment through records or references

determines that the individual has provided an accurate employment record. The additional Access Authorization requirement for two developed references provides the character and fitness-for-duty information needed.

Proposed Text:

§26.63 Suitable inquiry.

(a) The licensee or C/V who has a licensee-approved FFD program shall conduct a suitable inquiry, on a "best effort" basis, to verify the individual's self-disclosed information and to determine whether any potentially disqualifying FFD information is available~~, except as described in paragraph (g) of this section~~. If an individual previously held authorization under this part, and the licensee or C/V has verified that the individual's last period of authorization was terminated favorably, and the individual has been subject to a licensee-approved behavioral observation and arrest-reporting program throughout the period of interruption, the granting licensee need not conduct a suitable inquiry in order to grant authorization.

(b) To meet the suitable inquiry requirement, licensees and C/Vs who have a licensee-approved FFD program may rely upon the information that other licensees and C/Vs gathered for previous periods of authorization. Licensees and C/Vs may also rely upon those licensees' and C/Vs' determinations of fitness, as well as their reviews and resolutions of potentially disqualifying FFD information, for previous periods of authorization.

(c) The licensee or C/V who has a licensee-approved FFD program shall conduct the suitable inquiry on a "best effort" basis by questioning both present and former employers.

(1) For the claimed employment period, the suitable inquiry must ascertain~~, on a "best effort" basis~~, the reason for termination, eligibility for rehire, and other information that could reflect on the individual's fitness to be granted authorization.

(2) If the claimed employment was military service, the licensee or C/V who is conducting the suitable inquiry shall request a characterization of service, reason for separation, and any disciplinary actions related to potentially disqualifying FFD information. If the individual's last duty station cannot provide this information, the licensee or C/V may accept a hand carried copy of the DD 214 presented by the individual which on face value appears legitimate. A copy of a DD 214 provided by the custodian of military records may also be accepted.

(3) For claimed periods of education in lieu of employment~~ or periods of self-employment~~, if the educational institution will not release the requested information an alternate source may be used to verify the applicant was actively participating in the educational process. ~~the licensee or C/V shall ascertain potentially disqualifying FFD information through any reasonable method, including contacts with relatives or references.~~

(d) In response to another licensee's or C/V's inquiry and presentation of an individual's signed release authorizing the disclosure of information, a licensee or C/V shall disclose whether the subject individual's authorization was denied or terminated unfavorably as a result of a violation of an FFD policy and shall make available the information upon which the denial or unfavorable termination of authorization was based, including, but not limited to, drug or alcohol test results. The failure of an individual to authorize the release of information for the suitable inquiry is sufficient cause to deny authorization.

Fitness for Duty Comment Number 19
Sub-Part E: Collecting Specimens for Testing
April 30, 2004

Purpose: Comments on the following sections of Sub-part E:

1. Visual privacy for alcohol collection 26.87(b)
2. The Quality Assurance Program on ASD's 26.91(d) and 26.91(e)
3. Confirmatory Alcohol Testing 26.99
4. Emergency power equipment availability 26.115(j)

Issue: The industry does not have visual privacy for alcohol collection and this will add a great expense to restructure, the collection facilities.

The NRC has added the burden of Quality Program to ASD equipment, these programs from DOT were based on one type of equipment. Section 26.91(d)(3) references section 26.91e which requires your ASD's to meet the EBT Quality Assurance Program. This is not reasonable for initial alcohol testing on ASD's. Secondly, the way the testing is written for confirmatory the industry will need a particular type of EBT equipment that has screens easily accessible for review by donor. This will require softwear updates to have initial numbers on screen for confirmatory. EBT machines print all the required data, why can't you review the printed test with the donor? NRC is limiting the type of alcohol testing equipment that can be used with this detailed testing process.

Emergency power equipment for refrigeration: Why is NRC requiring the industry with collection sites only, to refrigerate specimens and also have the added burden of emergency power equipment, when the Certified labs do not have to refrigerate the specimens for 7 days (26.159h)? This is going to be a great financial burden to the industry. The industry had a specialist come speak to the NRC on May 2002, that submitted documentation on specimens stored at room temperature for 7 days did not affect the qualitative results.

Proposed Text:

§26.87 Collection sites.

(b) The collection site must provide for the visual privacy of a donor who is submitting a urine~~, oral fluids, or breath~~ specimen. Unauthorized personnel may not be present for the specimen collection.

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

(d) Quality assurance and quality control of ASDs.

(1) Licensees and C/Vs with licensee-approved FFD programs shall implement the most recent version of the manufacturer's instructions for the use and care of the ~~quality assurance plan submitted to NHTSA for any~~ ASD used for initial alcohol testing.

(2) Licensee and C/Vs may not use an ASD that fails the specified quality control checks or that has passed its expiration date.

~~(3) For ASDs that test breath specimens, licensees and C/Vs shall also follow the device use and care requirements specified in paragraph (e) of this section.~~

(e) Quality assurance and quality control of EBTs.

(1) Licensees and C/Vs shall implement the most recent version of the manufacturer's instructions for the use and care of the EBT ~~consistent with the quality assurance plan submitted to NHTSA for the EBT~~, including performing external calibration checks at the intervals the instructions specify.

(2) In conducting external calibration checks, only calibration devices appearing on NHTSA's CPL for "Calibrating Units for Breath Alcohol Tests" may be used.

(3) If an EBT fails an external check of calibration, the EBT must be taken out of service. The EBT may not be used again for alcohol testing under this part until it is repaired and passes an external calibration check.

(4) Inspection, maintenance, and calibration of the EBT must be performed by a maintenance representative trained on that EBT equipment. ~~its manufacturer or a maintenance representative certified either by the manufacturer or by a State health agency or other appropriate State agency.~~

§26.99 Conducting a confirmatory test for alcohol.

(a) The confirmatory test must begin as soon as possible, but not. ~~If the initial test was conducted at a DOT collection site at which an EBT is unavailable, the confirmatory test must begin no~~ more than 30 minutes after the conclusion of the initial test.

(b) To complete the confirmatory test, the collector shall —

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

(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 donor and insert it into the device in accordance with the manufacturer's instructions;

(5) Read the unique test number displayed on the EBT~~, and ensure that the donor reads the same number~~;

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

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

§26.115 Preparing urine specimens for storage and shipping.

(j) Collection site personnel shall arrange to transfer the collected specimens to the HHS-certified laboratory or the licensee testing facility. Licensees and C/Vs shall take appropriate and prudent actions to minimize false negative results from specimen degradation, which may include~~. Specimens that have not been shipped to the HHS-certified laboratory or the licensee testing facility within 24 hours of collection and any specimen that is suspected of having been substituted, adulterated, or tampered with in any way must be~~ maintainin~~ged~~ the specimens cooled to not more than 6 °C (42.8 °F) within 6 hours of collection.~~until they are shipped to the HHS-certified laboratory. Emergency power equipment must be available in case of prolonged power failure.~~ Specimens must be ~~transferred~~ shipped from the collection site to the HHS-certified laboratory or the licensee testing facility as soon as reasonably practical but, except under unusual circumstances, the time between specimen shipment and receipt of the specimen at the licensee testing facility or HHS-certified laboratory should not exceed 2 business days.

Fitness for Duty Comment Number 20
Subpart I- Recordkeeping and Reporting Requirements
April 30, 2004

Purpose: Prevent unnecessary safeguard event logging of suitable inquiry processes which are conducted in accordance with the regulation.

Section 26.197(f) FFD program authorization events should focus on violations of regulatory requirements and not used as a data collection tool. Throughout the security arena a logged event has special meaning and should require some sort of corrective action.

Data collection requirements should be clearly identified and justified and not hidden in event reporting requirements.

Issue: The safeguard event log is used to track significant event and programmatic failures. Under the proposed FFD rulemaking, suitable inquiry logging would be relegated to tracking an administrative process. The examples provided in (1) through (4), as written are not clear violations of the FFD program. The industry is also concerned that the context of the examples could lead to the wrong conclusion on what is required to be logged.

For example, Consider an individual is reinstated after completing an alcohol test and a drug sample is collected. If the drug test results were not available in 5 days and authorization was not administratively withdrawn it would be a program violation, even if the test results are ultimately negative. If a positive test result was received in 2 days and authorization was terminated unfavorably it would not be a program violation.

The proposed rule as currently written would require logging of an event that is not a significant FFD authorization event. When properly administered this is not a significant FFD authorization event.

Proposed Text: In effect (f) is adequate by itself and does not need the 4 examples. The industry would delete the bullets. If the NRC staff wants examples, then items (1) to (4) need to be changed to reflect program violations.

(f) Licensees and C/Vs shall log significant FFD authorization events (and retain those logs for at least 3 years), including, but not limited to, the following instances:

(1) Any instance in which-an individual is granted authorization under 26.59(c)(2) and the licensee or C/V subsequently determines potentially disqualifying information was available to the reviewing official and a review of that information results in unfavorable termination of authorization;

(2) Any instance in which an individual who has been granted authorization under 26.65(c) or (d) receives a confirmed non-negative pre-access drug test result and authorization is not promptly terminated;

(3) Any instance in which the suitable inquiry required under 26.59(c)(2) is not completed within 5 business days after authorization is granted and the licensee did not determine whether potentially disqualifying

information existed or did not administratively withdraw authorization or at the end of 10 days did not administratively withdraw authorization: and

(4) Any instance in which pre-access drug test results are not available within 5 business days after authorization is granted under §§26.65(c) or (d) and the authorization is not administratively withdrawn.

Fitness for Duty Comment Number 21
Preaccess Testing
April 30, 2004

Purpose: To provide more focused discussion of pre-access testing in 26.65 and random testing of 26.67. The attempt to link these two sections to applicant status has generated areas that need further discussion. The changes discussed in this paper are included in FFD 14.

Issue: When to test?

1. In general any individual applying for initial, updated authorization, or reinstated authorization greater than 30 days will have a pre-access drug and alcohol test conducted. It makes little sense to put an individual in a random program before the pre-access test is conducted, and this appears to be the general intent of 26.67. Further, the proposed text would require the individual to be under behavioral observation during this period for this test to be used. This combination should provide high assurance.
2. On an infrequent basis an individual has a test conducted within 30 days of authorization, but before application for access. It would be very difficult for the licensee to back date the individual being in a random program. How do you pick someone for testing a week before you knew they existed? The industry believes that licensees can only add the individual to the random pool when they, the licensee, not C/V, have an application, and realize that a test has been conducted that meets the 30 day requirements. This would be the point when the licensee takes its first formal action to process the application. The key is that it needs to be action taken at the licensee's inprocessing center.
3. There are exceptions to the testing requirements for individuals who have been under behavioral observation and in a random testing program. These individuals would be in the licensee's program or C/V program but do not currently have UA. These individuals would be expected to remain under parent companies' program throughout the in-processing period, thus by making changes in 26.25 to make the period thorough granting authorization the discussion in 26.67 can be avoided. They are under random testing, so they do not need to be placed under random testing.
4. Reinstatements of individuals less than 30 days is completed relatively quickly, in most cases on the same day. Since they must be in a random sampling pool when granted UA there is little difference between the time that some are sampled and the UA date. As written the individuals who provide a pre-access sample based on the

equivalent 50% exposure rate would be put in the pool at that time. The others when UA was granted. Again, both are effectively the same date.

5. With these changes, 26.67(e) is no longer needed.
6. Section 26.65 is rearranged to make the linkage of requirements easier to understand.
7. In new 26.65(b)(2) and 26.65(c)(4) the industry believes that the individual should only be required to be under the BOP from the time the sample is collected until the individual receives authorization. The restriction of under BOP since last access was terminated favorable is too restrictive. This relaxation will allow a C/V, while conducting background investigation elements, to provide the individual with BOP training, conduct the drug and alcohol test, and place the individual under BOP. This will speed the authorization process when the individual arrives at the licensee facility. The industry believes this is a reasonable approach since it is only allowed for a period not to exceed 30 days before authorization.

Proposed Text: with line-in line-out from March 29, 2004 draft FFD rule, Subpart C.

Subpart C – Granting and Maintaining Authorization

§26.65 Pre-access drug and alcohol testing.

(a) Purpose. This section contains pre-access testing requirements for granting authorization to individuals who either have never held authorization or whose last period of authorization was terminated favorably and about whom no potentially disqualifying FFD information has been discovered or disclosed that was not previously reviewed and resolved by a licensee or C/V who has a licensee-approved FFD program.

(b) Initial authorization and authorization update. Before granting authorization to an individual who has never been authorized or whose authorization has been interrupted for a period of more than 365 days, except as permitted in paragraphs (b~~f~~)(1~~2~~) and (b~~f~~)(2~~3~~) of this section, the licensee shall verify that the results of pre-access drug and alcohol tests are negative.

(1) If an individual previously held authorization under this part and has been subject to both a licensee-approved drug and alcohol testing program that included random testing and a licensee-approved behavioral observation and arrest reporting program from the date upon which the individual's last authorization was terminated through the date upon which the individual is is granted authorization, then the granting licensee may forego pre-access testing of the individual.

(2) If an individual has negative test results from drug and alcohol tests that were performed in accordance with the requirements of this part

within the 30-day period ending on the day that authorization is granted and the individual has been subject to a licensee-approved behavioral observation and arrest reporting program from the date upon which the drug and alcohol test was conducted through the date upon which the individual is granted authorization, the granting licensee may forego pre-access drug and alcohol testing of the individual.

(c) Authorization reinstatement greater than 30 days. In order to reinstate authorization to an individual whose authorization has been interrupted for a period of more than 30 days but fewer than 365 days, except as permitted in paragraphs (c)(3) and (c)(4) of this section, the licensee shall =

(1) Verify that the individual has negative results from alcohol testing and collect a specimen for drug testing before reinstating authorization; and

(2) Verify that the drug test results are negative within 5 business days of specimen collection or administratively withdraw authorization until the drug test results are received.

(3) If an individual previously held authorization under this part and has been subject to both a licensee-approved drug and alcohol testing program that included random testing and a licensee-approved behavioral observation and arrest reporting program from the date upon which the individual's last authorization was terminated through the date upon which the individual is granted authorization, then the granting licensee may forego pre-access testing of the individual.

(4) If an individual has negative test results from drug and alcohol tests that were performed in accordance with the requirements of this part within the 30-day period ending on the day that authorization is granted and the individual has been subject to a licensee-approved behavioral observation and arrest reporting program from the date upon which the drug and alcohol test was conducted through the date upon which the individual is granted authorization, the granting licensee may forego pre-access drug and alcohol testing of the individual.

(d) Reinstatement 30 days or less

(1) Pre-access testing is not required in order to reinstate authorization for an individual whose authorization has been interrupted for a period of 5 days or less.

(2) In order to reinstate authorization for an individual whose authorization has been interrupted for a period of more than 5 days but not more than 30 days, except as permitted in paragraph (df)(3~~1~~) of this section, the licensee or C/V shall take the following actions:

(i) The licensee shall subject the individual to random selection for pre-access drug and alcohol testing at a one-time probability that is equal to or greater than the normal testing rate specified in §26.31(d)(2)(vi) calculated for a 30-day period.

(ii) If the individual is not selected for pre-access testing under this paragraph, the licensee need not perform pre-access drug and alcohol tests;

(iii) If the individual is selected for pre-access testing under this paragraph, the licensee shall —

(A) Verify that the individual has negative results from alcohol testing and collect a specimen for drug testing before reinstating authorization ~~and at the earliest reasonable and practical opportunity when both the donor and collectors are available to collect specimens for testing and without prior notification to the individual that he or she has been selected for testing~~; and

(B) The licensee shall verify that the drug test results are negative within 5 business days of specimen collection or administratively withdraw authorization until drug test results are received.

(3) If an individual previously held authorization under this part and has been subject to both a licensee-approved drug and alcohol testing program that included random testing and a licensee-approved behavioral observation and arrest reporting program from the date upon which the individual's last authorization was terminated through the date upon which the individual is granted authorization, then the granting licensee may forego pre-access testing of the individual.

~~(3) In order to reinstate authorization to an individual whose authorization has been interrupted for a period of more than 30 days but fewer than 365 days, except as permitted in paragraphs (f)(2) and (f)(3) of this section, the licensee shall —~~

~~(i) Verify that the individual has negative results from alcohol testing and collect a specimen for drug testing before reinstating authorization; and~~

~~(ii) Verify that the drug test results are negative within 5 business days of specimen collection or administratively withdraw authorization until the drug test results are received.~~

(e~~d~~) Time period for testing. If drug and alcohol tests are required under this section, the testing must be completed within the 30-day period that ends on the date that the licensee ~~either~~ grants ~~or denies~~ authorization to an individual~~, except as permitted in paragraph (e) of this section~~.

(f~~e~~) Specimen collection and testing. The licensee may rely upon drug and alcohol test results to meet the requirements for pre-access testing in this section only if the specimens were collected and tested in accordance with the requirements of this part.

~~(f) Alternatives to pre-access testing.~~

~~(1) If an individual previously held authorization under this part and has been subject to both a licensee-approved drug and alcohol testing program that included random testing and a licensee-approved behavioral observation and arrest reporting program from the date upon which the individual's last authorization was terminated through the date upon which~~

~~the individual enters applicant status, then the granting licensee may forego pre-access testing of the individual.~~

~~(2) If an individual has negative test results from drug and alcohol tests that were performed in accordance with the requirements of this part within the 30-day period ending on the day that authorization is granted or denied and the individual has been subject to a licensee approved behavioral observation and arrest reporting program from the date upon which the individual's last authorization was terminated through the date upon which the individual enters applicant status, the granting licensee may forego pre-access of the individual.~~

~~(3) If an individual has negative test results from drug and alcohol tests that were performed in accordance with the requirements of this part within the 30-day period ending on the day that authorization is granted or denied, the granting licensee may forego the pre-access testing that is required for individuals whose authorization has been interrupted for a period of 31 days or more.~~

(g) Administrative withdrawal of authorization. If a licensee administratively withdraws an individual's authorization under paragraphs (c)(2) or (c)(3) of this section, and until the drug test results are known, the licensee may not record the administrative action to withdraw authorization as an unfavorable termination ~~and may not disclose it in response to a suitable inquiry conducted under the provisions of §26.63, a background investigation conducted under the provisions of §73.56 of this chapter, or any other inquiry or investigation.~~ The individual may not be required to disclose the administrative action in response to requests for self-disclosure of potentially disqualifying FFD information.

(h) If an individual has non-negative test results from any drug or alcohol tests that may be required in this section, the licensee shall, at a minimum and as appropriate:

(1) Deny authorization to the individual, in accordance with §§26.75(b), (d), (e)(2), or (g);

(2) Terminate the individual's authorization, if it has been reinstated, in accordance with §§26.75(e)(1) or (f); or

(3) Grant authorization to the individual only in accordance with the requirements of §26.69.

§26.67 Random drug and alcohol testing of individuals in applicant status.

(a) When a pre-access drug and alcohol sample is collected to meet the requirements of ~~Licensees shall conduct any random testing of individuals in applicant status that is required under~~ §§26.55, 26.57, 26.59, or 26.69 the individual shall be placed in a random testing program in accordance with §26.31(d)(2).

(b) Where a drug and alcohol test conducted prior to application is used to meet the pre-access requirements of 26.65, the individual shall be placed in the random testing program when the licensee takes the first formal action on the application. ~~If an individual is selected for random testing before the licensee has collected specimens for any pre-access testing that may be required under §26.65, the licensee may rely upon the test results from specimens collected under this section to meet any applicable requirement for pre-access testing in §26.65 as well as any applicable requirements for random testing in §§26.55, 26.57, or 26.59, provided that test results are received within the time limits specified in §26.65.~~

(c) If an individual is selected for one or more random tests after any applicable requirement for pre-access testing in §26.65 has been met, the licensee may grant authorization before random testing is completed in accordance with §26.31(d)(2), if the individual has met all other applicable requirements for authorization.

(d) If an individual has non-negative test results from any drug and alcohol testing required in this section, the licensee shall, at a minimum and as appropriate: —

(1) Deny authorization to the individual, in accordance with §§26.75(b), (d), (e)(2), or (g);

(2) Terminate the individual's authorization, if it has been granted, in accordance with §§26.75(e)(1) or (f); or

(3) Grant authorization to the individual only in accordance with the requirements of §26.69.

~~(e) If an individual in applicant status was subject to random testing by a licensee approved FFD program throughout the period during which the individual's authorization was interrupted, or if the applicant has negative test results from drug and alcohol tests that were performed in accordance with the requirements of this part within the 30 day period ending on the day that authorization is granted, the licensee may not forgo subjecting the individual to random testing if it is required under §§26.55, 26.57, or 26.59.~~

Fitness for Duty Comment Number 22
Subpart F – Licensee Testing Facility
April 30, 2004

Purpose: The industry has significant concerns with the Initial Validity Test Cutoff levels. The cutoff levels appear to be very similar to the cutoff levels for the validity tests as proposed for the SAMHSA certified laboratories.

Issues:

1. 26.131 Cutoff levels for initial validity tests. Licensee on-site testing laboratory is an initial screening process and does not need to have the stringent and overly burdensome requirements for validity testing.

Creatinine:
Calibrator: 20 mg/dl
Assay range: 0 to 400 mg/dl
Quality Control: Equipment Available through SYVA - Level 1 is 0 to 10 mg/dl
(10 CFR 26 range is 1-1.5 mg/dl)
Equipment Available through SYVA - Level 2 is 50 to 150 mg/dl
(10 CFR 26 doesn't have this higher range)
Equipment Available through SYVA - Level 3 is 15 to 35 mg/dl (10 CFR 26 range is 21-25 mg/dl)

Comment: Is there a typo on the calibrator concentration of 2 mg/dl. This seems to be more appropriate for serum testing instead of urine testing since the urine Creatinine concentrations are quite a bit higher than those of serum. Equipment Available through SYVA assay's calibrator is 20 mg/dl.

pH:
Calibrators: 4.0 and 9.0 (10 CFR 26 requires calibrators at 3.0 and 11.0)
Assay range: 4.0 to 9.0 (we recommend to use a pH meter for those samples outside of this range)
Quality Control: Equipment Available through SYVA - Level 1 is 8.5 to 10.5
Equipment Available through SYVA - Level 2 is 5.5 to 7.5
Equipment Available through SYVA - Level 3 is 2.4 to 4.4

Comment: 10 CFR 26 requires controls in the following ranges: 2.0-2.8, 3.2-4.0, 4.5-9.0, 10.0-10.8 and 11.2-12.0. Equipment Available through SYVA controls would only satisfy the range of 3.2-4.0 and not the other ranges. We would have to look for an outside vendor that has controls with these ranges available. At this time, I am unaware of any outside vendor that may have these ranges incorporated into their controls.

Oxidants:
Calibrators: 0.0 and 2.5 mg/dl
Assay range: not specified
Quality Control: Equipment Available through SYVA - Negative Calibrator
Equipment Available through SYVA - Chromate Calibrator 50 mg/dl

Nitrites:
Calibrators: 0.0 and 500 mg/L (these units are the same as mcg/ml)
Assay range: 0.0 to 1,000 mg/L
Quality Control: Equipment Available through SYVA - Level 1 is 1800 to 4800 mg/L
Equipment Available through SYVA - Level 2 is 550 to 700 mg/L
Equipment Available through SYVA - Level 3 is 0 mg/L

Comment: 10 CFR 26 requires one control in the range of 200-400 mg/L, another control in the range of 500-625 mg/L and a control without nitrites. Equipment Available through SYVA Levels 2 and 3 would satisfy two of the three required controls (do not have a control meeting the 200-400 mg/L range).

To summarize:

Creatinine assay: Assay calibrates at 20 mg/dl which doesn't satisfy the requirements of the 10 CFR 26 calibrator of 2 mg/dl. Unfortunately, due to FDA clearance, the equipment can not be altered for the calibrator for this assay from 20 mg/dl to 2 mg/dl as it would deviate from the FDA clearance and would alter the stated performance claims of the assay.

pH assay: Assay calibrates with 4.0 and 9.0 buffers which doesn't satisfy the requirements of the 10 CFR 26 calibrators of 3.0 and 11.0. Equipment Available through SYVA only have quality control material that satisfies the range of 3.2-4.0 and not the other ranges. We would have to obtain the additional quality control material from an outside vendor if these ranges were available commercially. Basically, the quality control material with these ranges may be really difficult to find.

Nitrite assay: Equipment Available through SYVA only has quality control material that satisfies two of the three control levels required. Again, may have difficulty finding quality control material with the specific range of 200-400 mg/L.

Proposed Text: Eliminate the stringent requirements.

2. **26.125 Licensee testing facility personnel.**
(a) Each licensee testing facility shall have one or more individuals an individual who are is responsible for day-to-day operations and supervision of the testing technicians. The designated ~~This~~ individual(s) shall have at least a bachelor's degree in the chemical or biological sciences, ~~or~~ medical technology, or an equivalent field I now read this that the person responsible for day-to-day operation for an on-site lab must have a bachelor's degree and cannot be someone knowledgable in the operation of the laboratory. This is an added burden and will require some licensee's to not be incompliance with this requirement. Recommend using wording in current rule.

3. **26.165(e) Testing split specimens and retesting single specimens.**
(e) Retesting a specimen for substitution. A second laboratory shall use its confirmatory creatinine and confirmatory specific gravity tests, when retesting an aliquot of a single specimen or testing Bottle B of a split specimen, to reconfirm that the creatinine concentration was less than 5 mg/dL and the specific gravity was less than or equal to 1.0010 or equal to or greater than 1.0200. However, the second laboratory shall apply the cutoff levels for a substituted result in this part and shall report the results as non-confirmed if the second laboratory's results exceed the original test cutoff parameters. The second laboratory may only conduct the confirmatory creatinine and specific gravity tests to reconfirm the substitution result reported by the first laboratory.

   Proposed Change: Testing split specimens and retesting single specimens to clarify that licensees shall proceed with management actions and impose sanctions on the basis of an MRO-confirmed non-negative test result, whether or not the donor requests Bottle B to be tested or an aliquot of a single specimen to be retested. Recommend, if non-negative test from first result is received, deny access until second result is received, however, do not enter into PADS until confirmed non-negative test. If recommending PADS entry after first result and a negative result is received on second test PADS entry must be removed. Also, negative on second and Pre-Access Test – Re-collect another specimen. If Random, negative result is acceptable, what about "For-Cause"?

   Proposed Change: The MRO must cancel the test if the donor requests that Bottle B be tested or that an aliquot of a single specimen be retested and either Bottle B or the single specimen are not available for retesting due to circumstances outside of the donor's control, including, but not limited to, circumstances in which there is an insufficient specimen volume in a single specimen to permit retesting, either Bottle B or the

original single specimen was lost in transit, Bottle B has been lost. (Note; there would not have been a request for a re-test if the original single specimen was lost in transit, is this referring to once the single specimen has been analyzed by HHS and subsequently lost while in storage?)

Fitness for Duty Comment Number 23
Sub-Part B: Program Elements
April 30, 2004

Purpose: To provide industry comments on Sub-Part B.

Issue:

1. Section 26.25 (c) purports to provide relief for those covered by two FFD programs. In the fall of 2002 the industry commented that the requirements were inflexible and made credit for another program impractical. We note that in the March 2004 draft there is even more detail. This part allows licensees to take credit for individuals covered by another Federal or State Program provided the program is equivalent or greater than 10CFR26. However, most programs are less stringent and the process of comparing the programs and ensuring those elements are met, would be time consuming, extremely difficult to manage, and sets us up to fail. The backfit analysis should not take credit for this purported relief.
2. The industry has concerns with the additional requirements in Section 26.39(c) that the review has been expanded to require more than one individual to perform the review. This appears to be a translation of persons into more than one. We believe that this is the wrong context and that the intent was related to reviews in general, as would be appropriate for a procedure. In some, complex cases, the licensee may want to take the team approach. However, it is not clear that this should be required for all cases. It seems that 26.39(a) states the basic requirement which does not need a lot of amplification.
3. In 36.31(d)(3)(ii) the March 2004 draft added the term "testing procedures are scientifically acceptable and properly validated". Subpart F then proceeds, in excruciating detail, to define the requirements for Licensee testing facilities. This addition would make sense if, at the same time, Subpart F was deleted from the document. As it stands all we have done is generated another pitfall for future users as licensees are asked to produce their certification of acceptability and the validation process. All this in addition to Subpart F!
4. Change in the requirement to test someone who is not available when selected for random testing from "as soon as reasonable practicable when both the donor and collectors are available" to "'at the earliest reasonable and practical opportunity when both the donor and collectors are available" and addition of the requirement that collections must be completed within 30 days after selection. [26.31(d)(2)(iv)].

Industry does not agree with a time limit. If an individual is called for random and unavailable due to off on vacation or medical leave, for 15 days, comes back and the collector is not available, then leaves for business trip for another 17 days, does this mean the individual's access should be terminated when the 30 days are up? Does the individual stay in a terminated status until the collector and individual are available?
The industry believes that the "earliest reasonable and practical opportunity" provides adequate regulatory guidance on the intent and is much more important than an arbitrary 30 day limit, which may or may not be as the "earliest...". The other issue that this generates is that the addition does not address what do when the 30 day limit is exceeded. As written it becomes a violation of regulation—but we already know it is going to happen. We assume the licensee with withdraw access, but that generates a whole new set of implementation issues. Again, we see the attempt to provide detailed implementation guidance in the rule generating additional issues that have not been addressed.

Proposed Text:

§26.39 Review process for fitness-for-duty policy violations.

(c) The procedure must ensure that ~~the~~ reviews are ~~is~~ conducted by ~~more than one individual and that the~~ individuals who ~~conduct the review~~ are not associated with the administration of the FFD program (see description of FFD program personnel in §26.25(a)(4))The individuals who conduct the review may be licensee or C/V management personnel.

§26.31 Drug and alcohol testing.

(d)(3)(ii) 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 that the licensee's staff possesses the necessary training and skills for the tasks assigned, the staff's qualifications are documented, ~~testing procedures are scientifically acceptable and properly validated.~~ and adequate quality controls for the testing are implemented.

§26.31 Drug and alcohol testing.

(d)(2)(iv) Ensure that all individuals in the population subject to testing have an equal probability of being selected and tested. ~~Make reasonable efforts to test persons selected for random testing.~~ ~~Persons offsite~~ Individuals who are off site when selected for testing, and not reasonably available for testing when selected, shall ~~must~~ be tested at the earliest reasonable and practical opportunity when both the donor and collectors are

available to collect specimens for testing and without prior notification to the individual that he or she has been selected for testing. ~~In these instances, collections must be completed within 30 days of the date on which the individual was originally selected to be randomly tested.~~;,

Fitness for Duty Comment Number 24
MRO review
April 30, 2004

Purpose: To provide comments from several MROs who have review of the draft FFD rule.

Issue: The following comments were provided by MROs:

1. **26.117 Determining "shy" bladder**
   I don't like this part because if the donor is unable to provide at least 30 cc of urine within 3 hours the "shy" bladder protocol has to be followed. This requires an evaluation by a physician with 'expertise' in the causes of "shy" bladder to provide a medical opinion. The problems with this are: 1) it is difficult to get an good evaluation and opinion in 5 business days, 2) not all physicians may want to do or are experts in evaluating "shy" bladder, 3) who is going to pay for the evaluation?, 4) is the employee going to be under paid leave while getting an evaluation?, 5) if the physician or MRO is not able to determine with high probability that the donor had a condition that would have precluded him/her to provide an adequate urine sample, then this a refusal to test with severe consequences – permanent restriction.

   "Shy bladder" is a nebulous term with no real medical definition. The medical evaluation for it would be very subjective unless the donor has clear medical problems such as severe kidney failure, definite urinary obstruction, etc. If the MRO, does not concur with the examining physician's findings, he/she has to declare it a refusal to test, again with severe consequences to the donor. This can put us at higher risk for litigation.

   I would prefer a longer waiting period rather than going through the "shy bladder" procedure.

2. **26.135 Split specimens**
   The requirement to obtain a written permission from the donor to test Bottle B (split specimen) would be logistically difficult for many donors. Some donors are interviewed outside the plant and by phone, and it may be difficult for them to provide written consent at the time of verification. If they had an FFD violation based on the results of Bottle A, they are not allowed to return to the plant to obtain a consent form. Many of them may not have a fax machine available. Also, we have donors who are not from the area and once they lose unescorted access (and their job) they move somewhere else and getting written permission is difficult, if not impossible. Some of our donors have invalid addresses and mailing blank consent forms to them will result

in retuned forms. How will we then respond to allegations from them that we did not have Bottle B tested based on the fact that we did not receive a signed permission from the donor. How will we respond to claims by donors that they mailed us a consent form but did not receive it, and, therefore, did not test Bottle B? Will there be a time limit when a donor verbally requests testing of Bottle B and for us to receive the written permission before deciding that the donor was not serious in having bottle B tested? How many telephone and written attempts are we supposed to make to obtain the signed permission statement before we conclude that the donor was not serious in wanting Bottle B tested?

3. **26.183 Medical Review Officer**
The proposed rule requires a certified MRO. Although, I do the vast majority of the verifications and am certified, if I'm not available we can not use our part-time physicians who are not certified MROs. Our procedures (redacted) require that the MRO obtain concurrence with another MRO before verifying an analytically positive drug test as negative, as is the case when the donor is using prescription medications. This will require that we have 2 certified MROs available every time we have a case like this. Aside from myself, only Dr. (redacted) is a certified MRO and he is not available all the time.

   This section of Part 26 also requires the MRO staff to be under the direct supervision and control of the MRO and MRO functions must be maintained independent from any licensee activity or function. This will lead to additional staff because it restricts the MRO "staff" from performing non-MRO functions. At this time we don't have an independent MRO staff and our current staff performs multiple functions. The section also states that the MRO shall be resident at the location at which the MRO staff members are performing their duties. Once we hire a doctor at (site redacted) and he becomes a certified MRO, he can not technically meet this requirement because the MRO staff will be located at Corporate.

4. **26.185 Verifying a fitness-for-duty policy violation**
Paragraph j, (3). This is not very clear to me. It says that if a donor used another individual's prescription and has no clinical evidence of drug abuse, the MRO shall report to the licensee that the donor has misused a prescription. It does not directly state that the MRO can declare this as a negative test. I think the rule should specifically state that the MRO can declare this as a negative test but still report to the licensee the misuse of a prescription. Because the consequences of a non-negative test are more severe in the nuclear industry (compared to DOT), and that there are certain circumstances that an individual has

to use another person's (e.g. family), I feel that the MRO should be able to verify analytically positive tests as negative in these circumstances.

5. 26.183 Medical Review Officer
(a) **qualifications**- Licensure: From my personal point of view, its fine as stands since I am right here in (state redacted) but it would be good to spell out the issue of being licensed in one state but doing MRO work in another one way or the other. Before it was spelled out by the DOT, the issue kept coming up. DOT specifically comments that you can be licensed in one jurisdiction and do MRO work in another without having to become licensed in the other state.

Training and Exam- The only requirement appears to be that you pass the exam. One would hope that means you are knowledgeable about the various issues of drug testing and substance abuse. DOT spells those requirements out but then again DOT didn't know what the "nationally recognized MRO certification board(s)" were going to look like and require when the Part 40 came out. So in the balance, I guess its ok. And it's noted in the section 26.185 that these skills are required.
b. Relationships- ok
c. The idea of having the MRO "resident at the location at which MRO staff members are performing their duties" is interesting and may have any number of unintended consequences. I'm not sure what "resident" means in this context- is it ok to have an office there but only pop in once a year, once a month, a week???. Does the MRO have to be present during all business hours, etc. So I think it's good but needs definition to be of value.
d. Responsibilities- pretty much what is done now regarding drug testing but doesn't do much in the line of other aspects of fitness for duty. May be covered elsewhere.

6. **26.184 Verifying a fitness-for-duty policy violation**
a. ok
b ok
c. ok
d. definition of "all reasonable effort" would help 3 attempts spread over 24 hours like DOT or every hour on the hour? When can the MRO go to the licensee to ask they try to reach.
e. The way it is written, the person could come back years later ? there should be a time frame
f. Alternative method for drug testing is pretty wide open-at least limit it to a set of types of testing.

g. Interesting that cold specimen automatically constitutes a basis for believing a "dilution for subversion attempt". May indeed be true but also could be person waited too long to bring it out. It indeed should be redone as observed but not sure I want to have to jump directly to subversion.
h. I think there is an error here- the specific gravity of 1.001 is fine, it goes along with DOT. But the 1.003 makes that a pretty narrow range. Perhaps 1.030 was meant although the DOT uses 1.020. And why not just make it mandatory for the lab to give that information in these circumstances instead of having to request. I am not quite clear why race, gender and body weight are considered as being "unsubstantiated personal characteristics" since they can be "substantiated" although diet cannot easily. I agree that they should not be a basis for accepting the test- indeed showing can produce is the criteria.
i. This section would imply that a clinical exam is needed for any claim of prescription or OTC as source would appear to require a clinical exam. On the other hand, no such claim does not seem to require a clinical (e.g. substituted, adulterated, dilute, no claim of meds as basis.). logistically this might mean we have to have a phone conversation with the person to determine if the claim of medication is made and if it is made then an in person clinical evaluation. I do like the idea that a clinical exam is needed but there appears to be this extra step of calling. Would be better to just schedule a clinical exam.
j. Ok- it takes a while to say it but covers the ground
k. Ok but interesting that the whole process is considered a fitness for duty (when it's really a review of drug test result) and then the notation is made that a determination of fitness is needed for medications that have potential for risks to public health and safety as a result of impairment. So the term fitness is being used both as freedom from drugs use illegally or inappropriately as well as legally with potential side effects.
l. Ok
m. Ok
n. does this mean a second verification interview?
o. I think the process re marijuana will be stretching the capability of science and will end up being done on "gut" if the levels are lower.
p. To keep in the time line, there needs to be better definition of timelines for reasonable attempts to reach the employee and the time frame they must be seen

7. 26.187 SAE
This is the same function as the SAP in DOT terminology. There are now a few people in the area who meet the requirements. What seems

to be missing is a prohibition on the SAE also doing the treatment. To allow that can lead to conflicts of interest with the defined role. There is a requirement in the qualifications that the SAE be aware of the prohibitions, but I don't seem to find them spelled out.

8. 26.189 Determination of fitness- looks like will need a panel of experts in many of the kinds of cases which have come up in the past.

9. 26.183 (c) Does the MRO really need to be physically present at every collection site where they supervise staff? This is currently not the case in many places and would be difficult to do.

10. 26.185 (d) "all reasonable efforts" should be defined - ex. 3 phone calls over 24 hours which is what most of us use and I believe is the DOT recommendation.
(e) how long does the donor have to present the MRO with a reason why they could not be reached ? After a certain amount of time, we should probably be able to not reopen the case irregardless of the information provided.
(f) (2) if there is a temporary medical explanation for why a specimen was reported invalid then I think the timing of the retest needs clarification -The reg states to do it "as soon as reasonably practical" but the MRO would first need to verify that the temporary explanation has resolved. If the medical explanation for the invalid test is chronic or permanent, then the reg states that the MRO may authorize alternative testing. This is also a bit vague and I'm not sure what alternative methods
I would suggest, since no testing other than urine is approved in any federal regs at this time. The bottom line is that the MRO would be making some decisions that do not necessarily have regulatory back-up and liability is an issue.
(g) (ii) if you do LOD testing on a cold specimen and detect a drug below the cut-off levels but the second repeat observed specimen is negative at the cut-offs, I am not sure how to proceed. I would be very hesitant to call this a positive or even a substituted urine;.
(h) use the DOT cut-offs for substituted specimens --spgrav less than or equal to 1.0010 or greater than or equal to 1.020.
(j) This section on the whole, is a bit confusing. In the past and with the DOT, the MRO only needed to obtain clinical evidence of abuse in certain cases of opiate positives. The wording here seems to indicate it now needs to be done on any prescription drug positive. My concern is if the prescription is legitimate, how far do I have to go to look for evidence of abuse before I can call this a negative drug screen? In the past, I have reported some drug screens in this category as negative

but recommended that a fitness for duty eval: be done based on medical information obtained in the MRO interview. Also part (3) seems to ask the MRO to report using another persons prescription as "the donor misused a prescription". I would be very uncomfortable using that phrasing to report a drug screen result when no clinical evidence of drug abuse was found. These have always, to my knowledge been reported as negative at the discretion of the MRO.
o) In some cases of follow-up testing, it will be possible to state that presence of the drug or metabolite clearly represents new drug use but I believe there will be cases where this cannot be determined even with additional testing and input from the lab toxicologist.

11. 26.187 SAE
(c) how does the SAE demonstrate knowledge and clinical experience? suggest this section and the qualification training be specifically defined. Also, I might be concerned that if the qualifications are too time-consuming or difficult to meet, there will not be enough practitioners who meet the requirements to do SAE work. The continuing ed should also be clarified. Would MRO continuing ed credits count? Presently, there are no specific SAE continuing ed programs in existence.
(g) This makes it sound like the SAE could be the treating physician or counselor and I think this could present a conflict of interest. Would it be better to state that the SAE approve the treatment and return to work plan that has been recommended by the treating practioner?

12. 26.189 I understand the rationale for this section and agree that when we are determining fitness-for-duty, the most qualified practitioner for that particular situation should be used. However, I'm not clear on who decides which SAE should be used in each particular situation. Also, this seems to require each employer/utility to keep a rather large list of qualified medical professionals and I'm not sure how easy this will be in practice. Will these various practitioners be willing to accept the liability risks involved in making these determinations? Also, can the employee request a second opinion fitness for duty eval. for any reason (ex, what if the employee states that their eval. was not done by someone with appropriate qualifications?)

Fitness for Duty Comment Number 25
Sub-Part E: Collecting Specimens for Testing
4/30/2004

Purpose: Comments on the following sections of Sub-part E:

1. Acceptable Identification 26.89(b)(2)
2. Explain the testing procedure 26.89(a)(3)
3. Preparing for Urine collection 26.103
4. Urine specimen quantity 26.107(b)(1) & (3)
5. Collecting a urine specimen under direct observation 26.113(a)(2)(i)
6. Collecting a urine specimen under direct observation - 26.113(d)

Issue:

1. **Acceptable identification:** How is the FFD program management going to ensure that the donor is positively identified? The proposed rule states that if the donor cannot produce acceptable identification, the collector shall proceed with the test and immediately inform FFD program management that the donor did not present acceptable identification. For random/follow-up testing this is not a problem but for pre-access testing the individual may have forgotten their ID and no one may be able to ID them (e.g., traveler). In these situations the industry does not believe that the donor should be tested. When individuals report to in-processing they typically know that they need a FFD test. Currently if individuals do not have their ID with them they are not allowed to in-process.
2. **Explain the testing procedure:** If the licensee has to stop and explain the testing procedure to each individual being tested we will never get anyone tested. The industry believes that it should suffice to give the individual a sheet explaining the process that they sign acknowledging its receipt. Eating and drinking, etc., has not been an issue with the industry. The industry believes that by pointing this out to the donors will encourage this type of behavior and delay the testing process. The donor must either be required to list prescription medication or not. Using the word "MAY" indicates that it will be required is certain circumstances. When would they be required if the word "may" remains? Industry believes that the "shall" replace "may"
3. **Preparing for Urine collection** – 26.103 (a) – (d) replace "the collector" with "the collection personnel" With processing efficiencies during pre-access testing it may be a different individual conducting these tasks than the actual collector assigned to collect a breath or urine specimen.

4. **Urine specimen quantity** - 26.107(b)(1) The collector shall encourage the donor to drink a reasonable amount of liquid (normally, 8 ounces of water every 30 minutes, but not to exceed a maximum of 24 oz.) until a specimen containing 30 mL or more has been collected. Does this mean that the collector can give the person 8-24 ounces every 30 minutes or 8 ounces every 30 minutes and after 1-1/2 hours a total of 24 ounces? (did not have time to line in/out)

5. **Urine specimen quantity** - 26.107(b)(3) If the donor has not provided a specimen of at least 30mL within 3 hours of the first unsuccessful attempt to provide a specimen of the predetermined quantity, the collector shall discontinue the collection and notify the FFD program manager or MRO to initiate the "shy bladder" procedures in 26.117. The industry would like that 3 hour timeframe to be limited to 1.5 hours. You cannot give them any more water and a person may be sitting there for quite sometime, increasing our costs for the specimen collection creating an unnecessary burden.

   A MRO has expressed concerns, see FFD 23, that medical determination of a "shy bladder" may be difficult and questioned the time limit. If the NRC is planning to provide explicit regulatory guidance in this area, there must have been a scientific basis for the 24 ounces of water and 3 hour limit that would be applicable to every individual in all circumstances. Otherwise, we would expect to see flexibility and the ability to take appropriate action based on the case at hand. **It is requested that the NRC staff make available to the public, and to industry MROs, the scientific basis for the 3 hours and 24 ounces.**

6. **Collecting a urine specimen under direct observation** - 26.113(a)(2)(ii) The donor's measured temperature varies by more than 1EC/1.8E/F from the temperature of the specimen; The temperature of specimen should never be greater than body temperature. It should read: The donor's measured temperature is less than the temperature of the specimen or the donor's measured temperature is greater than 1EC/1.8E/F than the temperature of the specimen; (remember, you only take a temperature if the specimen is already outside the 90 – 100 range).

7. **Collecting a urine specimen under direct observation** - 26.113(d) – The collector shall explain the reason to the donor the reason for direct observation of the collection. The industry believes that the it should read: The collector shall explain the reason, *if known*, to the donor the reason for direct observation of the collection.....The licensee does not always inform the collector the reason for the observed collection.

Proposed Text:

§26.89 Preparing to collect specimens for testing.

(b)(2) If the donor cannot produce acceptable identification (excluding pre-access testing), the collector shall proceed with the test and immediately inform FFD program management that the donor did not present acceptable identification. FFD program management will ensure that the donor is positively identified (e.g., through presentation of acceptable photo identification or identification by the employer's representative) and that the necessary steps are taken to determine whether the lack of identification was an attempt to subvert the testing process. If the donor is scheduled for a pre-access test and identity cannot be established, the collection site person shall not proceed with the collection, inform FFD program management that the individual did not present acceptable identification. FFD program management will ~~-~~take the necessary steps to determine whether the lack of identification was an attempt to subvert the testing process.

(b)(3) ~~The collector shall explain t~~The testing proces<u>s shall be provided</u> ~~dure~~ to the donor~~, show the donor the form(s) to be used,~~ and ask<u>ed</u> ~~the donor~~ to sign a consent-to-testing form. <u>This shall include a statement that the individual has not had anything to eat or drink, belched or put anything into his or her mouth (including, but not limited to cigarette, breath mint, or chewing gun, within 15 minutes prior to testing and the donor should avoid these activities during the collection process.</u> The donor ~~may~~ <u>shall</u> not be required to list prescription medications or over-the-counter preparations that he or she has recently used.

~~(c) Immediately before collecting a specimen for alcohol testing, the collector shall —~~

~~(1) Ask the donor whether he or she, in the past 15 minutes, has had anything to eat or drink, belched, or put anything into his or her mouth (including, but not limited to, a cigarette, breath mint, or chewing gum), and instruct the donor that he or she should avoid these activities during the collection process;~~

(2) If the donor ~~states~~ <u>indicates</u> that he or she has <u>not</u> ~~not~~ engaged in the activities listed in paragraph ~~(c)(1)~~ of this section, alcohol testing may proceed;

(3) If the donor states that he or she has engaged in any of the activities listed in paragraph ~~(c)(1)~~ of this section, inform the donor that a 15-minute waiting period is necessary. ~~to prevent an accumulation of mouth alcohol from leading to an artificially high reading;~~ <u>Testing will be conducted at the end of the waiting period, even if the donor has not followed directions.</u>

~~(4) Explain that it is to the donor's benefit to follow the instructions;~~

~~(5) Explain that the initial and confirmatory tests, if a confirmatory test is necessary, will be conducted at the end of the waiting period, even if the donor has not followed the instructions; and~~
~~(6) Document that the instructions were communicated to the donor.~~

(d) With the exception of the 15-minute waiting period, if necessary, the collector shall begin for-cause alcohol and/or drug testing as soon as reasonably practical after the decision is made that for-cause testing is required.

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

§26.103 Preparing for urine collection.

(a) The collection~~r~~ personnel shall ask the donor to remove any unnecessary outer garments, such as a coat or jacket, which might conceal items or substances that the donor could use to tamper with or adulterate his or her urine specimen. The collection~~r~~ personnel shall ensure that all personal belongings such as a purse or briefcase remain with the outer garments outside of the room or stall in which the urine specimen is collected. The donor may retain his or her wallet.

(b) The collection~~r~~ personnel shall also ask the donor to empty his or her pockets and display the items in them to enable the collection~~r~~ personnel to identify items that the donor could use to adulterate or substitute his or her urine specimen. The donor shall allow the collection~~r~~ personnel to make this observation. If the collection~~r~~ personnel identifies nothing that the donor could use to adulterate or substitute the specimen, the donor may place the items back into his or her pockets.

(c) The collector shall instruct the donor to wash and dry his or her hands prior to urination.

(d) After washing his or her hands, the donor shall remain in the presence of the collector and may not have access to any water fountain, faucet, soap dispenser, cleaning agent, or other materials that he or she could use to adulterate the urine specimen.

Fitness For Duty Comment Number 26
Subpart C
Clean Version with industry changes
April 30, 2004

Subpart C – Granting and Maintaining Authorization

§26.51 Purpose.

This subpart contains FFD requirements for granting and maintaining authorization to perform the activities or have the types of access that are specified in §26.25(a) of this part.

§26.53 General provisions.

(a) In order to grant authorization to individuals, a licensee or C/V who has a licensee-approved FFD program shall meet the requirements in this subpart for initial authorization, authorization update, or authorization reinstatement, as applicable.

(c) The licensee or C/V shall ensure that an individual has met the applicable FFD training requirements that are specified in §26.29 of this part before granting authorization to the individual.

(d) Licensees or C/Vs seeking to grant authorization to an individual who is subject to another FFD program that complies with this part may rely on the transferring FFD program to satisfy the requirements of this part. The individual may maintain his or her authorization if he or she 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.

§26.55 Initial authorization.

(a) In order to grant authorization to individuals who have never been authorized or whose authorization has been interrupted for a period of 3 years or more, the licensee or C/V shall —

(1) Obtain a self-disclosure in accordance with the applicable requirements of §26.61;

(2) Complete a suitable inquiry in accordance with the applicable requirements of §26.63;

(3) Ensure that the individual is subject to pre-access drug and alcohol testing in accordance with the applicable requirements of §26.65; and

(4) Ensure that the individual is subject to random drug and alcohol testing in accordance with the applicable requirements of §26.67.

(b) If potentially disqualifying FFD information is disclosed or discovered, the licensee may not grant authorization to the individual, except in accordance with §26.69.

§26.57 Authorization update.

(a) In order to grant authorization to individuals whose authorization has been terminated under favorable conditions more than 365 days but less than 3 years the licensee or C/V shall —

(1) Obtain a self-disclosure in accordance with the applicable requirements of §26.61;

(2) Complete a suitable inquiry in accordance with the applicable requirements of §26.63;

(3) Ensure that the individual is subject to pre-access drug and alcohol testing in accordance with the applicable requirements of §26.65; and

(4) Ensure that the individual is subject to random drug and alcohol testing in accordance with the applicable requirements of §26.67.

(b) If potentially disqualifying FFD information is disclosed or discovered, the licensee may not grant authorization to the individual, except in accordance with §26.69.

§26.59 Authorization reinstatement.

(a) In order to grant authorization for an individual whose authorization has been terminated under favorable conditions more than 30 days but not more than 365 days, the licensee shall: —

(1) Obtain a self-disclosure in accordance with the applicable requirements of §26.61;

(2) Complete a suitable inquiry in accordance with the requirements of §26.63 within 5 business days of reinstating authorization. If the suitable inquiry is not completed within 5 business days due to circumstances that are outside of the licensee's control and the licensee is not aware of any potentially disqualifying information regarding the individual within the past 5 years, the licensee may maintain the individual's authorization for an additional 5 business days. If the suitable inquiry is not completed within 10 business days of reinstating authorization, the licensee shall administratively withdraw the individual's authorization until the suitable inquiry is completed;

(3) Ensure that the individual is subject to pre-access drug and alcohol testing in accordance with the applicable requirements of §26.65; and

(4) Ensure that the individual is subject to random drug and alcohol testing in accordance with the applicable requirements of §26.67.

(b) In order to reinstate authorization for individuals whose authorization has been terminated under favorable conditions for not more than 30 days, the licensee shall:

(1) Obtain and review a self-disclosure in accordance with the applicable requirements of §26.61; and

(2) If authorization was interrupted more than five days, ensure that the individual is subject to pre-access drug and alcohol testing in accordance with the applicable requirements of §26.65; and

(3)If authorization was interrupted more than five days, ensure that the individual is subject to random drug and alcohol testing in accordance with the applicable requirements of §26.67.

(c) If a licensee administratively withdraws an individual's authorization under paragraph (c)(2) of this section, and until the suitable inquiry is completed, the licensee may not record the administrative action to withdraw authorization as an unfavorable termination. The individual may not be required to disclose the administrative action in response to requests for self-disclosure of potentially disqualifying FFD information.

(d) If potentially disqualifying FFD information is disclosed or discovered, the licensee may not grant authorization to the individual, except in accordance with §26.69.

§26.61 Self-disclosure and employment history.

(a) Before granting authorization, the licensee or C/V who has a licensee-approved FFD program shall obtain a written self-disclosure and employment history from the individual who is applying for authorization, except as described below.

(i) If an individual previously held authorization under this part, and the licensee or C/V has verified that the individual's last period of authorization was terminated favorably, and the individual has been subject to a licensee-approved behavioral observation and arrest-reporting program throughout the period since the individual's last authorization was terminated, the granting licensee need not obtain the self-disclosure or employment history in order to grant authorization.

(ii) An employment history is not required for reinstatements where the period of interruption is 30 days or less.

(b) The written self-disclosure must: —

(1) State whether the individual has: —

(i) Violated a licensee's or C/V's FFD policy;

(ii) Had authorization denied or terminated unfavorably under paragraphs §§26.75(b)–(d), 26.75(e)(1), or 26.75(e)(2);

(iii) Used, sold, or possessed illegal drugs;

(iv) Abused legal drugs or alcohol;

(v) Subverted or attempted to subvert a drug or alcohol testing program;

(vi) Refused to take a drug or alcohol test;

(vii) Been subject to a plan for substance abuse treatment (except for self-referral); or

(viii) Had legal action or employment action, as defined in §26.5, taken for alcohol or drug use;

(2) Address the specific type, duration, and resolution of any matter disclosed, including, but not limited to, the reason(s) for any unfavorable termination or denial of authorization; and

(3) Address the shortest of the following periods:

(i) The past 5 years;

(ii) Since the individual's eighteenth birthday; or

(iii) Since authorization was last terminated, if authorization was terminated favorably.

(c)The individual shall provide a list of all employers, including the current employer, if any, with dates of employment, for the shortest of the following periods:

(1) The past 3 years;

(2) Since the individual's eighteenth birthday; or

(3) Since authorization was last terminated, if authorization was terminated favorably within the past 3 years.

(d) Falsification of the self-disclosure statement or the individual's employment history required in paragraph (c) of this section is sufficient cause for denial of authorization.

§26.63 Suitable inquiry.

(a) The licensee or C/V who has a licensee-approved FFD program shall conduct a suitable inquiry, on a "best effort" basis, to verify the individual's self-disclosed information and to determine whether any potentially disqualifying FFD information is available. If an individual previously held authorization under this part, and the licensee or C/V has verified that the individual's last period of authorization was terminated favorably, and the individual has been subject to a licensee-approved behavioral observation and arrest-reporting program throughout the period of interruption, the granting licensee need not conduct a suitable inquiry in order to grant authorization.

(b) To meet the suitable inquiry requirement, licensees and C/Vs who have a licensee-approved FFD program may rely upon the information that other licensees and C/Vs gathered for previous periods of authorization. Licensees and C/Vs may also rely upon those licensees' and C/Vs' determinations of fitness, as well as their reviews and resolutions of potentially disqualifying FFD information, for previous periods of authorization.

(c) The licensee or C/V who has a licensee-approved FFD program shall conduct the suitable inquiry on a "best effort" basis by questioning both present and former employers.

(1) For the claimed employment period, the suitable inquiry must ascertain the reason for termination, eligibility for rehire, and other information that could reflect on the individual's fitness to be granted authorization.

(2) If the claimed employment was military service, the licensee or C/V who is conducting the suitable inquiry shall request a characterization of

service, reason for separation, and any disciplinary actions related to potentially disqualifying FFD information. If the individual's last duty station cannot provide this information, the licensee or C/V may accept a hand carried copy of the DD 214 presented by the individual which on face value appears legitimate. A copy of a DD 214 provided by the custodian of military records may also be accepted.

(3) For claimed periods of education in lieu of employment, if the educational institution will not release the requested information an alternate source may be used to verify the applicant was actively participating in the educational process.

(d) In response to another licensee's or C/V's inquiry and presentation of an individual's signed release authorizing the disclosure of information, a licensee or C/V shall disclose whether the subject individual's authorization was denied or terminated unfavorably as a result of a violation of an FFD policy and shall make available the information upon which the denial or unfavorable termination of authorization was based, including, but not limited to, drug or alcohol test results. The failure of an individual to authorize the release of information for the suitable inquiry is sufficient cause to deny authorization.

(e) In conducting a suitable inquiry, the licensee or C/V who has a licensee-approved FFD program may obtain information and documents by electronic means, including, but not limited to, telephone, facsimile, or email. The licensee or C/V shall make a record of the contents of the telephone call and shall retain that record, and any documents or electronic files obtained electronically, in accordance with §§26.197(a), (b), and (c), as applicable.

(f) The licensee or C/V shall conduct the suitable inquiry as follows:

(1) Initial authorization. The period of the suitable inquiry must be the past 3 years or since the individual's eighteenth birthday, whichever is shorter. For the 1-year period immediately preceding the date upon which the individual applies, the licensee or C/V shall conduct the suitable inquiry with every employer, regardless of the length of employment. For the remaining 2-year period, the licensee or C/V shall conduct the suitable inquiry with the employer by whom the individual claims to have been employed the longest within each calendar month, if the individual claims employment during the given calendar month.

(2) Authorization update. The period of the suitable inquiry must be the period since authorization was terminated. For the 1-year period immediately preceding the date upon which the individual applies, the licensee or C/V shall conduct the suitable inquiry with every employer, regardless of the length of employment. For the remaining period since authorization was terminated, the licensee or C/V shall conduct the suitable inquiry with the employer by whom the individual claims to have been employed the longest within each calendar month, if the individual claims employment during the given calendar month.

(3) Authorization reinstatement for periods of interruption greater than 30 days. The period of the suitable inquiry must be the period since authorization was terminated. The licensee or C/V shall conduct the suitable inquiry with the employer by whom the individual claims to have been employed the longest within the calendar month, if the individual claims employment during the given calendar month.

§26.65 Pre-access drug and alcohol testing. (See FFD 21 for line-in line-out)

(a) Purpose. This section contains pre-access testing requirements for granting authorization to individuals who either have never held authorization or whose last period of authorization was terminated favorably and about whom no potentially disqualifying FFD information has been discovered or disclosed that was not previously reviewed and resolved by a licensee or C/V who has a licensee-approved FFD program.

(b) Initial authorization and authorization update. Before granting authorization to an individual who has never been authorized or whose authorization has been interrupted for a period of more than 365 days, except as permitted in paragraphs (b)(1) and (b)(2) of this section, the licensee shall verify that the results of pre-access drug and alcohol tests are negative.

(1) If an individual previously held authorization under this part and has been subject to both a licensee-approved drug and alcohol testing program that included random testing and a licensee-approved behavioral observation and arrest reporting program from the date upon which the individual's last authorization was terminated through the date upon which the individual is granted authorization, then the granting licensee may forego pre-access testing of the individual.

(2) If an individual has negative test results from drug and alcohol tests that were performed in accordance with the requirements of this part within the 30-day period ending on the day that authorization is granted and the individual has been subject to a licensee-approved behavioral observation and arrest reporting program from the date upon which the drug and alcohol test was conducted through the date upon which the individual is granted authorization, the granting licensee may forego pre-access drug and alcohol testing of the individual.

(c) Authorization reinstatement greater than 30 days. In order to reinstate authorization to an individual whose authorization has been interrupted for a period of more than 30 days but fewer than 365 days, except as permitted in paragraphs (c)(3) and (c)(4) of this section, the licensee shall:

(1) Verify that the individual has negative results from alcohol testing and collect a specimen for drug testing before reinstating authorization; and

(2) Verify that the drug test results are negative within 5 business days of specimen collection or administratively withdraw authorization until the drug test results are received.

(3) If an individual previously held authorization under this part and has been subject to both a licensee-approved drug and alcohol testing program that included random testing and a licensee-approved behavioral observation and arrest reporting program from the date upon which the individual's last authorization was terminated through the date upon which the individual is granted authorization, then the granting licensee may forego pre-access testing of the individual.

(4) If an individual has negative test results from drug and alcohol tests that were performed in accordance with the requirements of this part within the 30-day period ending on the day that authorization is granted and the individual has been subject to a licensee-approved behavioral observation and arrest reporting program from the date upon which the drug and alcohol test was conducted through the date upon which the individual is granted authorization, the granting licensee may forego pre-access drug and alcohol testing of the individual.

(d) Reinstatement 30 days or less

(1) Pre-access testing is not required in order to reinstate authorization for an individual whose authorization has been interrupted for a period of 5 days or less.

(2) In order to reinstate authorization for an individual whose authorization has been interrupted for a period of more than 5 days but not more than 30 days, except as permitted in paragraph (d)(3) of this section, the licensee or C/V shall take the following actions:

(i) The licensee shall subject the individual to random selection for pre-access drug and alcohol testing at a one-time probability that is equal to or greater than the normal testing rate specified in §26.31(d)(2)(vi) calculated for a 30-day period.

(ii) If the individual is not selected for pre-access testing under this paragraph, the licensee need not perform pre-access drug and alcohol tests;

(iii) If the individual is selected for pre-access testing under this paragraph, the licensee shall: —

(A) Verify that the individual has negative results from alcohol testing and collect a specimen for drug testing before reinstating authorization; and

(B) The licensee shall verify that the drug test results are negative within 5 business days of specimen collection or administratively withdraw authorization until drug test results are received.

(3) If an individual previously held authorization under this part and has been subject to both a licensee-approved drug and alcohol testing program that included random testing and a licensee-approved behavioral observation and arrest reporting program from the date upon which the individual's last authorization was terminated through the date upon which

the individual is granted authorization, then the granting licensee may forego pre-access testing of the individual.

(e) Time period for testing. If drug and alcohol tests are required under this section, the testing must be collected within the 30-day period that ends on the date that the licensee grants authorization to an individual.

(f) Specimen collection and testing. The licensee may rely upon drug and alcohol test results to meet the requirements for pre-access testing in this section only if the specimens were collected and tested in accordance with the requirements of this part.

(g) Administrative withdrawal of authorization. If a licensee administratively withdraws an individual's authorization under paragraphs (c)(2) or (c)(3) of this section, and until the drug test results are known, the licensee may not record the administrative action to withdraw authorization as an unfavorable termination The individual may not be required to disclose the administrative action in response to requests for self-disclosure of potentially disqualifying FFD information.

(h) If an individual has non-negative test results from any drug or alcohol tests that may be required in this section, the licensee shall, at a minimum and as appropriate:

(1) Deny authorization to the individual, in accordance with §§26.75(b), (d), (e)(2), or (g);

(2) Terminate the individual's authorization, if it has been reinstated, in accordance with §§26.75(e)(1) or (f); or

(3) Grant authorization to the individual only in accordance with the requirements of §26.69.

§26.67 Random drug and alcohol testing of individuals in applicant status.

(a) When a pre-access drug and alcohol sample is collected to meet the requirements of r §§26.55, 26.57, 26.59, or 26.69 the individual shall be placed in a random testing program in accordance with §26.31(d)(2).

(b)Where a drug and alcohol test conducted prior to application is used to meet the pre-access requirements of 26.65, the individual shall be placed in the random testing program when the licensee takes the first formal action on the application.

(c) If an individual is selected for one or more random tests after any applicable requirement for pre-access testing in §26.65 has been met, the licensee may grant authorization before random testing is completed in accordance with §26.31(d)(2), if the individual has met all other applicable requirements for authorization.

(d) If an individual has non-negative test results from any drug and alcohol testing required in this section, the licensee shall, at a minimum and as appropriate: —

(1) Deny authorization to the individual, in accordance with §§26.75(b), (d), (e)(2), or (g);

(2) Terminate the individual's authorization, if it has been granted, in accordance with §§26.75(e)(1) or (f); or

(3) Grant authorization to the individual only in accordance with the requirements of §26.69.

§26.69 Authorization with potentially disqualifying fitness-for-duty information.

(a) Purpose. This section defines the management actions that licensees or C/Vs who have licensee-approved FFD programs shall take in order to grant or maintain the authorization of an individual who is in the following circumstances:

(1) Potentially disqualifying FFD information within the past 5 years has been disclosed or discovered about the individual by any means, including, but not limited to, the individual's self-disclosure, the suitable inquiry, drug and alcohol testing, the administration of the FFD program, a self-report of a legal action, behavioral observation or other sources of information, including, but not limited to, the background investigation conducted under §73.56 of this chapter and the criminal history check conducted under §73.57 of this chapter; and

(2) The potentially disqualifying FFD information has not been reviewed and favorably resolved by a previous licensee or C/V who has a licensee-approved FFD program.

(b) Authorization after a first confirmed positive drug or alcohol test result. The requirements in this paragraph apply to an individual whose authorization was denied or terminated unfavorably for a first violation of a licensee's or C/V's FFD policy involving a confirmed positive drug or alcohol test result. In order to grant, and subsequently maintain, the individual's authorization, the licensee shall: —

(1) Verify that the individual's self-disclosure, if one is required under §§26.55, 26.57, or 26.59 as appropriate, does not contain any previously undisclosed potentially disqualifying FFD information before granting authorization;

(2) Complete a suitable inquiry with all employers by whom the individual claims to have been employed in accordance with the requirements of §26.63 and as follows before granting authorization to the individual:

(i) Conduct the suitable inquiry for the applicable period, as specified in §26.63(f) of this section; and

(ii) Obtain any records that other licensees or C/Vs may have developed related to any potentially disqualifying FFD information about the individual from the past 5 years;

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

plans for treatment and followup testing were developed before granting authorization;

(4) Verify that the individual is in compliance with, and successfully completes, the treatment plans;

(5) Verify negative results of an alcohol test and a drug test, collected under direct observation, within 5 business days before granting authorization;

(6) Ensure that the individual is subject to followup drug and alcohol testing for a period of 3 years from the date authorization was terminated at a frequency of no less than once every 30 days for 4 months after authorization is granted, and at least once every 90 days for the next 2 years and 8 months; and

(7) Verify that any drug and alcohol tests required in this paragraph, and any other drug and alcohol tests conducted since authorization was terminated, yield results indicating no further drug or alcohol abuse, as appropriate, since the original confirmed positive test result.

(c) Authorization following a denial of authorization. The requirements in this paragraph apply to an individual whose authorization was denied for 5 years under §§26.75(c), (d), (e)(2), or (f). In order to grant, and subsequently maintain, the individual's authorization, the licensee shall —

(1) Verify that the individual has abstained from substance abuse for at least the past 5 years;

(2) Verify that the individual's self-disclosure, if one is required under §§26.55, 26.57, or 26.59 as appropriate, does not contain any previously undisclosed potentially disqualifying FFD information before granting authorization;

(3) Complete a suitable inquiry with every employer by whom the individual claims to have been employed during the past 5 years in accordance with the applicable requirements of §26.63 and obtain any records that other licensees or C/Vs may have developed related to the denial of authorization;

(4) Ensure that a determination of fitness has indicated that the individual is fit to safely and competently perform his or her duties before granting authorization;

(5) Ensure that any recommendations for treatment and followup testing from the determination of fitness are initiated before granting authorization;

(6) Verify that the individual is in compliance with, and successfully completes, any treatment plans;

(7) Perform an alcohol test within 5 business days before granting authorization and verify that the results are negative before granting authorization;

(8) Collect a specimen for drug testing under direct observation within 5 business days before granting authorization and verify that the results are negative before granting authorization; and

(9) Verify that the results of any followup drug and alcohol testing required in this paragraph are negative.

(d) Authorization with other potentially disqualifying FFD information. The requirements in this paragraph apply to an individual who has not previously had his or her authorization terminated unfavorably or denied for 5 years under this part, who is either in applicant status or is currently authorized, and about whom potentially disqualifying FFD information has been discovered or disclosed.

(1) If the individual is in applicant status, before granting authorization, the licensee or C/V shall —

(i) Complete a suitable inquiry with every employer by whom the individual claims to have been employed in accordance with the requirements of §26.63 and as follows:

(A) Conduct a suitable inquiry for the applicable period, as specified in §26.63(f); and

(B) Obtain any records that other licensees or C/Vs may have developed with regard to potentially disqualifying FFD information about the individual from the past 5 years;

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

(iii) Ensure that the individual is in compliance with, or has completed, any plans for treatment and drug and alcohol testing from the determination of fitness.

(iv) Verify that the results of pre-access drug and alcohol tests are negative before granting authorization.

(2) If the individual is authorized when the potentially disqualifying FFD information is disclosed or discovered, in order to maintain the individual's authorization, the licensee shall —

(i) Ensure that the licensee's designated reviewing official completes a review of the circumstances associated with the information;

(ii) If the designated reviewing official determines that a determination of fitness is required, verify that the determination of fitness has indicated that the individual is fit to safely and competently perform his or her duties; and

(iii) If the reviewing official determines that maintaining the individual's authorization is warranted, implement any recommendations for treatment and followup drug and alcohol testing from the determination of fitness, and ensure that the individual successfully completes them.

(e) If an individual leaves the FFD program in which a treatment and followup testing plan was required under paragraphs (b), (c), or (d) of this section, and is granted authorization by another licensee with a different

FFD program, the receiving licensee shall ensure that any treatment and followup testing requirements are met, with accountability assumed by the receiving licensee. If the previous licensee or C/V determined that the individual successfully completed any required treatment and followup testing, and the individual's authorization was terminated favorably, the receiving licensee may rely upon the previous determination of fitness and no further review or followup is required.

(f) If an individual has non-negative test results from any drug and alcohol testing required in this section, the licensee shall, at a minimum and as appropriate —

(1) Deny authorization to the individual, in accordance with §§26.75(b), (d), (e)(2), or (g); or

(2) Terminate the individual's authorization, if it has been granted, in accordance with §§26.75(e)(1) or (f).

§26.71 Maintaining authorization.

(a) Individuals may maintain authorization under the following conditions:

(1) The individual complies with the licensee's or C/V's FFD policies to which he or she is subject, including the responsibility to report any legal actions, as defined in §26.5;

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

(3) The individual remains subject to a licensee-approved behavioral observation program that complies with the requirements of this part; and

(4) The individual successfully completes required FFD training, in accordance with the schedule specified in §26.29(c).

(b) If an authorized individual is not subject to a licensee-approved FFD program for more than 30 days, then the licensee or C/V shall terminate the individual's authorization and the individual shall meet the requirements in this subpart, as applicable, to regain authorization.

Fitness for Duty Comment Number 27
Reporting Concerns
April 30, 2004

Purpose: To discuss individual responsibility for reporting FFD concerns.

Issue: The industry was surprised at the changes to policies section 26.27(b)(10) that changed from an individual responsibility to ability to report FFD concerns. In considering the new security environment, the Commission asked the industry to conduct various reviews and provide recommendations that would enhance the industry's security posture. In the area of Access Authorization and Fitness for Duty the number 1 industry recommendation was to provide behavioral training all individuals with Unescorted Access and require reporting of any behavioral concerns.

This recommendation was directed by the Commission in a January 07, 2003 order, item C.1.8. Although the order is Safeguards Information, the uncontrolled implementing guidance states, in part, "...that licensee and C/V personnel have sufficient awareness...with an expectation of promptly reporting noticeable changes in behavior to the licensee's or C/V's management for appropriate evaluation and action."(C.1.8.a.2) Training was conducted and this Commission requirement implemented by the industry on July 7, 2003.

The March 29, 2004 policy statement is also inconsistent with other, very recent, direction from the Commission.

The draft language will generate an implementation conflict with the Access Authorization requirements unless the Commission changes the January 7, 2003 Order

Proposed Text: See the Fall 2002 draft.

(10) Describe the individual's responsibility to report FFD concerns.