NUCLEAR ENERGY INSTITUTE

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(48)

December 20, 2005

Secretary
U.S. Nuclear Regulatory Commission
Washington, DC 20555-0001

Attention: Rulemakings and Adjudications Staff

Subject: Comments on the Proposed Rule, *Fitness for Duty Programs,* (70 Fed. Reg. 50442; August 26, 2005, RIN 3150–AF12)

On behalf of the commercial nuclear energy industry, the Nuclear Energy Institute (NEI)[1] provides the following comments on the Proposed Rule, *Fitness for Duty Programs.* NEI submits these comments on the Drug and Alcohol portions of the proposed rule contained in Subpart A through Subpart H, Subpart J and Subpart K. Separate comments are being submitted on Subpart I, *Managing Fatigue.*

The industry supports the majority of the provisions of the Drug and Alcohol portion of the proposed rule. The NRC staff has actively engaged stakeholders in the development in this rule package leading to clearly defined requirements that can be implemented. Most significant, is the correlation that Subpart C to this rule will provide with the requirements of the access authorization program. The ability to process individuals for unescorted access to the protected area under one, consistent set of implementation guidance is very important to the industry. This consistency of approach must be preserved in the final rule.

[1] NEI is the organization responsible for establishing unified nuclear industry policy on matters affecting the nuclear energy industry, including the regulatory aspects of generic operational and technical issues. NEI's members include all utilities licensed to operate commercial nuclear power plants in the United States, nuclear plants designers, major architect/engineering firms, fuel fabrication facilities, materials licensees, and other organizations and individuals involved in the nuclear energy industry.

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Detailed industry comments on the proposed rule are included in the enclosure to this letter. The majority of the industry comments provide recommendations for clarification in rule wording. Responses to the specific questions posed in the Federal Register Notice on the nine topics related to the drug and alcohol program are provided in Section 3 of the enclosure.

We appreciate the NRC's consideration of the industry's comments on the proposed Rule. If we can provide further information that would assist in resolving the concerns expressed in this letter, please contact me at jwd@nei.org or 202-739-8105; or John Rycyna at jxr@nei.org or 202-739-8127.

Sincerely,

James W. Davis

Enclosure

Comments of the Nuclear Energy Institute on the Drug and Alcohol portion of 10 CFR Part 26, Fitness for Duty Requirements Industry Comments on the Proposed Rule

In implementing the original fitness for duty rule the industry found that there were significant problems generated by lack of clarity, conflicts within the rule, and conflicts with the access authorization requirements of 10 CFR 73.56. A number of issues, such as the application of the rule to supplemental workers, had not been adequately considered by any of the parties involved in the development of the original rule. In 1991 NEI, on behalf of the industry, requested a number of changes to the rule to resolve implementation inconsistencies.

Based on past experience the industry has put emphasis on clarity of requirements that can be effectively implemented. Significant resources have been expended in participation in public meetings, review of draft rule text and testing various real world situations to find implementation problems before the rule was finalized. The industry also appreciates the time the NRC staff has spent reviewing proposals and working to find rule language that meets regulatory intent and supports implementation.

The industry has conducted an extensive review of the drug and alcohol portions of the draft fitness for duty rule. The complexity of this rule and the level of prescriptive detail make it very difficult to ensure there will be no unintended consequences. Experience over the last several years indicates that what seems like a simple change in one place can lead to significant problems in other areas.

The industry believes that the rule will be improved by making the changes recommended in Section 1 of this document. The industry has also reviewed several areas of the rule that are under consideration for change. Section 2 provides discussions of those areas reviewed where the industry team found the rule text to be appropriate as proposed. Section 3 provides responses to the NRC comment solicitations in the Federal Register Notice.

Section 1
Comments with recommended changes

The following comments are provided on the drug and alcohol section of the rule where the industry recommends changes to clarify the rule. Where possible, comments are provided in the same order as the rule text.

1.1 Issue: General—Rule implementation period.

Discussion: Licensees and other entities will require time to revise procedures, train entire plant staffs, and qualify individuals as required by the proposed rule. A 12 month implementation period is required to allow preparation of implementing guidance, development of procedures and training of site personnel.

In support of the 12 month implementation period the final rule package must establish a clear process for the cancellation of other guidance that could interfere with the implementation of this rule. For example, portions of the ***Order for Compensatory Measures Related to Access Authorization,*** EA-02-261, dated January 7, may conflict with the licensees implementation of this rule. Provisions need to be made to prevent licensees being subject to two, conflicting sets of requirements.

The NRC staff must also be prepared to review and endorse changes to industry implementing guidance in a timely manner. NEI 03-01, Revision 1, will require changes to reflect the revisions in 10 CFR Part 26. These revisions must be endorsed by the NRC staff and changes made to licensee security plans in accordance with 10 CFR 50.54. The rule supporting material should facilitate these changes.

The industry is also concerned that significantly outdated publications still exist and have not been cancelled or updated by the NRC. For example NUREG 1385 is no longer accurate in its responses to questions.

Additional complications are added in the work hour portion of the rule which will require licensee changes to Technical Specifications to avoid conflicting requirements. Additionally provisions must be provided to avoid conflict with the work hour order for security officers.

Recommendation: Allow licensees and other entities 12 months for implementation from the date the final rule is published in the Federal

Register. Maintain the two year implementation date for MRO in §26.183(a) and the SAE in §26.187(a).

1.2 Issue: Paragraph 26.3(e) Applicability to New Construction.

The nuclear industry believes that the proposed fitness for duty requirements for new plant construction should be modified based on the appropriate levels of fitness for duty for new construction sites. New plant construction sites should be treated in the same manner as other, major non-nuclear construction sites, which have industrial drug and alcohol programs. There is no reason to apply requirements beyond normal industrial programs when there are no protected areas, no fuel on site, and no effect on public health and safety.[2]

Discussion:

The NRC proposed language, Section 26.3 Scope, states:

> (e) Combined license holders (under Part 52 of this chapter), before the Commission has made the finding under §52.103 of this chapter, combined license applicants who have received authorization to construct under §50.10(e)(3), construction permit holders (under Part 50 of this chapter), construction permit applicants who have received authorization to construct under §50.10(e)(3), and holders of manufacturing licenses (under Part 52 of this chapter) shall—
> (1) Comply with §§26.23, 26.41, and 26.189;
> (2) Implement a drug and alcohol testing program, including random testing; and
> (3) Make provisions for employee assistance programs, imposition of sanctions, procedures for the objective and impartial review of authorization decisions, protection of information, and recordkeeping."

The industry believes the language should be modified as follows:

> (e) Combined license holders (under Part 52 of this chapter), before the Commission has made the finding under §52.103 of this chapter, combined license applicants who have received authorization to construct under §50.10(e)(3), construction permit holder (under Part 50 of this chapter), construction permit applicants who have received authorization to construct under §50.10(e)(3), and holders of manufacturing licenses (under Part 52 of this chapter) shall—

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[2] This assumes that the construction site is not accessed through an operating plant. In that case, the operating plant's program would have to be applied.

(1) Establish a drug- and alcohol-free workplace policy, including sanctions that may be imposed;
(2) Implement a pre-employment drug and alcohol testing program, and a for-cause testing program; and
(3) Make provisions for the objective and impartial review of sanctions decisions, protection of information, and recordkeeping.

Nuclear power plants go through a lifecycle from construction, to operation, to decommissioning. The fitness for duty requirements should be tailored to the industrial and nuclear safety considerations for each stage in the nuclear power plant's lifecycle. During construction, industrial safety is the principal consideration. During operation, nuclear safety is the principal consideration, while industrial safety is also important. During decommissioning and dismantlement, when used fuel is safely stored, industrial safety is the principal consideration once again.

By tailoring the fitness for duty rule to industrial and nuclear safety risks, the rule will meet the Commission's policy of having rules and regulations that are performance based and risk informed.

The industry proposed wording would treat new plant construction sites in the same manner as other, major non-nuclear construction sites, which have commercial drug and alcohol programs. Until fuel arrives on site, there is no public health and safety reason that the fitness for duty requirements should be any more stringent than those typically applied at large commercial construction facilities, such as refineries and large fossil-fired power plants. Assurance that the plant has been built as stated in the combined construction and operating license (COL) is accomplished by compliance with 10 CFR 50, Appendix B and the part 52 Inspections, Tests, Analyses and Acceptance Criteria (ITAAC).

We propose eliminating the references in paragraph 26.3(e) to sections 26.23, 26.41, and 26.189.

Section 26.23, Performance Objectives, states:

Fitness-for-duty programs must —
(a) Provide reasonable assurance that *individuals who are subject to this part* are trustworthy and reliable as demonstrated by the avoidance of substance abuse;
(b) Provide reasonable assurance that *individuals who are subject to this part* are not under the influence of any substance, legal or illegal, or mentally or physically impaired from any cause, which in any way adversely affects their ability to safely and competently perform their duties;

(c) Provide reasonable measures for the early detection of individuals who are not fit to perform the *job duties that require them to be subject to this part*;
(d) Provide reasonable assurance that the workplaces subject to this part are free from the presence and effects of illegal drugs and alcohol; and
(e) Provide reasonable assurance that the effects of fatigue and degraded alertness on individuals' abilities to safely and competently perform their duties are managed commensurate with maintaining public health and safety.
(Emphasis added.)

Applying paragraphs 26.23 (a), (b), and (c) to construction sites is inappropriate and conflicts with Section 26.25 (Individuals subject to the fitness-for-duty program) which states:

> (a) Individuals whose job duties require them to have the following types of access, or to perform the following activities are subject to the FFD program:
> (1) All persons who are granted unescorted access to nuclear power plant protected areas;
> (2) All persons who are required by a licensee to physically report to the licensee's Technical Support Center or Emergency Operations Facility, in accordance with licensee emergency plans and procedures;
> (3) SSNM licensee and transporter personnel ...
> (4) All FFD program personnel who are involved in the day-to-day operations of the program, as defined by the licensee's or other entity's procedures ...

Thus the proposed rule *applies to individuals who have unescorted access to the nuclear power plant protected area.* There will not be any protected area during the phase of construction cited in paragraph 26.3(e). We agree with the proposed language of section 26.25.

Applying paragraph 26.23(e) regarding fatigue and degraded alertness is inconsistent with Subpart I – Managing Fatigue, section 26.195 Applicability, which applies requirements for managing fatigue only to licensees and other entities identified in paragraphs 26.3(a) and (d), but not to paragraph 26.23(e), the construction phase.

Section 26.41, Audits and corrective action, and section 26.189, Determination of fitness, require administrative actions beyond those necessary for a commercial construction site at which there are no protected areas and no nuclear fuel.

It is not clear from the proposed rule what type of program the NRC expects on a new plant construction site. By referring to specific sections which must be met by operating plants by complying with other sections of the rule, NRC has apparently applied virtually the entire rule to new construction sites. It will be difficult to ensure compliance with the referenced sections of the rule without applying the entire rule.

We believe a more appropriate approach, which language we have proposed above, will provide adequate fitness for duty, given the level of risk and the need to provide industrial level protection to personnel and the construction site. Our language will:

(1) Establish a drug- and alcohol-free workplace policy, including sanctions that may be imposed;
(2) Implement a pre-employment drug and alcohol testing program, and a for-cause testing program; and
(3) Make provisions for the objective and impartial review of sanctions decisions, protection of information, and recordkeeping.

The industry is working with the NRC to develop an appendix to the NEI 03-12 security plan template to provide more details of security program requirements for new plant construction sites prior to fuel arrival on site and the establishment of protected areas. This language will provide the basis for the development of individual new plant construction site security programs, including fitness for duty, which must be approved by the NRC staff prior to acceptance of a COL. We believe this approach is more appropriate to the level of risk and the activities being conducted, and will minimize unnecessary regulatory burden.

Previously, the industry has focused on the fitness for duty requirements for operating nuclear power plants and not plants under construction, since no new plants were under consideration. The industry is now focusing attention on fitness for duty requirements at new plant construction sites because of the enactment of the Energy Policy Act of 2005, and the announcement by several utilities of plans to apply for licenses for new nuclear power plants.

Recommendation:

Paragraph 26.3(e) should be modified as follows:

(e) Combined license holders (under Part 52 of this chapter), before the Commission has made the finding under §52.103 of this chapter, combined license applicants who have received authorization to construct under §50.10(e)(3), construction permit holder (under Part 50 of this chapter),

construction permit applicants who have received authorization to construct under §50.10(e)(3), and holders of manufacturing licenses (under Part 52 of this chapter) shall—

(1) Establish a drug- and alcohol-free workplace policy, including sanctions that may be imposed;
(2) Implement a pre-employment drug and alcohol testing program, and a for-cause testing program; and
(3) Make provisions for the objective and impartial review of sanctions decisions, protection of information, and recordkeeping.

1.3 Issue: Section 26.5 Definitions of positive

It is unclear if "non-negative" and "positive" mean same when both are used in the new rule.

Discussion: The proposed rule has adopted the term "non-negative" in reference to drug and alcohol test results but there are many instances where the term "positive" is also used when referring to drug and alcohol tests. It is unclear if these are synonymous. If so, terminology should be consistent; if not, a definition for "positive" should be provided. Clarification of these terms will assist in improving FFD program effectiveness. This is consistent with Rulemaking Goal (6): "Improve clarity in the organization and language of the rule."

Examples of the confusing use of "positive:"
The definition of "Confirmed test result" in the proposed §26.5 contains "positive" twice.
The definition of "Non-negative test result in the proposed §26.5 contains "positive."
The proposed §26.31(d)(3)(iii)(A) contains "positive."
The proposed §26.69(b) contains "positive twice."
The proposed §26.69(b)(4)(i) contains "positive."
The proposed §26.69(b)(6) contains "positive."
The proposed §26.69(c) contains "positive."
The proposed §26.75(d) contains "positive."
The proposed §26.75(e) contains "positive."
The proposed §26.75(e)(1) contains "positive."
The proposed §26.75(e)(2) contains "positive."
The proposed §26.75(h) contains "positive."
The proposed §26.75(i) contains "positive."
The proposed §26.75(i)(1) contains "positive" twice.
The proposed §26.91(e)(3) contains "positive."

The proposed §26.103 contains "positive."
The proposed §26.103(a) contains "positive."
The proposed §26.137(b)(2) contains "positive."
The proposed §26.137(b)(3) contains "positive."
The proposed §26.137(e)(4) contains "positive" twice.
The proposed §26.139(e) contains "positive."
The proposed §26.159(i) contains "positive" twice.
The proposed §26.163(b)(1) contains "positive" twice.
The proposed §26.165(a)(4) contains "positive" twice.
The proposed §26.165(b)(1) contains "positive" twice.
The proposed §26.165(c)(1) contains "positive" twice.
The proposed §26.167(e)(2)(ii) contains "positive."
The proposed §26.167(f)(3) contains "positive" twice.
The proposed §26.167(f)(5) contains "positive."
The proposed §26.167(g)(3) contains "positive" thrice.
The proposed §26.169(b) contains "positive."
The proposed §26.169(d) contains "positive."
The proposed §26.169(e) contains "positive."
The proposed §26.169(f) contains "positive."
The proposed §26.169(k)(3) contains "positive."
The proposed §26.169(k)(6) contains "positive."
The proposed §26.185(f)(1) contains "positive."
The proposed §26.185(h)(1) contains "positive."
The proposed §26.185(j)(1) contains "positive" twice.
The proposed §26.185(j)(2) contains "positive" twice.
The proposed §26.185(j)(4) contains "positive."
The proposed §26.185(j)(5) contains "positive."
The proposed §26.185(j)(6) contains "positive."
The proposed §26.185(k) contains "positive" twice.
The proposed §26.185(n)(1) contains "positive."
The proposed §26.185(n)(3) contains "positive."
The proposed §26.185(o) contains "positive" seven times.
The proposed §26.217(d) contains "positive."
The proposed §26.219(c)(2) contains "positive."

Reference: The proposed §26.5: "*Non-negative test result* means a report by the licensee testing facility or the HHS-certified laboratory that a urine specimen meets the criteria for substitution established in this part or is positive for a drug, drug metabolite, or adulterant at a concentration equal to or greater than the designated cutoff levels, or the results of a test of oral fluids or breath that indicate the presence of alcohol at a concentration equal to or greater than the cutoff levels established by the FFD program or as specified in this part. A non-negative test result may be obtained from any initial or confirmatory drug, validity, or alcohol test."

Recommendation: The industry has always preferred the term "positive" as being more consistent with industry practice. We would prefer to see the term "non-negative" replaced with positive. However, recognizing the NRC staff desire to be consistent with HHS guidelines, if that change is not possible add the definition for positive as:

1. The same as HHS or
2. Positive – the result of a confirmatory test that has established the presence of adulterants, drugs, drug metabolites, or alcohol in a specimen at or above cut-off level. And that has been deemed positive by the MRO after evaluation.

1.4 Issue: Section 26.5: Validity screening definition

Discussion: The definition should allow for use of an instrumented device for validity screening as well as the non-instrumented device. The proposed change should make it clear that either device could be used.

Recommendation:

Change the definition to: "Validity screening test means the use of an instrumented or non-instrumented testing device to determine the need for initial validity testing of a urine specimen."

1.5 Issue: Paragraph 26.27(c)(1): Due process concern

Discussion: The term "due process" implies that licensee activities under the rule are subject to court review for compliance with the U. S. Constitution.

Reference: The proposed §26.27(c)(1): "Describe the methods and techniques to be used in testing for drugs and alcohol, including procedures for protecting the privacy and due process rights of an individual who provides a specimen, procedures for protecting the integrity of the specimen, and procedures used to ensure that the test results are valid and attributable to the correct individual;"

Recommendation: Reword §26.27(c)(1): "Describe the methods and techniques to be used in testing for drugs and alcohol, including procedures for protecting the privacy and other rights of an individual who provides a specimen, procedures for protecting the integrity of the specimen, and procedures used to ensure that the test results are valid and attributable to

the correct individual;"

1.6 Issue: Paragraph 26.27(c)(2)(ii): Clarification of alcohol consumption prohibition

Discussion: The wording should more clearly express the prohibition of any alcohol consumption during the mandatory pre-work abstinence period, or while on duty. The current wording could be interpreted as prohibiting only excess consumption.

Reference: The proposed §26.27(c)(2)(ii): "Consumed alcohol to excess before the mandatory pre-work abstinence period, during the mandatory pre-work abstinence period, or while on duty, as determined by a test that measures BAC;"

Recommendation: Reword §26.27(c)(2)(ii): "Consumed alcohol to excess before the mandatory pre-work abstinence period, or consumed any alcohol during the mandatory pre-work abstinence period or while on duty, as determined by a test that measures BAC;"

1.7 Issue: Paragraph 26.27(c)(3): Clarification of emergency

Discussion: The use of "emergency" could be confusing. The applicable circumstances are not limited to declared emergencies, as that term is used in Part 50. Current § 26.20(e)(3) also uses the word "emergency," but the context shows that "emergency" is not limited to declared emergencies under Part 50. The recommended wording is consistent with the wording, "unscheduled working tour" in the proposed §26.27(c)(3)(ii)(C).

Reference: The proposed §26.27(c)(3): "Describe the process that the licensee or other entity will use to ensure that individuals who are called in to perform an unscheduled working tour are fit for duty. Consumption of alcohol during the 5-hour abstinence period required in paragraph (b)(4)(i) of this section may not by itself preclude a licensee or other entity from using individuals who are needed to respond to an emergency. At a minimum — "

Recommendation: Reword §26.27(c)(3): "Describe the process that the licensee or other entity will use to ensure that individuals who are called in to perform an unscheduled working tour are fit for duty. Consumption of alcohol during the 5-hour abstinence period required in paragraph (b)(4)(i) of

this section may not by itself preclude a licensee or other entity from using individuals who are needed to respond to an unscheduled working tour. At a minimum —"

1.8 Issue: Paragraph 26.27(c)(3)(i): Call in reporting fitness for duty.

Discussion: Industry is concerned that the proposed §26.27(c)(3)(i), requires each individual to report that they meet requirements. It may result in an unintended audit requirement and requires unnecessary documentation. This has significant impact on automated call in systems which would preclude such a response. This change is consistent with Goal (5) of the Rulemaking Activity, "Improve Part 26 by eliminating or modifying unnecessary requirements."

The intent of this section can be met by having individuals report if they are not fit for duty or have consumed alcohol within the pre-duty period. Individuals will have to be trained on this provision of the rule no matter how the reporting is managed.

Reference: The proposed §26.27(c)(3)(i): The procedure must require the individual who is called in to state whether the individual considers himself or herself fit for duty and whether he or she has consumed alcohol within the pre-duty abstinence period stated in the policy.

Recommendation: Reword §26.27(c)(3)(i): "The procedure must require individuals called in, to report by exception. The procedure must require individuals called in to declare, as stated in licensee program when they consider themselves unfit for duty or have consumed alcohol within the pre-duty abstinence period stated in the policy."

1.9 Issue: Paragraph 26.27(c)(3)(ii)(C): Clarification of sanction applicability

Discussion: The proposed words could be interpreted to say that an employee who is called in is not subject to sanctions for any misconduct.

Reference: The proposed §26.27(c)(3)(ii)(C): "State that no sanctions may be imposed on an individual who is called in to perform an unscheduled working tour and has consumed alcohol within the pre-duty abstinence period stated in the policy."

Recommendation: Reword §26.27(c)(3)(ii)(C): "State that no sanctions may be imposed on an individual who is called in to perform an unscheduled working tour for having consumed alcohol within the pre-duty abstinence period stated in the policy."

1.10. Issue: Paragraph 26.31(c)(3)(i) appears to be have incorrect reference.

Discussion: Reference in proposed §26.31(c)(3)(i) should be 29 CFR 1904.7 not 29 CFR 1907.4. There is no subsection 29 CFR 1907.4.

Recommendation: Change reference to correctly refer to 29 CFR 1904.7.

1.11. Issue: Paragraph 26.31(d)(1)(ii) Dilute specimen clarification and typographical error correction

Discussion: A clarification is required for the case when a specimen is dilute to properly account for actions that may be taken under the proposed §26.185(g)(2) or (3). This recommendation is consistent with Rulemaking Activity Goal (6), "Improve clarity in the organization and language of the rule." The recommended change is also consistent with the proposed §26.185(g)(2) and §26.185(g)(3). Finally, references to §26.31(c)(1)(ii), which does not exist, should be corrected to §26.31(d)(1)(ii).

Reference: The proposed §26.31(d)(1)(ii) Test results that fall below the established cutoff levels may not be considered when determining appropriate action under Subpart D of this part.

Reference: The proposed §26.185(g)(2) If the MRO has reason to believe that the donor may have diluted a specimen in a subversion attempt, the MRO may require the laboratory to conduct confirmatory testing of the specimen at the LOD for any drugs or drug metabolites as long as each drug class is evaluated in accordance with §26.31(c)(1)(ii).

Reference: The proposed §26.185(g)(3) If the dilute specimen was collected under direct observation as required under §26.69, the MRO may require the laboratory to conduct confirmatory testing at the LOD for any drugs or drug metabolites, as long as each drug class is evaluated in accordance with §26.31(c)(1)(ii).

Recommendation: Reword §26.31(d)(1)(ii) to read: "Test results that fall below the established cutoff levels may not be considered when determining appropriate action under Subpart D of this part unless the specimen was

considered dilute and the licensee or other entity chooses to have the specimen evaluated in accordance with §26.185(g)(2) and (3)."

Reword §26.185(g)(2) to read: If the MRO has reason to believe that the donor may have diluted a specimen in a subversion attempt, the MRO may require the laboratory to conduct confirmatory testing of the specimen at the LOD for any drugs or drug metabolites as long as each drug class is evaluated in accordance with §26.31(d)(1)(ii).

Reword §26.185(g)(3) to read: If the dilute specimen was collected under direct observation as required under §26.69, the MRO may require the laboratory to conduct confirmatory testing at the LOD for any drugs or drug metabolites, as long as each drug class is evaluated in accordance with §26.31(d)(1)(ii).

1.12. Issue: Collection of specimens on an unpredictable schedule.

Discussion: The proposed §26.31(d)(2)(i)(B) reasonably requires collections of specimens on an unpredictable schedule, including weekends, backshifts, and holidays, and at various times during a shift. The proposed §26.31(d)(2)(i)(A) however takes from the unpredictability by very prescriptively requiring specimen collection at least four days in a calendar week. This would permit members of the work force to determine whether specimens must be collected during the later days of the week to be in compliance with the regulation. The proposed §26.31(d)(2)(i)(A) should be deleted to maximize the unpredictability of the collection schedule as required by §26.31(d)(2)(i)(B).

Reference: The proposed §26.31(d)(2)(i)(A): "Take reasonable steps to either conceal from the workforce that collections will be performed during a scheduled collection period or create the appearance that specimens are being collected during a portion of each day on at least 4 days in each calendar week at each site; and"

Reference: The proposed §26.31(d)(2)(i)(B): "Collect specimens on an unpredictable schedule, including weekends, backshifts, and holidays, and at various times during a shift;"

Recommendation: Delete §26.31(d)(2)(i)(A) and renumber §26.31(d)(2)(i)(B) as §26.31(d)(2)(i)(A).

1.13. Issue: Paragraph 26.31(d)(2)(iv) Individuals eligible for

random testing.

Discussion: The proposed §26.31(d)(2)(iv) could be interpreted as requiring individuals who are on site but not reasonably available for testing to be required to be tested. An example is an individual who is suited up for work in a radiological area controlled area from which they could not exit and go to be tested in a reasonable period of time. The change suggested is consistent with NEI 03-01, revision 1, section 8.3 which NRC has endorsed.

Reference: The proposed §26.31(d)(2)(iv) Ensure that all individuals in the population subject to testing have an equal probability of being selected and tested. Individuals, who are off site when selected for testing, and not reasonably available for testing when selected, shall 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.

Recommendation: Reword the second sentence of §26.31(d)(2)(iv) by changing "and" to "or" after "for testing." "Individuals, who are off site when selected for testing, or not reasonably available for testing when selected, shall 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."

1.14 Issue: Paragraph 26.35(b) The rule language is confusing regarding who must be provided the EAP.

Discussion: The discussion at 70 FR 50495 is clear: "In response to implementation questions, proposed § 26.35(b) would be added to clarify that licensees and other entities are not required to provide EAP services to C/V employees who are working at a licensee's or other entity's facility and are subject to this part." Also at 70 FR 50495: "The proposed paragraph would also state that licensees and other entities need not provide EAP services to individuals who have applied for authorization to perform job duties that would require them to be subject to this part. Licensees and other entities would not be required to provide an EAP to applicants for authorization because these individuals would not yet be performing job duties that could affect public health and safety or the common defense and security." This recommendation is consistent with Rulemaking Activity Goal (6), "Improve clarity in the organization and language of the rule."

Reference: The proposed 26.35 (b) Licensees and other entities need not provide EAP services to a C/V's employees and individuals who have applied for, but have not yet been granted, authorization.

Recommendation: Reword 26.35(b) as: "Licensees and other entities need not provide EAP services to C/V employees who are working at a licensee's or other entity's facility and are subject to this part. Licensees and other entities need not provide EAP services to individuals who have applied for, but have not yet been granted, authorization."

1.15 Issue: Paragraph 26.39(c) Consistency with Access Authorization Review Process.

Discussion: The review process required by the proposed 26.39(c) should be consistent with that required by 10 CFR 73.56(e) to simplify licensee procedures. This is consistent with Goal 4 of this rulemaking: "Improve consistency between FFD requirements and access authorization requirements established in 10 CFR 73.56, as supplemented by orders to nuclear power plant licensees dated January 7, 2003." The industry recommends licensees provide the opportunity to have the decision, together with any additional information, reviewed by at least one designated management level employee of the licensee who is equivalent or senior to and independent of the individual who made the initial decision to deny or terminate unfavorably authorization. The determination from this review will be final. If the wording remains as proposed, it will cause an unnecessary burden on licensees and other entities to establish two processes.

Reference: The proposed §26.39(c): The procedure must ensure that the review 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 the description of FFD program personnel in §26.25(a)(4)). The individuals who conduct the review may be management personnel.

Reference: The current §73.56(e): Review procedures. Each licensee implementing an unescorted access authorization program under the provisions of this section shall include a procedure for the review, at the request of the affected employee, of a denial or revocation by the licensee of unescorted access authorization of an employee of the licensee, contractor, or vendor, which adversely affects employment. The procedure must provide that the employee is informed of the grounds for denial or revocation and allow the employee an opportunity to provide additional relevant information, and provide an opportunity for an objective review of the

information on which the denial or revocation was based. The procedure may be an impartial and independent internal management review. Unescorted access may not be granted to the individual during the review process.

Recommendation: Reword 26.39(c) as: "The procedure must ensure that the review is conducted by at least one impartial and independent internal management individual and that the individual or individuals who conduct the review are not associated with the administration of the FFD program (see the description of FFD program personnel in §26.25(a)(4))."

1.16. Issue: Paragraph 26.63(d) Requirement for providing consent

Discussion: The word "presentation" in the proposed §26.63(d) is confusing and should be changed. A licensee should not have to present the signed release; verification of the existence of the release should be adequate. Industry implementing procedures for exchange of information require that a consent form must be obtained before requesting additional information from another licensee.

The requirement, as written, represents an unnecessary administrative burden. Under the industry's procedures for sharing information there are rigid requirements on when a consent form must be obtained from the individual. In the age of electronic information sharing, the requirement to provide hard copies of documents represents a significant reduction in the efficiency of the system. The process, required by the Personnel Access Data System Participation Agreement provides adequate protection of the individual's rights and insures that a release has been obtained.

It should be recognized that fundamental to the background investigation process is the individual providing consent. Consent is required at the time that the individual provides the personal information required to do the background investigation and licensees are prohibited from conducting any background checks prior to receiving consent. This is in part driven by the requirements that any denial of access must be documented and available electronically to other licensees. Thus, it is imperative that the investigation not be started until the individual has granted consent. It should also be noted that refusal to provide consent, or a withdrawal of consent is also considered a withdrawal of the request for unescorted access at a power reactor site.

Reference: The proposed §26.63(d): In response to another licensee's or other entity's inquiry and presentation of an individual's signed release authorizing the disclosure of information, a licensee or other entity 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.

Recommendation: Change the first sentence of §26.63(d) to: "In response to another licensee's or other entity's inquiry and verification that an individual has signed a release authorizing the disclosure of information, a licensee or other entity 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."

1.17. Issue: Testing before an individual applies for authorization

Discussion: The proposed paragraphs 26.65(c)(2) and 26.65(d)(2)(ii) contradict the proposed 26.65(b) and 26.65(f). Licensees should be able to rely on drug and alcohol tests that were conducted before the individual applied for authorization if the individual is subject to a behavioral observation and arrest reporting program.

Consider the following example: An individual has applied for initial authorization at site X on November 15 and there is no indication of PDI in any of the records reviewed. However, the individual had recently applied for authorization at another plant site (Y) and a pre-access drug and alcohol test conducted 15 days ago on November 1, by the plant. The individual's employer has redirected the individual to the higher priority job at plant X. The individual, at time of application was not under behavioral observation.

The applicable rule section for initial authorization is 25.55(a) and a pre-access test is specified.

> 26.55(a) Before granting authorization to an individual who has never held authorization under this part or whose authorization has been interrupted for a period of 3 years or more and whose last period of authorization was terminated favorably, the licensee or other entity shall--
>
> ...
>
> (3) Ensure that the individual is subject to pre-access drug and alcohol testing in accordance with the applicable requirements of Sec. 26.65; and
>
> (4) Ensure that the individual is subject to random drug and alcohol testing in accordance with the applicable requirements of Sec. 26.67.

The pre-access testing is specified in section 26.65. Section 26.65(a) just defines the purpose of the paragraph. Section 26.65(b) seems to be relevant, but we find that Section 26.65(c) contains the real criteria.

> 26.65(c) 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, the licensee or other entity shall verify that the results of pre-access drug and alcohol tests are negative. The licensee or other entity need not conduct pre-access testing if--

The licensee would of course review the two conditions to see if the pre-access test is needed.

> (1) An individual previously held authorization under this part and has been subject to both a drug and alcohol testing program that includes random testing and a behavioral observation and arrest reporting program which meet the requirements of this part from the date upon which the individual's last authorization was terminated through the date upon which the individual is granted authorization; or
> (2) The licensee or other entity relies upon negative results from drug and alcohol tests that were conducted before the individual applied for authorization, as permitted under paragraph (b) of this section, and the individual remains subject to a behavioral observation and arrest reporting program that meets the requirements of this part, beginning on the date upon which the drug and alcohol testing was conducted through the date upon which the individual is granted authorization and thereafter.

The first condition does not apply, this is an initial authorization. Even if an update, the individual would have been under behavioral observation and random testing program for over a year. The second condition does not apply since the individual has not been under behavioral observation for the entire period. We must conclude that a pre-access test is required.

Needing a pre-access test the licensee now looks at 26.65(b) and finds:

> (b) Accepting tests conducted within the past 30 days. If an individual has negative results from drug and alcohol tests that were conducted in accordance with the requirements of this part before the individual applied for authorization from the licensee or other entity, and the specimens for such testing were collected within the 30-day period preceding the day upon which the licensee or other entity grants authorization to the individual, the licensee or other entity may rely upon the results of those drug and alcohol tests to meet the requirements for pre-access testing in this section.

The licensee completes the process and grants the individual UA. This is based on the November 1 drug and alcohol test, a PHQ that was signed by the individual on November 15, a background investigation through November 15, arrest reporting that started on November 15, random drug testing that started on November 15, training that was completed on

November 20 and the individual being granted access and being subject to behavioral observation on November 21. Thus the 30 day pre-access testing requirements were met.

Extensive discussions between the industry and NRC staff on implementation of the Access Authorization Order and Fitness for Duty program has clearly established that the licensee has a 30 day period in which to complete the in-processing of an individual, as defined in NRC approved implementing guidance. This level of detail is not warranted in the rule. One element is that the investigation is through the date that the individual completes and signs the personal history questionnaire that reports employments, arrests and other potentially disqualifying information. Additionally, the arrest reporting requirements that an individual must understand and acknowledge by signature requires that all arrests from the date of the personal history questionnaire be reported. Thus no gaps are left in which undocumented arrests could occur.

Behavioral observation, under Section 26.33 is required when an individual has unescorted access, not prior to granting access. Actually it is the list of individuals in 26.25(a) which in each case define someone who is performing the job or has access to the protected area. A key part of the behavioral observation program is the training that each individual must receive to understand their responsibilities and required actions under the program. In practice, the training may be completed before or after the pre-access drug sample. Both have to be completed before granting access, but there is no linkage between the two.

The only linkage between elements of the in-processing program is the requirement that an individual be placed in a random testing program when the pre-access sample is collected or upon licensee first action when the individual arrives at the licensee facility.

The industry concludes that Section 26.65(c)(2) and 26.65(d)(2)(ii) contain requirements that are not needed. In light of 26.65(b) a sample conducted within 30 days is all that is needed. The added conditions are not required.

The industry has at least one contractor who meets all the requirements for conducting preaccess testing, training, behavioral observation, and random testing. The industry proposed a change to Sections 26(c)(2) and 26.65(d)(2)(ii) that would allow a contractor to conduct the preaccess sample more than 30 days before the individual applies for access at a licensee facility. Under this proposal this sample would be acceptable because training, behavioral observation, arrest reporting, and random sampling would be conducted from the time of the sample until authorization is

granted. This change represents a significant improvement in efficiency for companies whose employees visit a number of licensee sites, frequently on relatively short notice.

Reference: The proposed 26.65(b): *"Accepting tests conducted within the past 30 days.* If an individual has negative results from drug and alcohol tests that were conducted in accordance with the requirements of this part before the individual applied for authorization from the licensee or other entity, and the specimens for such testing were collected within the 30-day period preceding the day upon which the licensee or other entity grants authorization to the individual, the licensee or other entity may rely upon the results of those drug and alcohol tests to meet the requirements for preaccess testing in this section."

Reference: The proposed 26.65(c)(2) and (d)(2)(ii): "The licensee or other entity relies upon negative results from drug and alcohol tests that were conducted before the individual applied for authorization, as permitted under paragraph (b) of this section, and the individual remains subject to a behavioral observation and arrest reporting program that meets the requirements of this part, beginning on the date upon which the drug and alcohol testing was conducted through the date upon which the individual is granted authorization and thereafter."

Reference: The proposed 26.65(f): *"Time period for testing.* If preaccess testing is required under this section, the licensee or other entity must collect the specimens within the 30-day period that precedes the date upon which the licensee or entity grants authorization to an individual."

Recommendation: Change Sec. 26.65 Pre-access drug and alcohol testing as follows (line-in, line-out format used):

(a) Purpose. This section contains pre-access testing requirements for granting authorization to an individual who either has 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 other entity who is subject to this part.

(b) Accepting tests conducted within the past 30 days. If an individual has negative results from drug and alcohol tests that were conducted in accordance with the requirements of this part before the individual applied for authorization from the licensee or other entity, and the specimens for such testing were collected within the 30-day period preceding the day upon which the licensee or other entity grants authorization to the individual, the

licensee or other entity may rely upon the results of those drug and alcohol tests to meet the requirements for pre-access testing in this section.

(c) 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, the licensee or other entity shall verify that the results of pre- access drug and alcohol tests are negative. The licensee or other entity need not conduct pre-access testing if--

(1) An individual previously held authorization under this part and has been subject to both a drug and alcohol testing program that includes random testing and a behavioral observation and arrest reporting program which meet the requirements of this part from the date upon which the individual's last authorization was terminated through the date upon which the individual is granted authorization; or

(2) The licensee or other entity relies upon negative results from drug and alcohol tests that were conducted before the individual applied for authorization, ~~as permitted under paragraph (b) of this section~~, and the individual remains subject to ~~a behavioral observation and arrest reporting program that meets the requirements of this part, beginning on the date upon which the drug and alcohol testing was conducted through the date upon which the individual is granted authorization and thereafter.~~ both a drug and alcohol testing program that includes random testing and a behavioral observation and arrest reporting program which meet the requirements of this part from the date upon which the individual's last authorization was terminated through the date upon which the individual is granted authorization.

(d) Authorization reinstatement after an interruption of more than 30 days. (1) In order to reinstate authorization for an individual whose authorization has been interrupted for a period of more than 30 days but no more than 365 days, except as permitted in paragraph (d)(2) of this section, the licensee or other entity 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.

(2) The licensee or other entity need not conduct pre-access testing of these individuals if--

(i) The individual previously held authorization under this part and has been subject both to a drug and alcohol testing program that includes random testing and a behavioral and arrest-reporting program that meet the

requirements of this part from the date upon which the individual's last authorization was terminated through the date upon which the individual is granted authorization; or

(ii) The licensee or other entity relies upon negative results from drug and alcohol tests that were conducted before the individual applied for authorization, ~~as permitted under paragraph (b) of this section~~, and the individual remains subject to ~~a behavioral observation and arrest reporting program that meets the requirements of this part, beginning on the date upon which the drug and alcohol testing was conducted through the date upon which the individual is granted authorization and thereafter.~~ both a drug and alcohol testing program that includes random testing and a behavioral observation and arrest reporting program which meet the requirements of this part from the date upon which the individual's last authorization was terminated through the date upon which the individual is granted authorization.

1.18 Issue: Paragraph 26.63(c) Concern about requiring a suitable inquiry to "present" employer when the individual is hired at the time of application.

Discussion: Industry experience indicates that the present employer, for instance a C/V, may not be able to answer the questions about an individual due to lack of relationship with the individual in some cases. When the individual is hired by the C/V on the same day or just a few days before the individual is processed by a licensee or other entity, the C/V may not be able to answer any questions about the individual.

Reference: The proposed §26.63(c) The licensee or other entity shall conduct the suitable inquiry, on a best effort basis, by questioning both present and former employers.

Recommendation: Reword §26.63(c) as: "The licensee or other entity shall conduct the suitable inquiry, on a best effort basis, by questioning both present and former employers. If the individual is hired within three business days from completion of the self disclosure the present employer need not be queried."

1.19 Issue: Paragraph 26.65(f) Concern with requirement to only collect sample.

Discussion: The industry's current practice for pre-access drug and alcohol testing is to conduct testing rather than just collect the specimen within the

30-day period that precedes the date upon which the licensee grants authorization to an individual. The benefit of changing the requirement to only "collect a specimen" within this time constraint does not outweigh the effort to implement the change. The requirement would be clearer if the 30 day period to conduct testing were added to the proposed §26.65(c). This would then allow the proposed §26.65(f) to be deleted.

Reference: The proposed §26.65(c): *"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, the licensee or other entity shall verify that the results of pre-access drug and alcohol tests are negative. The licensee or other entity need not conduct preaccess testing if —"

Reference: The proposed §26.65(f): *"Time periods for testing.* If pre-access testing is required under this section, the licensee or other entity must collect the specimens within the 30-day period that precedes the date upon which the licensee or entity grants authorization to an individual."

Recommendation: Reword §26.65(c) as: *"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, the licensee or other entity shall verify that the results of pre-access drug and alcohol tests are negative within the 30-day period that precedes the date upon which the licensee or entity grants authorization to an individual. The licensee or other entity need not conduct preaccess testing if —." Delete §26.65(f).

1.20 Issue: Paragraph 26.69(e)(1) Treatment follow-up

Discussion: The industry is concerned that the proposed 26.69(e)(1) requires a licensee to be responsible for any treatment program that has been prescribed by a previous licensee. The discussion in the supplemental information at 70 FR 50513 does not clarify need for the proposed 26.69(e)(1). It merely describes the proposed requirement.

Individuals' medical insurance plans will dictate the appropriate level of care and location of treatment facility based upon the substance abuse professional's assessment and the insurance carrier's coverage. The treatment program will, most likely, be in a facility near the individual's home, rather than near licensee facilities. Program length and components will vary by individual. Further, treatment outcomes are tied to consistency and follow-through with the same program staff, not by "dropping in" to local

facilities near licensees. Aftercare requirements may be one year, or more, in duration. Programs may include more than individual drug/alcohol counseling (i.e., individual or family counseling, or medication management for dual diagnosis). There is, practically speaking, no way to manage this requirement appropriately to affect the outcome being sought.

Fitness for duty requirements provide for reasonable assurance of FFD through several means. As licensee's program requirements vary for length of denial for drug and alcohol violations, it does not add value to subject licensees to this burden. Several licensees do not grant authorization until any treatment recommendations are completed or deny access altogether subsequent to a drug or alcohol FFD violation. Present means to determine FFD include referring the individual to the MRO for assessment or for a clinical interview – both time-tested and appropriately used by licensees. Further, with PADS inclusion, follow-up FFD collections can be carried out with minimal effort and effect on licensee operations. Individuals authorized under Part 26 remain under continual scrutiny under licensee FFD requirements including BOP requirements.

Given these issues, it is the recommendation of the industry that the burden of completion, compliance and follow-up should remain with the individual, not the licensee to monitor and verify. This recommendation is consistent with the principle of Rulemaking Goal (5), "Improve Part 26 by eliminating or modifying any unnecessary requirements."

Reference: The proposed §26.69(e)(1): If an individual leaves the FFD program in which a treatment and follow-up testing plan was required under paragraphs (b), (c), or (d) of this section, and is granted authorization by the same or another licensee or entity, the licensee or other entity who grants authorization to the individual shall ensure that any treatment and follow-up testing requirements are met, with accountability assumed by the granting licensee or other entity.

Recommendation: Given no demonstrated need for the proposed §26.69(e)(1), the current success of FFD programs without it and the difficulties in implementing it, the industry recommends deleting §26.69(e)(1).

1.21 Issue: Paragraph 26.75(g): Clarification of five year sanction

Discussion: The five year sanction discussed in the proposed §26.75(g) applies to the proposed §26.75(e)(2) but not to the proposed §26.75(e)(1).

Reference: The proposed §26.75(g): "For individuals whose authorization was denied for 5 years under paragraphs (c), (d), (e), or (f) of this section, any subsequent violation of the drug and alcohol provisions of an FFD policy must immediately result in permanent denial of authorization."

Recommendation: Reword §26.75(g): "For individuals whose authorization was denied for 5 years under paragraphs (c), (d), (e)(2), or (f) of this section, any subsequent violation of the drug and alcohol provisions of an FFD policy must immediately result in permanent denial of authorization."

1.22 Issue: Paragraph 26.91(c)(2) EBT test number issue

Discussion: Some EBTs on the NHTSA list do not provide a number before a test. Part 26 should not restrict use of specific machines that are on the NHTSA list. Limiting use of some machines on the NHTSA list may have a significant economic impact on a substantial number of small entities who manufacturer EBTs, thus invalidating NRC's certification otherwise at 70 FR 50620, Regulatory Flexibility Act Certification.

Reference: The proposed §26.91(c)(2): "Assigns a unique number to each completed test, which the collector and donor can read before each test and which is printed on each copy of the test result;"

Recommendation: Revise §26.91(c)(2) to read "Assigns a unique number to each completed test that the collector and donor can read after each test."

1.23 Issue: Paragraph 26.91(e) External calibration check

Discussion: The proposed rule requires an external calibration check. The term "external calibration check" is not defined in the proposed §26.5 and it is not clear to the industry exactly what is intended. The most important aspects of the calibration check are use of the most recent version of the manufacturer's instructions for the use and care of the EBT and that appropriate calibration checks are performed no less frequently than at the intervals specified in the manufacturer's instructions.

Reference: The proposed §26.91(e): *"Quality assurance and quality control of EBTs*
(1) Licensees and other entities shall implement the most recent version of the manufacturer's instructions for the use and care of the EBT consistently with the quality assurance plan submitted to NHTSA for the EBT, including performing external calibration checks no less frequently than at the intervals specified in the manufacturer's instructions.

(2) When conducting external calibration checks, licensees and other entities shall use only calibration devices appearing on NHTSA's CPL for "Calibrating Units for Breath Alcohol Tests."
(3) If an EBT fails an external check of calibration, the licensee or other entity shall take the EBT out of service and cancel every positive test result that was obtained using the EBT from any tests that were conducted after the EBT passed the last external calibration check. The EBT may not be used again for alcohol testing under this part until it is repaired and passes an external calibration check."

Recommendation: Rewrite §26.91(e) by removing "external" in four places. The meaning does not change but the confusion caused by the undefined "external calibration check" is resolved.

1.24 Issue: Paragraph 26.91(e)(3) Action on failure of a calibration check

Discussion: The concept of all positives being suspect when an operability test fails is contradictory within this rule and contradicts a long history in the industry regarding security equipment.

The proposed §26.91 and §26.167 require negating or retesting all positives if errors in testing occur; the proposed §26.137 requires an investigation. This appears to be a contradiction within the rule. Also, maintenance of the equipment is required in accordance with the intervals specified in the manufacturer's instructions. However, having to negate all positives since the last successful test will probably cause an increase in the frequency of testing to minimize the impact from this occurring. The implied test frequency exceeds the required frequency, adding burden to FFD staff and increased costs not calculated in the regulatory analysis.

Also, since fitness for duty has traditionally been considered an aspect of physical plant security, it causes one to make a comparison to those situations when security equipment fails, and that comparison yields contradictory results. For instance, if access screening equipment fails, all personnel in the protected area are not required to be re-searched because there is not an automatic assumption made that the machine was inoperative and everyone in the plant was improperly screened. In the same manner, personnel within a vital area are not required to leave the area when the access device or door alarm fails because there is not an automatic assumption made that they were able to obtain unauthorized or undetected access. In each of these instances, the assumption is that the equipment

failed in the testing officer's presence and compensatory measures are implemented, to include an investigation.

The same line of thinking should be applied across the spectrum of security, including FFD. Unless evidence can be provided that can demonstrate failure occurred immediately following the last successful test, the assumption should not be that the equipment was not working, it should be that it worked properly until the failing test was performed.

The most conservative approach actually would be that all negative tests should be suspect, not the positives. Or, if the "all-fail" line of thinking is upheld, it should be applied as 100% failure – both positive tests and negative tests. In either case, retesting many people would be an unnecessary burden and still would not yield the same results (for a positive) as at the time of original testing. The discussion at 70 FR 50527 places due process rights of donors above the health and safety of the public, ensured by having the work force fit for duty.

Reference: The proposed §26.91(e)(3): "If an EBT fails an external check of calibration, the licensee or other entity shall take the EBT out of service and cancel every positive test result that was obtained using the EBT from any tests that were conducted after the EBT passed the last external calibration check. The EBT may not be used again for alcohol testing under this part until it is repaired and passes an external calibration check."

Reference: The proposed §26.137(f): "*Errors in testing* Each licensee testing facility shall investigate any testing errors or unsatisfactory performance discovered in the testing of quality control samples, in the testing of actual specimens, or through the processing of management reviews and/ or MRO reviews, as well as any other errors or matters that could adversely reflect on the licensee testing facility's testing process. Whenever possible, the investigation must determine relevant facts and identify the root cause(s) of the testing or process error. The licensee testing facility shall take action to correct the cause(s) of any errors or unsatisfactory performance that are within the licensee testing facility's control. A record of the investigative findings and the corrective actions taken, where applicable, must be dated and signed by the individuals who are responsible for the day-to-day management of the licensee testing facility and reported to appropriate levels of management."

Reference: The proposed §26.167(g): "*Errors in testing* The licensee or other entity shall ensure that the HHS certified laboratory investigates any testing errors or unsatisfactory performance discovered in blind performance testing, in the testing of actual specimens, or through the processing of

reviews, as well as any other errors or matters that could adversely reflect on the testing process.
(1) Whenever possible, the investigation must determine relevant facts and identify the root cause(s) of the testing or process error. The licensee or other entity, and the HHS-certified laboratory, shall take action to correct the causes of any errors or unsatisfactory performance that are within their control. Sufficient records shall be maintained to furnish evidence of activities affecting quality. The licensee or other entity shall assure that the cause of the condition is determined and the corrective action taken to preclude repetition. The identification of the significant condition, the cause of the condition, and the corrective action taken shall be documented and reported to appropriate levels of management.
(2) Should a false positive error occur on a blind performance test sample or on a regular specimen, the licensee or other entity shall require the laboratory to take corrective action to minimize the occurrence of the particular error in the future. If there is reason to believe that the error could have been systematic, the licensee or other entity may also require review and re-analysis of previously run specimens.
(3) Should a false positive error occur on a blind performance test sample and the error is determined to be technical or methodological, the licensee or other entity shall instruct the laboratory to provide all quality control data from the batch or analytical run of specimens that included a false positive sample. In addition, the licensee or other entity shall require the laboratory to retest all specimens that analyzed as positive for that drug or metabolite, or as nonnegative in validity testing, from the time of final resolution of the error back to the time of the last satisfactory performance test cycle. This retesting must be documented by a statement signed by the laboratory's certifying scientist. The licensee or other entity and the NRC also may require an onsite review of the laboratory, which may be conducted unannounced during any hours of operation of the laboratory."

Recommendation: Reword §26.91(e)(3): "If an EBT fails a calibration check, the licensee or other entity shall take the EBT out of service. The EBT may not be used again for alcohol testing under this part until it is repaired and passes a calibration check."

Also reword 26.167(g)(3): "Should a false positive error occur on a blind performance test sample and the error is determined to be technical or methodological, the licensee or other entity shall instruct the laboratory to provide all quality control data from the batch or analytical run of specimens that included a false positive sample. The licensee or other entity and the NRC also may require an onsite review of the laboratory, which may be conducted unannounced during any hours of operation of the laboratory."

1.25 Issue: Section 26.111 Use of the word "validity"

Discussion: Three definitions in the proposed §26.5 contain the word "validity." There may be confusion with the proposed §26.111 containing the word "validity." Noting that the proposed §26.111(g) uses the word "acceptable" it seems "acceptability" rather than "validity" might be used to avoid confusion with defined phases that contain "validity."

Reference: The proposed §26.5:
Confirmatory validity test means a second test performed on a different aliquot of the original urine specimen to further support a validity test result.
Initial validity test means a first test used to determine whether a specimen is adulterated, diluted, or substituted, and may require confirmatory validity testing.
Validity screening test means the use of a non-instrumented testing device to determine the need for initial validity testing of a urine specimen.

Reference: The proposed §26.111: "Checking the validity of the urine specimen."

Reference: The proposed §26.111(g): "An acceptable specimen is free of any apparent contaminants, meets the required basic quantity of at least 30 mL, and is within the acceptable temperature range."

Recommendation: Reword §26.111 as "Checking the acceptability of the urine specimen."

1.26 Issue: Section 26.111 Urgency in getting donor temperature.

Discussion: The temperature range for an acceptable urine specimen has increased slightly and a specific criterion for donor body temperature difference from the specimen has been provided. The industry agrees with these improvements. Licensees and other entities will modify their processes as required by the new requirements. However the proposed §26.115(a)(2)(ii) temperature difference criterion lacks a scientific basis without a time consideration, its inclusion in HHS guidelines not withstanding. The specimen will begin to cool immediately and will cool until it reaches temperature equilibrium with the surrounding air. The cooling rate is largely a function of the temperature difference between the specimen and the surrounding air. The temperature difference would typically be fairly significant, approximately 25 degrees F, given the expected temperatures of the specimen and an air conditioned or heated room. The donor's

temperature should be taken as soon as possible after the collector has informed the donor that he or she may volunteer to have his or her temperature taken to provide evidence to counter the reason to believe the donor may have altered or substituted the specimen. The typographical error is that "E" should be "degrees" in two places.

Reference: The proposed §26.111(b): "If the temperature of a urine specimen is outside the range of 90 °F to 100 °F, the collector shall inform the donor that he or she may volunteer to have his or her temperature taken to provide evidence to counter the reason to believe the donor may have altered or substituted the specimen."

Reference: The proposed §26.115(a)(2): "The donor has presented, at this collection, a urine specimen that falls outside the required temperature range, and
(i) Either the donor declines to provide a measurement of body temperature; or
(ii) The donor's measured body temperature varies by more than 1EC/ 1.8EF from the temperature of the specimen;"

Recommendation: Modify §26.111(b): to add a time urgency for both the collector and the donor: "If the temperature of a urine specimen is outside the range of 90 °F to 100 °F, the collector shall inform the donor that he or she may volunteer to have his or her temperature taken to provide evidence to counter the reason to believe the donor may have altered or substituted the specimen. The collector shall be prepared to take the donor's temperature immediately after each collection as soon as the collector informs the donor of the option. If the donor consents to have his or her temperature taken, the donor shall cooperate with the collector taking the temperature."

Modify §26.115(a)(2)(ii) by replacing "E" with "degrees."

1.27 Issue: Paragraph 26.153(f)(3) Guidance is needed for determining an MRO conflict of interest.

Discussion: If an MRO, being a licensed physician, has a private practice and that private practice uses the same laboratory for his/her patients' specimens, it should be clear that this would not be a relationship "that may be construed as a potential conflict of interest" by the Commission.

Reference: The proposed §26.153(f)(5), "The laboratory may not enter into any relationship with the licensee's or other entity's MRO(s) that may be

construed as a potential conflict of interest, and may not derive any financial benefit by having a licensee or other entity use a specific MRO; and"

Reference: The proposed §26.183(b)

Relationships

The MRO may be an employee of the licensee or other entity or a contractor. However, the MRO may not be an employee or agent of, or have any financial interest in, an HHS-certified laboratory or a contracted operator of a licensee testing facility for whom the MRO reviews drug test results. Additionally, the MRO may not derive any financial benefit by having the licensee or other entity use a specific drug testing laboratory or licensee testing facility operating contractor and may not have any agreement with such parties that may be construed as a potential conflict of interest.

Recommendation: §49 CFR 40.101(b) provides examples of MRO conflicts of interest for Department of Transportation regulations. They should be added to §26.153(f)(5) and §26.183(b) for clarification. This change is consistent with Goal (1) of the Rulemaking Activity: "Update and enhance the consistency of 10 CFR Part 26 with advances in other relevant Federal rules and guidelines, including the U.S. Department of Health and Human Services Mandatory Guidelines for Federal Workplace Drug Testing Programs and other Federal drug and alcohol testing programs (*e.g.*, those required by the U.S. Department of Transportation [DOT]) that impose similar requirements on the private sector)."

From §49 CFR 40.101(b):

The following are examples of relationships between laboratories and MROs that the Department regards as creating conflicts of interest, or the appearance of such conflicts. This following list of examples is not intended to be exclusive or exhaustive:

(1) The laboratory employs an MRO who reviews test results produced by the laboratory;

(2) The laboratory has a contract or retainer with the MRO for the review of test results produced by the laboratory;

(3) The laboratory designates which MRO the employer is to use, gives the employer a slate of MROs from which to choose, or recommends certain MROs;

(4) The laboratory gives the employer a discount or other incentive to use a particular MRO;

(5) The laboratory has its place of business co-located with that of an MRO or MRO staff who review test results produced by the laboratory; or

(6) The laboratory permits an MRO, or an MRO's organization, to have a financial interest in the laboratory.

1.28 Issue: Paragraph 26.183(d)(1)(i) Restrictions on the MRO staff

Discussion: The industry is concerned that the proposed §26.183(d)(1)(i) limits the flexibility of MRO staff who are licensee employees. Licensee employees who perform MRO staff functions part time must be able to perform other duties when they are not working to support the MRO.

The Proposed Rule Supplementary Information (70 FR 50567) states:

> Proposed § 26.183(d)(1)(i) would require that MRO staff duties must be independent from any other activity or interest of the licensee or other entity. The proposed rule would add this requirement because, by contrast to other Federal agencies' regulations, Part 26 permits employees of licensees and other entities to perform MRO staff activities for MROs who work off site and are not physically present to supervise the staff. These circumstances may provide greater opportunities for inadvertent compromise of the independence of the MRO function than situations in which the MRO and his or her staff are physically co-located, such as the inadvertent release of nonnegative test results before the MRO has reviewed the results with the donor. Therefore, the NRC believes that the proposed requirement is necessary to protect the integrity of the MRO function and donors' privacy.

Most nuclear power plant licensees do not have a sufficient day-to-day volume of work to maintain a full-time MRO staff as would be required under the proposed rule. Under the current model utilized at nuclear power plants the MRO staff is assigned to perform collections and process results. On many days there are no collections or results activity to be processed.

The NRC recognized this fact in NUREG 1385 which states in part:

> 5.4 With whom may the results of initial screening tests be shared?
>
> 10 CFR 26.24(d) states that access to the results of *a preliminary* test must be limited to the licensee testing staff, the MRO, the Fitness-for-Duty Program Manager, and the employee assistance program staff, when appropriate. The results of the *initial* screening test at the certified laboratory may be provided to the MRO only after confirmatory tests and laboratory reviews have been completed [Section 2.7(g) of Appendix A to 10 CFR Part 26]. Negative results of initial screening tests and MRO-determined negative and confirmed positive results

may be provided to management. Negative results of preaccess tests may be provided immediately.

The NRC, in the Proposed Rule Supplementary Information section, 70 FR 50568, states that:

> "...the NRC is unaware of any instances in which the MRO function has been compromised by MRO staff in Part 26 programs..."

The reason that there have been no compromises of MRO functions by the MRO staffs is that the nuclear power plant programs are different from Federal programs in that the trustworthiness and reliability of the FFD staffs has been ascertained and are recertified on a periodic basis. In addition, the FFD personnel are trained in behavior observation techniques and responsible to report aberrant behavior. Unlike the DOT program for instance, the FFD staff continually deal with a consistent population of donors. Therefore, the licensees have been operating in accordance with the Section 5.4 of NUREG 1385 since it publication in 1989.

While the industry understands the noteworthy objective to make the FFD rule consistent with other Federal programs (Rulemaking Goal (4)), the nuclear power plant licensees believe that in this instance meeting Goal (4) is inconsistent with Goal (5) which is to improve Part 26 by eliminating or modifying unnecessary requirements because the licensees and other entities will have to hire or contract for full-time staffs to support the FFD operations. NRC's desire for consistency with other Federal programs does not justify imposing this extra cost on licensees.

Finally, the NRC's Regulatory Analysis Appendix 1, Page H-2 and Page 484 states:

> Paragraph 26.183(d)
> This paragraph of the proposed rule [including subparagraphs 26.183(d)(1)–(2)] imposes no incremental cost and affords no saving because it merely clarifies and explicitly states the MRO staff responsibilities that are already effective under the current rule. The paragraph also adds requirements to ensure that MRO staff are properly supervised by the MRO and are independent from the licensee or other entity management. This provision does not result in an incremental cost because it incorporates existing practices into written regulation and makes the procedures consistent with HHS-recommended practices.

The analysis does not properly consider the latitude the nuclear power plant licensees have been permitted to exercise since 1989.

In conclusion, the industry believes that, in this instance, the NRC is solving a problem that does not exist and is not fairly giving proper credit for substantive programs that protect the integrity of the FFD program and the privacy of the donor. The industry recommends that licensees and other entities be permitted to continue to assign individuals to the MRO staff on a part-time basis in accordance with current practices.

Reference: The proposed §26.183(d)(1)(i) The duties of MRO staff must be maintained independent from any other activity or interest of a licensee or other entity, in order to protect the integrity of the MRO function and donors' privacy.

Recommendation: Reword §26.183(d)(1)(i) as: "The duties of MRO staff must be maintained independent from any other activity or interest of a licensee or other entity, in order to protect the integrity of the MRO function and donors' privacy. Employees of licensees and other entities may function as MRO staff. When functioning as MRO staff they shall take direction from the MRO only."

1.29 Issue: Paragraph 26.183(d)(2)(iii) MRO Staff Function

Discussion: MRO staff should be permitted to validate donor prescription information as an administrative function for the MRO. This allows MRO staff to assist the MRO in obtaining the information necessary to make decisions about specimens.

Reference: The proposed §26.183(d)(2)(iii): "The staff may not conduct interviews with donors to discuss non-negative drug test results nor request medical information from a donor. Only the MRO may request and review medical information related to a nonnegative drug test result or other matter from a donor."

Recommendation: The industry recommends 26.183(d)(2)(iii) be modified to read: "The staff may not conduct interviews with donors to discuss non-negative drug test results nor request medical information from a donor. Only the MRO may request and review medical information related to a nonnegative drug test result or other matter from a donor."

1.30 Issue: Paragraph 26.183(d)(2)(iv) Restrictions on MRO staff

Discussion: The proposed §26.183(d)(2)(iv) appears to prohibit MRO staff from discussing test results with licensees and other entities. Clarification is needed to permit the MRO staff to relate confirmed results and to discuss those results with licensee and other entity personnel. It is neither effective nor efficient to have only the MRO discuss results with licensee and other entity personnel. This is not consistent with Rulemaking Goal (3): "Improve the effectiveness and efficiency of FFD programs."

For instance, compliance with the proposed §26.185(c) could be seen as preventing the MRO staff from arranging the meeting between the MRO and the donor.

For instance, compliance with the proposed §26.185(p) could be seen as preventing the MRO staff from handling the written notification from the MRO to the licensee or other entity.

Reference: The proposed §26.183(d)(2)(iv): "Staff may not report nor discuss any non-negative test results received from the HHS-certified laboratory with any individuals other than the MRO and other MRO staff."

Reference: The proposed §26.185(c)

Discussion with the donor.

Before determining that a non-negative test result or other occurrence is an FFD policy violation and reporting it to the licensee or other entity, the MRO shall give the donor an opportunity to discuss the test result or other occurrence with the MRO, except as described in paragraph (d) of this section. After this discussion, if the MRO determines that a non-negative test result or other occurrence is an FFD policy violation, the MRO shall immediately notify the licensee's or other entity's designated representative.

Reference: The proposed §26.185(p)

Time to complete MRO review.

The MRO shall complete his or her review of non-negative test results and, in those instances in which the MRO determines that the donor has violated the licensee's or other entity's FFD policy, notify licensee or other entity's designated representative within 10 days of an initial non-negative test result. The MRO shall notify the licensee or other entity of the FFD policy violation in writing and in a manner designed to ensure the confidentiality of the information.

Recommendation: Reword §26.183(d)(2)(iv): "Staff may not report nor discuss any non-negative test results received from the HHS-certified

laboratory with any individual other than the MRO and individuals designated by licensees and other entities."

1.31 Issue: Paragraph 26.185(a): MRO determination

Discussion: The proposed words require the MRO to determine if the donor has violated the FFD policy. Since some MROs serve several licensee this is onerous for the MRO whose expertise is medical rather than the policies of various clients. It also violates Goal (1) if this rulemaking "Update and enhance the consistency of 10 CFR Part 26 with advances in other relevant Federal rules and guidelines, including the U.S. Department of Health and Human Services Mandatory Guidelines for Federal Workplace Drug Testing programs and other Federal drug and alcohol testing programs (*e.g.*, those required by the U.S. Department of Transportation [DOT]) that impose similar requirements on the private sector." MROs in those programs do not report FFD policy violations.

Reference: The proposed §26.185(a): "*MRO review required.* A nonnegative drug test result does not automatically identify an individual as having used drugs in violation of the NRC's regulations, or the licensee's or other entity's FFD policy, or as having attempted to subvert the testing process. An individual who has a detailed knowledge of possible alternate medical explanations is essential to the review of the results. The MRO shall review all non-negative test results from the HHS certified laboratory to determine whether the donor has violated the FFD policy before reporting the results to the licensee's or other entity's designated representative."

Recommendation: Reword §26.185(a): "*MRO review required.* A nonnegative drug test result does not automatically identify an individual as having used drugs in violation of the NRC's regulations, or the licensee's or other entity's FFD policy, or as having attempted to subvert the testing process. An individual who has a detailed knowledge of possible alternate medical explanations is essential to the review of the results. The MRO shall review all non-negative test results from the HHS certified laboratory before reporting the results to the licensee's or other entity's designated representative."

1.32 Issue: Paragraph 26.185(g)(2): Undermining MRO professional opinion

Discussion: The proposed words restrict the MRO from acting based on professional judgment by limiting rationale MRO may consider in

determining that a donor may have diluted a specimen. While the rationale may seem appropriate now, in the future they may be found lacking and negatively impact the effectiveness of FFD programs.

Reference: The proposed §26.185(g)(2): "If the MRO has reason to believe that the donor may have diluted a specimen in a subversion attempt, the MRO may require the laboratory to conduct confirmatory testing of the specimen at the LOD for any drugs or drug metabolites as long as each drug class is evaluated in accordance with § 26.31(c)(1)(ii). For purposes of this paragraph, the following circumstances are the exclusive grounds constituting a reason to believe that the donor may have diluted the specimen in a subversion attempt:"

Recommendation: Reword §26.185(2): "If the MRO has reason to believe that the donor may have diluted a specimen in a subversion attempt, the MRO may require the laboratory to conduct confirmatory testing of the specimen at the LOD for any drugs or drug metabolites as long as each drug class is evaluated in accordance with § 26.31(c)(1)(ii)." That is, delete the last sentence. Also delete §26.185(2)(i), §26.185(2)(ii) and §26.185(2)(iii).

1.33 Issue: Paragraph 26.185(i)(3): Clarification of legitimate medical explanation

Discussion: The proposed words are in contrast to the discussion of the paragraph at 70 FR 50570.

Reference: The proposed §26.185(i)(3): "If the MRO determines that there is no legitimate medical explanation for the adulterated test result and no drugs or drug metabolites were detected in the specimen, the MRO shall report to the licensee or other entity that no FFD policy violation has occurred."

Recommendation: Reword §26.185(i)(3): "If the MRO determines that there is a legitimate medical explanation for the adulterated test result and no drugs or drug metabolites were detected in the specimen, the MRO shall report to the licensee or other entity the test is negative."

1.34. Issue: Paragraph 26.185(p) Clarify "business" days for MRO notification requirements

Discussion: The requirements for the laboratory to provide the results and for the MRO to report are inconsistent. Using business days in one case and calendar days in the other should be corrected to specify business days in both cases.

Reference: The proposed §26.185(p):
Time to complete MRO review
The MRO shall complete his or her review of non-negative test results and, in those instances in which the MRO determines that the donor has violated the licensee's or other entity's FFD policy, notify licensee or other entity's designated representative within 10 days of an initial non-negative test result. The MRO shall notify the licensee or other entity of the FFD policy violation in writing and in a manner designed to ensure the confidentiality of the information.

Reference: The proposed §26.169(a):
The HHS-certified laboratory shall report test results to the licensee's or other entity's MRO within 5 business days after receiving the specimen from the licensee or other entity. Before reporting any test result to the MRO, the laboratory's certifying scientist shall certify the result as correct. The report must identify the substances for which testing was performed; the results of the validity and drug tests; the cutoff levels for each; any indications of tampering, adulteration, or substitution that may be present; the specimen identification number assigned by the licensee or other entity; and the specimen identification number assigned by the laboratory.

Recommendation: Revise §26.185(p):
Time to complete MRO review
The MRO shall complete his or her review of non-negative test results and, in those instances in which the MRO determines that the donor has violated the licensee's or other entity's FFD policy, notify licensee or other entity's designated representative within 10 business days of an initial non-negative test result. The MRO shall notify the licensee or other entity of the FFD policy violation in writing and in a manner designed to ensure the confidentiality of the information.

1.35 Issue: Section 26.187 MRO and SAE function performance by one person

Discussion: Section 26.187 provides requirements for a Substance Abuse Expert (SAE). It does not specifically exclude the MRO from performing SAE functions. In some cases an MRO may have the qualifications to perform the SAE functions. Paragraph 26.189 (a)(5) mentions an MRO who is also an

SAE. Section 26.187 should be clarified to explicitly permit an MRO who meets the qualifications of this section to perform the SAE functions described in this section.

Reference: The proposed §26.187(a): *"Implementation.* By [insert date 2 years after publication of the final rule in the Federal Register], substance abuse experts (SAEs) upon whom licensees and other entities rely to make determinations of fitness under this part shall meet the requirements of this section."

Reference: The proposed §26.189(a)(5): "As a physician with specialized training, the MRO may determine the fitness of an individual who may have engaged in substance abuse or may be ill, injured, fatigued, taking medications in accordance with one or more valid prescriptions, and/or using over-the counter medications, but may not be qualified to assess an individual's fitness to be granted authorization following an unfavorable termination or denial of authorization under this part, unless the MRO is also an SAE."

Recommendation: Add a second sentence to 26.187(a): "One person who qualifies as both an MRO as required in section 26.183 and an SAE as required by this section may perform the functions of both positions."

1.36 Issue: Paragraph 26.189(a): Clarification of determination of fitness

Discussion: The proposed words are confusing. The determination of fitness is required when there are indications that an individual may be in violation of the FFD policy. It is not required to determine whether there are indications.

Reference: The first sentence of the proposed §26.189(a): "A determination of fitness is the process whereby it is determined whether there are indications that an individual may be in violation of the licensee's or other entity's FFD policy or is otherwise unable to safely and competently perform his or her duties."

Recommendation: Reword the first sentence of §26.189(a): "A determination of fitness is the process entered when there are indications that an individual may be in violation of the licensee's or other entity's FFD policy or is otherwise unable to safely and competently perform his or her duties."

1.37 Issue: Paragraph 26.189(b)(3): Clarification of need to perform a determination of fitness

Discussion: The proposed words are confusing. The determination of fitness is required when potentially disqualifying FFD information is identified that has not previously been evaluated by another licensee or entity who is subject to this part.

Reference: The proposed §26.189(b)(3): "Before an individual is granted authorization when potentially disqualifying FFD information is identified and has not previously been evaluated by another licensee or entity who is subject to this part; and"

Recommendation: Reword the first sentence of §26.189(b)(3): "Before an individual is granted authorization when potentially disqualifying FFD information is identified that has not previously been evaluated by another licensee or entity who is subject to this part; and"

1.38 Issue: Paragraph 26.189(c) Unnecessary requirement for a face-to-face determination in fitness determinations.

Discussion: The proposed §26.189(c) requires: "A determination of fitness that is conducted "for cause" must be conducted through face-to-face interaction between the subject individual and the professional making the determination. Electronic means of communication may not be used."

The determination of the appropriate approach to this determination should be left to the professional making the determination. The proposed §26.189(a) provides extensive criteria for the qualifications of the professional that will make the determination. As in other parts of the rule, the professional would be expected to make that determination using techniques that are generally acceptable in the professional community. In many cases this may require a face-to-face interview with the individual. There will be cased where this approach is not required. For example, if the ultimate issue is whether a certain psychoactive medication will prevent an individual from performing assigned duties, a clinical psychologist may be able to provide the needed determination without a face-to-face interaction.

Reference: The proposed §26.189(c): "A determination of fitness that is conducted "for cause" must be conducted through face-to-face interaction between the subject individual and the professional making the determination. Electronic means of communication may not be used.

Recommendation: Delete 26.189(c). Renumber (d) as (c) and place paragraphs (1) and (2) under the new paragraph (c).

Section 2
Comments in support of proposed rule language

The industry has conducted an extensive review of several provisions that have been previously discussed or raised during recent public meetings. Based on this review the industry supports the proposed rule language in the as indicated below.

2.1 Issue: Paragraph 26.31(d)(5)(ii) Post event testing

Discussion: The industry agrees that required medical treatment should not be delayed to conduct post event testing.

Reference: The proposed §26.31(d)(5)(ii): "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."

Recommendation: The industry recommends NRC implement §26.31(d)(5)(ii).

2.2 Issue: Section 26.65 Pre-access testing

Discussion: The proposed 26.65 is generally aligned with current industry practice.

Reference: The proposed §26.65

Recommendation: The industry recommends NRC implement 26.65.

2.3 Issue: Paragraph 26.75(a) Sanctions

Discussion: Industry agrees with the proposed §26.75(a). Each licensee and other entity should view these sanctions as a continuum from previous versions of the rule. Licensees and other entities may impose stricter sanctions than the rule requires.

Reference: The proposed §26.75(a): "This section defines the minimum sanctions that licensees and other entities shall impose when an individual has violated the drug and alcohol provisions of an FFD policy. A licensee or other entity who is subject to this part may impose more stringent sanctions, except as specified in paragraph (h) of this section."

Recommendation: The industry recommends NRC implement §26.75(a).

2.4 Issue: Paragraph 26.89(b)(1) Donor identification

Discussion: The industry agrees with the NRC discussion at 70 FR 50524. The proposed revision will provide greater assurance that the individual who appears for testing is the designated donor and, thereby, strengthen the effectiveness of FFD programs in detecting substance abuse. This is consistent with Goal (3) of the rulemaking, "Improve the effectiveness and efficiency of FFD programs."

Reference: The proposed §26.89(b)(1): "Acceptable identification includes photo-identification issued by a licensee or other entity who is subject to this part, or by the Federal, State, or local government. Licensees and other entities may not accept faxes or photocopies of identification."

Recommendation: The industry recommends NRC implement §26.89(b)(1).

2.5 Issue: Section 26.103 Confirmatory alcohol testing

Discussion: The industry agrees with NRC discussion on 70 FR 50531 about the proposed §26.103. It does improve the effectiveness of FFD programs by ensuring that confirmatory alcohol testing identifies donors who have been impaired from alcohol use while on duty and, therefore, may have posed a risk to public health and safety. It further improves the effectiveness of FFD programs by ensuring that the alcohol use of individuals who may have been impaired when reporting for duty is assessed to determine whether such individuals' alcohol use is problematic and may pose a future risk to public health and safety and the common defense and security.

Reference: The proposed §26.103(a): "Determining a confirmed positive test result for alcohol.
(a) A confirmed positive test result for alcohol must be declared under any of the following conditions:
(1) When the result of the confirmatory test for alcohol is 0.04 percent BAC or higher;
(2) When the result of the confirmatory test for alcohol is 0.03 percent BAC or higher and the donor had been in a work status for at least 1 hour at the time the initial test was concluded (including any breaks for rest, lunch, dental/doctor appointments, etc.); or
(3) When the result of the confirmatory test for alcohol is 0.02 percent BAC or higher and the donor had been in a work status for at least 2 hours at the

time the initial test was concluded (including any breaks for rest, lunch, dental/doctor appointments, etc.)."

Reference: The proposed §26.103(b): "When the result of the confirmatory test for alcohol is equal to or greater than 0.01 percent BAC but less than 0.02 percent BAC and the donor has been in a work status for 3 hours or more at the time the initial test was concluded (including any breaks for rest, lunch, dental/doctor appointments, etc.), the collector shall declare the test result as negative and inform FFD program management. The licensee or other entity shall prohibit the donor from performing any duties that require him or her to be subject to this part and may not return the individual to performing such duties until a determination of fitness indicates that the donor is fit to safely and competently perform his or her duties. "

Recommendation: The industry recommends NRC implement §26.103.

2.6 Issue: Paragraph 26.107(a)(3) Time limit for collecting urine specimen

Discussion: The industry agrees with NRC's discussion at 70 FR 50532 and 50533 which allows collectors to rely on professional judgment during collections. This allows a collector to give more time when appropriate but gives the collector the authority to prevent an individual donor from disrupting the process by taking an unreasonable length of time.

Reference: The proposed §26.107(a)(3): "The collector may set a reasonable time limit for voiding."

Recommendation: The industry recommends NRC implement §26.107(a)(3).

2.7 Issue: Paragraph 26.111(a) Validity testing

Discussion: The proposed rule has a sufficient number of checks for validity at the collection point such that specific gravity checks are not also required. The attributes checked include temperature, color, clarity, and any signs of contaminants or adulteration.

Reference: The proposed §26.111(a): "Immediately after the donor provides the urine specimen to the collector, including specimens of less than 30 mL but greater than 15 mL, the collector shall measure the temperature of the specimen. The temperature measuring device used must accurately reflect

the temperature of the specimen and not contaminate the specimen. The time from urination to temperature measurement may not exceed 4 minutes, and may need to be less if the ambient temperature is low or the specimen quantity is less than 30 mL."

Reference: The proposed §26.111(b): "If the temperature of a urine specimen is outside the range of 90 °F to 100 °F, the collector shall inform the donor that he or she may volunteer to have his or her temperature taken to provide evidence to counter the reason to believe the donor may have altered or substituted the specimen. "

Reference: The proposed §26.111(c): "Immediately after the donor provides a urine specimen, including specimens of less than 30 mL but greater than 15 mL, the collector shall also inspect the specimen to determine its color and clarity and look for any signs of contaminants or adulteration. The collector shall note any unusual findings on the custody-and-control form. "

Recommendation: The industry recommends NRC implement §26.111(a)(b)(c) with minor change to 26.111 as described in Comment 1.18.

2.8 Issue: Paragraph 26.127(b) Chain-of-custody procedures

Discussion: The requirement for written chain-of-custody procedures ensures that licensees and other entities will take appropriate corrective actions if there is an issue with the chain-of-custody for any specimen.

Reference: The proposed §26.127(b): "Written chain-of-custody procedures must describe the methods to be used to maintain control and accountability of specimens from receipt through completion of testing and reporting of results, during storage and shipping to the HHS-certified laboratory, and continuing until final disposition of the specimens."

Recommendation: The industry recommends NRC implement §26.127(b).

2.9 Issue: Paragraph 26.129(a) Security at licensee testing facilities and for specimens

Discussion: The industry believes security requirements for licensee testing facilities and for specimens described in the proposed rule are adequate. NRC notes at 70 FR 50545 that it is not aware of any instances in which specimens that were subject to tampering had been altered in such a manner as to affect specimen identity and integrity.

Reference: The proposed §26.129(a): "Each licensee testing facility shall be secure at all times. Each facility shall have in place sufficient security

measures to control access to the premises and to ensure that no unauthorized personnel handle specimens or gain access to the licensee testing facility's processes or areas where records are stored. Access to these secured areas must be limited to specifically authorized individuals whose authorization is documented. All authorized visitors and maintenance and service personnel shall be escorted at all times while in the licensee testing facility."

Reference: The proposed §26.129(b): "When specimens are received, licensee testing facility personnel shall inspect each package for evidence of possible tampering and shall compare information on specimen containers within each package to the information on the accompanying custody and control forms. Licensee testing facility personnel shall attempt to resolve any discrepancies identified in the information on specimen bottles or on the accompanying custody-and-control forms. Indications of tampering with specimens in transit from the collection site, or at a licensee testing facility, must be reported to senior licensee or other entity management as soon as practical and no later than 8 hours after the indications are identified. In response to such reports, licensee or other entity management personnel shall initiate an investigation to determine whether tampering has occurred. If the investigation determines that tampering has occurred, licensee or other entity management shall ensure that corrective actions are taken. If there is reason to believe that the integrity or identity of a specimen is in question (as a result of tampering or discrepancies between the information on specimen bottle and on the accompanying custody-and-control forms that cannot be resolved), the specimen may not be tested and the licensee or other entity shall ensure that another collection occurs as soon as reasonably practical."

Recommendation: The industry recommends NRC implement §26.129(a) and (b).

2.10 Issue: Paragraph 26.135(b) Time frame for requesting testing of bottle B

Discussion: Three days are adequate. Experience indicates the decision is typically made on the day of notification.

Reference: The proposed §26.135(b): "Within 3 business days (Monday through Friday, excluding holidays) of being notified by the MRO that the HHS-laboratory reported that donor's specimen yielded a non-negative test result, the donor may request that the split specimen in Bottle B be tested by another HHS-certified laboratory. The MRO shall inform the donor of this option, and the specimen in Bottle B may be tested only at the request of donor. When requested, the licensee or other entity shall ensure that Bottle

B is forwarded to an HHS-certified laboratory other than the laboratory that tested the specimen in Bottle A as soon as practical, and not later than one business day following the day of the donor's request to have Bottle B tested. The donor shall provide his or her written permission for the testing of bottle B and neither the licensee, MRO, NRC, nor any other entity may order testing of Bottle B without the donor's written permission."

Recommendation: The industry recommends NRC implement §26.135(b).

2.11 Issue: Paragraph 26.153(f)(4) Employee access to laboratory records

Discussion: Consistent with Rulemaking Activity Goal (7), "Protect the privacy and due process rights of individuals who are subject to Part 26." the industry believes access to laboratory records, beyond that required for licensee or other entity FFD program functions, should be restricted to individual donors viewing their own records.

Reference: The proposed §26.153(f)(4): "Consistent with the principles established in Section 503 of Public Law 100–71, any employee of a licensee or other entity who is the subject of a drug test shall, upon written request, have access to the laboratory's records related to his or her validity and drug test and any records related to the results of any relevant certification, review, or revocation-of-certification proceedings; "

Recommendation: The industry recommends NRC implement §26.153(f)(4).

2.12 Issue: Section 26.131 Time frame for validity testing

Discussion: No time requirement is required for validity testing. Licensees and other entities should be free to process specimens in the most efficient manner for their particular site as long as time requirements in other subsections of Part 26 are met.

Reference: The proposed §26.131(a): "Each validity test result from the licensee testing facility must be based on performing either a validity screening test or an initial validity test, or both, on one or more aliquots of a urine specimen. The licensee testing facility shall forward any specimen that yields a non-negative validity screening or initial validity test result to the HHS certified laboratory for further testing. Licensee testing facilities need not perform validity screening tests before conducting initial validity tests of a specimen."

Reference: The proposed §26.131(b): "At a minimum, the licensee testing facility shall test each urine specimen for creatinine, pH, and one or more oxidizing adulterants. Licensees and other entities may not specify more stringent cutoff levels for validity screening and initial validity tests than those specified in this section. If tests or observations indicate one or more of the following from either a validity screening test or an initial validity test, the licensee testing facility shall forward the specimen to the HHS-certified laboratory for additional testing: "

Recommendation: The industry recommends NRC implement §26.131(a) ands (b).

2.13 Issue: Section 26.161 New adulterants

Discussion: The industry needs to be able to identify new adulterants.

Reference: The proposed §26.161(c)(8): "The presence of any other adulterant not specified in paragraphs (c)(3) through (c)(7) of this section is verified using an initial test on the first aliquot and a different confirmatory test on the second aliquot."

Reference: The proposed §26.161(g): "*Additional testing by a second laboratory.* If the presence of an interfering substance/adulterant is suspected that could make a test result invalid, but it cannot be identified (*e.g.*, a new adulterant), laboratory personnel shall consult with the licensee's or other entity's MRO and, with the MRO's agreement, shall send the specimen to another HHS-certified laboratory that has the capability to identify the suspected substance."

Recommendation: The industry recommends NRC implement §26.161(c)(8) and §26.161(g).

2.14 Issue: Paragraph 26.185(h)(1) Review of substituted and adulterated specimens

Discussion: The industry believes fives business days are adequate for the donor to have medical records sent to the MRO from the donor's physician who is familiar with the donor's medical issues.

Reference: The proposed §26.185(h)(1): "If the HHS-certified laboratory reports a specimen as substituted (i.e., the creatinine concentration is less than 2 mg/dL and the specific gravity is less than or equal to 1.0010 or equal to or greater than 1.0200), the MRO shall contact the donor and offer the

donor an opportunity to provide a legitimate medical explanation for the substituted result. The burden of proof resides solely with the donor, who must provide legitimate medical evidence within 5 business days that he or she produced the specimen for which the HHS-certified laboratory reported a substituted result. Any medical evidence must be submitted through a referral physician who is experienced and qualified in the medical issues involved. Claims of excessive hydration, or claims based upon unsubstantiated personal characteristics, including, but not limited to, race, gender, diet, and body weight, are not acceptable evidence without medical studies which demonstrate that the donor did produce the laboratory result."

Reference: The proposed §26.185(i)(1): "If the HHS-certified laboratory reports a specimen as adulterated with a specific substance, the MRO shall contact the donor and offer the donor an opportunity to provide a legitimate medical explanation for the adulterated result. The burden of proof resides solely with the donor, who must provide legitimate medical evidence within 5 business days that he or she produced the adulterated result through normal human physiology. Any medical evidence must be submitted through a referral physician experienced and qualified in the medical issues involved."

Recommendation: The industry recommends NRC implement §26.185(h)(1) and §26.185(i)(1) as proposed.

2.15 Issue: Section 26.185 MRO judgment regarding medical explanations

Discussion: The industry believes MRO judgment is adequate and appropriate when a donor submits medical evidence to the MRO.

Reference: The proposed §26.185(f)(2): "If the MRO and the laboratory agree that further testing would not be useful and there is no technical explanation for the result, the MRO shall contact the donor and determine whether there is an acceptable medical explanation for the invalid result. If there is an acceptable medical explanation, the MRO shall report to the licensee or other entity that the test result is not an FFD policy violation, but that a negative test result was not obtained. If the medical reason for the invalid result is, in the opinion of the MRO, a temporary condition, the licensee or other entity shall collect a second urine specimen from the donor as soon as reasonably practical and rely upon the MRO's review of the test results from the second collection. The second specimen collected for the purposes of this paragraph may not be collected under direct observation. If the medical reason for the invalid result would similarly affect the testing of another urine specimen, the MRO may authorize an alternative method for

drug testing. Licensees and other entities may not impose sanctions for an invalid test result due to a medical condition."

Reference: The proposed §26.185(f)(3): "If the MRO and the laboratory agree that further testing would not be useful and there is no legitimate technical or medical explanation for the invalid test result, the MRO shall require that a second collection take place as soon as practical under direct observation. The licensee or other entity shall rely upon the MRO's review of the test results from the directly observed collection."

Reference: The proposed §26.185(g)(1): "If the HHS-certified laboratory reports that a specimen is dilute and that drugs or drug metabolites were detected in the specimen at or above the cutoff levels specified in this part or the licensee's or other entity's more stringent cutoff levels, and the MRO determines that there is no legitimate medical explanation for the presence of the drugs or drug metabolites in the specimen, the MRO shall determine that the drug test results are positive and that the donor has violated the FFD policy. "

Reference: The proposed §26.185 (h)(1): "If the HHS-certified laboratory reports a specimen as substituted (i.e., the creatinine concentration is less than 2 mg/dL and the specific gravity is less than or equal to 1.0010 or equal to or greater than 1.0200), the MRO shall contact the donor and offer the donor an opportunity to provide a legitimate medical explanation for the substituted result. The burden of proof resides solely with the donor, who must provide legitimate medical evidence within 5 business days that he or she produced the specimen for which the HHS-certified laboratory reported a substituted result. Any medical evidence must be submitted through a referral physician who is experienced and qualified in the medical issues involved. Claims of excessive hydration, or claims based upon unsubstantiated personal characteristics, including, but not limited to, race, gender, diet, and body weight, are not acceptable evidence without medical studies which demonstrate that the donor did produce the laboratory result."

Reference: The proposed §26.185(i)(1): "If the HHS-certified laboratory reports a specimen as adulterated with a specific substance, the MRO shall contact the donor and offer the donor an opportunity to provide a legitimate medical explanation for the adulterated result. The burden of proof resides solely with the donor, who must provide legitimate medical evidence within 5 business days that he or she produced the adulterated result through normal human physiology. Any medical evidence must be submitted through a referral physician experienced and qualified in the medical issues involved."

Recommendation: The industry recommends NRC implement §26.185(f)(2), §26.185(f)(3), §26.185(g)(1), §26.185(h)(1) and §26.185(i)(1) as proposed.

2.16 Issue: Paragraph 26.185(j)(6) Drugs contained in Schedule I of section 202 of the Controlled Substances Act

Discussion: The industry agrees with the proposed §26.185(j)(6). The use of drugs contained in Schedule I is a fitness for duty policy violation.

Reference: The proposed §26.185(j)(6): "The MRO may not consider the use of any drug contained in Schedule I of section 202 of the Controlled Substances Act [21 U.S.C. 812] as a legitimate medical explanation for a positive confirmatory drug test result, even if the drug may be legally prescribed and used under State law."

Recommendation: The industry recommends NRC implement §26.185(j)(6) as proposed.

Section 3
Responses to NRC Comment Solicitations

The following responses are provided for the specific questions contained in the Federal Register Notice. The issue number is the same as the requested supplemental information.

3.1 Issue 1. Proposed sanction for attempted subversion of the testing process. Proposed §26.75 in Subpart D would increase the sanctions for certain testing-related actions by requiring that: "Any act or attempted act to subvert the testing process, including refusing to provide a specimen and providing or attempting to provide a substituted or adulterated specimen, for any test required under this part must result in permanent denial of authorization," and "for individuals whose authorization was denied for 5 years ... any subsequent violation of the drug and alcohol provisions of an FFD policy must immediately result in permanent denial of authorization." The NRC requests comments regarding these proposed changes specifically when compared to the 5-year ban available through the agency's enforcement policy for other acts of deliberate misconduct.

Response: Many in the industry are currently have policies of permanent denial as an individual sanction and program element to deter such acts. Attempted subversion must also be considered by the reviewing official during the trustworthiness and reliability decision required in §73.56(b).

3.2 Issue 2. Need for "shy lung" procedures. Proposed §26.119 [Determining "shy" bladder] would establish a process for determining whether there is a medical reason that a donor is unable to provide a urine specimen of at least 30 mL. The NRC added this proposed section in response to stakeholder requests and adapted the process from the DOT's Procedures for Transportation Workplace Drug and Alcohol Testing Programs (49 CFR 40.197). The DOT Procedures also include processes for determining whether there is a medical reason that a donor is unable to provide a specimen of oral fluids (49 CFR 40.263) or a breath specimen (49 CFR 40.265) of sufficient quantity to support alcohol testing. The NRC invites comments on whether the NRC should consider incorporating these processes for insufficient oral fluids and breath specimens in Part 26.

Response: The industry sees no need for a shy lung provision based on many years experience with the current rule requirements.

3.3 Issue 3. Forensic toxicologist. Proposed §26.31(d)(3)(iii)(C) would permit licensees and other entities to specify more stringent cutoff levels for the panel of drugs for which testing is required under this part without informing the NRC within 60 days and without obtaining the written approval of the NRC. Proposed §26.31(d)(1)(i)(D) and (d)(1)(ii) would also permit licensees and other entities to test for drugs and drug metabolites in addition to those specified in proposed §26.31(d)(1) without informing or obtaining the written approval of the NRC. However, the proposed paragraphs would require that the scientific and technical suitability of the more stringent cutoff levels and of the assays and cutoff levels used to test for additional drugs or drug metabolites must be evaluated and certified, in writing, by a qualified, independent forensic toxicologist. Certification by a forensic toxicologist would not be required in three circumstances: (1) if the HHS issues more stringent cutoff levels in the HHS Guidelines and the licensee or other entity adopts the revised HHS cutoffs; (2) if the HHS Guidelines are revised to authorize use of the assay in testing for the additional drug or drug metabolites and the licensee or other entity uses the cutoff levels established in the HHS Guidelines for the drug or drug metabolites; and (3) if the licensee or other entity received written approval from the NRC for the lower cutoff levels and/or for testing for the additional drugs or drug metabolites, under current Section 1.1(2) in Appendix A to Part 26. The proposed paragraphs differ from the current requirement in Section 1.1(2) of Appendix A to Part 26. The NRC requests comments regarding these proposed changes.

Response: The industry has no comments.

3.4 Issue 4. Changes to opiate testing. Proposed §26.133 and §26.163 would raise the cutoff levels for initial and confirmatory tests for opiates from 300 nanograms (ng) per milliliter (mL) to 2,000 ng/mL. The proposed rule would also require testing for 6-acetylmorphine (6-AM), a metabolite that comes only from heroin, using a 10 ng/mL confirmatory cutoff level for specimens that tested positive on the initial test. The proposed cutoff levels and new test would be consistent with those used by HHS and DOT, and would reduce the number of specimens in Part 26 programs that test positive for opiates at an HHS-certified laboratory but are subsequently determined to be negative by the MRO after consultation with the donor. The NRC invites comment on these proposed changes.

Response: The industry strongly supports with the proposed requirement as it increases the efficiency of FFD programs. The proposed requirement is consistent with Goal (3) of the Rulemaking Activity: "Improve the effectiveness and efficiency of FFD programs."

3.5 Issue 5. Specimen validity testing. In proposed §26.131, §26.137, §26.161, and §26.167, the NRC would add new requirements for validity testing of urine specimens to detect specimens that may have been adulterated, substituted, or diluted. The new requirements are adapted from practices the HHS published in the Federal Register on April 13, 2004 (69 FR 19643) as a final rule. The NRC invites public comment on the following issues related to the proposed validity testing requirements.

a. QA/QC requirements. Proposed §26.137 would establish quality assurance and quality control requirements for conducting validity and drug tests of urine specimens. The NRC seeks input regarding any technical and methodological barriers to implementing these requirements at licensee testing facilities.

b. Criteria for identifying a substituted specimen. Proposed §§26.161(d) and 26.185(h) would establish criteria and procedures for determining whether a specimen has been substituted. A specimen would be reported by the HHS-certified laboratory to the MRO as substituted if it has a creatinine concentration of less than 2 mg/dL and specific gravity of less than or equal to 1.0010, or equal to or greater than 1.0200. For the HHS-certified laboratory to report a specimen as substituted, results in these ranges would be necessary on both the initial and confirmatory creatinine and specific gravity tests on two separate aliquots of the specimen. The NRC invites comments on the proposed provisions.

Response: The industry agrees that these requirements should be consistent with criteria established by HHS. The industry does not support more stringent requirements.

3.6 Issue 6. MRO training. Proposed §26.183(a) requires that "The MRO shall be knowledgeable of this part and of the FFD policies of the licensees and other entities for whom the MRO provides services." The NRC invites comments on whether Part 26 should establish specific training requirements for the MRO related to this part and the licensee's or other entity's programs for which the MRO provides services.

Response: The industry recommends NRC not regulate training for MROs. MROs are licensed by individual states and will be certified as required by the proposed rule. Additional regulation is not required to ensure MROs understand licensee policies and procedures.

3.7 Issue 7. Non-instrumented validity tests. The NRC is considering incorporating future changes to the draft HHS Guidelines that were published as a proposed rule for public comment in the Federal Register on April 13, 2004 (69 FR 19672) relating to the permission in this proposed Part 26 rule for licensees and other entities to use non-instrumented validity tests to determine whether a urine specimen appears to be adulterated, diluted, or substituted and requires further testing at an HHS-certified laboratory. Proposed Part 26 would permit licensees and other entities to use these devices for validity screening tests, in lieu of the instrumented validity testing required in the April 13, 2004, final version of the HHS Guidelines. Should any changes be made to those draft HHS Guidelines between issuing this proposed rule and issuing the final 10 CFR Part 26 rule, those changes would be considered for incorporation. Any comments related to the potential incorporation of those changes are of interest.

Response: The industry disagrees with the proposal. NRC should follow its own requirements in 10 CFR 2 Subpart H, Rulemaking. Particularly lacking in the proposal is the opportunity for participation by interested persons described in §2.805. Also lacking are the backfit analyses required by 10 CFR 50.109, 70.76, and 76.76. The NRC has offered no justification for bypassing its own processes in the brief discussion of this issue.

3.8 Issue 13. Adopting future changes to the HHS Guidelines without backfit. The NRC is considering amending 10 CFR 50.109, 70.76, and 76.76 to exclude certain future changes to Part 26 from current backfit requirements. The scope of the exclusions would be limited to only those changes to Part 26 that would be necessary to incorporate relevant revisions to the HHS Guidelines when they are published by HHS as final rules. Examples of changes to the HHS Guidelines that may be incorporated into Part 26 in future rulemakings may include, but would not be limited to
(1) adopting changes to the cutoff levels established in the Guidelines;
(2) the addition or deletion of drugs and adulterants for which testing would be required; and
(3) changes in the specimens, instruments, or assays used in drug and validity testing.
The NRC requests comment on excluding such future changes to Part 26 from backfit analysis requirements.

Response: The industry believes changes should not be made to 10 CFR 50.109, 10 CFR 70.76 and 10 CFR 76.76 to exclude certain future changes to Part 26 from current backfit requirements. Examples of the changes the NRC would like to make without backfit analyses, given in the comment solicitation, do not appear to provide "... a substantial increase in the overall protection of the public health and safety or the common defense and security

..." described in the subsections above. Lacking the "substantial increase" the industry believes NRC should not change 10 CFR 50.109, 10 CFR 70.76 and 10 CFR 76.76 to allow revision of regulations without determining whether the direct and indirect cost of the suggested changes are actually cost beneficial.

Further, the proposed §26.31(d)(1)(i) allows licensees and other entities to add other drugs to the panel of substances for testing. This allows licensees and other entities to add additional drugs popular in their local geographical areas. It also allows them to appropriate cutoff levels for any additional substances for which testing will be conducted. There is no need to revise 10 CFR 50.109, 10 CFR 70.76 and 10 CFR 76.76 given the proposed rule requirements.

Finally, the NRC has offered no justification for bypassing its own processes in the brief discussion of this issue. The examples given are not inclusive so the scope of possible changes is boundless.

3.9 Issue 14. Testing Bottle B of a split specimen. Proposed §26.135(b) and §26.165(a)(4) and (b)(1) would prohibit licensees and other entities, the MRO, and the NRC from initiating testing of the specimen in Bottle B or retesting an aliquot from a single specimen without the donor's written permission. The NRC is considering an alternative approach that would permit a licensee or other entity to initiate testing of the specimen in Bottle B or retesting an aliquot from a single specimen without the donor's written permission only if all of the following conditions are met:
(1) the first results from testing the specimen were confirmed as non-negative by the MRO;
(2)the donor has requested a review under proposed §26.39 or initiated legal proceedings; and
(3) the testing is conducted in accordance with proposed §26.165(c)–(e), as applicable.
Under either the proposed provisions or the alternative approach, the proposed rule would require the licensee or other entity to administratively withdraw the donor's authorization until the results from Bottle B or the retest results are available and to rely only on those results in determining whether the licensee or other entity would be required to take management actions or impose sanctions on the donor. The NRC is seeking an appropriate balance between protecting donors' rights to privacy and due process under the rule and the protection of public health and safety and the common defense and security, and invites public comment on the proposed and alternative approaches.

Response: The industry recommends NRC consider the protection of public health and safety and the common defense and security as the more significant goal. Nothing in the proposal negatively impacts the donor's rights under the rule. It appears that only the donor, the MRO and one employee of the licensee or other entity know the rationale for the administrative withdraw of the donor's authorization. It is difficult to envision a smaller number of people with this knowledge, so the donor's right to privacy is protected as well as it could be.