CHARLES H. CRUSE
Vice President
Nuclear Energy

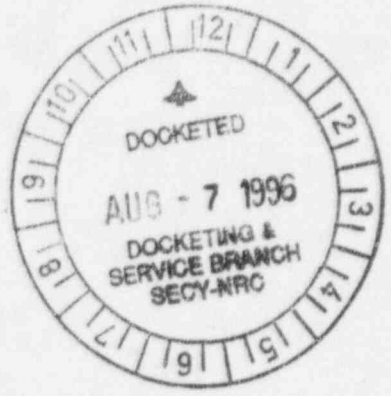
Baltimore Gas and Electric Company
Calvert Cliffs Nuclear Power Plant
1650 Calvert Cliffs Parkway
Lusby, Maryland 20657
410 495-4455

(10)

DOCKET NUMBER
PROPOSED RULE PR 2b
(61FR21105)

BGE

August 6, 1996



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

ATTENTION: Docketing and Service Branch

SUBJECT: Calvert Cliffs Nuclear Power Plant
Unit Nos. 1 & 2; Docket Nos. 50-317 & 50-318
Comments on Proposed Rule: Modifications to Fitness-For-Duty Program Requirements (61 FR 21105)

The Baltimore Gas and Electric Company is pleased to provide comments on the subject proposed rule. During preparation of our comments, we reviewed the comments submitted by the Nuclear Energy Institute and the Nuclear Utility Backfitting and Reform Group.

We support Nuclear Regulatory Commission's (NRC's) effort to revise the existing rule. We agree that some of the proposed revisions would substantially reduce the cost of implementation to licensees; enhance overall program integrity, effectiveness, and efficiency; and help to ensure the continued protection of public health and safety. We are pleased with your efforts to reduce ambiguities and improve the clarity of the rule. We applaud your effort to properly balance safeguarding an individual's rights and protecting public health and safety.

We believe it is important for the NRC to appreciate that the fitness-for-duty testing they require is a minor percentage of the total workplace forensic testing required. As such, the NRC should be consistent with the Mandatory Guidelines for Federal Workplace Drug Testing Programs recently adopted by the Department of Health and Human Services. Our concern is if the NRC develops a program with unique requirements, then drug testing laboratories may decide that there is no commercial incentive to maintain a separate test regimen to meet NRC requirements. We are concerned that many would stop performing the tests that we need. We have experienced similar situations in other product areas where the supplier decided that the burden of being a nuclear supplier was just too great. In these cases, our costs have often risen sharply. We believe that by making the proper decisions during this rulemaking, the NRC's requirements will match those of the Department of Health and Human Services and the Department of Transportation. As a result, our concerns will be eliminated.

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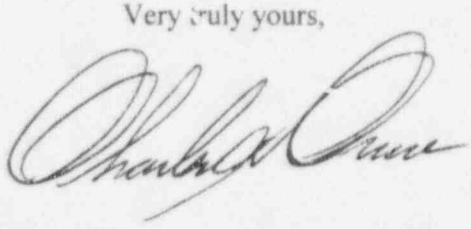
Should you have questions regarding this matter, we will be pleased to discuss them with you.

Very truly yours,



CHC/JMO/dlm

Attachment: (1) Baltimore Gas & Electric Company's Comments on Proposed Rule: Modifications to Fitness-For-Duty Program Requirements

cc: D. A. Brune, Esquire
J. E. Silberg, Esquire
Director, Project Directorate I-1, NRC
A. W. Dromerick, NRC
T. T. Martin, NRC
Resident Inspector, NRC
R. I. McLean, DNR
J. H. Walter, PSC

ATTACHMENT (1)

BALTIMORE GAS & ELECTRIC COMPANY'S

COMMENTS ON

PROPOSED RULE MODIFICATIONS

TO

FITNESS - FOR - DUTY PROGRAM REQUIREMENTS

Calvert Cliffs Nuclear Power Plant
August 6, 1996

BALTIMORE GAS & ELECTRIC COMPANY's
COMMENTS ON PROPOSED RULE
MODIFICATIONS TO FITNESS - FOR - DUTY PROGRAM REQUIREMENTS

1. **Do the proposed Fitness-for-Duty (FFD) Rule Amendments provide a substantial increase in the overall protection of the public health and safety. Should the proposed amendments be promulgated as an exemption to the backfit rule?**

Although we believe that the proposed changes do not "provide a substantial increase in the protection of public health and safety," the majority of the changes lessen the burden of the FFD program on licensees without decreasing the protection of public health and safety. The implementation of the changes should be delayed no longer than necessary. However, we believe that the Nuclear Regulatory Commission (NRC) should be held to the obligations under 10 CFR 50.109 and demonstrate that there will be a "substantial increase" in safety resulting from the proposed requirements. Grouping proposed changes can be an effective approach to addressing new requirements and meeting the backfit regulations. We believe that true reductions in burden are not backfits. New requirements, including those necessary to comply with Health and Human Services (HHS) guidelines or other national standards, require a backfit analysis.

2. **Should the NRC revise Appendix A to 10 CFR Part 26 to incorporate revisions to the HHS Mandatory Guidelines for Federal Workplace Drug Testing Programs?**

Yes, the changes to Appendix A of 10 CFR Part 26 should mirror the changes to the HHS Guidelines without the addition of more requirements or deletion of some HHS requirements. Appendix A should also include a statement that all future revisions to HHS Guidelines will be automatically incorporated into Appendix A. The Department of HHS sets both qualitative and quantitative standards for collection of urine for drug testing that withstand the scrutiny of the legal system. Automatically incorporating these guidelines will keep the nuclear industry testing consistent with the recommended Federal testing process used by other regulatory agencies and:

(1) provide uniform standards for testing performed by the certified laboratories;
(2) provide uniform specimen collection procedures to reduce collector errors; and,
(3) permit the HHS semiannual inspections of the laboratory to meet the inspection requirements of 10 CFR Part 26, as it does the Department of Transportation (DOT) drug testing program.

3. **Are there alternative techniques for testing for alcohol that should be considered for adoption by the NRC?**

No, the use of National Highway Traffic Safety Administration approved evidential breath testing equipment provides testing that is recognized in the legal arena. If the NRC permitted testing with equipment other than National Highway Traffic Safety Administration approved equipment for an initial/screening test, an evidential breath testing would still be needed for legally-recognized, confirmatory testing. Although the initial cost for an evidential breath testing appears to be high, proper maintenance and use of the equipment produces an overall lower per test cost than the use of alternative testing methods.

4. **Should the licensee be required to collect, analyze and submit additional types of information to the NRC?**

No, the requirement for additional data increases the cost of the program to the licensee without increasing protection of public health and safety.

5. **Should testing to determine the specimen validity be required before performing the screening test for drugs:**

a. **including pH and creatinine and/or specific gravity in the required testing to determine specimen validity;**

Yes, at the laboratory.

b. **requiring tests to determine specimen validity (specific gravity, pH and/or creatinine) immediately after specimen collection at all sites and immediate collection of a second specimen from those individuals providing specimens with abnormal qualities;**

No. Individuals can have dilute urine for many reasons other than attempts to subvert the testing process. An HHS report (1993) noted a study of 10,000 dilute samples which found that 90 percent of the specimens were negative for illegal substances. Requiring a "viewed sample" can be a humiliating experience for the donor and can create an inappropriate sense that the individual is not trusted. Statistics do not support a conclusion that the usual reason samples are dilute is subversion. In fact they show that hydration is due to many reasons such as diet or medical reasons.

c. **requiring tests at one-half of the cut-off levels specified for each drug, instead of at the HHS certified laboratory's limit of detection for suspect specimens?**

No. Confirmation for positive tests which results in employment action taken against an individual should be based on levels deemed acceptable as positive by HHS, not by one half the cut-off or limit of detection (LOD). The only time lower levels or LOD should be used is when the sample is being reanalyzed on an appeal. Prolonged storage and/or freezing can lower the level of the metabolite in the sample. Testing a "suspect sample" at LOD increases the cost to the utility since gas chromatography/mass spectrometry testing must be requested for each substance in the hope that one will be found.

6.a. **Should testing for adulterant/masking agents be required?**

Yes, at the laboratory and reported that an abnormal response occurred. As any substance could be an adulterant, it is not necessary for the laboratory to report which adulterant was used.

6.b. **Should cut-off levels for opiates be raised to reduce unnecessary medical review officer (MRO) determinations for drug interference from authorized prescriptions? Should requirements for 6-acetylmorphine remain as is pending for HHS action on opiate testing?**

Changes should be made if and when HHS makes the changes.

7.a. **Should the NRC require licensees to assure that "spiked" blind performance samples be within a defined concentration range?**

No. Per HHS, the purpose of blind performance testing is to determine a laboratory's ability to detect a substance, not to verify quantification levels. Levels must be confirmed by gas chromatography/mass spectrometry and be stable. Since there are no standards for manufacturing blind samples, manufacturers should make samples that they determine will allow the laboratory to detect the metabolite. Some metabolites adhere to their plastic containers and metabolites may leach out of the blind sample. As a result, lower levels of metabolites may be reported for the blind sample.

7.b. **Should performance test specimen providers be separate and independent from contract providers of other laboratory functions for the licensee?**

Yes. It will avoid questions of conflict of interest should a problem arise with the results. It will ensure the laboratory does not pre-record results matched with blind specimens in its reporting system.

8. **Should the NRC authorize the on-site use of non-instrumented, qualitative immunoassay methods that involve the use of inexpensive, disposable devises?**

Yes.

If so, what guidelines, quality assurance procedures, and performance standards should be used to govern the use of these inexpensive, disposable devises?

These devices are evaluated by Food and Drug Administration (FDA) for use in medical diagnosis. Only those devices meeting FDA acceptance criteria for medical diagnostic needs and possessing built-in quality controls should be permitted. The manufacturer's recommended quality assurance procedures should be followed. Although these devices are not a cost efficient testing method for doing a large number of tests, they give accurate results in a few minutes. They are useful for immediate results in "for-cause" examinations or "return-to-work" tests. Additionally, licensees can verify quality assurance by contracting an independent testing program that sends blind performance samples to a testing site.

COMMENTS ON SPECIFIC CHANGES TO 10 CFR PART 26

26.2 Scope

(a)(4)(i) and (iii) We agree with the proposed changes. These changes should be reviewed as required by the backfit rule.

(a)(4)(ii) Make removal and return-to-work recommendations or decisions.
Delete "or decisions." Fitness-For-Duty Program personnel who make removal or return-to-work recommendations to management should be included in the scope of the program. Our MROs and employee assistance program personnel make recommendations to management who in turn make removal or return-to-work decisions. We believe that many licensees are administratively organized such that the individuals who make the removal or return-to-work decisions for FFD program personnel are sufficiently removed from the intended scope of 10 CFR Part 26 that they should not be included in its scope. We believe that the NRC's intended scope is met by focusing on those who make removal or return-to-work recommendations. We believe there is an unnecessary increase in the scope of the program and an unnecessary increase of burden on licensees by including individuals who make removal or return-to-work decisions. This change should be reviewed as required by the backfit rule.

(e) We agree with the proposed changes.

(f) We agree with the proposed changes. We commend the NRC on accepting "general performance objectives" of other Federal agencies for individuals who perform activities under 10 CFR Part 26 and other federal drug testing programs. However, the NRC should elaborate on the meaning of "general performance objectives."

26.3 Definitions

Confirmatory test, Confirmed Positive, Laboratory Confirmed Positive, Verified Positive: Change these terms to match HHS and DOT definitions. Confirmatory test is the second analytic procedure (HHS Mandatory Guidelines, 1.2 ; NRC 10 CFR 26.3: and 49 CFR 40.3), but what the laboratory reports to the MRO is a confirmed positive. The MRO then verifies the test is positive. Using the same terms for 10 CFR Part 26 processes will reduce confusion. The terms would thus be:

Confirmatory Test - remain as in 10 CFR Part 26 proposed rule May 9, 1996.

Confirmed Test - the result of a confirmatory test that has established the results of the presence of drugs, or drug metabolites, at a sufficient level to be an indication of prohibited drug use.

Verified Test - a confirmed test result that has been verified as a violation of FFD policy by the MRO after evaluation. A confirmed positive test for alcohol is obtained as a result of a confirmation of blood alcohol levels of 0.04 percent or higher with a second breath analysis without MRO evaluation or as the result of an extrapolation time performed by the MRO.

Unconfirmed positive test: Delete the term since it is a replacement for "presumptive positive." Since "screening test" is replacing "initial test," a positive test can be referred to as a "positive screening test."

Screening test: delete "Initial screening may be performed at . . . a HHS-certified laboratory."

Supervisor: change to "any person who has the assigned responsibility of observing the work performance of an individual covered under this part."

We agree with the remainder of definition changes.

26.7 Communications - No comment.

26.8 Information collection requirements - No comment.

26.20 Written policy and procedures - No comment.

26.22 Training of supervisors and escorts

We agree with the proposed changes. However, "refresher training" should be clarified to include reading of training material, computer-based training and/or other equivalent training techniques.

26.23 Contractors and vendors - No comment.

26.24 Chemical testing

(a)(1)(i)(A) Change to read, "Has been covered by a program meeting the requirements of this part within the last 60 days prior to authorizing unescorted access." Since pre-access testing is conducted within the 60 days before the access is authorized, the individual may not report for up to 60 days without being under behavior observation and receive unescorted access authorization. The same time should be applied to an individual who: 1) was covered by 10 CFR Part 26; 2) previously had pre-access testing; and 3) was not only subject to testing, but 4) was also under behavioral observation for the previous 60 days.

(a)(1)(ii) Change "and has either had a negative test result meeting the standards of this part performed within six months before granting unescorted access or has been covered by a program meeting the standards of this part for two consecutive weeks during that period," to "has been covered by a program meeting the standards of this part within six months before authorizing unescorted access." For example, in a case where an individual may have been at one site for a few days and then immediately transferred to another site, the licensee has to determine if the individual was covered for two consecutive weeks in the last six months. In cases like these, there is no safety benefit, but significant unnecessary burden, to determine if an individual meets the two consecutive week criteria.

(a)(2) We agree that reasonable attempts to test individuals selected for random testing should be instituted. However, unless they are absent for 60 days or more, company employees on excused absences should not have to be tested when they return-to-work if they were selected for random testing during their absence. An excused absence includes illness, vacation, or company

business. Because of a general familiarity with its employees, a licensee is aware of absent employees' activities. In contrast, contractors can often be absent for several days while pursuing activities unknown by the licensee. Therefore, contractors should be covered by this policy, but licensee employees should be exempt. This proposed change should be reviewed as required by the backfit rule.

(d)(2) Unescorted access authorization should be suspended following the receipt by the MRO of a confirmed (confirmatory in NRC's current terminology) positive test for marijuana, cocaine, phencyclidine, amphetamine with dextro (right) isomer, or 6-acetylmorphine positive opiate until the individual interviews with the MRO. There are times when the MRO is unable to contact the individual due to vacation, scheduled off days, etc. The suspension of the unescorted access authorization will prevent the individual from entering the protected area. Since there is rarely a medical reason why these substances are present, the tests are almost always determined to be positive tests by the MRO. This will prevent an individual, now known to be unreliable and untrustworthy by a company employee or contractor of the company (the MRO), from having access to the protected area. Although this would be a new requirement, it would increase the safety of the plant by removing the possibility of an individual who needs an MRO review for a confirmed test from entering the protected area.

(h) The extrapolation requirement should be deleted. Sanctions in 10 CFR Part 26 requirements should mirror the DOT requirements for blood alcohol content (BAC) less than 0.04 percent. They require removal from safety sensitive functions until the next scheduled workshift or for 24 hours. This change should be reviewed as required by the backfit rule.

26.25 Employee assistance program (EAP) - No comment.

26.27 Management actions and sanctions to be imposed

(a)(3) Change "shall complete a suitable inquiry" to "shall initiate a suitable inquiry." There are times when the licensee may feel there is enough information to authorize unescorted access, even though there is an outstanding item on a suitable inquiry which can delay authorizing access.

(b)(2)(ii) Change to: "A confirmatory breath test of 0.04 percent or greater."

(b)(3) Change sanctions for alcohol to: "The first violation shall result in the individual receiving reeducation about alcohol, its metabolism, and its effects on workers. Additionally, the individual shall be evaluated by an Employee Assistance Program. The second violation shall include the sanctions of the first violation plus removal from activities within the scope of 10 CFR Part 26 for at least 14 days." The second violation shall include all the sanctions for the first violation for a confirmed positive drug test listed in 10 CFR 26.27. The third violation for alcohol shall mirror the second violation for a confirmed positive drug test.

26.28 Appeals - No comment

26.29 Protection of information.

(c) Change "of all records pertaining to the determination of a violation to the licensee's FFD policy . . . and management determinations of results" to "copies of the test results and the MRO and management determination of a violation to the licensee's FFD policy."

26.70 Inspections - No comment.

26.71 Recordkeeping requirements

We strongly support changing the semi-annual report to an annual report.

26.73 Reporting Requirements - No comment.

26.80 Audits

The NRC should not require an audit of HHS-certified laboratories' testing methods. These laboratories receive biannual inspections in order to remain HHS-certified. These inspections should fully satisfy audits desired by the NRC. Additionally, annual audits of the HHS laboratories by the licensee add an unnecessary financial burden. It was appropriate that the original 10 CFR Part 26 did not require audits of the HHS-certified laboratories.

APPENDIX A

1.1 Applicability - No comments

1.2 Definitions

No comments other than those made in 26.3.

2.1 The Substances - No comment.

2.2 General Administration of Testing - No comment.

2.3 Preventing Subversion of Testing

(2) Personnel administering the FFD program are under the same behavior observation and the substance testing program as all individuals covered under 10 CFR Part 26. The additional requirement to do follow-up background checks appears to say that the other methods of detecting unreliable or untrustworthy individuals are not adequate for FFD personnel. We believe that FFD personnel should be treated as any other individual covered by 10 CFR Part 26. The NRC has data demonstrating removal of FFD personnel for performance issues that were identified as part of a behavioral observation program. The NRC has no data to demonstrate that any FFD personnel were removed due to the current three year follow-up background checks and psychological evaluation. Reducing the requirement from three to five years does provide some relief to licensees, but it still is an unnecessary expense and tracking burden.

2.4 Specimen Collection Procedures

(g)(13) Add "Samples less than 30 cc may not be within the acceptable temperature band. Every attempt to obtain a temperature should be made on samples less than 30 cc. The inability to obtain a sample within an acceptable temperature band for samples less than 30 cc should be noted on the chain of custody form under remarks."

(g)(19) Extrapolation of BAC should not be added to the revision of 10 CFR Part 26. Therefore, the need to have blood drawn for BACs less than 0.04 percent should be eliminated.

2.5 HHS-Certified Personnel - No comment.

2.6 Licensee Testing Facility Personnel - No Comment

2.7 Laboratory and Testing Facility Analysis Procedures

(e) This proposed change should be deleted. Dilute samples should not be tested using the LOD until HHS develops scientific procedures that will support a licensee taking employment action based on LOD. There are no consistent levels of LOD between HHS certified laboratories. Differences occur due to sophistication of equipment and laboratory personnel expertise as well as differences with reagent batches. Confirmation for positive tests which results in employment action taken against an individual should be based on levels deemed acceptable as positive by HHS, not by one-half the cut-off or LOD. The only time lower levels or LOD should be used is when the sample is being reanalyzed on an appeal. Prolonged storage and/or freezing can lower the level of the metabolite in the sample. Testing a "suspect sample" at the LOD increases the cost to the utility as gas chromatography/mass spectrometry testing must be requested for each substance in the hope that one will be found. This is a new requirement that is both costly and burdensome to a licensee. There is no HHS scientific evidence to support its validity. It should be reviewed as required by the backfit rule.

(h)(1) The HHS certified laboratories' requirement to report test results to the MRO should remain at five days in order to be consistent with HHS guidelines and DOT requirements. Since the majority of Federally-mandated tests are non-NRC, a laboratory's inadvertent non-compliance is avoided.

2.8 Quality Assurance and Quality Control

The written discussion (61 FR 21126) on Appendix A, Section 2.8 states that the NRC intends for utilities with multiple collection sites to submit specimens from each collection site to the same HHS laboratory. Since multiple collection sites are often many miles apart, there is an unnecessary burden for having utility personnel send samples from these multiple sites. The only area challenged by submitting from multiple sites is the courier, who can be a laboratory courier, the U.S. Postal Service or a private courier service. The courier does not sign the chain of custody, nor does 10 CFR Part 26 have any requirements for the courier to do so. The purpose of blind performance tests is to assure that the HHS laboratory correctly identifies the substances it is testing for. Submitting samples from each one of the multiple sites to the same HHS laboratory does not benefit public health and safety.

(e)(ii)(3) Delete the requirement "In addition, 10 percent of the positive blind samples must be properly adulterated or diluted and "spiked" to 60 percent of the cut-off value to challenge the laboratory's ability to determine specimen validity as required by section 2.7 (e)." There are no manufacturing requirements for blind performance samples. Also, there are no manufacturing requirements for adulterated or dilute blind performance samples. The NRC should not impose more stringent requirements on HHS-certified laboratories than even the certifying agency requires. This is especially true when the NRC required testing is a minority of the total workplace forensic testing performed by these HHS-certified laboratories. Limit of detection testing should not be permitted unless sanctioned by HHS.

2.9 Reporting and Review of Results - No comment.

4.1 Use of HHS Certified Laboratories

The Substance Abuse and Mental Health Services Administration (SAMHSA) has advised caution when taking action on cutoff levels more stringent than specified by HHS guidelines. They point to concerns about defensibility. The NRC should not advise licensees to test dilute samples at LOD. Although these proposed revisions to 10 CFR Part 26 have been reviewed by SAMHSA, they are NOT approved by SAMHSA. The purpose of the drug testing requirements in 10 CFR Part 26 is to identify users through scientifically recognized and legally defensible methods. In an effort to identify users with methods that are currently questioned and not approved by HHS, the proposed requirements only add additional paperwork and time burden, testing expense, and defensibility risk. The proposed requirements to test at LOD and take action based on the results of such testing should be reviewed as required by the backfit rule.