ACTION - Murley, N
Cys: Taylor
Sniezek
Thompson
Blaha
Halman

UNITED STATES
NUCLEAR REGULATORY COMMISSION
WASHINGTON, D.C. 20555

OFFICE OF THE
SECRETARY

March 27, 1991

IN RESPONSE, PLEASE
REFER TO: M910307A

MEMORANDUM FOR: James M. Taylor
Executive Director for Operations

FROM: Samuel J. Chilk, Secretary

SUBJECT: STAFF REQUIREMENTS - BRIEFING ON STATUS OF FITNESS FOR DUTY PROGRAMS, 10:00 A.M., THURSDAY, MARCH 7, 1991, COMMISSIONERS' CONFERENCE ROOM, ONE WHITE FLINT NORTH, ROCKVILLE, MARYLAND (OPEN TO PUBLIC ATTENDANCE)

The Commission was briefed by the NRC staff on the status of the Fitness-For-Duty program.

The Commission expressed an interest in a more detailed breakdown of the test data to include the following:

1. Specific results on licensed operators, including the drugs for which they tested positive and the percentage of the initial positive tests which were confirmed positive

2. Correlation between the reasons for each of the for-cause testing categories and the associated results for each category

3. Details on test reliability and comparisons from NIDA on other drug testing programs used by other industries or agencies

4. How differences in the cutoff level for each drug tested may be affecting the number of initial and confirmed positive results obtained

5. Any data available on licensee Fitness-For-Duty program costs -- both for initial set-up as well as annual implementation.

~~(EDO)~~ (NRR) (SECY Suspense: 9/13/91) 9100061

The Commission requested more detail on a sampling of specific programs being used by various utilities and the rate at which initial positive results are confirmed by the second test.

~~(EDO)~~ (NRR) (SECY Suspense: 4/26/91) 9100062

Rec'd Off. EDO
Date 3-27-91
Time 2:00 p.m.

The Commission also raised several concerns which the staff should investigate for potential changes to the Fitness-For-Duty rule. The staff should consider 1) the process for extrapolating test results back to the time an individual reported for duty, 2) requiring that the individuals involved in the testing process also be subject to the testing, 3) specifically requiring individuals to be provided copies of their drug test records, and 4) the need to be more explicit in setting requirements for individuals to participate in follow-up testing.

~~(EDO)~~ (NRR) (SECY Suspense: 9/13/91) 9100063

The Commission was also interested in the dissemination of the Fitness-For-Duty report to ensure that those subjected to the program were apprised of the results. The licensed operators in particular should be sent a copy of the report. The staff should also consider methods of making the report available to contractors who are subject to the testing program.

~~(EDO)~~ (NRR) (SECY Suspense: 5/15/91) 9100064

Commissioner Curtiss, in a memorandum dated March 8, 1991 (attached),* requested the staff to respond to several questions related to the reliability of initial screening tests and the propriety of taking personnel actions solely on the basis of such test results. Because this information is central to the issue raised in SECY-91-048, Amendment To The Fitness-For-Duty Rule, Commissioner Curtiss wishes to review the staff's response before voting on the amendment.

*EDO-6205 - Proposed response received EDO 3/25/91

Attachment:
As stated

cc: Chairman Carr
Commissioner Rogers
Commissioner Curtiss
Commissioner Remick
OGC
GPA
ACRS
PDR - Advance
DCS - P1-24

POLICY ISSUE
(Notation Vote)

September 17, 1991 SECY-91-293

For: The Commissioners

From: James M. Taylor
Executive Director for Operations

Subject: ASSESSMENT OF IMPLEMENTATION OF THE FITNESS-FOR-DUTY (FFD) RULE AND NEED FOR CHANGES TO THE RULE

Purpose: To inform the Commission of the staff's assessment of the implementation of FFD programs, to inform the Commission of changes to the rule recommended by the staff to address identified problems, and to obtain the Commission's approval on certain alternate courses of action.

Background: On June 7, 1989, the Commission published 10 CFR Part 26, "Fitness-for-Duty Programs," in the Federal Register (54 FR 24468). The FFD rule, which requires each licensee authorized to operate or construct a nuclear power reactor to have an FFD program, became effective on July 7, 1989, and was to be implemented by January 3, 1990.

When the Commission directed the staff by memorandum dated March 22, 1989, to finalize the FFD rule and publish it in the Federal Register it instructed the staff to review the need for changes to the rule within 18 months following the rule's implementation date.

On March 7, 1991, the staff briefed the Commission on the status of implementation of the rule and on its observations of program implementation. Following that briefing, the Commission directed the staff by memorandum dated March 27, 1991, to investigate and change, where appropriate, the following specific areas of the rule: (1) a process for

Contact: L. Bush, NRR
492-0944

NOTE: TO BE MADE PUBLICLY AVAILABLE WHEN THE FINAL SRM IS MADE AVAILABLE

extrapolating alcohol test results back to the time an individual reported for duty; (2) a requirement that the individuals involved in the testing process also be subject to testing; (3) a specific requirement for individuals to be provided copies of their drug test records; and (4) an explicit requirement for individuals to participate in followup testing.

During the status briefing of the Commission on March 7, 1991, the staff summarized its assessment of the effectiveness of the rule as follows: (1) the rule is sound and provides a means for both detection and deterrence, (2) the staff identified a number of implementation issues that need to be addressed, and (3) the staff has observed noteworthy licensee programs and personnel that have contributed to successful implementation of the rule.

Discussion:

The staff has evaluated information from a number of sources to determine the effectiveness of the rule and identify areas that may need to be changed. These sources include inspections, periodic reports by licensees on program performance, reports of significant FFD events, industry-sponsored meetings, initiatives by the Nuclear Management and Resources Council (NUMARC) and the National Institute on Drug Abuse (NIDA), and reviews of current literature.

While the staff concludes that its assessment of the rule provided to the Commission on March 7, 1991, continues to be valid and that no fundamental changes to 10 CFR Part 26 are needed, a number of implementation issues have been identified that should be addressed. In most cases, the staff believes the Commission should address these issues by revising the rule. In a few other cases, courses of action other than rulemaking may suitably address the issue. In Enclosure 1, the staff describes four significant implementation issues where alternatives to rulemaking should be considered, discusses alternative approaches for resolution, and presents its recommendations.

In Enclosure 2, the staff describes amendments to the rule it proposes to develop and states the reason why the amendment would be appropriate. These amendments would address lessons learned from experience with implementation of the rule. While none of the amendments proposed in Enclosure 2 represent major changes, they do represent modifications that the staff considers would enhance overall program integrity.

The areas that the Commission directed the staff to consider on March 27, 1991, are addressed by items 1, 6, 8, 14, 16, and 33 of Enclosure 2. Additionally, several minor changes to the rule are needed to ensure consistency or to achieve clarity and are not specifically identified, but will be included in the proposed amendment.

Enclosure 3 provides a description of each source of information that the staff reviewed. Enclosure 4 is a copy of the NUMARC letter recommending changes to the rule based upon the industry's first year of experience with FFD programs. Many of NUMARC's recommendations are consistent with the changes recommended by the staff. In developing the proposed amendment to the rule, the staff will consider NUMARC's comments in more detail.

Subject to Commission approval, the staff will initiate rulemaking to address the issues identified in Enclosures 1 and 2, which will include a more detailed regulatory analysis of each issue. This analysis, particularly for the issues discussed in Enclosure 2, may show that some of the proposed changes do not meet criteria for rule change. Also, further experience with implementation of the rule may identify additional areas of the FFD rule where amendments may be needed. The changes to the rule discussed herein, as well as any other changes to the rule, will be processed in accordance with procedures for proposed rulemaking, which will include review by the Committee to Review Generic Requirements and the Advisory Committee on Reactor Safeguards.

Resource Impacts: The development of the proposed rule will be accomplished within existing budgeted resources.

Coordination: The Office of the General Counsel has no legal objections to the staff's recommendations.

Recommendation: That the Commission:

1. Approve the staff's recommendations in Enclosure 1.

2. Direct the staff to develop a proposed amendment to the FFD rule as summarized in Enclosure 2 and provide it to the Commission by March 31, 1992.

James M. Taylor
Executive Director
for Operations

Enclosures:
1. Significant Issues: Alternatives to Changes to the FFD Rule
2. Summary Description of Proposed Amendments
3. Sources of Information
4. Letter from NUMARC, April 7, 1991

Commissioners' comments or consent should be provided directly to the Office of the Secretary by COB Tuesday, October 1, 1991.

Commission Staff Office comments, if any, should be submitted to the Commissioners NLT Tuesday, September 24, 1991, with an information copy to the Office of the Secretary. If the paper is of such a nature that it requires additional review and comment, the Commissioners and the Secretariat should be apprised of when comments may be expected.

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ENCLOSURE 1

SIGNIFICANT ISSUES: ALTERNATIVES TO CHANGES TO THE FFD RULE

ENCLOSURE 1

SIGNIFICANT ISSUES: ALTERNATIVES TO CHANGES TO THE FFD RULE

1. Issue: Should the Commission address technical drug testing issues that are concurrently being addressed by HHS/NIDA?

Discussion

Appendix A of Part 26 is the NRC's adaptation of the U. S. Department of Health and Human Services' (HHS) "Mandatory Guidelines for Federal Workplace Drug Testing Programs" (HHS Guidelines). NIDA is developing a number of revisions to the HHS Guidelines that would address issues identified by the NRC. They include the following:

a. Lowering the cutoff level for marijuana screening tests from 100 ng/ml to 50 ng/ml.

b. Eliminating the requirement that certified laboratories report as a "batch" the testing results of all specimens received at the same time as a quality control measure.

c. Reducing the required minimum quantity of each urine specimen from 60 ml to 30 ml.

NIDA is not planning to revise the HHS Guidelines to set lower cutoff levels for marijuana confirmation tests and for cocaine testing. Also, NIDA is not planning changes that would add barbiturates and benzodiazepines to the required drug testing panel. In addition, the staff is not aware of any initiatives by NIDA to revise the specified procedures designed to detect tampering with, or adulterating, the urine specimen. Similarly, the current requirements do not include measures for preventing surrogate specimens from being submitted, a problem that has been reported by licensees on several recent occasions. The central issue is whether the Commission should follow NIDA's lead in these technical testing matters, or whether the Commission should direct the staff to independently develop changes to Appendix A of Part 26.

Alternatives

a. Revise Appendix A of Part 26 independent of NIDA's efforts. This may provide a more timely approach for addressing some technical drug testing issues.

b. Coordinate the revision to Appendix A of Part 26 with NIDA's current work to revise its Guidelines. This would provide for a "united" Federal approach. Most NRC licensees must meet both the NRC's and the U.S. Department of Transportation's (DOT's) requirements for drug testing which, in some cases, is for over 300 employees. Differences in testing requirements between the NRC and the DOT, which follows the HHS Guidelines, could cause problems for licensees in implementing their programs. Variations of this alternative would be to use NIDA's

proposed amendments as the basis for NRC's proposed amendments and possibly modify them according to NRC's needs or wait until NIDA has considered public comments and published the final amendments.

Recommendation

Track NIDA's development of its amended HHS Guidelines and revise Appendix A of Part 26 according to NIDA's revisions with minor modifications appropriate to NRC needs. The staff will not include matters NIDA determined inappropriate, as described above. The staff would work with NIDA on modifications to Appendix A that are deemed appropriate but not addressed by NIDA, such as providing records to tested persons, reporting certain testing errors, establishing more restrictive temperature standards for urine specimens, and requiring measures to prevent surrogate specimens from being introduced.

2. Issue: Should action be taken to eliminate predictability of random testing?

Discussion

The NRC staff believes that any predictability in random testing will reduce the desired deterrent effect required by 10 CFR 26.24(a). The two most significant causes of predictability in random testing are (a) the failure to test persons with infrequent access when they are not on site, and (b) the failure to test on weekends and holidays. Other causes of predictability have been resolved.

a. Infrequent access. Some licensees have a large number of people (mostly contractors and vendors, but also corporate and other licensee employees) who are retained on the site's unescorted access list and, therefore, must be included in the licensee's FFD program. The fact that these people infrequently enter the site creates problems for certain licensees in implementing their programs.

   - At some sites, these persons are only at risk of being tested on those infrequent occasions when they are on site.
   - Persons normally on site are tested at a higher frequency to compensate for those in the testing population who have infrequent access and a lesser probability of being tested.

b. Testing on weekends and backshifts. Many licensees have devised methods to randomly test individuals at various times and during weekends and backshifts. Some of these are token efforts and are not very effective. Such testing requires significant amounts of labor and produces little results. Some licensees were not conducting such tests when the staff inspected their facilities and claimed that the rule did not require such testing.

Alternatives

a. Revise the rule to establish more specific testing requirements for persons with infrequent access and for testing during weekends and holidays. For example, testing could be required before a person obtains unescorted access if that individual had not been at risk of random testing for a specified period. This should not affect those programs where these individuals are randomly tested when not on site. However, it is unlikely a rule change to address these issues could address all variations.

b. The staff could develop a regulatory guide that presents acceptable approaches.

c. NUMARC could develop guidance documents that present alternatives for addressing these issues. At public meetings with the NRC, NUMARC has indicated a willingness to undertake such a task. The staff could follow NUMARC's development of these documents and monitor licensee adherence to these practices. NUMARC has demonstrated an ability to obtain the industry's consensus on a number of similar issues under both the Access Authorization and Fitness-for-Duty Programs.

Recommendation

The staff considers that this issue should be addressed by a combination of alternatives a and c discussed above. The rule should be revised to specify drug testing before access or return to service for persons who have prolonged absences from the risk of being randomly tested. With this broad regulatory basis established, NUMARC would develop guidance which would be reviewed and possibly endorsed by the NRC staff.

3. Issue: What is an appropriate random testing rate?

Discussion

This issue was discussed at length during the rulemaking process. The Commission specifically invited the public to comment on the rates of random testing that would provide an acceptable probability of detection and adequate deterrence (53 FR 36796). Public comments strongly opposed a 300 percent rate; NUMARC and most licensees proposed a 100 percent rate which should be re-evaluated based on utility experience and be reduced to 25 percent if warranted (54 FR 24472). The Commission indicated that it would consider reducing testing rates after several years if it obtained information of positive experience in the industry (54 FR 24474).

Reducing the testing rate would reduce testing costs for licensees and may not significantly affect the effectiveness of the program. However, the staff has no empirical evidence to support any changes to the random testing rate. Some theoretical evidence indicates that reducing the testing rate moderately would not significantly affect the deterrent effect of random testing. Furthermore, positive tests are more likely the result of the frequency of use and the metabolic absorption rate of the drug than of the

frequency of random testing. Our contractor evaluated drug metabolism rates and the probabilities of being tested early in the metabolism process and concluded that the probabilities of detecting a frequent abuser during a 5-year period are fairly high, whereas the probability of detecting an infrequent user of a quickly metabolized drug are quite small.

During the March 7, 1991, briefing of the Commission on the status of the implementation of the FFD rule, the staff explained that it and its contractor are developing a test program to demonstrate the effectiveness of various testing rates and program strategies. On May 17, 1991, the Federal Railroad Administration announced a similar test program (56 FR 22905).

Alternatives

a. Finish developing the test program and recommend it to the Commission before selecting participating licensees and implementing the test program. Upon receiving the Commission's approval, announce the program in the Federal Register. Analyze the results of the program and, if appropriate, propose an amendment to the rule.

b. Accept the assumption that reducing the rate of random testing would minimally affect deterrence and detection, and modify the regulation to lower the rate. Although this alternative is not a scientific approach, it would be accomplished quickly with the least effect on the staff's resources.

Recommendation

Direct the staff to conduct a test program, analyze the results, and recommend an appropriate random testing rate by the middle of 1994. The direction should allow the staff to collect and analyze data over 2 years (CY 92 and 93) with a controlled variation of testing rates at about 8 sites.

4. Issue: Should the Commission specify how positive test results obtained prior to the FFD rule must be treated?

Discussion:

Part 26 does not require a licensee to treat positive drug tests obtained before the rule was implemented on January 3, 1990, as a positive test with respect to the imposition of the current required minimum sanctions. Licensees, on their own initiative, may choose to do so. Consequently, this initiative has resulted in some inconsistencies in the manner in which licensees consider test results obtained before the rule and the actions they take. Some licensees will provide employment opportunities (i.e., retention or rehiring) to those who tested positive before the rule was implemented and who can demonstrate current fitness for duty. Frequently, licensees will not consider using such persons.

Those licensees who do not consider positive test results obtained before the rule was implemented as a disqualifying factor, do so because they believe the results may be questionable in many cases, for the following reasons:

- There was no HHS laboratory certification program, and many of the laboratories being used did not meet current performance standards for accuracy and reliability.

- In some cases, confirmation tests may not have been conducted.

- In many cases, there was no review by a technically qualified person, such as a Medical Review Officer (MRO), to determine if legitimate uses of drugs were causing the results reported by the laboratories.

Not considering positive test results obtained before the rule was implemented could result in persons who have a significant past history of drug abuse being summarily granted unescorted access. Those licensees who do consider tests performed before the rule was implemented often have taken an uncompromising position with any past evidence of a person's past drug use or current fitness for duty. The staff has been informed of several cases in which persons alleged they had a record of a questionably positive drug test 5 to 10 years ago, have since worked in the nuclear industry with a good work record and no positive drug tests, and are now denied employment.

Alternatives

a. Modify the rule to specify certain conditions under which to accept (or reject) a test performed before the rule was implemented. For example, the rule could be amended to preclude licensees from considering information (1) that was greater than 10 years old, (2) that was not confirmed by a gas chromatography/mass spectrometry (GC/MS) test and reviewed by an MRO, and (3) that covered positives from the drugs for which the results are most likely questionable, such as amphetamines and opiates. A companion modification to the rule would be to establish a standard for acceptable rehabilitation from a valid positive test result obtained before the rule. This alternative could also eliminate possible conflict with other laws.

b. Make no regulatory changes. The Americans With Disabilities Act may have precedence in this area and may preclude licensees from taking action for past drug use if rehabilitation could be verified. However, if the NRC did not make changes to the regulations, "case law" could eventually establish the standards that would be developed under alternative a.

Recommendation

Make no regulatory changes. To establish criteria under which a test performed before the rule may be acceptable (or not acceptable) could not possibly cover all circumstances and would be difficult for licensees to implement.

ENCLOSURE 2

SUMMARY DESCRIPTION OF PROPOSED AMENDMENTS

ENCLOSURE 2

SUMMARY DESCRIPTION OF PROPOSED AMENDMENTS

This enclosure contains changes to 10 CFR Part 26 that the staff intends to pursue in the rulemaking process. The proposed actions do not address significant programmatic issues, but do address some distinct issues identified during implementation of the rule. Most of the proposed actions provide enhancements or clarifications that would strengthen the overall integrity of licensee's FFD programs.

NRC inspection findings identified nearly two thirds of the issues addressed by the proposed actions and over one half were identified by licensees' event reports. NUMARC's proposed changes to the rule (Enclosure 4) cover many of the same issues addressed by the following proposed actions. Six of the proposed actions (Items 1, 6, 8, 14, 16, and 33) address actions the Commission asked the staff to consider.

The proposed actions are presented in order of the organization of 10 CFR Part 26. It should be noted that Proposed Actions 16 through 33 present proposed actions associated with changes to 10 CFR Part 26, Appendix A. These changes generally cover more specific laboratory processes issues.

10 CFR PART 26: FITNESS-FOR-DUTY PROGRAMS

Section 26.2: Scope

Proposed Action 1: Revise the scope to include as subject to testing those individuals responsible for administering the FFD program (MROs, collection and testing staff, those responsible for selecting and notifying those chosen for testing, and any person responsible for determining fitness for duty or suitability for return to service or prescribing treatment for or monitoring a condition covered by 10 CFR Part 26).

Reason: The current rule, in response to several incidents of subversion by the FFD staff, requires that such personnel meet the highest standards for honesty and integrity. However, at many sites these individuals are not tested because they work outside the protected area and are therefore not covered by the rule. One licensee recently added the collection personnel to the testing pool after an investigation of an allegation determined that two of the specimen collectors were substance abusers. Actions by these personnel may indirectly affect safety by permitting substance abusers to remain undetected. Furthermore, their omission undermines the credibility of the program. In the SRM of March 27, 1991, the Commission asked the staff to consider this change.

Proposed Action 2: Clarify the requirements for plants being decommissioned or in long-term shutdown.

Reason: Provide the regulatory basis for actions to reduce FFD program requirements according to the plant's decommissioning status.

Section 26.3: Definitions

A number of changes have been suggested for the definitions. In most cases, these are minor changes to clarify the meaning of the rule. Two examples of key suggested changes are discussed below.

Proposed Action 3: Define "determination of fitness."

Reason: Adding this definition would provide a standard regarding what constitutes a determination that someone is fit to return to duty. The staff has learned of cases in which the determination had little or no basis. For example, in some instances, the determination was made after simply administering a drug or alcohol test that yielded a negative result. In other cases, the determination included only a cursory observation by a medical person.

Proposed Action 4: Clarify or define terms for different types of chemical tests and use these terms consistently. Examples of terms that would be clarified include the following: Preliminary screening test, initial screening test, laboratory-confirmed positive, MRO-verified confirmed positive, and non-negative as opposed to presumptive positive.

Reason: These terms are used in 10 CFR Part 26 in ways that could confuse the reader. For example, "initial screening tests" and "preliminary initial screening" are used in some sections to refer to the onsite screening test.

Section 26.24: Chemical testing

Proposed Action 5: Add a requirement to Section 26.24(a) for "Return to Service" testing after any removal for cause as described under Section 26.27(b)(2), or after a prolonged absence from a risk of being randomly tested.

Reason: This would more clearly define the grounds for determination of fitness (see proposed action 3) before an individual resumes his or her duties and provides a basis on which the industry could develop guidance for the testing of persons with infrequent access (see discussion at item 2 of Enclosure 1).

Proposed Action 6: Clarify followup testing, perhaps by adopting words from Section 26.27(b)(4).

Reason: This would ensure that such testing is flexible and designed for a specific patient's medical history and needs. Some licensees have not met expectations since the rule does not specify the

minimum requirements for followup testing, particularly after a person's first confirmed positive test. In the SRM of March 27, 1991, the Commission asked the staff to consider this change.

Proposed Action 7: Change the requirement for MRO review so that the review would be completed within 12 working days of collecting the specimen instead of 10 days of the initial screening test.

Reason: The current time requirement is unclear ("initial" test sometimes refers to onsite testing) and does not address the manner in which the licensees actually administer their programs as indicated by MROs during inspections and meetings.

Proposed Action 8: Revise the regulation to specifically address the use of calculations in alcohol tests to extrapolate back to the time an individual reported for duty.

Reason: This requirement would ensure that alcohol abusers tested late in their work shift could be identified since alcohol is metabolized rapidly. However, the staff's contractor indicated that there were some situations where extrapolating backward may be difficult to defend technically and legally. For example, a person reporting to work with a .03% BAC may not have violated the abstention requirement. In the SRM of March 27, 1991, the Commission asked the staff to consider this change.

Section 26.27: Management actions and sanctions to be imposed

Proposed Action 9: Clarify this section to specifically address the duration and frequency of followup testing.

Reason: This modification to followup testing (and clarification of testing for return to service) would be consistent with the modifications to Section 26.24(a), discussed in Proposed Actions 5 and 6.

Proposed Action 10: Specify minimum sanctions for alcohol.

Reason: Licensees vary widely in their responses to alcohol abuse, ranging from issuing a 3-day suspension to terminating employment. This variation could affect the overall effectiveness of the program. If the licensee is lenient, this variation may prompt individuals to substitute alcohol for illegal drugs as a substance for abuse.

Proposed Action 11: Clarify that refusals to provide a specimen and resignation before being removed for an FFD violation must be documented on the employee's record and treated as if it were a positive test result.

Reason: By refusing a test or resigning, a worker may avoid having a record of the FFD violation that would be found under a suitable inquiry if the person were to apply for unescorted access to another facility.

Proposed Action 12: Reevaluate the amount of time that licensees must keep various types of records.

Reason: Some industry experience suggests that, by requiring licensees to keep records longer, the NRC might facilitate the transfer of information from one licensee to another and may improve the efficiency and effectiveness of suitable inquiries required as part of the FFD rule.

Section 26.28: Appeals

Proposed Action 13: Modify this section to clearly include in the appeals process all persons whose specimens may be used for pre-access testing regardless of employment status. A supporting change to Section 26.24 would require that any test for which the licensee takes credit as a pre-access test must meet all provisions of Part 26.

Reason: Although the careers of applicants for unescorted access (particularly individuals not employed by the licensee) can be negatively affected if they test positive, the rule does not clearly require licensees to afford such applicants an opportunity to appeal test results. The staff believes that if a specimen is to be used to meet Part 26 requirements all of Part 26, including appeals and protection of information, should be applicable.

Section 26.29: Protection of information

Proposed Action 14: Clarify this section so that it requires the licensee to provide written disclosure of positive test results and associated records to the individual or his or her representative upon written request.

Reason: Some licensees have been interpreting this section in ways that make it difficult for employees to obtain their records. In the SRM of March 27, 1991, the Commission asked the staff to consider this change.

Proposed Action 15: Permit the licensee to disclose information to a contractor or vendor employer of a tested individual.

Reason: The staff's original intent when this section was written was to permit such disclosure. However, omission of clear statements in the rule to allow this practice complicates implementation, particularly the conduct of suitable inquiries.

APPENDIX A, "GUIDELINES FOR NUCLEAR POWER PLANT DRUG AND ALCOHOL TESTING PROGRAMS"

Section 1.2: Definitions

A number of changes have been suggested to the definitions. Most of these are minor changes to clarify the meaning of the rule.

Section 2.3: Preventing Subversion of Testing

Proposed Action 16: Revise this section to include as subject to testing those individuals responsible for administering the FFD program (MROs, collection and testing staff, those responsible for selecting and notifying those chosen for testing, and any person responsible for determining fitness for duty or suitability for return to service or prescribing treatment for or monitoring a condition covered by 10 CFR Part 26). Also, revise to ensure that they are subject to testing (companion change to 10 CFR 26.2).

Reason: At many sites, these individuals are outside the protected area and are therefore not covered by the rule. Actions by these personnel may indirectly affect safety by permitting substance abusers to remain undetected. Furthermore, their omission undermines the credibility of the program. In the SRM of March 27, 1991, the Commission asked the staff to consider this change.

Section 2.4: Specimen Collection Procedures

Proposed Action 17: Require licensees to test for the specific gravity and acidity (pH) of the specimen at the collection site.

Reason: These simple tests provide important information that would reveal attempts to subvert testing by persons being tested and would form the basis for immediately collecting an observed specimen, which now occurs several days later when the laboratory report is received. The staff also considered proposing onsite testing for creatinine (an amino acid found in urine), but has concluded that the tests for specific gravity and acidity are sufficient. Furthermore, the test for creatinine requires sophisticated equipment and highly trained personnel.

Proposed Action 18: Clarify that the chain of custody must be maintained between the licensee and the laboratory in accordance with standard forensic practices (i.e., a registration number is shown as the "person" having custody) while the specimen is being shipped.

Reason: The lack of a clear requirement for a chain of custody can undermine the integrity of the program.

Proposed Action 19: Change the amount of urine required to 30 mils or "sufficient quantity" instead of 60 mils.

Reason: This would adopt, with some modifications, expected revisions in NIDA guidelines, but would accommodate the licensee's unique needs, for onsite testing, split samples, and tests for additional drugs. This change would be made consistent with the alternatives recommended in Enclosure 1, Item 1.

Proposed Action 20: Establish more restrictive standards on the temperature of an acceptable urine specimen at the time of collection. The current requirement is to measure the temperature within 4 minutes and to ensure that it is within the temperature range of 90.5 °F to 99.8. °F.

Reason: Current technology can improve the ability to assess the temperature of the urine and would make it more difficult to subvert the testing process. This change would support the changes taken in proposed action 21. The staff would obtain NIDA's comments on this departure from the HHS Guidelines.

Proposed Action 21: Require measures to prevent surrogate specimens from being submitted. For example, this could take the form of denying opportunities to obtain a surrogate sample after notification or pat-down searches. NOTE: A diminished expectation of privacy is already established since all persons entering the protected area are subject to such searches under conditions specified in 10 CFR 73.55(d)(1).

Reason: The staff is aware of several cases where surrogate samples have been submitted. For example, an undercover investigator successfully did so during one licensee's investigation into an allegation of its vulnerability to such acts, a security supervisor described how he successfully submitted his son's urine during two different random tests, and a licensed operator failed in his attempt when the temperature of the surrogate specimen was only one-half of a degree below the standard.

Section 2.7: Laboratories and Testing Facilities Analysis Procedures

Proposed Action 22: Review and improve, if needed, requirements to refrigerate and freeze specimens on site and in transit (requirements for specimens at the HHS-certified laboratory are adequate).

Reason: Changes, if needed, would ensure the maximum possible integrity of the specimens. For example, one MRO reported that a number of onsite presumptive positives had not been confirmed. Several licensees submitted reports of blind performance specimens degrading below the cutoff levels. In many cases, the licensee or the laboratory postulated that the specimens had become degraded in storage or shipment.

Proposed Action 23: Require the licensee to use a different HHS-certified laboratory to retest appealed specimens.

Reason: This change would reduce the possibility of false positive results. This was a solution used by a licensee in addressing a false positive and by NIDA in addressing process errors in testing for amphetamines. NIDA has informed the staff that since the certified laboratories currently use different analytical procedures, e.g., extraction procedures, derivatizing reagents, GC parameters, and mass analysis procedures, requiring the use of a different laboratory would be sufficient to protect against a repetitive false positive result.

Proposed Action 24: Modify the section to permit management to act on information concerning adulteration and trace amounts of drugs found in suspect specimens currently required by Section 2.7(d) to be reported to the MRO.

Reason: This change would permit management to act on information regarding suspected subversion of specimens and provide additional deterrence from an individual's attempts to subvert his or her test.

Proposed Action 25: Lower screening level for marijuana to 50 ng per ml.

Reason: This change would make the rule consistent with the expected revision to the HHS guidelines. This change would be made consistent with the alternative recommended in Enclosure 1, Item 1.

Proposed Action 26: Make the test for 6 monoacetylmorphine (6-MAM) optional rather than mandatory.

Reason: The industry has found that this test is unnecessary and technically limited. For example, (1) the test would provide evidence only of recent heroin use and not other opiates, and (2) the 6-MAM is present in detectable quantities for only a very short period of time, typically up to 8 hours after the use of heroin.

Proposed Action 27: Eliminate the requirement for batch reporting.

Reason: To make the rule consistent with the expected revision to the HHS guidelines. This change would be made consistent with the alternatives recommended in Enclosure 1, Item 1.

Proposed Action 28: Require laboratories to report to the MRO the quantitative results of both positive and negative specimens, and require the MRO to review reports with detectable amounts of drugs and initiate appropriate medical treatment where a problem is indicated. Reporting such test results and treatment to management and the imposition of any sanctions would be prohibited.

Reason: This change would increase the number of substance abusers who are identified and would allow the MRO to identify and confront the substance abuser and begin treatment when the probability of

successful rehabilitation is greatest. For example, as demonstrated in at least one case to the staff, a laboratory report was negative but indicated levels of marijuana and cocaine below the cutoff levels. The MRO confronted the employee (a licensed operator) who admitted his substance abuse problem and then entered a rehabilitation program. In this instance, management sanctions were inappropriate because the MRO acted in response to test results below cutoff levels.

NIDA opposes this proposed action because (1) the limit of detection of each GC/MS procedure replaces the cutoff levels, and (2) there is an increased opportunity for this information to lead to adverse personnel actions and not be limited to treatment/rehabilitation purposes. Staff believes this action could be beneficial to the overall effectiveness of the FFD program and potentially adverse aspects can be controlled by prohibiting management from being informed and taking actions.

Proposed Action 29: Permit the MROs to request their staffs to accomplish a number of administrative tasks. These include receiving and collecting data and documents to prepare for the MRO's interview and notifying the person of need to see the MRO.

Reason: These changes would improve the timeliness of the MRO's interview of a person whose specimen was reported by the certified laboratory as positive and to relieve the MRO of routine administrative responsibilities that can be done equally well by others who can be more attentive to these details.

Proposed Action 30: Add a statement to permit the licensee to send specimens to another certified laboratory without first auditing the second laboratory if the laboratory with which it had contracted loses its certification in whole or in part. A prompt audit would be required. Licensees could take credit for an audit by another licensee.

Reason: This change would maintain the integrity of the program and permit the licensee to continue testing with minimal interruption.

Section 2.8: Quality Assurance and Quality Control

Proposed Action 31: Review and revise, as appropriate, the sections on requirements for quality assurance (such as the quality control requirements for the licensee's testing facility and the blind performance testing rates) and the section on the licensee's investigation and reporting of unsatisfactory test results from HHS-certified laboratories. For example, the current rule requires the reporting of errors on blind performance tests but does not require the reporting of an actual false positive.

Reason: This change would improve the efficiency and effectiveness of these measures.

Section 2.9: Reporting and Review of Results

Proposed Action 32: Review and modify, as necessary, the responsibilities and the reporting requirements of the MRO.

Reason: These changes would take advantage of lessons learned and better support the broad spectrum of fitness-for-duty issues that MROs are encountering. For example, many MROs interpret the requirement to determine if there is clinical evidence of unauthorized use of opiates to mean that there must be clinical evidence of abuse before an opiate positive can be declared. Some MROs contend that this is the reason that so few opiates were declared as positives. To a lesser extent, the same problem exists with prescription and over-the-counter drugs. Also, MROs need to document activities and data considered in the review process so that they can testify, an activity they are not usually prepared to perform.

Section 3.2: Individual Access to Test and Laboratory Certification Results

Proposed Action 33: Add statements to allow the individual to obtain copies of the test records, specify that this allowance is limited to positive test results (to prevent unnecessary administrative burden on licensee), and give the individual the right to obtain records regarding the findings and basis thereof relating to the tests.

Reason: This change would improve the protection of the employee's rights. In the SRM of March 27, 1991, the Commission asked the staff to consider requiring that individuals be provided copies of their drug test records.

ENCLOSURE 3

SOURCES OF INFORMATION

ENCLOSURE 3

SOURCES OF INFORMATION

The staff evaluated information from the following sources to evaluate the effectiveness of the FFD rule and identify areas that should be changed.

Inspections

Before licensees were required to implement all aspects of the FFD rule, NRC inspectors observed in accordance with Temporary Instruction (TI) 2515/104, "Inspection of Initial Training Programs," the FFD training required to be given by the licensees. In July 1990, the staff began to inspect the licensees' implementation of their FFD programs. The staff conducted these inspections in accordance with TI 2515/106, "Fitness-for-Duty: Initial Inspection of Implemented Program."

As of July 1, 1991, the staff had conducted inspections in accordance with TI 2515/106 at 56 operating reactor sites. The staff evaluated information from both its earlier observation of FFD training and its inspections of FFD program implementation to identify possible problems that may be attributed to faults in the rule's requirements.

Periodic Reports on Program Performance

Every 6 months, licensees must report specific data on FFD program performance to the Commission. Since implementation of the rule, the Commission has received performance data for two reporting periods (January - June 1990 and July - December 1990). The staff evaluated the information from these reports to assess the effectiveness of the rule and to identify regulatory problems. The staff has submitted for publication NUREG/CR-5758, "Fitness for Duty in the Nuclear Power Industry: Annual Summary of Program Performance Reports (CY 1990)," which reports the program performance data for the first year of implementation of the FFD rule. In September 1991, the staff will receive the performance data for the reporting period January - June 1991.

Significant FFD Events

The FFD rule requires licensees to report certain significant FFD events to the NRC Operations Center. These events include the sale, use, or possession of illegal drugs within the protected area and certain acts by reactor operators or supervisory personnel. Other informal reports by licensees to the NRC and allegations also provide useful information on implementation of licensees' FFD programs. Analysis and followup actions on these events have provided some insights on problem areas and the effectiveness of licensees' programs.

Industry-Sponsored Meetings and Other Dialogues

The staff participated in industry-sponsored FFD workshops and professional meetings, and numerous other dialogues. The staff has responded to numerous questions on issues concerning licensees' implementation of the FFD rule. Information received from these activities has indicated aspects of the rule that should be clarified and that have caused recurring problems in implementation.

Initiatives by NUMARC and NIDA

On April 17, 1991, NUMARC forwarded by letter to the staff a number of recommendations for changes to the rule based upon the nuclear power industry's first year of experience. Enclosure 4 is a copy of that letter. Many of NUMARC's recommendations are consistent with the changes proposed by the staff in the enclosures to this paper. In developing the proposed amendment to the rule, the staff will consider NUMARC's comments in more detail.

NIDA informed the staff that, in the near future, NIDA anticipates publishing proposed amendments to the "Mandatory Guidelines for Federal Workplace Drug Testing Programs" which was adopted, with modifications, by the NRC in Appendix A to 10 CFR Part 26. Item 1 of Enclosure 1 presents a brief summary of the major changes known to the staff. The staff will consider adopting each of NIDA's proposed revisions when it develops the proposed amendments to 10 CFR Part 26.

Reviews of Current Literature

The staff, primarily through work done by Battelle's Human Affairs Research Centers (HARC), has continued to review current literature and technology developed to improve FFD programs, particularly regarding drugs and alcohol. The staff has assessed technical developments in these areas to determine if changes to the regulations are needed. HARC is preparing a NUREG/CR report to discuss this work and to summarize lessons learned from the staff's inspections. The staff will provide a copy of the final draft of this report to the Commission as soon as possible.

ENCLOSURE 4

LETTER FROM NUMARC, APRIL 7, 1991

NUCLEAR MANAGEMENT AND RESOURCES COUNCIL

1776 Eye Street, N.W. • Suite 300 • Washington, DC 20006-2496
(202) 872-1280

Thomas E. Tipton
Vice President & Director
Operations, Management and
Support Services Division

April 17, 1991

Mr. Brian K. Grimes
Director
Division of Reactor Inspection and Safeguards
Office of Nuclear Reactor Regulation
U.S. Nuclear Regulatory Commission
Washington, DC 20555

Re: Current Rule - Fitness-for-Duty Programs
54 Fed.Reg. 24468 (June 7, 1989), 10 CFR 26
Industry Comments to Improve Programs Under the Rule

Dear Mr. Grimes:

The purpose of this letter is to provide comments concerning the nuclear power industry's first year of experience with the NRC's Fitness-for-Duty (FFD) Rule, 10 CFR 26. Enclosure 1 contains our preliminary recommendations for specific wording changes in the rule with appropriate rationale/justification.

These preliminary recommended rule modifications were developed from industry feedback on a series of NUMARC issue papers on fitness-for-duty that had been provided to our members in January 1991. A copy of Enclosure 1 will be provided to our members for further review and comment. We are interested in discussing the reasons for the recommended modifications with you and/or your staff at your earliest convenience.

I would also like to take this opportunity to provide our preliminary assessment of the industry's first year under the FFD regulation. Utility data performance evaluations demonstrate that there is minimal use of drugs and alcohol at commercial nuclear power plants and that, based on feedback we have received, the employees recognize the benefits of the FFD program. Even with the noted success of the FFD program there are several program areas that need to be less cumbersome. We feel that the recommendations provided herein, if accepted, would make utility programs more cost effective and efficient without diminishing the excellent results achieved to date.

Should you, or your staff, have any question on this input, please call Rich Enkeboll, Bob Whitesel or me.

Sincerely,

Thomas E. Tipton

TET/REE:plg
Enclosure

Enclosure 1

RECOMMENDED MODIFICATIONS

TO 10 CFR 26,

FITNESS-FOR-DUTY (FFD) RULE

The following specific rule modifications with supporting rationale are proposed in support of the NRC's current Fitness-for-Duty Rule evaluation effort. (Page and column references are to the text of the rule as published in 10 CFR Part 26 Revised as of January 1, 1990. Additions are highlighted, deletions are indicated by line-through.)

1. Page 342, Column 2, § 26.2(a), change the 3rd sentence to read:

   The provisions of the fitness-for-duty program must apply to all persons granted unescorted access to protected areas, and to licensee, vendor, or contractor personnel whose decisions could directly affect public health and safety and who are required to physically report to a licensee's Technical Support Center (TSC) or Emergency Operations Facility (EOF) in accordance with licensee emergency plans and procedures.

Rationale: This modification would authorize the licensee to decide if a TSC/EOF person needs to be subject to Part 26 requirements based on his/her ability to directly affect public health and safety.

2. Page 343, Column 1, § 26.3, alphabetically, add the following definitions:

   "Behavior observation (BO)" means a procedure that uses observation techniques to detect degradation in performance, impairment or changes in individual behavior which may indicate the need to evaluate an individual's fitness-for-duty. This subject is sometimes referred to as a "continual behavioral observation program (CBOP)."

   "Best effort" means that the licensee or the licensee's agent requesting information pursues the effort sufficiently to be reasonably assured that further effort would not be fruitful. There needs to be sufficient information recorded to show the intended action and the corresponding result or lack of result. These documented items include attempts to

contact previous employers, obtaining verification by telephone, letter or other means.

"Confirmed positive laboratory test" is the result of a GC/MS test that shows a positive quantitative result at or above the specified confirmatory test cut-off level for specified drugs. This result does not become a "confirmed positive test," as defined in this section, until evaluated and so judged by the licensee's Medical Review Officer (sometimes referred to as a certified positive).

"Denied access" means access was not (or will not) be granted at a particular time because of an overall negative evaluation of received information. The reasons may be one or more of the following: incomplete information furnished during processing; failure to list reasons for removal or a revocation of unescorted access under a fitness-for-duty program; unfavorable psychological evaluation; unfavorable criminal records check; incomplete program requirements, such as training and preaccess testing; the individual was determined to have had a confirmed positive test result under a similar program during a previous employment.

"Drug testing" means the measurement process by which urine, breath or blood specimens are examined to discover and measure levels of specific drugs or alcohol. Further, the following drug testing terms are to be considered interchangeable as appearing in this Part: prescreening, preliminary test, initial screening, initial test, and preliminary initial test. These terms can all be used in the context of the definition below titled, "Initial or screening tests."

"Employee" means an individual hired for fulltime work by the licensee (not a contractor/vendor).

"Escort" means any individual granted unescorted access to the protected area and who has satisfied the training requirements for accompanying individuals who do not have unescorted access in the protected area.

"For-cause test" is a drug and alcohol test conducted for reasonable suspicion. The individual is normally referred for this test by a supervisor who has personal knowledge of a degradation of performance or other noticeable indicator, or has received credible information from someone else, e.g., a co-worker, an escort, a contract administrator.

"Infrequent access" refers to individuals who are granted unescorted access to the protected/vital areas of the plant but who enter the plant sporadically, on an unscheduled basis, occasionally, or intermittently. Examples are: company employees assigned to other locations, plant employees whose normal work area is outside the protected area, contractors and vendors such as food service and vending machine

suppliers, telephone repair persons, photocopier repair persons, etc., who are not under a licensee-approved behavior observation program.

"Presumptive positive test" is the result of a screening test, on-site or at an HHS-certified laboratory, that shows a positive immunoassay result at or above the specified screen test cut-off level (also referred to as a presumptive positive).

"Supervisor" means any individual, acting in the interest of the licensee who has the personal oversight responsibility to direct the on-site activities of workers performing their duties.

"Suspended access" means an unescorted access to the protected/vital areas which has been temporarily withdrawn pending the resolution of a particular situation; individuals with suspended access may not be escorted into the protected area without prior approval as specified in company procedures.

"Test-out" means a procedure that is used to meet a training or retraining requirement by passing a written and/or oral test that gives the licensee confidence that the individual has been adequately trained on that subject.

"Terminated unescorted access" means a previously granted unescorted access that has been withdrawn due to employment termination or a violation of or noncompliance with requirements of the Fitness-for-Duty or Access Authorization Programs.

"Unescorted access" means access to the protected area unaccompanied by escorts which has been granted to an individual who has met the access authorization and fitness-for-duty requirements of a licensee.

Rationale: Questions from the industry indicate that including these definitions will enhance the understanding of rule phraseology and provide consistent interpretations of their meaning.

3. Page 343, Column 2, § 26.3, change the listed definition as follows:

"Protected area" ~~has the same meaning as in § 73.2(g) of this chapter,~~ means an area encompassed by physical barriers and to which access is controlled.

Rationale: The lined-through phrase is unnecessary and inaccurate in that the definition is not found elsewhere in this chapter nor in § 73.2(g) but is a subpart of §73.2(a)(3) although not clearly numbered.

4. Page 343, Column 2, § 26.3, modify the phraseology in definition of "Suitable inquiry" to read: "Suitable inquiry" means the drug and alcohol questioning portion of a best-effort verification of employme history for the past five years, but in no case less than three years (if the individual has had employment that long). This information is obtained through contacts with the last licensee, if any, who provided the individual unescorted access authorization under Part 26 requirements and subsequent employers. If the licensee condition isn't met, ~~obtained through~~ contacts with previous employers are necessary to determine if a person was, in the past five years:

   - tested positive for illegal drugs or alcohol, or if the result of such use was on-duty impairment;
   - subject to a plan for treating substance abuse (except for self-referral for treatment);
   - removed from, or made ineligible for activities within the scope of 10 CFR Part 26;
   - ~~or~~ denied unescorted access at any other nuclear power plant; or
   - ~~other~~ denied employment or removed from employment due to alcohol or drug involvement in accordance with a fitness-for-duty policy.

Rationale: Industry experience shows that suitable inquiry is better served by contacting licensees who had previously granted the individual unescorted access rather than just previous employers. This rewritten definition removes potential ambiguity by combining the requirements of § 26.27 into the definition of § 26.3.

5. Page 344, Column 2, § 26.20, change second sentence to read:

Each licensee shall retain a copy of ~~the current~~ its latest written policy and procedures (including the last 3 years for any superseded material) as a record until the Commission terminates ~~each~~ the license for which the policy and procedures were developed. ~~and, if any portion of the policies and procedures are superseded, retain the superseded material for three years after each change.~~

Rationale: The change is intended to clarify what records are to be retained and for how long.

6. Page 345, Column 1, § 26.20(g), add new subparagraph:

(g) A procedure that specifies the necessary conditions to accept all or part of another company's Part 26 program. Since all licensees must meet the requirements of this Part, licensees can accept each other's personnel for unescorted access with verification of the individual's status. The individual must be currently authorized for unescorted access and continue to be subject to the random testing program of either his employer or that of the host utility. There is no requirement to audit another licensee's program to use this authority.

Rationale: Many utilities will not give FFD clearance to a "peer evaluator" from another licensee because their interpretation of the rule is that they would have to audit many other licensees' fitness-for-duty programs in order to accept their programs and grant unescorted access. This addition is intended to remove that potential obstruction.

7. Page 345, Column 1, § 26.20(e)(1) to read:

(1) Require a statement (verbal or written) to be made by a called-in person as to whether he or she considers himself/herself to be fit to perform the task assigned and if he/she has consumed alcohol within the length of time stated in the pre-duty abstinence policy;

Rationale: The additional words are intended to get a personal determination of fitness to perform the task assigned in addition to whether alcohol had been consumed within the last 5 hours. Also, a verbal statement serves the purpose as well as a written statement.

8. Page 345, Column 1, § 26.20(e)(2), change to read:

(2) If alcohol has been consumed within this period, require a determination of fitness-for-duty by breath analysis or ~~other means~~ behavioral observation; and

Rationale: It is not clear to what "or other means" refers but it is possible to make a determination through behavioral observation which could use field sobriety techniques.

9. Page 345, Column 2, § 26.21(b), change to read:

(b) Initial training must be completed within 365 days prior to assignment to activities within the scope of this Part. Refresher training must be completed on a nominal ~~12 month~~ biennial frequency or more frequently where the need is indicated. Refresher training can be waived by the use of an appropriate "test out" exam. A record of the training must be retained ~~for a period of at least three years~~ until the next refresher training is completed.

Rationale: NUREG-1387, § 7.3, interprets the rule in such a way as to require initial FFD training as if the individual is a "new employee" each time the individual's unescorted access authorization is interrupted for a period of 60 days or more. The current wording of the rule says that the training is good for a year with unbroken access authorization. The amount of FFD knowledge retained is independent of an individual's access authorization status. Additionally, we recommend specifying at least a 365 day period for which initial training is acceptable between site transfers. Individuals are normally trained on program changes as they occur and are updated on site specific programs when going from one site to another. Additionally, since fitness-for-duty information is neither technical nor difficult to remember, retraining should be required no more frequently than once every two years. One way to determine if an individual knows the subject is to require him/her to pass a written and/or oral examination. We believe the rule should allow waiving classroom refresher training through a demonstration of knowledge, which can be accomplished by a "test-out" procedure.

10. Page 346, Column 1, § 26.22(c), beginning with the second sentence modify to read:

Refresher training must be completed on a ~~nominal 12 month~~ biennial frequency, or more frequently where the need is indicated. Refresher training can be waived by the use of an appropriate "test out" exam. A record of the training must be retained ~~for a period of at least three years~~ until the next refresher training is completed.

Rationale: Since this training is not technical in nature, it should only be required to be accomplished every two years. This modification accommodates the "test out" process described previously. Retaining retraining records for an arbitrary 3 year period serves no useful purpose; retaining the latest record of training should be adequate.

11. Page 346, Column 1, § 26.23(a)(2), change to read:

~~Personnel~~ Unescorted access will not be requested for personnel having been denied access or removed from activities within the scope of this Part at any nuclear power plant for violations of a fitness-for-duty policy; nor will it be requested for those individuals previously denied employment or removed from employment due to alcohol or drug involvement unless a complete record detailing the individual's rehabilitation is provided concurrently. The licensee's evaluation of the case will determine if assignment within the scope of this part will be made. ~~will not be assigned to work within the scope of this Part without the knowledge and consent of the licensee.~~

Rationale: The modification makes a positive statement about reassignment to work within the scope of the FFD rule rather than the passive phrase of "knowledge and consent."

12. Page 346, Column 1, § 26.23(a), add new subparagraph (3):

(3) A contractor or vendor supervisor that performs his function for the licensee on-site is to be trained under the licensee's FFD training program for supervisors (§ 26.22). If the individual provides no function on-site, there is no requirement for the licensee to train the off-site supervisor.

Rationale: Requiring contractor supervisory training for a supervisor that does not perform his/her function on-site is considered an extension beyond the reasonable bounds of Part 26.

13. Page 346, Column 1, § 26.24(a), change to read:

To provide a means to deter and detect substance abuse, the licensee shall implement the following five chemical testing programs for persons subject to this Part:

Rationale: The modification is to alert the reader that there are to be a total of five categories of testing (including a new alcohol-only test). This additional word will provide emphasis to the categories of chemical testing programs to follow.

14. Page 346, Column 1, § 26.24(a)(1) delete and substitute as follows:

(1) ~~Testing within 60 days prior to the initial granting of unescorted access to protected areas or assignment to activities within the scope of this Part~~ "Preaccess test" - a test for drugs and alcohol associated with the process of obtaining unescorted access to the protected area:

(i) Preaccess drug testing is required within 60 days prior to the initial granting of unescorted access to protected areas or assignment to activities within the scope of this Part. A pre-employment test may serve as the preaccess test. The collected sample must be submitted for testing but the results do not have to be received before a licensee may provisionally authorize unescorted access;

(ii) For individuals currently covered by a Part 26 random drug testing program (licensee or accepted contractor/vendor program) the preaccess test is not required.

(iii) For individuals removed under favorable conditions from a Part 26 random drug and alcohol testing program within the past 60 days, the preaccess test is not required even though the individual had not, in fact, been tested pursuant to that random testing program.

Rationale: There is insufficient specificity in the rule as to what constitutes preaccess testing. Also, specifying the "60-day rule" will avoid varied interpretations.

Analysis of the performance data statistics for 1990, shows no appreciable drug/alcohol abuse problem at nuclear power plants -- less than one out of a hundred tested positive. There is also a behavioral observation program in place at each site. A major impediment to effectively starting an outage is the time it takes to get negative test results for contract personnel back from the HHS-certified laboratory.

The rule should provide credit for prior random drug testing programs to which an individual was subjected. It is logical to consider that the deterrent effect of the FFD program that makes an individual subject to a random drug and alcohol test until the day he/she leaves the last program is sufficient to meet the preaccess drug testing requirement for the following 60 days en route to the next FFD program.

15. Page 346, Column 2, § 26.24(a)(2), change to read:

(2) "Random test" - unannounced drug and alcohol tests imposed in a random manner. The tests must be administered so that a person

completing a test is immediately eligible for another unannounced test. As a minimum, tests must be administered on a nominally weekly frequency and at various times during the day. Random testing shall be conducted at an annual selection rate equal to at least ~~100~~ 50 percent of the workforce.

Rationale: The minor word additions improve the formatting of the drug test categorization and specifies the type of tests imposed.

The reduction in the random test population to 50 percent is considered justified based on the results of the first year of testing. We also note that the results of the Federal Aviation Administration's (FAA) rug testing program are very similar to the results of the NRC's program. The FAA drug testing population is 50 percent as specified by the Department of Transportation (DOT). Most utilities are subject to both the DOT and the NRC FFD Rules. Working to the same federal standard would remove one unnecessary burden and be a significant cost saving.

The number of positive random drug and alcohol tests reported for the period January 3 - June 30, 1990, was 298 out of 73,570 or 0.4 percent. Checking some previous industry experience (before the FFD rule) for correlation between sample size and positive random drug test percentage results, we find the fraction of positive test results remained relatively the same with sample sizes ranging from 10 percent to 125 percent. Based on this experience, no deterrence will be lost by reducing the testing population by 50 percent.

When the percentage of positives identified is very low, it makes sense to investigate smaller testing rates while maintaining an overall deterrent effect. The disruption and lost manpower/productivity resulting from the larger testing rates is a significant aspect of the program cost.

16. Page 346, Column 2, § 26.24(a)(3), change to read:

(3) ~~Testing for cause, i.e.,~~ "For-cause test" - a drug and alcohol test conducted for reasonable suspicion as soon as possible following an observed behavior indicating possible substance abuse; ... or after receiving credible information that an individual is abusing drugs or alcohol. Until pronounced fit-for-duty by the designated licensee representative, e.g., MRO, the individual's unescorted access status shall be suspended.

Rationale: The modifications improve the formatting, ties in the new subparagraph on alcohol-only testing, and specifies the suspension of unescorted access until determined fit-for-duty

17. Page 346, Column 2, § 26.24(a)(4), add a new subparagraph:

(4) "Alcohol-only test" - A breath test for alcohol based on reasonable suspicion. If there is suspicion that an individual may have violated the company's alcohol policy, e.g. the odor of an alcoholic beverage around a person, the individual will be asked to take a breath test for alcohol in accordance with Appendix A, paragraph 2.3(g)(18). Depending on circumstances and the outcome of the breath test, at the licensee's discretion, a drug test may also be directed. Unescorted access for the individual may be suspended until the test results are determined.

Renumber the next subparagraph as (5) and change to read:

(45) "Follow-up test~~ing~~" ~~on an~~ has been defined previously. These unannounced tests are needed ~~basis~~ to verify continued abstention from the use of substances covered under this Part. The period of this testing is dependent on any previous failures/recidivism.

Rationale: It is considered necessary to allow testing for alcohol without requiring a concurrent urine test for drugs. Industry experience with for-cause testing has shown that an odor of alcohol determination does not frequently lead to a positive urine test but does create a significant burden in the suspension of access for approximately 75 percent of the for-cause tests that are not confirmed positive.

The new subparagraph (5) modification makes the terminology consistent without redefining "follow-up testing" and observes that the duration of the follow-up period is determined by the individual's previous drug test failure history.

18. Page 347, Column 1, § 26.24(d), change to read:

(d) Licensees may conduct initial screening tests of an aliquot prior to ....quality controls are implemented. Individuals whose tests are determined to be a presumptive positive for illegal drugs (marijuana, cocaine or phencyclidine) may have their unescorted access temporarily suspended pending a resolution by the MRO. Quality control procedures for initial ....tested as negative. Access to the results of positive preliminary tests (by on-site laboratory or NIDA certified laboratory) should ~~must~~ be limited to the licensee's testing staff, the Medical

Review Officer, the individual, and the Fitness-for-Duty Program Administrator/Manager. ~~and employee assistance program staff when appropriate~~. The Fitness-for-Duty Program Administrator/Manager may inform appropriate management of a presumptive positive test result for illegal drugs (marijuana, cocaine or phencyclidine). Management may administratively remove the individual's unescorted access with no impact to the individual's employment status or compensation. It is not a requirement that an individual with a presumptive positive drug test be removed from unescorted access. Management evaluation of circumstances is to be the determining factor while being careful not to allow an unsubstantiated drug screen test result to impugn an individual's reputation.

Rationale: It is acknowledged that the NRC currently has rulemaking in progress to preclude a licensee from taking administrative action to suspend unescorted access on the basis of a presumptive positive drug screening test. However, we continue to believe that it is important for a licensee to be able to take prompt administrative action if the licensee deems such action to be appropriate to protect public health and safety. Because of our concerns for the potential negative impact on affected individuals, we also intend to develop industry guidance (if not precluded by NRC rulemaking) that would establish acceptable procedures that would preclude action for other than illegal, non-medicinal drugs for which testing interferences are not probable. The guidance would provide considerations to minimize the possibility of impugning an individual's reputation as a result of an unsubstantiated drug screen test result.

This modification would enable site collection personnel or certified laboratory personnel to inform licensee management when a urine sample has screened positive for the specified drugs. Company policy would then be applied to determine the appropriate administrative action, if any, to be taken as a result of the presumptive positive test. Although administrative action (e.g. reassignment to a less critical position) may be deemed appropriate because of an individual's responsibilities, no disciplinary action would be taken until the specimen test result is confirmed to be positive and an evaluation by the Medical Review Officer (MRO) can be completed. We believe that this strikes an appropriate balance between the rights of an individual and the responsibilities of the licensee to protect public health and safety.

Additionally, there are individuals who must be informed of unescorted access suspension to carry out necessary administration. These individuals would be trained to ensure confidentiality of the process.

19. Page 347, Column 2, § 26.24(g), change the last sentence to read:

Should the person ~~demand further confirmation~~ appeal a confirmed positive breath test, the test must be a gas chromatography analysis of blood.

Rationale: The implication of the original wording is that the confirmed breath test can be challenged as being an insufficient test and an individual can substitute the results with a blood test. In reality, the blood test is an appeal of the breath test results and it should be treated accordingly. (See Rationale of items 35 and 37.)

20. Page 347, Column 2, § 26.27(a), change to read:

(a) Prior to the initial granting of unescorted access to a protected area ~~or the assignment to activities within the scope of this Part~~ to any person, the licensee shall obtain a written statement from the individual as to whether he or she was, in the last 5 years, denied employment or removed from employment due to alcohol or drug involvement or whether activities within the scope of this Part were denied the individual during said period. The licensee shall ~~complete~~ ensure that a suitable inquiry is then completed. ~~on a best efforts basis to determine if that person was, in the past, tested positive for drugs or use of alcohol that resulted in on-duty impairment, subject to a plan for treating substance abuse (except for self-referral for treatment), or removed from activities within the scope of this Part, or denied unescorted access at any other nuclear power plant in accordance with a fitness-for-duty policy.~~ A previously completed suitable inquiry is valid for a period of 365 days from the date the individual last held unescorted access authorization under the same conditions as a transfer and reinstatement of unescorted access pursuant to the Access Authorization Rule (Part 73.56). If the individual had been subject to random testing under a Part 26 program within the last 60 days, no further pre-access drug or alcohol testing would be required. If such a record is established, the new assignment to activities within the scope of this Part or granting of unescorted access must be based upon a management and medical determination of fitness-for-duty and the establishment of an appropriate follow-up testing program, provided the restrictions of paragraph (b) of this section are observed. To meet this requirement, the identity of persons denied unescorted access or removed under the provisions of this Part and the circumstances for such denial or removal, including test results will be made available in response to a licensee's, contractor's, or vendor's inquiry supported by a signed release from the individual specifying the authorized distribution of the information. Failure to list reasons for removal or

revocation of unescorted access shall be sufficient cause for denial of unescorted access. Temporary access provisions included in the Access Authorization Rule, 10 CFR 73.56, shall not be affected by this part....

Rationale: The specific requirements for suitable inquiry appear in the definition in § 26.3 and may result in confusion if duplicated in this paragraph.

There have been many interpretations of the time period for which an updating of the suitable inquiry is not required. NUREG-1385, § 7.5 states: "[s]uitable inquiries conducted under 10 CFR Part 26 in the cited examples need not be conducted if the contractor employee is continuously covered by an FFD program in conformance with the rule." The "continuously covered" aspect is further explained in § 7.1 of the same NUREG; there can be a gap in this coverage while the individual is traveling between job sites as long as the transfer period is "reasonably short." The Access Authorization Rule and associated Regulatory Guide endorses the Guidelines of NUMARC 89-01, where, in § 8.1, it states that an "individual's unescorted access authorization granted by one utility in accordance with these guidelines may be transferred to another utility" with "confirmation that the individual currently holds a valid unescorted access authorization or had a valid unescorted access authorization which was terminated under favorable conditions within the previous 365 days" and the individual is properly identified. The fitness-for-duty program should not put unnecessary restrictions on the already accepted access authorization programs under NUMARC 89-01, the logical maximum time period for a valid transfer of suitable inquiry is 365 days. Of course, if the individual has not been subject to random testing for the previous 60 days, he/she would require a preaccess drug and alcohol test.

To preclude using industry suitable inquiry information for employment decisions, the phrase "authorized distribution of information" is deemed necessary.

21. Page 348, Column 1, § 26.27(b)(2), change the third sentence to read:

Plans for treatment, follow-up, and future employment (if applicable) must be developed, and any rehabilitation program deemed appropriate must be initiated during such suspension period.

Add the following after the fourth sentence:

Any person granted unescorted access or whose access is reinstated under these provisions must be given unannounced follow-up tests at least once every month for four months and at least once every three months for the next year to verify continued abstinence from the prescribed drug panel.

Rationale: The follow-up test requirement was not spelled out for the first positive situation but was construed from paragraph 26.27(b)(4) below, after the second positive drug test or such testing was determined to be unnecessary in some FFD programs. Medical/EAP evaluations of persons who test positive for drugs the first time indicate that most recidivism occurs, if it is going to, during the first year after counselling/treatment. Therefore, 4 months of frequent unannounced drug and alcohol testing plus one year of quarterly follow-up testing is considered sufficient after "first positive" sanctions have been completed.

22. Page 349, Column 1, § 26.27(c), change second sentence to read:

~~These~~ All suitable inquiry records must be retained for a period of five years for the purpose of meeting the requirements of § 26.27(a) and § 26.71 (note that records to support permanent removal of unescorted access are to be retained for the life of the plant).

Rationale: Since suitable inquiry is the primary reason to keep drug testing records and, since the inquiry is only for a period of five years, it seems appropriate to clarify the length of retaining records in context with their purpose.

23. Page 349, Column 1, § 26.27(d), change the first sentence to read:

(d) If a licensee has a reasonable belief that an NRC employee, or NRC contractor, may be under the influence of any substance, ...

Rationale: This modification is for completeness since an NRC contractor is not an NRC employee.

24. Page 349, Column 2, § 26.71(a), change to read:

(a) Retain records of inquiries conducted in accordance with § 26.27(a), that resulted in the granting of unescorted access to protected areas, ~~until~~ for five years after initiation of the unescorted

access authorization process. ~~following termination of such access authorization~~

Rationale: Suitable inquiry information is only useable, under the rule, for five years. Therefore there is no reason to keep the information beyond that period. Positive drug test results are retained in such a manner as to cover any later suitable inquiry requests.

25. Page 350, Column 1, § 26.73(a)(2), change to read:

(2) Any acts by any person licensed under 10 CFR Part 55 to operate a power reactor or by any supervisory personnel assigned to perform duties within the scope of ~~this~~ Part 26--

Rationale: There was confusion in the past for this particular paragraph as to whether the reference to "this Part" was Part 55 or Part 26. This modification removes any confusion potential.

26. Page 350, Column 1, § 26.73(a)(2)(iii), change to read:

(iii) involving the unauthorized use or the misuse of alcohol within the protected area, or

Rationale: Since someone can use a substance containing alcohol, e.g., cough medicine, for purposes other than those assumed for alcoholic beverages and as such may be authorized to use some form of alcohol within the protected area, this modification is needed to clarify the intent.

27. Page 350, Column 2, § 26.80(c), change last sentence to read:
~~NRC Guidelines require~~ [L]icensee audits of the laboratory portions of the utility's drug testing program at HHS-certified laboratories are required, ~~as described in Appendix A.~~

Rationale: There is no audit specificity in Appendix A that licensees find meaningful. This modification will minimize potential ambiguity.

28. Page 353, Column 1, Appendix A, Subpart B, § 2.2(d)(4), change to read:

Each individual has t[T]he option to provide a blood specimen for GC/MS analysis to appeal a confirmatory analysis ~~following~~ that resulted from a positive breath test and this procedure shall be specified in the written instructions provided to individuals tested. The instructions shall also state that failure to promptly request such an appeal a ~~confirmatory~~ blood test indicates that the individual accepts the breath test results.

Rationale: As discussed in items 19, 35 and 37 the second set of breath analyses is the alcohol confirmation test. A blood test is the mechanism to appeal the confirmatory blood test results, not a substitute for the breath test.

29. Page 353, Column 1, Appendix A, § 2.3, change to:

Licensees shall carefully select and monitor persons, (not to include specific off-site laboratory personnel), responsible for administering the testing program (e.g., collection site persons, laboratory technicians, ~~specimen couriers,~~ and those selecting and ....

Rationale: The licensee does not select persons for off-site laboratories. A specimen courier should not be included in the category of "persons responsible for administering the testing program." By the time a courier is allowed to be involved in the process, all specimens have been sealed with tamper evident tape and placed in shipping containers that are similarly sealed. No documentation leaving the licensee identifies specimens by name of the donor. Tampering and substitutions are prevented by current procedures. The licensee does need to have a tracking system that indicates the path/carrier to the HHS-certified laboratory chain-of-custody system.

30. Page 353, Column 2, Appendix A, § 2.3(2), change to read:

For personnel who do not have unescorted access to the protected areas, [a]ppropriate background checks and psychological evaluations ~~shall~~ are to be completed prior to assignment of ~~any~~ tasks directly associated with the licensee's administration of the program, and shall be conducted at least once every three years.

Rationale: This modification puts more specificity into the requirements for collection site persons who are not covered by the licensee's access authorization program.

31. Page 353, Column 2, Appendix A, § 2.3(3), change to read:

(3) Persons directly responsible for administering the testing program shall be subjected to a behavioral observation program.....

Rationale: This modification makes the requirement more specific resulting in fewer variations in interpretation.

32. Page 354, Column 1, Appendix A, § 2.4(d), change second sentence as follows:

Handling and transportation of urine and blood specimens from one authorized individual or place to another shall ~~always~~ be accomplished through chain-of-custody procedures. The transportation courier does not have to be in the chain-of-custody as long as the specimens are sealed in temper-evident packages/containers and there is a tracking system that indicates the path/carrier to the HHS-certified laboratory chain-of-custody system. Every effort shall be made.....

Rationale: This modification makes it clear that the courier is not required to be in the chain-of-custody but is to be included as part of the material transfer system.

33. Page 355, Column 1, Appendix A, § 2.4(g)(11), change to read:

Upon receiving a urine specimen from the individual, the collection site person shall determine that it contains ~~at least 60 milliliters~~ a quantity of urine sufficient to meet specific laboratory requirements, nominally 30 milliliters, plus the amount desired for split samples. This total is to be predetermined but must be of sufficient quantity for all anticipated analysis and reanalysis. If there is less than ~~60 milliliters~~ the predetermined quantity of urine in the container, additional urine shall be collected in a separate container to reach a ~~total of 60 milliliters~~ the required quantity. (The temperature of ~~the~~ any partial specimen in ~~each~~ its separate container shall be measured in accordance... (e.g., a glass of water). If the individual fails for any reason to provide ~~60 milliliters~~ a sufficient quantity of urine, ...

Rationale: The NIDA Consensus Report distributed in June 1990, states: "[a] urine volume of 30 ml should be an acceptable specimen volume, provided that it does not create any technical problems for the laboratory." It is expected that DHHS will soon modify their guidelines accordingly.

34. Page 355, Column 2, Appendix A, § 2.4(g)(18), substitute the following for the original:

(18) ~~Alcohol breath tests shall be delayed at least 15 minutes if any source of mouth alcohol (e.g., breath fresheners) or any other substances are ingested (e.g., eating, smoking, regurgitation of stomach contents from vomiting or burping). The collection site person shall ensure that each breath specimen taken comes from the end, rather than the beginning, of the breath expiration. For each screening test, two breath specimens shall be collected from each individual no less than two minutes apart and no more than 10 minutes apart. The test results shall be considered accurate if the result of each measurement is within plus or minus 10 percent of the average of the two measurements. If the two tests do not agree, the breath tests shall be repeated on another evidential grade breath analysis device. Confirmatory testing is accomplished by repeating the above procedure on another evidential grade breath analysis device.~~

Alcohol breath tests shall be performed by using evidential-grade equipment (Section 2.7(o)(3) of Appendix A). The equipment shall be operated in accordance with the manufacturer's instructions by individuals trained and proficient in the use of the equipment. The screening test consists of two breath specimens on the same piece of equipment. If the initial screening breath test is essentially zero (less than 0.01 percent BAC), the test is considered negative and no further testing is required but can be performed if desired by the collector. For each individual whose initial screening breath specimen is at or above 0.01 percent, a second breath specimen is to be collected and compared after two minutes but no later than 10 minutes after the first sample is taken. If there is reason to believe a source of alcohol in the mouth exists (e.g. breath freshener or stomach contents) and the testing device doesn't have built in protection for this condition, the breath test shall be delayed 15 minutes to allow for dissipation of the material. If the two screening specimens are within plus or minus 10 percent of the average of the two measurements, then the test result is considered accurate. If the two screening tests do not agree, the series of two breath tests shall be repeated on another evidential-grade breath analysis device ensuring that the plus or minus 10 percent accuracy is achieved. If the result of this screening test is greater or equal to the alcohol cut-off level of 0.04 percent BAC, a confirmatory test is to be accomplished. The confirmatory test is a repeat of the screening test procedure done on another evidential-grade

breath analysis device not used to obtain the screening test result. If the confirmation result is between 0.01 percent BAC and 0.04 percent BAC, any action will be in accordance with established company policy.

Rationale: This rewritten paragraph removes potential confusion; allows for no further action after an initial essentially zero breath test; and clarifies the situation when there needs to be a 15 minute waiting period before conducting the initial breath test. Additionally, this modification clarifies that it is a licensee's option to have a policy to consider action for an alcohol level that is below the specified cut-off level.

35. Page 356, Column 1, Appendix A, § 2.4(g)(19), change to read:

(19) If the alcohol breath tests indicates that the individual is positive for a BAC at or above the 0.04 percent cut-off level, the individual may appeal the positive result by requesting a ~~confirmatory~~ blood test.~~at his or her discretion.~~ If a blood sample cannot be drawn immediately, the company procedures on delayed blood samples is to be followed. Collection personnel should be alert for attempted subversion of the program if an individual has had the opportunity to delay for a period of time sufficient to metabolize alcohol (nominally 0.015 percent BAC per hour) in the body to a concentration less than the cut-off level. Appeal samples are not subject to cut-off levels; any detectible alcohol will constitute a confirmed positive and the individual must be so informed. All vacuum tube and needle assemblies .....

Rationale: This modification makes it clear that an individual is not to consider a blood test as a substitute for a confirmed positive alcohol breath test but as an appeal of that confirmation. As in the case of a positive drug appeal there is no specified cut-off level for retested samples; any amount of the substance tested for is to be considered a positive result. This minimizes the potential for subversion of alcohol test results by delaying tactics. (See the Rationale of items 19 and 37.)

36. Page 356, Column 1, Appendix A, §2.4(g)(23)(ii), change to read:

(ii) The individual shall be ~~provided an opportunity~~ requested to set forth on the urine chain-of-custody form or an attachment, any information concerning medications taken or had administered to them in the past 30 days.

Rationale: This modification makes it a request vice just an opportunity to obtain information on an individual's use of authorized but potentially interfering drugs. It also alleviates the concern that the requirement will force disclosure of personal information not needed in the evaluation process.

37. Page 357, Column 1, Appendix A, § 2.4(j), change to read:

(j) "Failure to Cooperate." If the individual refuses to cooperate with the urine collection or breath analysis process (e.g., refusal to provide a complete specimen, complete paperwork, initial specimen), then the collection site person shall inform the ~~Medical Review Officer~~ FFD Program Administrator/Manager and shall document the non-cooperation in the permanent record book and on the specimen custody and control form. The ~~Medical Review Officer~~ FFD Program Administrator/Manager shall report the failure to cooperate to the appropriate management. The provision of blood specimens for use to ~~confirm~~ appeal a positive breath test for alcohol ~~shall be entirely voluntary~~ is to be made available at the individual's ~~discretion~~ option. ~~In the absence of a voluntary blood test, the second positive breath test shall be considered a confirmed positive.~~

Rationale: The Medical Review Officer is normally not the person who is responsible to administer a "failure to cooperate" or appeal situation; the FFD Program Administrator/Manager holds the responsible position. Additionally, the modification carries the concept that a blood test is voluntary, not as a substitute for a breath test but as an appeal to challenge the results of a confirmed positive breath test. (See Rationale of items 19 and 35.)

38. Page 359, Column 2, § 2.7(e)(1) table change cut-off level to read:

Marijuana metabolites.....~~100~~ 50

Rationale: The combination of technological improvements coupled with drug testing program experience has demonstrated that a screen cut-off level for marijuana (THC) of 50 ng/ml could be used without degradation of the ability to prevent false positive test results. Performance data collected (January - June 1990) shows that the use of marijuana cut-off levels more stringent than those of DHHS/NRC uncovers a number of drug users that would not otherwise have been detected, specifically 43 percent (143 individuals) of the positives were revealed by using lower cut-off levels. Since the issue is trustworthiness and not impairment, the logical

requirement is to use the proven cut-off level that reveals these additional users of this illegal drug.

39. Page 359, Column 2, Appendix A, § 2.7(f)(2), change to read:

(2) All urine samples identified as presumptive positive on the screening test performed by a HHS-certified laboratory shall be confirmed using gas chromatography/mass spectrometry (GC/MS) techniques at the cut-off values listed in this paragraph for each drug, ~~and~~ or at the cut-off values required by the licensee's unique program where differences exist.

Rationale: The NRC has previously advised that testing at both cut-off values is not required. The accepted practice has been for the laboratory to test a licensee's specimens at one specific cut-off level. If that cut-off level was more stringent than that required by the NRC, then an extrapolated result was acceptable for reporting those results that would have been positive at the NRC/DHHS level.

40. Page 359, Column 2, Appendix A, § 2.7(f)(2) table, change cut-off level to read:

Marijuana metabolite.....~~15~~ 10*

Rationale: From a toxicological standpoint the confirmation cut-off level for the predominant marijuana metabolite, Delta-9, should be one-fifth of all metabolite screen test. Therefore the confirmation cut-off level for marijuana should be reduced from 15 ng/ml to 10 ng/ml. This is well above the minimum detection level of the gas chromatography/mass spectrometry (GC/MS) techniques required by Part 26. This modification would also minimize the many presumptive positives that are not subsequently confirmed.

41. Page 359, Column 2, Appendix A, § 27(f)(2), change the last sentence under the table to read:

In addition, licensees may specify more stringent cut-off levels. Results shall be reported for both levels in such cases but this may be done by extrapolation/interpretation techniques instead of actual laboratory test.

Rationale: This modification is consistent with the rationale of item 39 above.

42. Page 360, Column 1, Appendix A, § 2.7(f)(5), change to read:

(5) If required, confirmatory tests for opiates shall include a test for 6-monoacetylmorphine (MAM) if the ~~screening~~ confirmatory test is ~~presumptive~~ positive for morphine.

Rationale: Experience has shown that there is no reason to do the MAM test unless the confirmatory test for morphine is positive. Additionally, the NRC should evaluate whether the entire test should be eliminated based on a lack of usefulness to the program.

43. Page 360, Column 1, Appendix A, § 2.7(g)(1), change to read:

(1) The HHS-certified laboratory shall report negative test results to the licensee as soon as determined and positive test results to the licensee's Medical Review Officer within 5 working days after receipt of the specimen by the laboratory. Before any positive test result is reported...

Delete the last sentence:

~~The results (positive and negative) for all specimens submitted at the same time to the laboratory shall be reported back to the Medical Review Officer at the same time when possible.~~

Rationale: This modification removes the unnecessary "batch" reporting requirement for positive and negative test results. Negative test results are needed promptly to minimize work delays. Additionally, the NIDA Consensus Conference minutes recommended deletion of the batch reporting requirements since: "[p]rejudicial treatment based on the time required to receive completed test results has not been a practical problem."

44. Page 360, Column 1, Appendix A, § 2.7(g)(2), change the 3rd sentence to read:

Presumptive positive results for illegal drugs (cocaine, marijuana, phencyclidine) of ~~preliminary~~ screen testing ~~at the licensee's testing facility will not~~ may be reported to licensee management if the Medical Review Officer deems it prudent. Any management action taken as a result of this report must be evaluated in view of the circumstances

and, if taken, to be only administrative in nature. Such action must be accomplished confidentially, without impugning the reputation of the individual. Unless the presumptive positive is confirmed, no record is to be maintained other than a negative notation.

Rationale: This modification is consistent with the position taken in item 18 above. The same rationale is germane here.

45. Page 363, Column 1, Appendix A, § 2.8(e)(2), delete and substitute as follows:

(2) ~~During the initial 90 day period of any new drug testing program, each licensee shall submit blind performance test specimens to each HHS-certified laboratory it contracts within the amount of at least 50 percent of the total number of samples submitted (up to a maximum of 500 samples) and thereafter a minimum of 10 percent of all samples (to a maximum of 250) submitted per quarter.~~ Each employer shall submit at least three blind performance test specimens for each 100 specimens submitted. No more than 100 blind performance test specimens per quarter are required to be submitted.

Rationale: Experience to date indicates that the present level is not necessary. NIDA certified laboratories have had sufficient experience to show that a lesser quantity of performance tests could be submitted by licensees. The substitute paragraph uses the identical requirements of § 40.31(d)(2) of the Department of Transportation's (DOT) drug testing rule (54 Fed. Reg. 49851 of December 1, 1989). DOT also does not espouse the "two-tier (first vs. subsequent quarters) approach" embodied in the NRC rule. The logical position for the NRC to take is one that is no more restrictive than the Department of Transportation's requirements for this industry-independent issue.

46. Page 363, Column 1, Appendix A, § 2.8(e)(3), change the last sentence to read:

The positive samples shall be spiked ~~only with~~ to at least 25 percent above the cut-off level for only those drugs for which the licensee is testing.

Rationale: Industry experience has shown that blind samples must be spiked to a minimum concentration (25 percent above the test cut-off level) to adequately account for variabilities inherent in the process of

providing blind samples. Several licensees have received unexpected blind test results because of this variability.

47. Page 363, Column 1, Appendix A, § 2.8(e)(4), change the first sentence to read:

The licensee shall investigate, or shall refer to DHHS for investigation, any unsatisfactory performance testing result related to laboratory performance, and based on this investigation....

Rationale: A licensee should not have to report an event such as a negative blind sample as an "unsatisfactory performance test result." No unsatisfactory laboratory performance would be involved for an insufficiently spiked quality control sample.

48. Page 363, Column 2, Appendix A, § 2.8(e)(5), add after the 1st sentence:

If the investigation concerns a blind test sample unanticipated result, (e.g. false negative), and the testing laboratory is determined to not be at fault, then there is no finding of an "unsatisfactory performance testing result." For laboratory errors the licensees shall require the laboratory....

Rationale: This modification is for the same reasons described in item 47 above.

49. Page 363, Column 2, Appendix A, § 2.8(e)(6), change the 1st sentence to read:

(6) Should a false positive error occur, as a result of a laboratory error, on a blind performance test....

Rationale: This modification continues the theme that the specified action is to be taken only if a false positive blind sample result is caused by laboratory error.

50. Page 363, Column 2, Appendix A, § 2.9(a), change the first sentence to read:

(a) "Medical Review Officer shall review positive results."

Rationale: This modification clarifies the requirement that the MRO reviews positive drug testing results but not negative results. No action is authorized if a sample contains a quantity of a drug that has a negative test result (i.e. below the cut-off level).

51. Page 364, Column 1, Appendix A, § 2.9(d), change the 4th sentence to read:

This requirement does not apply if the GC/MS confirmation testing for opiates confirms the presence of morphine and 6-monoacetylmorphine.

Rationale: This modification is a follow-on to item 42 above.

UNITED STATES
NUCLEAR REGULATORY COMMISSION
WASHINGTON, D.C. 20555

OFFICE OF THE
SECRETARY

ACTION - Murl

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PDR

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Bird, OP
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November 7, 1991

MEMORANDUM FOR: James M. Taylor
Executive Director for Operations

FROM: Samuel J. Chilk, Secretary

SUBJECT: SECY-91-293 - ASSESSMENT OF IMPLEMENTATION OF THE FITNESS-FOR-DUTY (FFD) RULE AND NEED FOR CHANGES TO THE RULE

This is to advise you that Commission (with all Commissioners agreeing) has approved the staff recommendation to develop proposed amendments to the fitness-for-duty rule, subject to the following:

1) With respect to the recommended rulemaking actions, staff should prepare and submit to the Commission a thorough regulatory analysis that addresses each recommendation at the time that the proposed rulemaking package is submitted for Commission review and approval.

2) The Commission strongly encourages the staff to continue to consider further experience with implementation of the rule as it says it will, in order to identify possible additional areas of the FFD rule where amendments may be needed. Along the lines of the staff's recommendation for Issue 1 of Enclosure 1, the most effective way to implement this rule is by utilizing specific information gained by licensees and the NRC since promulgation of the rule, in order to realize its maximum benefit.

3) As proposed by the staff in Issue No. 1, the NRC should adhere to the HHS Guidelines, absent a compelling reason why a departure is necessary to address a unique situation in the nuclear industry. In this regard, proposed Actions 19 (change in specimen quantity requirement), 25 (lowering of screening level for marijuana), and 27 (elimination of batch reporting requirement) of Enclosure 2 appear to go beyond what NIDA/HHS have currently endorsed. For this reason, these proposed changes to Appendix A of Part 26 should not be adopted unless and until the HHS guidelines are actually modified.

Dec'd Off. EDO
Date 11-7
Time 3:...

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3PP.

The Commission also notes that, in several cases, the proposed changes are based on the assumption that the HHS guidelines will be modified. The Commission approves these proposed changes only if the HHS guidelines are modified as expected. If the HHS modifications are not made, these should also not be made.

4) In regard to the phased study on random testing rates, the first phase of the study should include applicable evidence from outside the nuclear industry. The results of the Railroad Administration's test program should be included in the staff's evaluation and analysis. The staff should provide the Commission with a report on work that has been done to date on the deterrent effect of different testing rates (attitudinal studies and actual rest results, if any), with recommendations of the applicability of such work to the nuclear industry. On the basis of that report, the Commission may be able to make a decision on a trial reduction in testing rate, or it may need to initiate an attitudinal study (second phase study) within the nuclear industry before deciding on a reduced random testing rate study (possible third phase).

5) The Commission agrees with the staff's recommendation to take no action on the matter of the handling of test results prior to implementation of the FFD rule, but believes that the staff should document somewhere (perhaps in the Statement of Considerations) the fact that, because the results of early tests may be questionable in many cases, the Commission believes such results should be used with great care.

6) In addition to the above items, the Commission has approved the specific rulemaking activities proposed by staff with the exception of the following:

   a. Action 11: The Commission disapproves a rule change that would record an incomplete FFD investigation as positive based on the concurrent resignation of an employee. The resignation may be coincidental, and/or a further investigation could exonerate the employee. The record should simply record the facts that a positive test result was obtained and that the employee resigned before the investigation was completed.

b. Action 24: The Commission approved the portions of this proposal regarding adulteration, but disapproved including a provision to act on information concerning trace amounts of drugs in specimens. Short of corroborating clinical evidence or an admission by the individual such results should not be treated as positive. While the potential for hydration is a concern, there may also be legitimate reasons for apparent hydration. The Commission would be amenable to a proposal to confirm a suspicion of hydration through other measures, such as follow-up testing.

c. Action 28: The Commission disapproved this provision. Test results below the positive thresholds are not sufficiently reliable indicators of illegal drug use to warrant selective actions. Detectable levels of drug metabolites may result from legal drugs, foods, etc. Singling out employees for counseling would jeopardize employee privacy rights and would be unnecessary harassment of personnel.

d. Action 32: The Commission approved revisions of MRO responsibilities to improve efficiency, but disapproved any portion of that revision which would permit MROs to declare a positive opiate test result to be a true positive unless there is corroborating evidence.

7) In developing a proposed amendment to the FFD rule, the staff should review each of the recommendations submitted by NUMARC in their April 17, 1991 letter. The resolution of these recommendations should be consistent with the above guidance and should be included in the staff's submittal to the Commission.

The ACRS should be provided the opportunity to review and comment on the proposed amendments prior to staff submittal of the proposed amendments to the Commission. The staff submittal to the Commission should address any ACRS input.

The staff should proceed to develop proposed amendments to the FFD rule based upon the above guidance and forward it to the Commission. **(EDO) (SECY SUSPENSE: 7/1/92)**
NRR 8900042

cc: The Chairman
Commissioner Rogers
Commissioner Curtiss
Commissioner Remick
OGC
GPA
OIG
ACRS