

**Staff Comments on NEI 06-06, Rev. 0,
“Fitness for Duty Program for
New Plant Construction Sites”**

Background

The staff reviewed the document against the requirements of current 10 CFR 26.2(c). Paragraph 26.2(c) states (titles of cross-referenced sections added):

Certain regulations in this part apply to licensees holding permits to construct a nuclear power plant. Each construction permit holder, with a plant under active construction, shall comply with §§ 26.10 [general performance objectives], 26.20 [written policy and procedures], 26.23 [contractors and vendors], 26.70 [inspections], and 26.73 [reporting requirements] of this part; shall implement a chemical testing program, including random tests; and shall make provisions for employee assistance programs, imposition of sanctions, appeals procedures, the protection of information, and recordkeeping.

The staff also considered the NRC’s goals in the current Part 26 rulemaking in this review, as documented in 70 FRN 50442 (August 26, 2005).

General Comments

In order to endorse this document without qualifications, the staff would require resolution of the following issues:

1. Other than post-accident testing, the document does not clearly identify the conditions under which drug and alcohol testing would be required or the conditions under which alcohol testing will occur.
2. The categories of workers who would be subject to each of the FFD program elements are not clearly defined in the document.
3. The method by which individuals who are subject to the FFD policy will be informed of the policy’s requirements and their responsibilities under the policy is unclear.
4. For-cause testing in response to indications of impairment and other indicators is discussed, but the document does not require training in behavioral observation for any categories of workers.
5. The procedures for random testing described in Section 6.8 would be ineffective to deter substance abuse, particularly for any portion of a calendar month after which testing has occurred.
6. The NRC would not endorse the use of urine or the routine use of blood samples for alcohol testing.
7. The extent to which the use, sale, and possession of alcohol will be addressed by the FFD program is unclear.
8. The document does not require initial and confirmatory drug testing to be conducted by an HHS-certified laboratory or other laboratory that meets equally stringent quality control procedures (e.g., certification by the College of American Pathologists).
9. The NRC would not endorse searches without cause in Section 5.5.

Enclosure

Questions and Comments by Section

Section 1 - Introduction

- The stated goal of the document is to establish consistency among FFD programs at nuclear power plant construction sites. However, it does not appear that it will achieve this goal because (1) the level of detail is insufficient to ensure consistency; (2) the document provides for significant management flexibility in implementing the program; and (3) the testing provisions permit significant flexibility.
- The document appears to apply only to COL applicants and facilities. Is there a reason that it wouldn't apply to construction permit holders, manufacturing licensees, and entities with a limited work authorization (including entities with early site permits who have limited work authorization)?
- Two concepts are used in this section without definition. These include "eligibility for being granted access" and "COL property or facilities." Please define these concepts.
- Paragraph 2 of this section includes C/Vs as "COL entities." Please clarify which organization(s) are ultimately responsible to the NRC for the effectiveness of the FFD program and the relationship of the licensee, permit holder, etc. to the C/V's FFD program.

Section 2 - Purpose and Scope

- Please clarify the meaning of the phrases, "suitability of personnel" and "access to the COL entity."
- "Sharing of data" is mentioned in the first paragraph, but no provisions for sharing data are included in the document. Please describe the data that will be shared, the purpose(s) of such sharing, any protections afforded for individuals' privacy, and the means by which such data will be shared.

Section 3 - Responsibility

- The intended meaning of the first sentence in this section is unclear. Is the intended meaning that each COL entity is responsible for determining that its employees or contractors are fit? All employees and contractors at the construction site or only certain categories of workers? How will this determination be made?
- What, if any, responsibility do individuals have for being fit for duty under this program?

Section 4 - Definitions

- Why is "alcohol" defined as a legal beverage being in excess of 3 percent alcohol by volume? Using this definition, individuals could be permitted to bring and consume "near beer" on-site. Is this the intent of this definition?
- The definition of conviction addresses only drug-related convictions. However, alcohol-related convictions may also indicate a substance abuse problem. Please clarify the basis for limiting the definition of a conviction to drug statutes only.
- Please explain why the definition of "illegal drugs" does not include prescribed drugs that are not being used as prescribed. An individual can over-use a prescription medication taken for "prescribed purposes" (e.g. take more pain medication than directed because

it “helps” relieve pain), which may also lead to impairment or indicate an active substance abuse problem.

- Please define the terms, “construction site,” “construction phase,” and “operational phase.”
- Please provide a definition of the term, “will.” Is “will” used to mean “shall” wherever it occurs in the document or does it have another meaning (e.g., “may”)?

Section 5 - Drug and Alcohol Policy

- Limiting the scope of the policy to a concern with “Dependency on alcohol and/or drugs” is inconsistent with the performance objectives of Part 26, which also address recent and/or current use of drugs and alcohol, particularly as they may adversely affect an individual’s ability to safely and competently perform his or her duties. The distinction is important. Consider replacing “Dependency on...” with “Use of...” or another term that appropriately incorporates the regulatory objectives of Part 26.
- Similarly, the second sentence of this paragraph is incomplete, given that a main objective of having a “drug-free workplace” does not adequately capture all of the performance objectives in § 26.10.

Section 5.1 - Use, Possession, or Sale of Drugs or Alcohol

- Section 5.1 does not prohibit the use, possession, or sale of alcohol on a nuclear power plant construction site. Permitting the use of alcohol is inconsistent with § 26.20(a)(2).
- In 5.1.1, please clarify/define the meaning of the phrases, “in a COL entity facility, on a COL entity jobsite, or while performing COL entity business...” The use or presence of illegal drugs in any COL facility, jobsite, or while performing any COL business is beyond the scope of the NRC’s regulatory concern. In addition, the use or possession of illegal drugs by any individual is also beyond the scope of the NRC’s regulatory concern. Please clarify the locations, activities, and categories of individuals to whom this section would apply.
- Please clarify how excluding a requirement to self-report convictions on alcohol-related charges meets the performance objectives in § 26.10.
- In 5.1.2, NEI 06-06 states that an individual taking prescription drugs that may cause impairment (and other adverse consequences) “should” notify the COL entity of such use. This recommendation raises important questions of privacy and confidentiality as well as procedure. Please clarify how an individual will determine whether prescription or over-the-counter medications may adversely affect co-workers, his or her job performance, or the safety and security of property or facilities? What qualifications/training/knowledge will individuals rely upon to make this determination? What is the timeframe, if any, within which an individual “should” report such use? What, if any, management actions can an individual expect in response to a self-report? Please clarify what qualifications does “management” have to determine whether use of the drug imposes a risk?

Section 5.2 - Disciplinary Action (Sanctions)

- This section indicates that violations of any portion of the policy will result in immediate termination of access. Please clarify the meaning of the term, “access,” in this context.
- The meaning of the term, “immediate,” is unclear and may impose unwanted audit or

enforcement consequences. Please clarify the intended meaning of this term and how it would be implemented.

- The apparent requirement to immediately terminate access appears to be inconsistent with referring a COL entity employee who tests positive to an EAP in Section 5.4.
- The requirement to sign the Authorization and Consent form does not ensure that the individual is aware of the policy to which he or she is subject. Please clarify the manner in which individuals will be informed of the policy.
- Please clarify the meaning of the term, “prior to assignment.” That is, assignment to what? What is the relationship of “assignment” to “access?”

Section 5.3 - Drug and Alcohol Screening

- This section appears to permit collecting and testing of any specimens for drugs and alcohol. Please provide the scientific and technical basis for permitting such wide latitude in the selection of specimens for testing, which would seem to permit, for example, the use of hair samples to test for alcohol. The apparent latitude provided to COL entities to use any specimens for testing in this section is inconsistent with § 26.20(c), which requires quality controls to ensure that test results are valid.
- This section does not appear to require testing under any specific set of conditions. Please clarify the conditions under which testing will be required, the categories of workers who would be subject to testing, and the means that will be used to ensure that individuals will be protected from inappropriate testing. For example, will COL entity management receive training in determining conditions that represent a reasonable suspicion?
- Again, please define the term, “assignment to the COL entity,” and its relationship to “access.”

Section 5.4 - Relationship of Drug/Alcohol Use Policy to Employee Assistance Program

- The first sentence of the Employee discussion is unclear. Is the term, “provides,” intended to mean “shall provide?”
- As noted with respect to Section 5.2, referral to the EAP after a positive test result appears to be inconsistent with the sanction of immediate termination of access. Also, because the definition of COL entity includes C/Vs, this paragraph appears to impose on C/Vs a requirement to provide an EAP. Further, because nearly every individual on the jobsite will be an employee of either a licensee, permit holder, or C/V, it appears that the sanction of immediate termination of access would not apply to any individuals who have a positive test result.
- Please define “non-employee.”
- Please define “immediate termination of assignment” and its relationship to “access.”

Section 5.5 - Searches

- As noted in the staff’s General Comments, the NRC cannot endorse searches without cause as a regulatory requirement.
- Further, the basis for conducting searches for alcohol is unclear because the FFD policy does not appear to prohibit the possession of alcohol on the jobsite.

Section 6.1 - Acknowledgement and Consent Form

- Please define “assignment to perform services on a construction jobsite.”
- Will the consent form include a requirement to consent to alcohol testing?

Section 6.2 - Testing Procedures

- Please define “involved in” in the first sentence of this section. Would this include individuals who observed the circumstances, were affected by it but had no role in causing it, etc.?
- In 6.2.b, what is the basis for limiting post-accident testing to automobiles, rental cars, and COL entity company vehicles? The scope of this requirement appears to be inconsistent with the procedures in Section 6.9.2, which appears to include any self-propelled machinery.
- In 6.2.c, the definition of “near miss” is vague. Consider providing either several examples or a more precise definition.
- In 6.2.d, please provide the basis for the \$500,000 property damage threshold and a definition of “COL entity property.”
- What is the basis for excluding wilful property damage or other forms of sabotage as a condition for post-accident testing?
- The last paragraph of this section discusses the consent to drug screening form. Will signing that form also provide the individual’s consent to the alcohol testing required in this section? Also, please define the phrase, “access to the COL entity,” and its relationship to “access” and “assignment.”

Section 6.3 - Standards of Testing

- What is the scientific and technical basis for restricting drug screening to EMIT testing? While this method is currently accepted for forensic drug testing, it is not the only method that is used. Immunoassay testing, the current Federal forensic standard for drug urine screening, may use enzyme, radioactive, fluorescent, or other approaches that are equally valid.
- Further, limiting screening tests to EMIT testing would prohibit COL entities from using some specimens other than urine for drug screening, as EMIT tests do not exist for many physiological specimens. Is this the intent of this requirement? If so, it appears to conflict with the permission in Section 5.3 to use any specimens for drug testing.
- Similarly, what is the scientific and technical basis for restricting confirmatory drug testing to the GC/MS technique? There are other more sensitive methodologies, including GC/MS/MS, that drug-testing laboratories are now using. Please clarify why this document would prohibit their application.
- The first paragraph of this section establishes the panel of substances for which testing will be conducted, “unless stated otherwise in the client contract.” Please define “client contract.”
- Please explain why the permission for a “client contract” to establish the substances for which testing will be performed would permit a client contract to “state” that no, one, or a very large number of substances could be included in the panel. This permission does not achieve consistency in FFD programs. Further, because a client contract could involve not testing for any or only one or two substances, it is unclear how the FFD program could achieve the performance objectives in § 26.10.

- The second paragraph of this section adopts DOT cutoff levels for drugs and alcohol, “unless stated otherwise in the client contract.” Permitting “client contracts” to establish alternate cutoff levels does not meet the stated goal of this document, which is to ensure consistency among FFD programs. More importantly, although the DOT cutoff levels are acceptable, if a “client contract” establishes higher cutoff levels, it is unclear whether such higher cutoff levels would meet the performance objectives in § 26.10. Please explain why the cut-off levels are higher than DOT cutoff levels.
- What is the scientific and technical basis for using urine as an appropriate specimen for alcohol testing? There is no scientific agreement on the quantifiable validity of urine alcohol tests and they are not authorized in any Federal regulatory program. Unlike urine drug tests, where there is a per se standard -- that is, the confirmed presence of a drug is all that is needed to declare the drug a positive – alcohol testing uses an impairment standard, which requires rather precise measurement of the amount of alcohol in an individual’s system. This type of measurement cannot be done with a single urine test, and there is scientific dispute if it can be accomplished with two or more consecutive urine specimens collected over a designated period of time.
- What is the scientific and technical basis for restricting oral fluids alcohol screening tests to the Q.E.D. test? There are many more oral fluids tests available on NHTSA’s conforming products list. Please clarify.
- This section does not establish quality control requirements for using breath specimens in alcohol testing. Please clarify how FFD programs will ensure that test results are valid without establishing requirements for acceptable testing devices, instruments, and procedures for their use?
- As noted in the staff’s General Comments, the staff would not endorse mandatory blood draws for all confirmatory alcohol tests. The staff’s position is based upon the current rule’s lack of a requirement for mandatory blood draws, but rather leaves it within the discretion of the individual tested.

Section 6.4 - Specimen Collection/Laboratory

- The HHS Guidelines do not establish procedures for collecting specimens and conducting alcohol tests. Therefore, it appears that no specimen collection standards would apply to conducting alcohol tests. Please clarify how this will ensure that test results are valid and attributable to the donor.
- The HHS Guidelines do not establish procedures for collecting specimens and conducting drug tests of any specimens other than urine. If a COL entity chooses to collect specimens for drug testing other than urine, please clarify how the collection and testing will be conducted in a manner to ensure that test results are valid and attributable to the donor.
- Please define “qualified agency.”
- The document does not appear to require urine specimen validity testing. Please clarify how this achieves the requirement in § 26.20 for test results to be valid?
- This section does not require initial and confirmatory drug testing by an HHS-certified laboratory or other laboratory that follows similarly stringent quality control and chain-of-custody procedures. Please clarify how the FFD program will meet the requirement in § 26.20 for quality assurance procedures to ensure that test results are valid?
- The document does not require a review of confirmed positive drug test results by an MRO. Therefore, it appears that sanctions may be imposed on individuals who have used a legally prescribed medication in accordance with the physician’s instructions.

Please clarify how the FFD program will meet the requirement in § 26.20 for protecting the employee without an MRO review.

Section 6.5 - Recordkeeping and Confidentiality

- Please define “discretely,” “confidential,” and “need to know.”
- This section does not appear to establish any requirements or procedures for protecting the “confidentiality” of alcohol test results. Please explain this position.
- This section limits access to the locked files to management personnel who have a “need to know.” Are Human Resources personnel always management personnel? In addition, this document would not permit NRC inspectors to have access to these documents, which is inconsistent with § 26.70. Please explain this position.
- This section also appears to prohibit the release of records to law enforcement officials under a court order, judicial personnel involved in legal proceedings related to a positive test result, etc. Please explain this position.
- How long will records be retained and for what purposes?
- It is unclear how these procedures meet the requirements for protecting records created under a Federal program, which are subject to the Privacy Act among other regulations.
- What is the basis for establishing a 10-day waiting period before individuals who have requested records will receive them?
- The third paragraph of this section appears to limit the individual’s access to information to only that information contained in the file. This paragraph appears to prevent the individual from obtaining any records related to the procedures followed in conducting drug or alcohol testing by the COL entity, the specimen collection facility, or the laboratory that conducted the drug tests. Please clarify whether this is the intent of this paragraph and, if so, the manner in which this limitation protects the employee?
- The purpose of the last paragraph in this section is unclear with respect to its relationship to recordkeeping and confidentiality. Please clarify.

Section 6.6 - Positive Results

- The terms used to describe the management actions/sanctions that will be implemented in the event of a positive test result are inconsistent with those used in other sections of the document. Please define these terms and use them consistently to ensure that the intended meaning is clear.
- Terminating an individual’s employment and barring an individual from assignment to a COL entity’s non-regulated projects is outside of the scope of the NRC’s concern. Please identify the minimum actions that will be required to comply with Part 26.
- Please clarify the intent of the term, “treatment.” In this context, does the term mean medical intervention, referral to a “drug-treatment” program (e.g. in-patient, out-patient, residential etc.), or something else? Individuals who are referred for EAP evaluation often do not need “treatment” in this sense, but more likely some form of reinforced education with follow-up testing.
- What is the rationale for not requiring an individual who has had a positive test result to be subject to pre-access or pre-employment testing before being permitted “access” or “assignment” to a construction site after completing treatment?
- Who will determine that the individual has successfully completed treatment? What will their qualifications be for making this determination?
- How frequently will periodic, unannounced testing occur following treatment? Who will

determine the frequency and what qualifications will they possess to make this determination?

- This section does not address positive alcohol test results. What actions will be taken, if any, in response to positive results for alcohol? If no minimum sanctions are planned, please clarify how the FFD program will meet the performance objectives of § 26.10?

Section 6.7 - Audits

- This section establishes the COL entity's right to conduct audits of C/Vs and others. It does not establish any requirements for audits of the COL entity's program.
- The audit program appears to be limited to a review of drug testing records, but not alcohol testing records.
- The purpose of audit activities is not addressed.
- A minimum audit frequency is not established.
- Desired qualifications of auditors are not addressed.
- Corrective actions in response to audit findings are not required.
- What is the purpose of conducting only announced, scheduled audits?
- What is the purpose of limiting the scope of audits to drug-screening records?
- How will licensees, permit holders, and other entities subject to Part 26 establish on-going program effectiveness?

Section 6.8 - Periodic Announced (Random) Drug Testing

- The title of this section refers to periodic "announced" drug testing, with "random" in parentheses. Section 26.3 defines a random test as "a system of unannounced drug testing administered in a statistically random manner to a group so that all persons within that group have an equal probability of selection." Announced testing would not fall within the definition of random testing.

Section 6.8.1 - Random Selection and Frequency

- The primary purpose of random testing is to deter substance abuse by creating the belief that any worker may be tested any time he or she reports for duty. As noted in the staff's General Comments, conducting announced testing once per month will not achieve deterrence, particularly for the portion of the month following the day of testing.
- Please specifically identify the categories of individuals who will be subject to this periodic announced drug testing. The second sentence of this paragraph uses the phrase, "including," to refer to management and oversight personnel, but it is unclear whether any other categories of individuals will also be tested.
- Another purpose of random testing is to detect substance abuse. What procedures will be implemented, if any, to prevent individuals who may have recently used drugs from "gaming" the system by not reporting to work or leaving the jobsite on the day that testing will occur?
- This section discusses only drug testing. Please clarify the rationale for not also conducting alcohol testing, if that is the intent.
- What is the technical basis for the 10% testing rate? Please provide any research or operating experience available that supports the effectiveness of a 10% rate of testing on day per month at deterring and detecting substance abuse.

Section 6.8.2 - Notification Procedures

- Employment decisions are outside the NRC's regulatory purview. Please revise the fourth bullet in this section appropriately.
- In the fifth bullet, what qualifications will the site manager possess for interpreting laboratory drug test results? If the site manager will not have the qualifications of an MRO, how will the FFD program protect the employee, as required under § 26.29(c)?
- The document does not establish any time frames within which drug test results must be received or within which disciplinary action will be taken. As a result, an individual who has abused drugs may be permitted to continue working at the construction site for an indeterminate period of time following a positive test result. Please clarify.
- What actions, if any, will be taken if the laboratory reports that tests results indicated that a specimen was adulterated, substituted, or invalid?

Section 6.9 - Post Accident Drug Testing Procedures

- The title of this section indicates that only drug testing will occur after an accident. What is the rationale for excluding post-accident alcohol testing, if such is the intent?
- The circumstances under which post-accident testing will occur are broadly described, and appear to either require substantial knowledge on the part of supervisors and COL entity management (e.g., OSHA-recordable injuries and illnesses) or provide them with significant latitude in determining whether the threshold for testing has been met. Please explain why this meets the performance goals of § 26.10.

Section 6.9.1 - Occupational Injury and Illness

- What training will be provided to individuals that will enable them to identify OSHA-recordable injuries and illnesses? What qualifications will onsite supervisors have to determine whether an injury or illness requires drug testing? Please clarify.
- This section does not address circumstances in which an individual may be to ill or injured to travel to a collection site. What procedures will be followed in such instances?
- Please define "drug screen."

Section 6.9.2 - Occupational Motor Vehicle Accident (includes self-propelled machinery)

- This section appears to require post-accident testing under any circumstances involving self-propelled machinery. Therefore, it appears that post-accident testing could be required for minor nicks and scrapes associated with any machinery that has moving parts, as well as more significant accidents with substantial property damage or injuries. Is the intent that any and all accidents would result in testing?
- This section does not address circumstances in which the driver may be unable to report the accident or is injured and unable to report to a collection site. What procedures will be followed in such circumstances?

Section 6.9.3 - Near Miss Accident

- How will COL entity management be informed that a near miss accident has occurred?
- Please define the phrase, "as soon as practical after the incident."

Section 6.9.4 - Significant Property Damage

- The \$500,000 threshold in this section and in Section 6.2 is very high, with the result that drug or alcohol use by individuals involved in accidents below that threshold would not be identified. Please clarify how this very high threshold meets the performance objectives of § 26.10.

Section 6.10 - Review Process

- Please clarify the intent of the last sentence of the third bullet in this section, which states, "The determination from this independent review is final."
- How will an individual provide additional information related to an FFD policy violation, if he or she is unable to obtain information about the specimen collection and chain-of-custody procedures used in handling his or her specimens, the collection site's or laboratory's testing equipment and procedures, and the qualifications of the individuals who determined that a test result was positive? Please clarify how such circumstances protect the employee?