80 pages

OFFICE OF THE UNDER SECRETARY OF DEFENSE

WASHINGTON, DC 20301-3000

ACQUISITION

September 18, 1992

DP(DARS)

MEMORANDUM FOR SHIRLEY CURRY, OASD(PA)(DFOI & SR)

SUBJECT: DAR Case 88-083, Drug Free Work Force

Attached are 14 public comments received to date on the proposed rule of subject case published in the Federal Register on July 23, 1992, (57FR32769). This case involves revisions to DFARS Parts 223 and 252, Drug Free Work Force.

Additional public comments received before the closing date, October 21, 1992, will be forwarded at a later date.

These comments are provided for the public's review or request for copies. Our case manager is Mrs. Linda Neilson, at 697-7266.

Nancy Ladd

Nancy L. Ladd
Colonel, USAF
Director, Defense Acquisition
Regulations Council

Attachments

DAR Case 88-083, Drug-Free Work Force
Public Comments
Received as of September 18, 1992

(Public Comment period 7/23/92 - 9/21/92)

Canning, Donald T. (Atty)	5 pgs
Chimera Research & Chemical, Inc.	1 pg
[no letterhead/same text as Chimera Research	1 pg]
Chimera Research & Chemical, Inc.	57 pgs
DCS Corporation	2 pgs
DoDIG	1 pg
Government Contractor's Assistance Network	1 pg
International Association of Machinists & Aerospace Workers	1 pg
Mission Research Corporation	1 pg
Shipbuilders Council of America	2 pgs
Spectra Diode Laboratories, Inc.	1 pg
Tampa Shipyards Incorporated	1 pg
Tampa Metal Trades Council	1 pg
3-M Corporation	2 pgs

August 5, 1992

11208 Harbor Court
Reston, VA 22091

Defense Acquisition Regulation Council
ATTN: Mrs. Linda W. Neilson
OUSD(A) 3063 Defense
Pentagon
Washington DC. 20301-3062

Reference: Proposed Rule, DoD Drug-Free Work-force
DAR Case 88-083

Dear Mrs. Neilson:

I submit the following comments regarding the "Proposed Rule and Request For Comments" on Department of Defense (DoD) regulations implementing the Drug-Free Workplace Act. See 57 Fed. Reg. 32769. In short, the regulation imposes unreasonable cost and administrative burdens upon contractors; imposes significant litigation risks on both contractors and DoD; fundamentally misconstrues DoD's ability to preempt state law by regulation; and ignores the impact on contractor employee morale. Each of these subjects is treated below.

I. COST AND ADMINISTRATIVE BURDENS

This implementing regulation will place, in fact already has placed, a significant burden on DoD contractors, both large and small. While the text of the regulation does not appear on its face to require great time or effort, the reality is quite different. The following are steps which contractors must, prudently, undertake to comply with the regulation as proposed:

(A) Promulgate a Policy Statement: The regulation clearly requires a written policy statement, and its dissemination to employees. All company policy statements, particularly those which arguably involve an intrusion into employees' privacy, require review by legal counsel. The state of the law in this area is in extreme flux, making legal review all the more critical.

The Supreme Court has upheld random drug testing only of public employees engaged in safety-sensitive positions, drug interdiction, or where firearms are used in job performance (see NTEU v. Von Raab, 489 U.S. 656 (1989) and Skinner v. RLEA,

489 U.S. 602 (1989)). The U.S. Court of Appeals for the D.C. Circuit struck down the random drug testing portions of the Department of Justice's drug testing program as it applied to all employees with access to grand jury proceedings (Harmon v. Thornberg, 878 F.2d 484 (D.C. Cir. 1989)). The Court only upheld the program's application to personnel required to maintain Top Secret security clearances. See also NTEU v. Yeutter, 918 F.2d 968 (D.C. Cir. 1990) and AFGE v. Cheney, 944 F.2d 503 (9th Cir. 1991).

If the government cannot constitutionally subject broadly based groups of its own employees to such intrusion, neither can it force its contractors to subject their employees to similar treatment. Governmental action (e.g., implementing procurement regulations) cannot be transformed into purely private conduct between employer and employee so easily and transparently. More on this subject below.

Given the state of the law and the propensity of disgruntled former employees to assert wrongful termination claims, professional advice in drafting the policy statement is a necessity for any prudent business person. If the employer is without the benefit of inside legal counsel versed in this obtuse area, the cost for competent counsel will likely be on the order of $10,000 to $15,000.

(B) "Supervisory Training": Without the benefit of further guidance or definition, the contractor is required to "train supervisors to identify and assist" employees with drug problems. While these terms are obviously not self-defining, the prudent contractor will assume, at a minimum, that it must engage the services of a physician or qualified substance abuse counselor to conduct seminars to teach supervisors these subjects. Very few DoD contractors have this resource in-house. While the cost (and the quality) of such services certainly vary greatly, the costs can reasonably be expected to be something on the order of $10,000 per year, including the cost of the supervisors' time to attend such training seminars.

(C) The Testing Program: The regulation requires contractors to institute a program of random drug use testing of employees in "sensitive positions" (as that term is defined in the regulation, and which definition goes well beyond those holding Top Secret security clearances). It is perfectly safe to assume that no (or only a very few) DoD contractors maintain NIDA approved laboratories in-house. The cost of collection, laboratory fees, medical review of results, and reporting is approximately $100 per test, based upon my survey of the market. The total cost to the contractor is, of course, completely dependent upon the number of tests performed per year. This variable is, in turn, completely dependent upon the overall size of the work-force, the number of employees in sensitive positions, and the percentage of sensitive position - employees the contractor decides to test. The regulations provide not one whit of guidance on these question, thus an estimation of actual cost is not possible.

Quantifying the total costs of implementing the mandated program is impossible given the differing sizes of DoD contractors, the lack of definition (or even guidance)

contained within the regulation itself about important details (e.g., random testing sample size, frequency of random testing, frequency of supervisors' training, etc.), and varying in-house resources contractors posses. It is reasonable to conclude, however, that for a contractor with 75 to 100 employees, the start-up and first year running costs of the Drug-Free Workplace program under this regulation will be on the order of $50,000. In all fairness, costs should decrease substantially in following years.

II. LITIGATION RISKS

The regulation appears to proceed from an assumption that either: (1) As a private employer, the contractor may randomly test employees without regard to legal prohibitions or litigation risk rooted in tort law and/or constitutional search and seizure constraints, or (2) The contractor is immunized from such legal risk by virtue the last sentence of the regulation which reads: "The requirements of this clause take precedence over any State [sic] or local laws to the contrary." Neither assumption is tenable.

A survey of the case law regarding wrongful termination and invasion of privacy is well beyond the scope of this comment. It should be pointed out, however, that an employer (public or private) is not normally privileged to conduct inquiry into the private, non-job related conduct of its employees. Failure to observe this principle can, and has, resulted in significant civil judgments against employers.

Perhaps the best way to illustrate this risk, both to the contractor and DoD, is to pose a few hypothetical (although by no means worst-case) scenarios.

Scenario (1): Employee A , whose hiring predates this regulation and who has excellent performance reviews, is in a sensitive position (as defined by the regulation). Employee A does not hold a Top Secret security clearance. Employer has no reason to believe he is a drug user, on or off-duty. After the drug testing program has been published in Employer's policy statement and has been running for several months without incident, Employee A is randomly selected for testing.

Employee A refuses to be tested, and challenges Employer to demonstrate any factual predicate (or reason to believe) he does, or ever has used illegal drugs, and/or that his work was thereby affected. Employer cannot make this demonstration, but nonetheless terminates his employment. Employee A sues Employer, in federal court, alleging a deprivation of civil rights under the Civil Rights Act (42 USC 1983), a Fourth Amendment violation, ERISA violations (arguing his termination was a pretextual firing to prevent him from becoming fully vested in Employer's retirement plan), and attaches pendent state law causes of action for wrongful termination, invasion of privacy, slander, and whatever else he can think of. As to the claims based upon federal statutes, Employer impleads the United States, arguing that if its

(Employer's) actions were wrongful as to Employee, it did so only because it was forced to by DoD.

Scenario (2): Prospective Employee B, a resident of California (or any other state or local jurisdiction which prohibits no-cause random drug testing) applies to Employer, doing business in California, for employment in a sensitive position (as defined by the regulation). Her education, work experience, and subjective ratings clearly place her as the candidate of choice. She holds a Secret security clearance, which can be transferred to Employer without administrative difficulty. She is offered the position contingent upon passing a drug test as required by Employer's policy statement (supplied to her). She refuses testing, and Employer rescinds its employment offer.

Prospective Employee B sues Employer in state court alleging a violation of the state statute, and simultaneously files against both Employer and the United States in federal court under the Civil Rights Act and the Fourth Amendment.

Other scenarios, involving botched testing or poorly conceived administrative procedures (both of which were rampant in the early years of the testing programs for military personnel) could be postulated. All scenarios present real world nightmares for contractors.

DoD has not agreed to indemnify contracts from losses incurred when (not if) some of these scenarios play out. No doubt it cannot without Congressional authorization. Instead, it carries forward the transparent fiction that the mandated testing program is a private matter between employers and employees, untouched by federal action with its attendant statutory and constitutional constraints.

III. THE PREEMPTION QUESTION

The last sentence of the proposed regulation purports to preempt "State [sic] and local law to the contrary." Federal *legislation* can preempt state law (both statutory and common law) by virtue of the Supremacy Clause of the U.S. Constitution. However, federal preemption is not assumed merely from the existence of a conflict between federal and state *statutes*, much less from a conflict between state statute and federal *regulation*.

To establish preemption by federal *statute*, the following must be shown: (1) A clear Congressional intent to preempt state law; (2) Pervasive federal activity within the substantive area; (3) An overriding federal, as opposed to state, interest in the subject matter, requiring national uniformity; and (4) A danger of a conflict between state and federal programs (see Pennsylvania v. Nelson, 350 U.S. 497 (1956)). See also Hillsborough County v. Automated Medical Labs 471 U.S. 707 (1985) and Pacific Gas & Electric v. Energy Resources Comm'n, 461 U.S. 190 (1983). The Drug-Free Workplace Act, under which this proposed regulation is promulgated, contains none of

these elements. The *regulation's* one sentence recital of intent to preempt state and local law could not be more beside the point.

The proposed regulation puts contractors in states and localities which have statutes or ordinances prohibiting non-cause random drug testing at greatest legal risk. The argument that the regulation preempts state law is not only a transparent fiction, it is just plain silly.

IV. EMPLOYEE MORALE CONCERNS

The majority of DoD contractors' employees are not fresh from the military where random drug testing is standard operating procedure. Nor are they aircraft pilots or train engineers. Most are civilians who have never been assumed to be wrongdoers, and who will resent being required to prove that they do not use illegal drug. There is a cost (however non-quantifiable) to this type of intrusion, both to the employer and, ultimately, to DoD.

V. SUMMARY

The proposed rule will place a significant financial and administrative burden on contractors, both large and small, and will adversely affect the morale of the work-force. There is not the slightest empirical evidence that DoD contractor employees, as a class, have a drug use problem, nor that a random drug testing program will advance the public interest by protecting national security. DoD appears to be attempting to cloth its desire to extend random drug testing into the civilian community with the imprimatur of private employer, voluntary action. It thus hopes to avoid statutory and constitutional constraints applicable to governmental action.

The proposed regulation is ill conceived, overly broad as to the work-force covered, and is poorly drafted. I would recommend that it be withdrawn completely before it engenders yet another round of drug testing litigation.

As we say in Virginia, this dog of a regulation won't hunt.

Respectfully Submitted,

Donald T. Canning
Attorney at Law

CHIMERA RESEARCH & CHEMICAL, Inc.

Defense Acquisition Regulations Council
c/o Mrs. Linda W. Neilson
OUSD(A)
3062 Defense Pentagon
Washington, DC 20301

RE: DAR CASE 88-083

Mrs Neilson,

Upon review of the proposed DOD Drug-Free Work Force program I have noted a GLARING DEFICIENCY in the testing requirements. This rule does not require that a urine sample submitted for analysis be subjected to testing for evidence of adulteration. Over the last few years, as workplace drug testing programs have proliferated, so too have information pipelines which disseminate data on ways to defeat the drug test (i.e. HIGH TIMES 900-988-4637 phone service). These adulteration techniques range from simple (table salt, or mineral acid added to the specimen) to sophisticated (consumption of ammonium chloride), and are very effective at masking drugs present in urine. The only effective methods for detection of most of these adulterants are pH and Specific Gravity. This fact is supported by numerous independent research articles published over the last few years. One such article was authored by Dr. Cody, the Deputy Director of the Air Force Drug Testing Lab at Brooks Air Force Base, and published in FORENSIC SCIENCE REVIEW (2:63; 1990, p 64-74). Technology is currently available which enables any laboratory facility to perform pH and Specific Gravity for literally pennies (10 cents per sample).

Any drug testing program that does not address the issue of adulteration will FAIL to unmask the serious and savvy drug user. If the DOD is dedicated to eliminating illicit drug use in the workplace it is imperative that it require an effective adulteration detection program that includes pH and Specific Gravity.

Sincerely,

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Edna J. K

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Sincerely,

Jesse Carter, V.P. Tech. Sales

1

Specimen Adulteration in Drug Urinalysis

J. T. Cody
Air Force Drug Testing Laboratory
Brooks AFB, TX 78235-5000

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1042-7201/02-01-90/63-75/$6.50 •

A. In Vivo Adulteration

In vivo adulteration refers to substances individuals administer to themselves for the purpose of altering drug testing results. These adulterants fall into several general categories. One of the most popular idea is that there is a "magic" potion that a drug abuser can take to mask the presence of the drug in the urine or flush the drug out of their system before the test.

1. "Magic" Potions

A variety of substances have been reputed to interfere with the drug testing process when taken by the drug abuser prior to providing a sample for testing purposes. Many of these myths are perpetuated by the fact that a drug user who is taking substance "X" is given a drug test and is reported as negative. The fact that the drug was no longer in the system or perhaps present but below established cutoff limits is inconsequential to the drug user.

Not all advice given to the drug user is worthless. A fairly extensive treatment of methods to avoid detection of drug use has been reported by Hoffman [8]. Many of the technical issues discussed in this reference are incorrect, but much of the advice from this reference, along with magazines generally associated with the drug community, have much advice for the drug user to follow.

Simple dilution of the urine by self administration of large volumes of fluid can cause the concentration of the drug to be significantly lowered. In addition, some of the substances can, as a consequence of taking large amounts, alter urine pH to some extent. The excretion profile of some drugs can be altered by shifts in urinary pH as exemplified by the amphetamines excretion patterns reported by Beckett and Rowland and others [1,2,7,27]. With an alkaline pH, the excretion rate of amphetamines is slower, and the time the drug can be detected in urine is longer; at the same time, the concentration is lower than if excretion is completed in a shorter period of time. Done [6] also reported an enhanced phencyclidine (PCP) excretion pattern by acidification of the urine. Thus, knowing when a sample will be taken becomes the most crucial factor.

Some substances which are reputed to have caused urine to test negative, regardless of whether or not the drug is actually present, are vitamin C, vinegar, a variety of acidic fruit juices, and golden seal root either in capsule form or, less frequently, brewed as a tea. As reported by Morgan [20], golden seal root gained its reputation in the urine drug testing arena due to the presence of alkaloids in the plant material that interfere with the thin layer chromatography (TLC) tests for opiates. Schwartz and Bogema [26] have demonstrated, however, that the interfering effect can be avoided by the use of current test methodologies. Nevertheless, the specific drug class and test methodology associated with this adulterant seem to have been forgotten, and it has been continuously considered effective in causing negative test results for several drug categories. Although there is little scientific data to prove that in vivo adulteration does not work, this fact is accepted in the scientific community [15,19,25] and recognized in drug culture publications [8,18].

Brunk [4] reported that ibuprofen may cause false negative results in the confirmation analysis of the marijuana metabolite, 11-nor-Δ^9-tetrahydrocannabinoid-9-carboxylic acid (THC-COOH). This report would make self administration of large doses of ibuprofen a desirable step for marijuana users. It is interesting to note that ibuprofen has been reported by Blanke [3], McBay [16], and Warner [32] as the cause of false positive results in the EMIT screening assay. Despite the fact that Syva Company [28] has eliminated this problem by the use of a different enzyme in the assay system, the rumor still persisted that ibuprofen caused false positive results for the marijuana assay. Similarly, Larsen and Fogerson [12] reported that with fluorescent polarization immunoassay (FPIA) false positives of benzodiazepine and barbiturate can result from the presence of nonsteroidal anti-inflammatory drugs ibuprofen and fenoprofen, and naproxen, respectively. In a recent study, however, Rollins et al. [23] reported that subjects using the nonsteroidal anti-inflammatory drugs ibuprofen, naproxen and fenoprofen in both acute and chronic doses were not found to be positive for cannabinoids, benzodiazepines, or barbiturates using either the EMIT or FPIA assay systems. While there were some unconfirmed positive samples in this study, they did not occur in samples which contained the highest concentrations of the drugs/metabolites indicating the possibility that the positive result was most likely due to some other influence.

2. Diuretics

While studies conducted by Podkowik et al. [22] indicated that the diuretic itself typically would not interfere with the test, it was also reported by Manno [15] that it might have the capability of diluting the concentration of the drug to a level which is either not detectable or is below the established administrative cutoff limits. Some diuretics are very potent and fast acting. These can be used to cause significant dilution of the drug in the urine in a very short time. Some over-the-counter "water loss" pills do have some diuretic effect as do some commonly encountered foodstuffs like tea. If the individual has access to potent prescription diuretics, the impact can be substantial. Diuresis induced by simply ingesting large volumes of liquids can cause dilution of

very near the "normal" range. It should be noted that the potential for punitive action to be taken against an individual who has been identified as having adulterated a sample brings a significant burden on either the collection site personnel or laboratory who identifies the sample as being adulterated; thus, the identification of some suspicious samples may go unreported to avoid defending observations that may be considered inconclusive.

A. Collection Site

The first place adulteration of a sample can be detected is at the collection site. At the time the sample is provided, there are a number of measures which may provide signs of adulteration that cannot be monitored even a short time after the sample was collected. It is unusual for a collection site to have the capability to carry out many tests on the sample; but even the look, smell, and temperature of freshly voided urine can give clues to some forms of adulteration.

The Mandatory Guidelines [14] which describe collection in the federal civilian employee drug program call for denying access to water or other chemicals which could be used for dilution or adulteration, removal of excess clothing (i.e., coats), and allows the individual to provide the specimen in privacy. The temperature of the voided sample is to be tested within four minutes of collection and must be within the range of 32.5-37.7 °C (90.5-99.8 °F). If there is any indication of substitution, dilution or adulteration, the individual is requested to provide another sample under direct observation. It is also required that both the suspect sample and the sample taken under observation are sent to the laboratory for testing. In a study concerning the use of temperature measurement as an alternative to observed collection, Judson et al. [9] indicated that a temperature range of 32.5-36.7 °C would include 99% of the population based on a sample of 782 urine specimens taken from individuals in a drug treatment program. This same study evaluated the potential for deception by taking water heated to body temperature (37 °C), placed into condoms, and held under the arms of 12 persons for a period of one hour. The water was then dispensed into a urine collection bottle and the temperature measured. The results showed an average temperature of 33.9 °C and all twelve samples fell within the acceptable limits. This clearly demonstrated that the use of temperature measurement is helpful but will not eliminate dilution or substitution of a sample as described above by Hoffman [8].

The appearance of a sample can give an indication of many forms of adulteration, as can the smell. Some adulterants, even salt, may not completely dissolve if too

Table 1. Effect of adulterants on urine pH and specific gravity (Reprinted with permission from *J Anal Toxicol* 13:277; 1989.)

Adulterant		pH			Specific[a]
Name	Conc. (%)[a]	Day 1[b]	Day 2[c]	Day 7[d]	Gravity
Ammonia	1	6.4	6.5	6.5	1.021
	5	8.8	7.9	7.8	1.021
	10	9.5	9.0	8.8	1.020
Ascorbic acid	1	4.2	4.3	4.5	1.025
	5	3.5	3.6	3.7	1.035
	10	3.1	3.2	3.3	1.035
Bleach	1	6.0	6.1	6.2	1.021
	5	6.0	6.1	6.2	1.022
	10	6.1	6.2	6.2	1.025
Blood	0.1	6.0	6.1	6.1	1.020
	1	6.0	6.0	6.1	1.020
	5	6.3	6.3	6.3	1.020
	10	6.4	6.5	6.4	1.021
Detergent (ionic)	1	6.1	6.4	6.4	1.020
	5	8.1	7.8	7.7	1.021
	10	9.5	9.3	9.1	1.022
Drano®	5	13.4	13.3	12.9	1.035
	10	13.5	13.4	13.1	1.035
Golden seal root	0.009	6.0	6.0	6.1	1.021
	0.090	6.0	6.0	6.1	1.021
	0.450	6.0	6.0	6.5	1.022
	0.900	6.0	6.0	7.0	1.022
Lemon juice	10	3.5	3.5	3.7	1.022
Lime-A-Way®	1	4.4	4.5	4.7	1.021
	5	2.1	2.2	2.3	1.024
	10	1.8	1.9	2.0	1.027
Methanol	10	6.0	6.0	6.0	1.025
Salt	1	6.0	5.9	5.9	1.025
	5	5.7	5.8	5.9	1.035
	10	5.5	5.7	5.8	1.035
Soap	1	6.0	6.0	6.1	1.022
	5	6.0	6.1	6.1	1.024
	10	5.9	6.0	6.1	1.026
Sodium phosphate (tribasic)	1	8.7	8.6	8.5	1.020
	5	11.5	11.3	11.1	1.029
	10	12.0	11.9	11.8	1.035
Vanish®	1	4.2	4.4	4.5	1.020
	5	1.8	1.9	2.0	1.031
	10	1.4	1.5	1.7	1.035
Vinegar	1	5.6	5.7	5.8	1.021
	5	4.9	5.0	5.1	1.021
	10	4.4	4.7	4.9	1.020
Visine®	1	6.0	6.0	6.1	1.021
	5	6.0	6.1	6.1	1.020
	10	6.0	6.1	6.0	1.020
	25	6.0	6.1	6.1	1.017
pH 13[f]		13.0	12.8	12.7	NT[g]
Control		6.0	6.1	6.1	1.020

[a]Weight:weight.
[b]Day of preparation of adulterated sample.
[c]One day after addition.
[d]Six days after addition.
[e]Measured on day one.
[f]pH adjusted but not buffered.
[g]Not tested.

detergents, but they too are not designed for testing urine samples. Some adaptation of these testing procedures may be developed, but currently the most effective methods are several general clinical parameters including pH, specific gravity, sodium and chloride and creatinine contents. Although interpretation of the results may be complicated in old samples, they can still be useful tools.

IV. IMPACT OF ADULTERANTS

A. Screening Procedures

The screening procedure is more sensitive to the impact of adulterants than is the typical confirmatory test like gas chromatography/mass spectrometry (GC/MS). Although a wide variety of screening procedures are available and used, the most commonly used methodology is immunoassay, including enzyme multiplied immunoassay (EMIT), fluorescent polarization immunoassay (FPIA), and radioimmunoassay (RIA). Each system is vulnerable from the standpoint of the antibody protein. Any substance which will bind with or disrupt the structure of the antibody will have a potentially significant impact on the test results. In the case of the enzyme or fluorescent immunoassays, the possibility also exists for adulterants to impact the coupled reaction for the enzyme system, or to cause absorbance in the range used by either system to measure the presence of the drug. Radioimmunoassay is less sensitive to the influence on the measurement step of the assay procedure, because none of the common adulterants would be expected to interfere with normal radioactive decay or its measurement.

The impact of adulterants also depends on the drug involved and the test being used. Published data show the immunoassay tests for the marijuana metabolite, THC-COOH, are most likely to be impacted by the presence of a variety of adulterants [5,17,21,31]. As observed by this author [5] and Warner [31], the effect might be a positive rather than a negative one, just opposite to the intended purpose. In some cases, whether the end result is positive or negative depends upon which immunoassay system is utilized. For example, detergent caused a false negative result in the EMIT assay [10,17,24,30,31] but caused samples to appear to have significantly higher concentrations of drug in the RIA assay [5].

A variety of different substances have been used in an attempt to circumvent drug-testing programs. Many have no documented effects; most that do are not obtained under stringent scientific investigation. There are many stories in the forensic community about the use of various substances which have been discovered in "urine" samples,

Table 2. Summary of references showing analytical data associated with adulterants and assays

Compound	Assay[a] RIA	EMIT	FPIA
Alcohol	5,31	31	31
Ammonia	5		
Ascorbic acid	5	26	
Bleach	5,31	17,24,31	31
Blood	5	24	
Detergent	5,31	24,31	31
Drano®	5	17	
Golden seal root	5	17,26	
Lemon juice	5	17,24	
Lime-a-way®	5		
Peroxide	31	31	31
Salt	5,31	10,17,24, 30,31	31
Soap	5	17,30	
Sodium phosphate (tribasic)	5		
Vanish®	5		
Vinegar	5		
Visine®	5	17,21	
pH 13[b]	5		

[a]Data from GC/MS and TLC described in text.
[b]pH adjusted but not buffered.

unfortunately, little of that information has made it into the literature. While in vitro data are not wide spread, data from in vivo studies are virtually nonexistent. Table 2 is a summary of the few available references concerning the effects of various adulterants on common drug testing methodologies.

1. Alcohol

When tested by RIA in this author's laboratory [5], the presence of methanol at a concentrations of up to 10% showed no influence on the results of positive (150% of the cutoff level as define by the Mandatory Guidelines [14]) or negative samples for amphetamine, barbiturates, benzoylecgonine (cocaine metabolite), opiates, PCP, or THC-COOH.

Addition of ethanol, isopropanol, and ethylene glycol showed no effect on the EMIT assay system. A small effect of these alcohols was reported by Warner [31] for the RIA and FPIA assay systems, but in no case did they cause a false positive or false negative result.

2. Ammonia

In the RIA system, the presence of ammonia at concentrations of 5 and 10% caused benzoylecgonine positive samples to be negative after seven days. Al-

7. Drano®

At a concentration of 10%, Drano® produced the most dramatic and consistent results of any of the adulterants on the RIA system. All samples, both positive and negative, showed counts which were consistent with a high concentration positive sample. The THC-COOH, morphine, amphetamine, PCP, and barbiturate assays were likewise effected at the 5% level. The benzoylecgonine negative sample, although still negative, showed a significant change in apparent concentration. At the opposite extreme, at a concentration of 1%, the benzoylecgonine assay gave a false negative result. In this case, results obtained from the positive samples and the negative controls were indistinguishable [5].

False negative results for positive drug samples were seen with the EMIT assay system for amphetamine, benzodiazepine, barbiturate, benzoylecgonine, opiates, and THC-COOH. Drano® showed a concentration dependent impact on several of the assays; but in other assays, the EMIT system gave false negative results regardless of the concentration of the drug. In all cases, the effect of Drano® on the EMIT system was to cause a false negative result [17].

8. Golden Seal Root

In the RIA system, golden seal root, as an in vitro adulterant at a concentration of 0.9%, had no influence on the results of either positive or negative samples for any of the drug classes tested except for the THC-COOH assay. The effect on the positive THC-COOH samples was to cause the apparent concentration to be lowered; but there was no measurable effect on the negative THC-COOH samples. At lower concentrations of the adulterant, there was a measurable, but less marked, effect. At 0.45% the positive sample was at the cutoff level after one day, and showed clearly negative results after seven days. At the highest concentration, equivalent to the contents of one capsule in a 60-mL sample of urine (0.9%), the results were clearly negative on both days. At each level, there was an apparent decrease in concentration between day one and day seven. The difference between these ratios was larger with the increasing concentrations of the adulterant [5].

A study which used tea brewed from the golden seal plant material as the in vitro adulterant showed a concentration dependent effect on the EMIT THC-COOH assay [17]. In that study, concentrations of golden seal at 30 mg/mL caused samples containing over 100 ng/mL of the drug to give a false negative result. In an in vivo study [26], five subjects each smoked a marijuana cigarette and then consumed 1,560 mg of golden seal root in capsule form one and a half hours later. Several hours later, a urine sample was collected from each individual with a subsequent sample taken at a later time. Test results for all samples from all subjects were positive by the EMIT assay system and by GC/MS.

9. Lemon Juice

The presence of lemon juice at a concentration of 10% had no influence on the results of either positive or negative samples for amphetamines, barbiturates, benzoylecgonine, opiates, PCP, or marijuana when tested with the RIA system [5].

Lemon juice and its effect on the EMIT assay system was evaluated and shown to effect only urine samples supplemented with drugs, and even then only at an adulterant concentration of 500 mL/L [17]. Samples from actual marijuana, amphetamine, barbiturate, cocaine, or opiate users were not affected.

10. Lime-A-Way®

In the RIA assay system, the presence of Lime-A-Way® (a strong household cleaner) in urine samples caused both the amphetamine and morphine positive samples to read at the cutoff level. The THC-COOH assay showed no effect with an adulterant concentration of 1%, but there was a substantial effect at the 5% and 10% levels, with the 10% sample reading at the cutoff level for the negative samples [5].

11. Peroxide (H_2O_2)

Adulteration of urine samples with hydrogen peroxide caused an apparent increase in the apparent concentration for both positive and negative benzodiazepine samples tested by the FPIA system; these increases were not significant enough to caused false positives. The RIA and FPIA THC-COOH assays showed an apparent increase in concentration for positive samples but those that contained no drug were not effected [31].

12. Salt

The presence of salt at 10% showed no influence on negative samples for amphetamines, barbiturates, benzoylecgonine, opiates, PCP, or marijuana when tested with RIA. Likewise, there was no effect on positive samples except for THC-COOH samples which showed an apparent decrease in concentration to the cutoff level [5].

The impact of salt on the EMIT assay system has been the subject of several studies [10,17, 24,30,31]. It was reported by Kim and Cerceo [10] that, at a levels of 50 g/L, salt caused the EMIT assay to produce false negative

Although consumption of large amounts of vinegar is reputed to cause false negatives, there is no scientific evidence to support this claim. Even *High Times* magazine acknowledges that there is no evidence that any substance, including vinegar, will cause a false negative drug test. In an interesting comment regarding the use of vinegar to defeat drug tests, Montague [18] reported that individuals that were sick due to the consumption of a large amount of vinegar, in an attempt to foil an employer's urine drug testing program, had virtually no chance of success suing their employers for damages.

17. Visine®

Except for the THC-COOH positive samples, the presence of Visine® at concentrations of up to 10% had no influence on the results of either positive or negative samples for amphetamines, barbiturates, benzoylecgonine, opiates, PCP, or marijuana when tested with RIA. Analysis of samples positive for THC-COOH showed results at the cutoff level at Visine® concentrations of 1, 5, 10, and 25% after only one day [5].

Visine® was also shown to affect the EMIT analysis of benzodiazepines and THC-COOH by causing false negative results [17]. A mechanism for the action of Visine® on the THC-COOH EMIT assay was proposed as the effect of benzalkonium chloride micelles interacting with the THC-COOH in the samples. The borate buffer also seemed to have an additive effect with the benzalkonium chloride. GC/MS analysis conducted by Pearson et al. [21] indicated that the drug was not chemically altered; the adulterant presumably impacted the assays by affecting the solubility and binding to the vessel wall resulting in the lowering of detectable concentration in the specimen.

18. pH Variation

Evaluation of the RIA system showed that adjusting the urine pH to 13 had no influence on the results of either positive or negative samples for PCP, amphetamine, barbiturate, and morphine. The benzoylecgonine assay showed no effect on negative samples, but positive samples gave the same result as the negative control after only one day. The same result was seen on day seven. THC-COOH analysis showed only a slight apparent increase in concentration for the positive samples; however, the negative samples were at the cutoff level on day one and gave positive results on day seven [5]. While this was the only study which directly investigated the effect of high pH, several other studies attributed the effects of some adulterants to the effect of the pH on the assay rather than a direct action of the adulterant. In the RIA assay, adulterants which raised the pH to around 10 were associated with positive results. Likewise adulterants which dropped the pH to less than 4 caused negative samples to read at the cutoff level [5].

The effect of the pH of a urine sample on the assay is dependent on the buffering capacity of the urine sample and the reagent mixture. The THC-COOH assay was shown to be more readily affected by samples which had extreme pH values than other RIA assays tested. This was most likely due to the larger amount of urine used in the THC-COOH assay and the lower buffering capacity of the reagent mixture [5].

B. Confirmation Procedures

The confirmation of the presence of a drug or its metabolite in urine samples is most often carried out using a sophisticated analytical procedure and instrumentation like GC/MS. With the absolute specificity of a properly conducted assay using this methodology, it is rare for an adulterant to interfere with the testing process. The entire analytical procedure must be sufficiently robust to prevent extremes of pH to affect extraction, or loss of a derivatizing reagent due to reaction with a high concentration of an adulterant. An example of interference with a confirmation assay is the impact of high concentrations of ibuprofen on a THC-COOH assay as reported by Brunk [4]. Use of a deuterated internal standard or addition of sufficient derivatizing reagent would eliminate or at least detect this kind of interference. This same impact would be expected with a number of other acidic drugs which might be found in urine.

The adulterants which actually cause a change to the drug, as is seen with benzoylecgonine at high pH, will indirectly affect the confirmation test because the system will correctly show there is little or no drug present in the sample due to degradation. The decreased benzoylecgonine, unfortunately, does not correctly reflect the actual sample status when it was provided. There is little or nothing that can be done about this situation unless the samples are tested for pH at the collection site or are tested as soon as they enter the laboratory. In situations where the time between collection and testing is extended, changes in pH may not necessarily be attributed to adulteration.

V. CONCLUSION

There is little doubt that with the increased use of urine drug testing, particularly in the American workplace, there will be an increased probability that urine specimens will be adulterated. Samples collected without direct observation are far more susceptible to this possibility. In

CORRECTIONS

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Drug Urinalysis-Related Review Articles Published in Forensic Science Review

Title	Author(s)	Vol/Issue	Publication Date
Morphine and Codeine in Biological Fluids: Approaches to Source Differentiation	ElSohly MA & Jones AB	1/1	June, 1989
Urinary Excretion of Commonly Abused Drugs Following Unconventional Means of Administration	Cone EJ & Huestis MA	1/2	Dec., 1989
Specimen Adulteration in Drug Urinalysis	Cody JT	2/1	June, 1990
Stability of Drugs of Abuse in Biological Specimens	Levine B & Smith ML	2/2	Dec., 1990
The Interaction of Ethanol and Drugs	Havier RG	3/1	June, 1991
Applications of Solid-Phase Extraction to Drug Urinalysis	Platoff GE & Gere JA	3/2	Dec., 1991

Should Adulteration testing be performed on urines for drugs of abuse? Are Drug testing laboratories taking the necessary steps to detect Adulterated urines?

The following booklet includes articles, monographs, and excerpts from journals and federal government publications that affirm the need for testing for **adulteration** as part of a complete urine drug testing program. Analysis for **pH** and **specific gravity** will detect in **VITRO** (in test tube) and in **VIVO** (in living body) adulteration that can mask the presence of drugs of abuse.

Is knowledge of how to adulterate urine readily obtainable by the average drug abuser? The answer is **yes**. There are publications (e.g. High Times, etc.) available to the general public as well as 900 phone services that disseminate this information to the general public. Many adulterants are easily obtainable (table salt, diet salt, liquid hand soap, bleach, vinegar, Visine®, sodium bicarb., Goldseal Tea®, Drano®, soft drinks, hydrogen peroxide, etc.). Use of some, but not all in **VITRO** adulterants can be eliminated by direct observation of the subject during the collection process. Direct observation, however, is not acceptable in most cases. In **VIVO** adulterants present an additional problem because they must be consumed several hours or days prior to testing and can only be detected in the laboratory.

In conclusion, a complete and thorough analysis for drugs of abuse must include tests for **adulteration**. Evidence shows that the most effective indicators of adulteration are **pH** and **specific gravity**. NOTE: **Creatinine is not a substitute for specific gravity.** As stated by Dr. C.G. Duarte in Renal Function Tests, " daily urinary excretion of creatinine can not be used as a reliable index of the completeness of urine collection." A random urine can be diluted by a factor of 5 and still contain sufficient creatinine to test normal. Therefore, creatinine testing is a poor indicator of dilution. In Fact, some soft drinks will test normal for creatinine. College of American Pathologists and National Institute of Drug Abuse (primary national drug testing regulatory agencies) recommend adulteration testing be performed by drug testing labs.

BOTTOM LINE:

A drug testing laboratory that is not doing pH and specific gravity as part of their drug testing program for adulteration, should not perform urine drug testing for drugs of abuse!

All of the following articles acknowledge that adulteration of positive specimens using household items is possible. These adulterants can affect all three screening methods (**FPIA, EIA, RIA**, and etc.). In some cases false positives are also produced. These false positives can also be very costly to the laboratory because of the labor-intensive nature of GC/MS confirmation testing, and the ensuing delays in reporting results.

The **NIDA** monograph enclosed refers to the in vivo acidification of the urine. This process speeds up elimination of basic drugs (such as cocaine, opiates, amphetamines, PCP, etc.) thereby possibly avoiding detection. In order to be successful, in **VIVO** acidfication must occur some hours in advance of collection. The only means of detection for the technique is urine **pH** testing. All of the enclosed references point out that testing each specimen for **pH** and **Specific Gravity** is the best way to detect adulterated specimens, and thereby preventing false negatives.

THE FOLLOWING IS A SYNOPSIS OF THE ENCLOSED FINDINGS IN A CONVENIENT FORMAT:

FALSE NEGATIVES

ADULTERANT	TEST						
	Amp	Ba	Bz	Coc	THC	Op	PCP
NaCl [B]	E	E	E	E	E	E	E
Bleach [A]	E/F/R	E	E	E	E/F	E/F/R	E/F/R
Drano [A,1,2]	E	E	E	E	E	E	
Soap [A,C]		E	E		E		E
Sodium Bicarb. [A]						E	E
Vinegar [A,1,2]					E		
Visine [1,2]					E		
GoldSeal Tea [D,1,2]					E		

FALSE POSITIVES

	Amp	Ba	Bz	Coc	THC	Op	PCP
Sodium Bicarb.	R	R				R	
Soap	F	F	F/R		F/R		
Bleach			F				
H_2O_2			F				

A= Detected by pH
B= Detected by Specific Gravity
C= Detected by ionic strength
D= Detected by color
1= Not tested on FPIA, RIA assays
2= Not tested on any PCP assay
E= EIA
F= FPIA
R= RIA

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Booklet provided by: *CHIMERA RESEARCH & CHEMICAL, Inc.*

PREFACE and ACKNOWLEDGMENTS:
We at Chimera Research & Chemical would like to thank all of the researchers whom provided the information for the Journals (Clinical Chemistry, Forensic Toxicology, etc.) and booklets (NIDA, etc.) from which we obtained our information. We hope that this booklet will provide a valuble reference source for all drug testing adulteration programs.

CLIN. CHEM. 34/11, 2333–2336 (1988)

Adulterants Causing False Negatives in Illicit Drug Testing

Stephen L. Mikkelsen[1] and K. Owen Ash[2]

Illicit-drug users may attempt to falsify results by in vitro adulteration of specimens. We investigated eight additives (NaCl, Visine™, handsoap, Drano™, bleach, vinegar, golden-seal tea, and lemon juice) claimed by drug users to invalidate enzyme immunoassay (EIA) drug assays. We also analyzed adulterated urine specimens to determine if they could be identified, adding adulterants at several concentrations to 222 EIA-positive specimens confirmed by gas chromatography and mass spectrometry (GC/MS) to contain illicit drugs. To identify adulterated urines, we monitored pH, relative density, and urine color and turbidity at adulterant concentrations that falsified EIA results. Specimens contaminated with NaCl had relative densities >1.035. Liquid Drano™, bleach, and vinegar shifted urine pH outside the physiological range. Golden-seal tea caused a dark appearance, and specimens containing liquid soap were unusually cloudy. Lemon juice had no effect on the assays. Visine™ was the only adulterant not detected. The adulterants interfered somewhat differently with each of the drug assays. EIA assays for illicit drugs can be invalidated by specimen adulteration producing false-negative results. Therefore, if urine drug testing is to be conducted, pH, relative density, and appearance should be assessed and suspect specimens should be rejected. Not all adulterants can be detected, so observed collection is strongly recommended.

Growing public concern over the use of illicit drugs in the workplace has led to analysis of urine as a way to detect and deter drug use (*1*). Testing for illicit drugs has been implemented for many prospective and current employees in industry; personnel of the armed forces; parolees and bail seekers in civilian court systems; workers in the transportation industry; and some role models, such as athletes (*2*). Two factors have led to widespread testing for illicit drugs: technical advances, e.g., the development of the Syva EMIT d.a.u. procedures (*3*), and the growing demand for drug testing by industry (*4*). Society is becoming increasingly aware of the negative impact of drug use on public safety and the high costs of drug abuse in industry owing to related absenteeism, decreased safety, and lost productivity. Annual costs have been estimated at $33 billion in the United States (*3*).

The entire procedure must withstand vigorous legal scrutiny. Therefore, drug-testing laboratories are required to implement extensive precautions to ensure that their results include no false positives. However, adequate methods to secure the data from false-negative results are generally not in place.

Several methods of interference claimed to produce false-negative results are common knowledge to many individuals who undergo testing for illicit drugs (*6–9*). However, those subject to illicit drug testing are usually required to provide a urine sample with little or no advance notice, so they have little opportunity to do in vivo specimen manipulation. The present study is limited to in vitro urine adulteration. From the literature search and during interviews with admitted drug abusers, drug-abuse treatment-center personnel, and clinical toxicologists, eight substances were identified as additives being used by drug users to contaminate their urine specimens in the hope of avoiding detection of illicit drugs. These suspected interferents include household vinegar (*6*), table salt (*6*), liquid laundry bleach (*6*), concentrated lemon juice (*7*), caustic household cleansers (*7*), golden-seal tea (*8*), liquid handsoap (*9*) from rest-room dispensers, and Visine™ eyedrops. Salt concentrations >50 mg/mL (*10*), commercial soap concentrations of >10 mL/L (*9*), and solutions changing the urine pH to <5 or >8 are reported (*5*) to produce false-negative results with Syva EMIT assays. Ionic strength, pH, and relative density (specific gravity) measurements have been suggested as ways to screen for adulterated specimens (*11*).

Here we report an investigation of eight readily available substances claimed to cause false-negative results when added to urine that would otherwise test positive by the EIA screening assays for illicit drugs.[3] We also attempted to identify effective means of detecting urine specimens that are contaminated so that an unadulterated specimen may be obtained.

Materials and Methods

Morphine sulfate, benzoylecognine, and 11-nor-delta-9-THC-9-COOH were obtained from Alltech Associated Applied Science, Deerfield, IL. Amphetamine sulfate was obtained from Smith-Kline, Philadelphia, PA. Oxazepam was obtained from Wyeth Laboratories, Philadelphia, PA. Secobarbital was from Eli Lilly & Co., Indianapolis, IN. The interferents were purchased from a local supermarket or health-food store (golden-seal tea). EIA- and GC/MS-confirmed positive urine specimens (n = 222) were from Associated Regional and University Pathologists, Inc. The EMIT d.a.u. assay reagents and calibrators were from the Syva Co., Palo Alto, CA.

EIA analyses were done in a Hitachi 704 Analyzer from Boehringer Mannheim Diagnostics, Indianapolis, IN. Other instrumentation included a Beckman Expandomatic SS-2 pH meter and a Reichert TS meter.

Supplemented Urine Preparation

Solutions of the purified drugs (metabolite or standards) in isotonic saline were added to aliquots of urine from a healthy drug-free volunteer to achieve concentrations somewhat higher than the cutoff for a positive result. Amphetamine sulfate, benzoylecgonine, secobarbital, oxazepam, and morphine sulfate were added to give a final concentration, after a 1:1 dilution with normal saline, of 0.5 mg/L; 11-nor-

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[1] This investigation was in partial fulfillment of requirements for the M.S. degree in Medical Laboratory Science.

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[3] Nonstandard abbreviations: EIA, enzyme immunoassay; GC/MS, gas chromatography/mass spectrometry; THC, tetrahydrocannibinol.

delta-9-THC-9-COOH was added to 0.06 mg/L. The "positive" cutoff value for amphetamines, barbiturates, cocaine, benzodiazepines, and opiates was 0.3 mg/L. For marijuana, we selected a cutoff of 0.05 mg/L. Thus, 1:1 dilutions of supplemented urine with the potential interferents yielded drug concentrations exceeding the positive "cutoff" limits. Aliquots of the supplemented urines diluted 1:1 with isotonic saline were assayed to confirm the EIA-positive results on the diluted specimens before testing the interferents.

Adulterant Preparation

Before mixing with the drug-supplemented urine specimens, the potential interferents (e.g., liquid "Clorox" bleach, Heinz household vinegar, Vestal medicated liquid handsoap, liquid "Drano", "Visine" eye drops, "Real Lemon" concentrated lemon juice, Morton's table salt, and "Natural Brand" golden-seal tea) were added to saline to give concentrations thought to adversely affect drug-testing results (*5, 9, 10*). Isotonic saline, used because it approximates the ionic strength of physiological fluids, was the diluent for all interferent solutions. The golden seal was prepared as a tea by dissolving 120 mg of golden seal (ground leaves and stem) in 1.0 mL of isotonic saline at 37 °C. The tea was covered and allowed to sit overnight at 4 °C before filtering to remove undissolved residue. Liquid Clorox bleach contained sodium hypochlorite, 52.6 g/L; Drano contained 17 g of NaOH and 60 g of sodium hypochlorite per liter; Visine contained 1 g of EDTA, 500 mg of tetrahydrozaline hydrochloride and 100 mg of benzalkonium chloride per liter. Two ingredients of the golden seal that might interfere were hydrastine and berberine. Equivolume dilutions of the interferent solutions were added to the drug-supplemented urine to determine the minimum amount of interferent that would cause false-negative results.

Standard Enzyme Assay

The EMIT d.a.u. assays were performed according to the manufacturer's specified procedures. After we mixed the test urines with the potential interferents, the specimens were vortex-mixed and allowed to sit for 2 h at room temperature before analysis in the Hitachi 704 with the EMIT d.a.u. assays for six illicit drugs. Positive and negative (drug-free urine) controls were included in each run.

Urine specimens previously confirmed positive for each drug by EIA and GC/MS procedures were assayed to obtain baseline absorbance values, which were then used to estimate the drug concentrations in each specimen. These assays were conducted on 100-μL aliquots of positive urine mixed with 100 μL of drug-free urine. Absorbance readings for known drug or metabolite concentrations were plotted on semilogarithmic graph paper for semiquantification of the drugs in each positive urine specimen. The pH, relative density, and appearance of each test specimen were noted before the analysis for drugs.

Results

Drug-Supplemented Urines

The minimum adulterant concentrations required to produce a false-negative result for at least one of the test drugs were: NaCl, 50 g/L; vinegar, 85 mL/L; liquid bleach, 12 mL/L; liquid Drano, 12 mL/L; liquid handsoap, 12 mL/L; Visine, 500 mL/L; lemon juice concentrate, 500 mL/L; golden-seal tea, 15 g/L.

The interferent concentrations causing false-negative results for the drug-supplemented urines served as starting concentrations for investigation of specimens containing more-representative drug and metabolite concentrations, i.e., urine specimens that were confirmed positive by EIA and GC/MS procedures.

Adulterant Effects

The range of each drug concentration as estimated from the EIA absorbance values is given in the legends for Figures 1–6, which summarize the false-negative results caused by the adulterants.

Amphetamines: Two adulterants caused false-negative amphetamine results (Figure 1). Urines containing amphetamines up to 1.42 mg/L tested falsely negative at NaCl concentrations of 75 g per liter of urine. Drano (or bleach), the second adulterant, caused concentration-dependent interference. Positive urines containing amphetamine up to 0.52 mg/L tested negative at a Drano or bleach concentration of 12 mL per liter of urine, whereas drug concentrations up to 1.80 mg/L became negative when the Drano or bleach was increased to 23 mL/L. The false-negative results caused by Drano and bleach extended to amphetamine concentrations up to 4.65 mg/L. No effective interferent concentrations were found for the other five adulterants.

Barbiturates: Three adulterants caused false-negative results at low barbiturate concentrations (Figure 2). Urines containing barbiturates up to 0.38 mg/L tested negative at 75 g of NaCl per liter. Liquid handsoap and Drano (or bleach) at 125 mL/L altered all EIA tests for barbiturate concentrations <1.45 mg/L. None of the adulterants interfered when barbiturate concentrations exceeded 1.45 mg/L.

Benzodiazepines: Visine, handsoap, and Drano (or bleach) caused false-negative tests for benzodiazepines. Urines containing benzodiazepines up to 0.78 mg/L were falsely negative with Visine at 107 mL/L (Figure 3). Drano (or bleach) at 125 mL/L interfered when drug concentrations were <3.0 mg/L, and soap at 42 mL/L interfered at drug concentrations <6.5 mg/L. No effective concentrations of the other adulterants produced false-negative results.

Cocaine: Drano (or bleach) and NaCl caused concentration-dependent interference with the cocaine assay (Figure 4). Results for urines containing benzoylecgonine, the primary metabolite of cocaine, up to 1.18 mg/L were altered by Drano (or bleach) at 42 mL/L. This interference was extended to 1.82 mg/L by increasing the Drano (or bleach) concentration to 125 mL/L. No effective concentrations of the other interferents caused false-negative results.

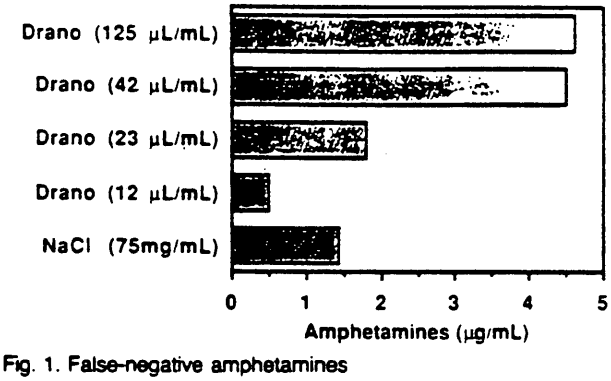

Fig. 1. False-negative amphetamines

Positive urines (n = 40) containing 0.34 to 4.72 mg of amphetamine per liter were tested with eight adulterants. Drano (or bleach) and NaCl caused false-negative tests for amphetamines. In Figures 1–6, adulterant concentrations specified on the *ordinate* caused false-negative results for the drug concentrations indicated by the *horizontal bars*

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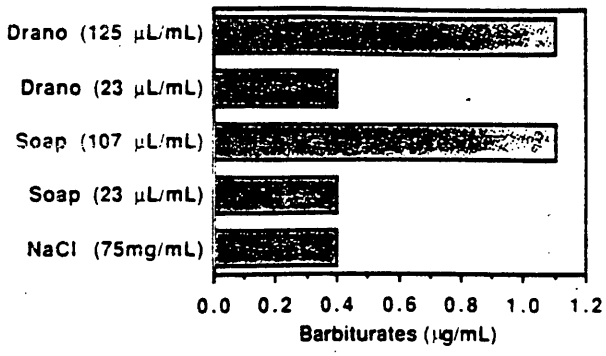

Fig. 2. False-negative barbiturates

Positive urines (n = 20) containing 0.38 to 2.90 µg of barbiturates per milliliter were tested with eight adulterants. NaCl, soap, and Drano (or bleach) caused false-negative tests for barbiturates

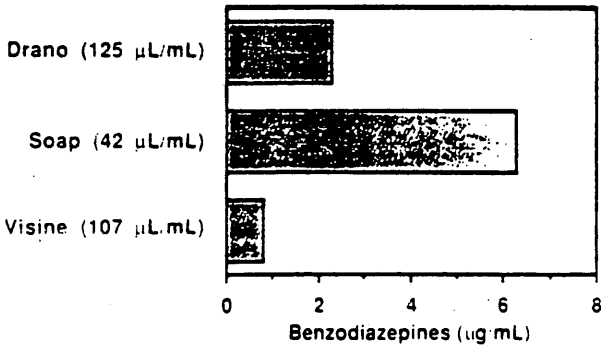

Fig. 3. False-negative benzodiazepines

Positive urines (n = 40) containing 0.38 to >6.50 mg of benzodiazepines per liter were tested with eight adulterants. Visine, Drano (or bleach), and soap caused false-negative results

Opiates: Drano (or bleach) and NaCl interfered with the EIA test for opiates (Figure 5). Urines with opiates up to 2.7 mg/L tested negative in the presence of 125 mL of Drano (or bleach) per liter. NaCl interfered only for drug concentrations <0.78 mg/L.

Marijuana: The test for THC was most sensitive to manipulation. Seven of the eight additives caused false-negative results (Figure 6). NaCl (25 g/L), Visine (125 mL/L), soap (12 mL/L), and Drano or bleach (12 mL/L) interfered at all drug concentrations investigated (31–122 µg/L). Golden seal and vinegar exhibited concentration-dependent interference. Lemon juice had no effect on any of the positive urine specimens regardless of the levels introduced; it did, however, interfere with the supplemented samples.

Urinalysis

All urines that contained sufficient NaCl to cause false-negative results had relative densities >1.035, outside the range for unadulterated urines (Table 1). Urines to which bleach, Drano, or liquid handsoap were added were alkaline. Conversely, urines containing vinegar were more acidic than unadulterated urines. Urines containing sufficient handsoap to affect the EIA assays adversely exhibited abnormal turbidity, and urines contaminated with golden-seal tea were obvious because of their brownish color. The only additive that gave urinalysis results physiologically similar to uncontaminated urine was Visine, which was not detected by routine urinalysis (Table 1).

Discussion

Four important conclusions are supported by the results of this investigation.

First, urine specimens can be adulterated to produce false-negative results. In vitro addition of NaCl, bleach, Drano, liquid handsoap, Visine, golden-seal tea, or vinegar can cause false-negative results when added to urines before testing for illicit drugs.

Second, the concentration of adulterants required to cause the false-negative results generally depends on the drug concentration in the urine, and is different for the positive urine samples than for the drug-free urines supplemented with parent drugs or metabolites. This suggests that interference may result from reactions between the adulterants and the drugs or metabolites. In contrast to the negative urines supplemented with a single drug or metabolite, the positive urine specimens probably contain several drug metabolites, any or all of which might react with the adulterants. The concentration effect is especially evident when bleach or Drano is added. However, the interference might also be explained by oxidation of NADH, which

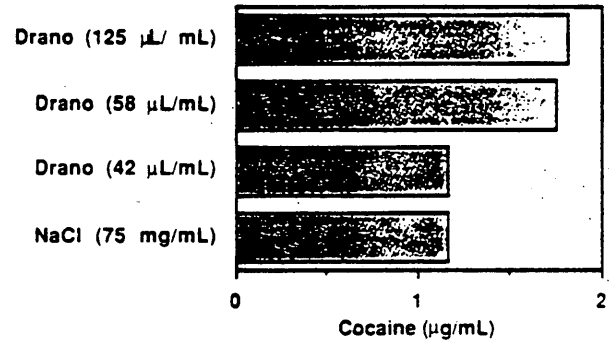

Fig. 4. False-negative cocaines

Positive urines (n = 40) containing 0.30 to >2.70 mg of benzoylecgonine, the primary cocaine metabolite, per liter were tested with eight adulterants. NaCl and Drano (or bleach) caused false-negative tests for cocaine

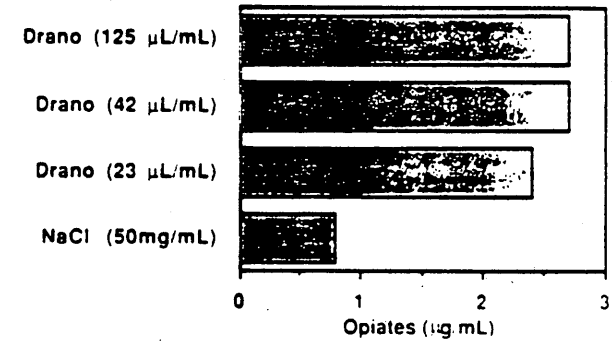

Fig. 5. False-negative opiates

Positive urines (n = 40) containing 0.31 to >2.70 mg of opiates per liter were tested with eight adulterants. NaCl and Drano (or bleach) caused false-negative results for opiates

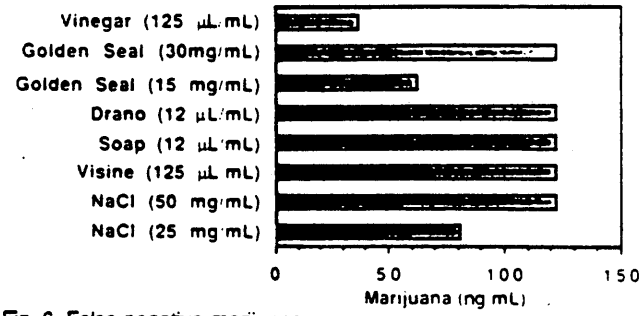

Fig. 6. False-negative marijuana

Urines (n = 42) containing 31–122 µg of 11-nor-9-carboxy-delta-9-tetrahydrocannabinol, the primary marijuana metabolite, per liter were tested with eight adulterants. All except lemon juice caused false-negative results for marijuana

Table 1. Urinalysis Results

	pH	Rel. density	Abnormal appearance
Unadulterated urines	5–7	1.005–1.030	
NaCl			
25–75 g/L	5.5	1.035	
Liquid Drano			
12–23 mL/L	6–7	1.018–1.019	
42–125 mL/L	8–11	1.020–1.028	
Liquid handsoap			
12–42 mL/L	6–7	1.018–1.021	Cloudy to turbid
107 mL/L	8	1.033	Cloudy to turbid
Visine			
107–125 mL/L	7	1.016–1.018	
Vinegar			
125 mL/L	4	1.018	
Golden seal			
15–30 g/L	6	1.022–1.024	Brown

provides the signal in the assay reaction. When the oxidizing capacity of the interferent is used up, NADH would accumulate and the result would be positive.

Third, consistent results are obtained with increasing concentrations of drugs, suggesting that the metabolites in the positive specimens had similar reactivity in the assay.

Finally, the adulterants interfere somewhat differently with the testing for separate drugs. Figures 1–6 show the minimum concentrations of adulterants causing false-negative results in authentic specimens with increasing drug concentrations. Because a continuum of drug concentrations was not tested, the upper value for a false negative for a given drug at any level of adulterant could differ somewhat from those shown. The mechanisms of interference appear to be related to the uniqueness of each drug's chemical and physical properties. The concentration of interferents causing false-negative results depends on both the specific drug and its concentration, because other components of the assay system are held constant. The THC assay, which is sensitive to seven of the eight adulterants, is the most easily manipulated to produce false-negative results.

In selecting the adulterants to investigate, we used three criteria.

First, the dilution must not be the cause of the false-negative results. Accordingly, the positive urine specimens were diluted 1:1 with isotonic saline and re-analyzed to verify that the diluted specimens remained positive.

Second, the quantities of the interferents that cause false-negative results must be small enough to be hidden on one's person. If illicit drug users intended to adulterate their urine for the purpose of avoiding detection, they must avoid detection as they transport the interferent into the collection room.

Third, the added interferent could not leave an obvious precipitate or residue in the urine specimen container, which would make the adulteration obvious. Typically, about 60 mL of urine is submitted to the drug-testing laboratory. Based on a 60-mL urine volume, the minimum amounts of the adulterants required to cause false-negative results ranged from 0.7 to 7.5 mL for the liquid interferents, the amount of solid interferents from 0.9 to 4.5 g. However, the quantities of interferents required to alter drug testing results depend not only on the specific drug but also on the drug and metabolite concentrations, so individuals intent on adulterating their urine specimen would not know how much adulterant would be required.

Determination of the mechanisms by which the adulterants can alter drug-testing results was beyond the scope of this study. Unfortunately, the specimens giving false-negative results were not available for GC/MS analysis. However, detailed investigation of several possible interference mechanisms is underway, including GC/MS analysis after introduction of the adulterants. Several different mechanisms could be involved. For example, the increased ionic strength due to addition of NaCl could alter protein structures to affect drug binding or enzyme activities. The high salt concentration conceivably could cause drugs to precipitate before sampling. The acidic pH caused by vinegar and the alkaline pH caused by liquid bleach and Drano could alter binding, reaction rates, or drug solubilities; changes in pH per se could not account for the interference. Liquid bleach and Drano probably affect the drug assays by oxidation reactions. Adding liquid bleach or Drano to NADH oxidizes it, decreasing the absorbance at 340 nm. Soap may interfere by a combination of pH and ionic strength or may remove the drug by forming an insoluble complex. Soaps may also increase drug-binding sites on the antibody, resulting in decreased activity in the assay reaction. The optical properties of the adulterated urine specimens may also interfere with absorbance measurements. With golden seal, the active ingredients are claimed to be hydrastine and, to a lesser extent, berberine. Future studies are planned to elucidate the mechanisms by which the adulterants interfered so that further measures can be taken to avoid false-negative results.

We recommend that testing for illicit drugs include assessment of pH, relative density, and urine appearance. Suspect urine specimens should be rejected and new specimens obtained. Because urine specimens can be successfully adulterated and not all adulterants can be detected, observed collection is strongly recommended.

Ed. note: See also Arch Pathol Lab Med 1988;112:769. This letter says that large doses of ascorbic acid do not interfere with cannabinoid testing.

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Interference of Common Household Chemicals in Immunoassay Methods for Drugs of Abuse

Ann Warner

I report how some adulterants affect results for drugs of abuse in urine as measured by Roche RIA, Syva EMIT d.a.u., and Abbott TDx FPIA (fluorescence polarization immunoassay) for the following drugs: amphetamines, barbiturates, benzodiazepines, cannabinoids, cocaine, opiates, and phencyclidine (PCP). Sodium chloride interfered negatively with all of these drugs when assayed by EMIT and caused a slight decrease in measured benzodiazepine concentration by FPIA. Drug concentrations were also decreased by added H_2O_2 (EMIT: benzodiazepine), Joy® detergent (EMIT: cannabinoid, benzodiazepines, PCP), $NaHCO_3$ (EMIT: opiate; FPIA: PCP), or $NaHClO_4$ (EMIT, RIA, FPIA: amphetamines, opiates, PCP; EMIT, FPIA: cannabinoid; EMIT: benzodiazepines). False-positive results were caused by H_2O_2 (FPIA: benzodiazepines) and Joy (RIA, FPIA: benzodiazepine, cannabinoid; FPIA: barbiturate, amphetamine). Sodium bicarbonate causes a suspiciously high pH in the urine, $NaHClO_4$ an apparently low pH (using pH paper).

A major issue in programs for testing urine for drugs of abuse is the development of a collection process that will ensure the integrity of the specimen. In no other type of laboratory testing does the person being tested have both the opportunity and the incentive to alter the collected specimen. Because of the opposition to witnessed collection, other approaches are needed to eliminate specimen switching or adulteration.

Procedures for identifying or eliminating specimen tampering at the collection site include requiring removal of all outer bulky garments and purses, or use of an examining gown; coloring of the water in the toilet; and collecting the specimen directly into a cup containing a temperature-sensitive material, after which the collection-site person pours the specimen into the transport container.

Use of a collection device such as the Franklin Collector (Franklin Diagnostics, Inc., 60 Franklin St., Morristown, NJ 07960) not only can assist in identifying specimens that may not be the subject's urine (urine kept in a plastic bag taped to the body will not achieve the normal temperature range of 96.4–100.4 °F), but also makes it difficult for the subject to add liquid adulterants, because it takes 1–2 min for the temperature to equilibrate. Further, the size of the container, approximately 85 mL, precludes adding solid adulterants and easily getting them into solution. At the time the collection person pours the urine into the transport container, adulterants such as isopropanol or sodium hypochlorite can be detected by smell, even if they have not already interfered with the temperature reading. Use of solid adulterants may be detected by the presence of residues in the container. Pre-analytical checks of pH and relative density will identify samples adulterated with sodium chloride, sodium hypochlorite, and sodium bicarbonate.

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However, given the desperation and cunning of many drug users and the potential for improper collection and lack of adulteration testing, I examined the effect of several common chemicals on immunoassay methods in case they escaped detection in pre-analytical examinations. Some of these chemicals have been recommended for use as potential adulterants (*1*).

Materials and Methods

Drug-free normal human urine collected at different times but from a single individual was used for all testing. To separate portions of the urine I added a single drug to give a concentration that would yield a positive result at or near the cutoff value for the assay, after diluting the sample with the adulterant. Table 1 lists the drugs studied, their approximate final concentrations, and the assay methods used. I added 1 volume of liquid adulterants to 4 volumes of drug-containing urine, using an automatic dilutor (Micromedic Systems, Horsham, PA).

Cannabinoid specimens, so diluted, gave results that indicated that the drug was being absorbed by the plastic tubing as the drug-containing urine passed through the dilutor. Some additional testing of an unadulterated specimen containing the same cannabinoid metabolite, divided into different types of storage containers, including glass and several types of plastic, verified that drug concentrations were decreased after contact with some of the plastics used, but not with glass, and that ethanol could partly reverse the process. Thus, for this study, all the dilutions were done with glass pipets.

Liquid adulterants used were ethanol (950 mL/L), isopropanol, ethylene glycol, sodium hypochlorite (52.5 mL/L, as Clorox®), hydrogen peroxide (30 mL/L), and Joy® detergent (10-fold predilution). Solid adulterants used were sodium chloride (250 g/L final concentration) and sodium bicarbonate (200 g/L final concentration). Drug-free urine, 1 mL, was added to samples adulterated with sodium chloride and sodium bicarbonate, to equalize the drug concentrations in all samples to be tested. An unadulterated sample was prepared containing the same concentration of drug as the adulterated samples. Results for all samples were then compared with those for the unadulterated specimen.

The sodium hypochlorite caused vigorous fizzing the first few minutes after addition; and sodium bicarbonate, at the concentration tested, gave a saturated solution, with some residue present. Otherwise, none of the adulterants caused any changes in the appearance or turbidity of the urine.

I tested each set of specimens by RIA (Roche Diagnostics, Nutley, NJ), the EMIT d.a.u. enzyme immunoassay (Syva Co., Palo Alto, CA) in an Hitachi 705 (BMD, Indianapolis, IN), and fluorescence polarization immunoassay (FPIA) in the TDx (Abbott Laboratories, N. Chicago, IL). I evaluated the results of these assays to determine if the adulterated specimens produced changes in counts per min, absorbance, or net polarization, respectively, when compared with unadulterated specimens containing the same concentration of drug. A second set of adulterated specimens, containing either no drug or a drug other than the one being assayed, was evaluated along with the samples containing the drug of interest. Samples were tested in duplicate in the RIA and singly in the EMIT and FPIA assays.

Results

Drug concentrations that fell within the linear portion of the assay curves were used so that the effects caused by the adulterants could more readily be observed, because I was mainly interested in relative results for adulterated specimens as compared with unadulterated specimens containing the same concentration of drug.

The results are summarized in Tables 2, 3, and 4. I anticipated that solvents such as ethanol, isopropanol, and ethylene glycol might affect viscosity and thus the accurate pipetting of samples, but I observed no effects with these solvents except in the case of the cannabinoid-containing specimens, and this may have had more to do with an effect on solubility or adherence of the drug to the containers used. For unknown reasons, this effect was not observed with the EMIT assay.

The effect of NaCl in the EMIT assays has been previously reported (*2–4*). I also noted that the absorbance changes in drug-free samples containing NaCl were decreased com-

Table 1. Drugs and Concentrations Tested, and Cutoff Values for Each

Drug added	Drug concn, ng/mL[a]	Cutoff concn for positive result, ng/mL		
		EMIT	RIA	FPIA
Amphetamine · HCl	530, 600	300	1000	300
Benzoylecgonine · $4H_2O$	570, 500	300	300	300
Morphine sulfate · $5H_2O$	336, 300	300	300	200
Oxazepam	351, 250	300	—	200
Phencyclidine · HCl	75, 100	75	25	75
Secobarbital	510, 800	300	200	500
9-Carboxy-11-nor-delta-9-THC	38, 38	20	100[b]	25

[a] The final concentrations in the samples evaluated by EMIT and FPIA are in the first column, those by RIA are in the second column.
[b] Control with a concentration of 30 ng/mL included here.

Table 2. Effect of Adulterants on Immunoassay Results When Drug Being Tested Is Present[a]

Assays	H_2O_2			NaCl			$NaHCO_3$			JOY®			$NaHClO_4$		
	EMIT, A	RIA, C	FPIA, P	EMIT, A	RIA, C	FPIA, P	EMIT, A	RIA, C	FPIA, P	EMIT, A	RIA, C	FPIA, P	EMIT, A	RIA, C	FPIA, P
Amphetamine	—	—	—	−13[b]	—	—	—	+18	—	—	—	+10	−31[b]	−19[b]	−14[b]
Barbiturate	—	—	—	−13[b]	—	—	+8	+14	—	+8	—	+38	—	+14	—
Benzodiazepine	−6	—	+19	−16[b]	—	−6	—	—	—	−10[b]	+69	+19	−16[b]	—	—
Cocaine	—	—	—	−12[b]	—	—	—	—	—	—	—	—	—	—	—
Opiates[c]	—	—	—	−26[b]	—	—	−6[b]	+60	—	—	—	—	−40[b]	−100[b]	−57[b]
Phencyclidine	—	—	—	−35[b]	—	—	—	—	−14[b]	−10[b]	—	—	−12[b]	−29[b]	−35[b]

[a] % change in absorbance (A), counts/min (C), or polarization units (P) observed for the adulterated sample, in comparison with that for the unadulterated sample. The sign indicates effect on drug concentration. Only changes >5% (EMIT, FPIA) or >10% (RIA) are shown. [b] Change sufficient to cause a false negative at the concentration of drug tested and the cutoff value used. [c] Results reported previously (*5*).

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Table 3. Effect of Adulterants on Immunoassay Results When Drug Being Tested Is Absent[a]

	H_2O_2			NaCl			$NaHCO_3$			JOY®			$NaHClO_4$		
Assays	EMIT, A	RIA, C	FPIA, P	EMIT, A	RIA, C	FPIA, P	EMIT, A	RIA, C	FPIA, P	EMIT, A	RIA, C	FPIA, P	EMIT, A	RIA, C	FPIA, P
Amphetamine	—	—	—	−13	—	—	—	+9	—	—	—	+9	—	—	—
Barbiturate	—	—	—	—	—	—	—	+16	—	—	—	+43	—	—	—
Benzodiazepine	—	—	+22	−14	—	—	—	—	—	−9	+71	+72	—	—	+10[b]
Cocaine	—	—	—	−21	—	—	—	—	—	—	—	—	—	—	—
Opiates	—	—	—	−12	—	—	—	+9	—	—	—	—	—	—	—
Phencyclidine	—	—	—	−13	—	—	—	—	—	—	—	—	—	—	—

[a] % change in absorbance (A), counts/min (C), or polarization units (P) observed for the adulterated sample, in comparison with that for the unadulterated sample. The sign indicates effect on drug concentration. Only changes >5% (EMIT, FPIA) or >10% (RIA) are shown, and only positive changes resulting in a false-positive result are reported. [b] Apparent concentrations were 117–176 (cutoff value, 200 ng/mL).

Table 4. Effect of Adulteration on the Cannabinoid Assay

	Cannabinoid present			Cannabinoid absent		
	EMIT, A	RIA, C	FPIA, P	EMIT, A	RIA, C	FPIA, P
Adulterant	% Change[a]					
Ethanol	—	+38	+29	—	—	—
Isopropanol	—	+45	+31	—	—	—
Ethylene glycol	—	+14	+19	—	—	—
$NaHClO_4$	−25[b]	—	−14[b]	—	—	—
H_2O_2	—	+34	+14	—	—	—
Joy®	−34[b]	+70	+38	−23	+61[c]	+14[c]
NaCl	−20[b]	—	—	−20	—	—
$NaHCO_3$	—	+38	—	—	+17[d]	—

[a] Reported as in Tables 2 and 3. [b] Sufficient change for specimen to be less than the cutoff (falsely negative). [c] Sufficient change for sample to be greater than the cutoff (falsely positive). [d] C was decreased, indicating increased concentration; however, result was strongly negative.

pared with normal drug-free urine, adding evidence that the effect of NaCl is on the EMIT assay reagents. Sodium chloride did not affect RIA, and only a slight effect was noted with one of the FPIA assays.

I expected that pH extremes would have a negative effect, and strongly basic specimens ($NaHCO_3$) actually yielded increased values for some of the RIA assays, with the same effect for drug-free specimens, indicating that pH per se is affecting assay reagents. Sodium bicarbonate depressed apparent concentrations for one EMIT and one FPIA assay.

Handsoap reportedly is an effective adulterant for the EMIT benzodiazepine, barbiturate, and cannabinoid assays (*4*). Using the liquid detergent, Joy, I found these same three assays were affected; however, barbiturates demonstrated increased rather than decreased concentrations. The effect of Joy on the EMIT assays was found in both drug-free and drug-containing specimens. The most interesting effect of Joy, however, is that it causes false-positive results for three of the FPIA and one of the RIA assays, along with increased concentrations for drug-containing specimens for these same assays.

The effect of $NaHClO_4$ on all three immunoassays for several of the drugs, coupled with the fact that drug-free specimens were not affected, suggests that $NaHClO_4$, a strong oxidizing agent, may react with the drugs or antibody and interfere with the antibody reaction. Harder to explain are the effects on the FPIA benzodiazepine and RIA barbiturate assays, and the fact that the EMIT and FPIA cannabinoid assays give decreased concentrations but the RIA does not. The finding of benzodiazepine (by FPIA) in the drug-free specimen is coupled with a slight decrease in concentration of the drug-containing sample. These may be off-setting effects, with actual drug reacting with $NaHClO_4$ to give a decreased value coupled to a positive effect on the assay as a whole. The increased apparent concentrations observed for the barbiturate and cannabinoid RIA may be due to pH, because these assays also gave increased results in the presence of (basic) $NaHCO_3$.

Hydrogen peroxide, on the other hand, is acidic, and may be exerting a pH effect upon the FPIA benzodiazepine assay, because increased apparent concentrations were observed in both drug-containing and drug-free specimens. The diluent-well solution was bright yellow in the presence of peroxide. The RIA and FPIA for cannabinoids gave enhanced results for the drug-containing specimens with no effect observed in the drug-free samples.

Although the cannabinoid assay seems particularly sensitive to adulterants, with at least one type of immunoassay affected by every one of the adulterants tested, overall only four of the 15 effects observed resulted in decreased concentrations, and therefore successful adulteration with these chemicals to achieve a negative result will be difficult. The RIA was affected by six of the eight adulterants, all of the effects being in a positive direction. The only false-positive results was the Joy (RIA, FPIA). If a specimen containing Joy is confirmed by use of the Toxi-Lab TLC system (Marion Scientific, St. Louis, MO), the extraction will be very messy even when the three-extraction clean-up procedure is used. A weak but definite positive, compared with the unadulterated specimen, was observed for a drug-containing specimen.

Evidently adulteration is a two-edged sword, with the possibility of producing a false negative outweighed, in many cases, by the specter of false positives.

Discussion

At least some of the advice being given to drug users on how to adulterate urine samples successfully will not be totally effective if immunoassay is used for screening—with some notable exceptions.

The most effective of the adulterants I tested is sodium chloride, which will be a concern only for laboratories that use the EMIT technology. This and other studies indicate that the minimum amount of sodium chloride that must be added to produce a negative result varies with different assays, but it is substantial. The effective amounts used in this study would be difficult to store (e.g., under fingernails) and require time and stirring for solution to be complete. Others have reported that amounts from 50 to 75 g/L are effective in producing false negatives, depending upon the assay and drug concentration used (*3–5*). I found that 50 g/L was insufficient to affect the EMIT cannabinoid assay. Sufficient sodium chloride to produce falsely negative results will result in a residue (which can be noted by the collection-site person), a high relative-density reading, and a delta absorbance value less than the negative calibrator.

Other adulterants that might be problematic include $NaHClO_4$, which should be readily recognized by its smell (even one adulterated sample in a group is easily detected) and its reaction with pH paper. Although $NaHClO_4$ is basic and a urine treated with it will give a pH reading of ~10 with a pH meter, if pH paper is used, a bright-red (but rapidly fading) color indicative of an acid pH of ~1 is produced.

Other false negatives of concern are those caused by dilute Joy and $NaHCO_3$. Sodium bicarbonate in the concentration tested will not go completely into solution and will result in a pH of 8–9, which should be considered abnormal by the laboratory and should result in a request for a fresh sample. Joy did not cause any changes in appearance, pH, or relative density, but can be detected by vigorously shaking a small amount of the urine. More copious, longer-lasting bubbles are formed compared with normal urine, and when held to the light they refract it to give the typical rainbow appearance of soap bubbles.

A major drawback, for the subject, to the use of Joy or $NaHCO_3$ is the fact that these compounds also cause false-positive results in several assays, hardly the result desired by the subject adding adulterants to ensure a negative result.

Of the two assays currently of most interest, cocaine and cannabinoids, the cocaine assay was found to be a robust one, with only NaCl producing a decreased result with the EMIT assay. The cannabinoid assay appears to be very sensitive to adulterants, yielding both decreased and increased results, depending upon the adulterant and immunoassay method used; however, most of these effects were in the positive rather than the negative direction.

These results indicate that specimen adulteration is complicated for the subject by the fact that some adulterants shown to cause falsely lowered results can be readily detected by either trained collection-site personnel or by simple laboratory procedures such as temperature, pH, relative density, residue checks, and shake and sniff tests. In addition, the undesired result of an enhanced or false positive, produced by a number of potential adulterants, makes their use less attractive as a mechanism for producing a false-negative result. The laboratory needs to assess, based upon the methods used for screening, what preanalytical tests for detection of adulterants are necessary. This study was designed to serve as a starting point in making such decisions.

I gratefully acknowledge the gift of reagents by Roche Diagnostic Systems, and thank Damien Brandeis, George Wadih, Tom Mertens, and Lori Hindenlang for their technical assistance.

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Serum Creatine Kinase Isoenzyme BB Is a Poor Index to the Size of Various Brain Lesions

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We divided patients with brain lesions into three groups: (*a*) patients with primary or metastatic brain cancer, (*b*) brain infarctions, and (*c*) brain contusion(s). We analyzed each patient's sera for creatine kinase isoenzyme BB (CK-BB), using a monoclonal antibody kit (Impres-BB; International Immunoassay Laboratories). Computerized axial tomography (CAT) scans were performed on each patient. The size of the various lesions was measured from the CAT scan and recorded in milliliters. Total CK, CK-BB, and their ratios were compared with the volume of damaged brain tissue. We found no correlation between any of the variables and the various brain lesions. We attribute this lack of correlation to an intact blood–brain barrier, the rapid elimination or inactivation of CK-BB, or some combination of these factors.

Biochemical diagnosis of brain injury has traditionally been confined to analysis of cerebrospinal fluid. No specific blood test has been available, and there has been uncertainty whether such a test could be devised because of the blood–brain barrier.

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curve fitting methods. However, procedure *d* and the procedures of Jones (*2*) and Loo and Brien (*4*) resulted in peaks eluting with vitamin D that were more than twice the size of the peaks in procedures *a* to *c*. Moreover, the thin-layer chromatograms show that lipid removal is improved by increasing the number or volume of successive washes.

The liquid-chromatographic results show a similar picture. Specifically, fewer lipids are eluted when gentle pressure is applied than when the solvent simply drips through the cartridge. With the drip procedure, backward diffusion may be occurring within the cartridge, whereas the use of injected washes under pressure overcomes these effects by allowing a more rapid transport of solvent through the column.

C18 cartridges have been used in this role by several other workers (*6–8*). Turnbull et al. (*7*) used one wash with 3 mL of methanol/water (7/3 by vol), and both Kohl and Schaefer (*8*) and Kao and Hesser (*6*) used one wash with 10 mL of methanol/water (7/3 by vol). Our experiments support the effectiveness of the latter procedure. Jones (*2*) based his extraction on an earlier reported method that extracted all the lipids. The further filtration steps clarified the sample efficiently, but did not separate or decrease the lipids; consequently, his extraction must be considered unsatisfactory. The procedure of Loo and Brien (*4*) was much quicker, but again it yielded an unsatisfactory, lipid-rich extract.

We conclude that: A single extraction, as used by Traba et al. (*3*), leaves substantial amounts of lipid on the cartridge. Both the Jones (*2*) and Loo and Brien (*4*) extracts are lipid rich. The cartridge-washing system described by Kohl and Schaefer (*8*) is satisfactory, as is that of Traba et al. (*3*) when two additional washes are performed. A decrease in lipids may be demonstrated by the peak area or by the presence of lipids in the cartridge wash.

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EMIT® Tests for Drugs of Abuse: Interference by Liquid Soap Preparations

To the Editor:

The EMIT (Syva, Palo Alto, CA 94304) enzyme immunoassay technique is widely used in screening for drugs of abuse in urine. Addicts resort to any stratagem to avoid positive results: substitution, dilution, addition of extraneous compounds to the urine. When several drugs are regularly screened for, negative results for all may sometimes arouse suspicion: when their urine is to be sampled, some addicts attempt any new trick to cause it to test negative. The analysis usually is directed to detection of a single drug; e.g., in this country, screening for opiates is only a recommended procedure for those addicts who are on a treatment program. Non-experienced personnel may perform drug determinations in a physician's office, and toxicological laboratories commonly are asked to assay urine but are given no insight into the sampling precautions.

Interference by NaCl with EMIT tests for drugs of abuse has been described (*1*). Liquid soaps such as those found in restrooms or used for dish washing and bathing can also interfere. They dissolve quickly, leaving the appearance of the urine specimen unchanged. We report some laboratory experiments to investigate this interference.

Urine samples supplemented with drugs were tested with four different-purpose commercial liquid-soap preparations. All EMIT determinations were done with the semi-automatic Gilford Stasar System 101.

Typical results are summarized in Table 1 for one liquid soap. A positive ΔE value corresponds to a positive urine. We confirmed these observations, using authentic positive urine samples containing the excreted drugs.

The effect occurs when less than 1 mL of liquid soap is present per deciliter of urine, and it affects all EMIT-DAU tests in which the labeled enzyme is lysozyme and the enzyme substrate is the *M. lateus* bacterial suspension. It occurs at 3 mL/dL with all EMIT-St single tests in which the labeled enzyme is malate dehydrogenase or glucose-6-phosphate dehydrogenase and the substrates are, respectively, malate and glucose 6-phosphate in the presence of NAD^+.

The sodium concentrations of the liquid soaps we tested, determined by flame photometry, are in the range of 2 to 3 mmol for every 1 mL/dL, 10-fold less than the concentration indicated in ref. *1*, in which the effect is attributed to NaCl and its role in modifying the ionic strength. Normal drug-free urine contains 90 mmol/L.

Unless the ionic strength is measured, there is no evidence that there is interference by soap with the EMIT tests. The neutralizing effect of NaCl is drug-concentration dependent. At 3 mol of NaCl per liter a positive urine can remain positive. Comparatively the effect of liquid soaps is greater for EMIT-DAU.

pH is an important factor in any enzymic reaction, but the measured pH of the urines remain unchanged, before the EMIT buffer is added, throughout the indicated (Table 1) soap concentrations.

The hemagglutination inhibition test for opiates ("Agglutex"; Roche Diagnostics, Nutley, 07110 NJ) does not show negative results until the concentration of liquid soap exceeds 10

Table 1. Interference of Liquid Soap and NaCl with Methadone EMIT-DAU Tests

Liquid soap, mL/dL	NaCl, mol/L	ΔE
Negative		
0		−18
*Positive, 0.5 μg/mL**		
0		+42
0.1		+40
0.5		−7
Positive, 2 μg/mL		
0		+79
15		−56
0.5		−8
0.1		+7
Positive, 2 μg/mL		
	0	+106
	1	+83
	3	+10
	4	−20

*Methadone HCl added.

mL/dL. Radioimmunoassays (Roche Diagnostics) of positive urines to which liquid soaps were added up to 15 mL/dL remained positive; negative urines remained negative.

Those involved in urine collection and laboratory personnel should be aware of this kind of interference; 0.5 mL of liquid soaps per deciliter is just two drops in the typical urine sample!

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Stability of Norepinephrine in Blood

To the Editor:

Measurement of plasma catecholamines has become more important because increasingly it is used as an index to overall activity of the sympathetic nervous system (*1*). However, the assay techniques can be tedious and capricious and the concentrations being measured in plasma are extremely small.

Zuspan (*2*) reports that the conditions under which blood is taken and the validity of the control groups used are important considerations in interpreting plasma norepinephrine concentrations. However, Rubin et al. (*3*), using radioenzymatic techniques, go further, saying that norepinephrine is unstable in plasma and is easily degraded in whole blood at room temperature. They also indicate that special procedures such as transferring the blood to chilled tubes and immediate centrifugation at 4 °C are necessary. Carruthers et al. (*4*), who used fluorometry, found that plasma catecholamines were either rapidly degraded or taken up by erythrocytes, or both, so that even slight delays in separating the plasma become important.

By contrast, Petterson et al. (*5*) found that catecholamines in plasma, as measured by a radioenzymatic method, were markedly stable in either plasma or whole blood. They found that storage of whole blood for several hours at room temperature did not result in any losses of plasma catecholamines, but that these were swiftly degraded when stored in buffer solutions in the absence of thiols. Moreover, human erythrocytes possess an active transport system for both norepinephrine and epinephrine uptake (*6*). However, the efficiency of the transport system depends critically on the surrounding temperature, and it is only induced at temperatures that substantially exceed room temperature (*6*).

These differing reports (*3, 5, 6*), together with the problems associated with collecting blood specimens from hospital wards, prompted us to check the apparent stability of norepinephrine in plasma and whole blood. We found that whole blood could be left standing at room temperature for as long as 5 h or more before removing the plasma for extraction without detectable loss of norepinephrine. Details of the experiment were as follows.

We collected 40 mL of whole blood from six normal, recumbent subjects into heparinized tubes at room temperature. Ten milliliters of the specimen was centrifuged and two 2-mL samples of plasma were extracted without delay. Three 10-mL samples of the blood specimens were left standing at room temperature for 1, 2, and 5 h, respectively, before we separated the plasma (two 2-mL samples each time) for extraction. For the assay we used a modification of a "high-performance" liquid-chromatographic assay with electrochemical detection (*7*). The extractions with alumina were carried out by customary procedures (*7*), except that we found antioxidants and special arrangements for blood collection and processing such as chilled tubes and refrigerated centrifuges were not required. Using a two-way analysis of variance, we saw no significant difference, within experimental error, between the plasma norepinephrine concentrations measured at each time for a given subject (zero-time values ranged from 96.5 to 208.0 ng/L for the six subjects).

These findings are in agreement with the results of Petterson et al. (*5*) and Danon and Sapira (*6*), but are clearly at variance with those of other workers (*3, 4*). Our findings and those of others (*5, 6*), who used radioenzymatic methods, suggest that catecholamines are stable in plasma and whole blood. Results obtained by the older, less sensitive and specific methods of fluorometry, together with the well-known observation that catecholamines are unstable when stored in buffers, may account for the belief that catecholamines are unstable and are easily degraded in whole blood and plasma at room temperature (*3*). Table 1 summarizes the differing reports on this subject.

Although precautions regarding sampling and processing of blood specimens used for plasma catecholamine determinations should not be neglected, we believe that, when one may check the stability of catecholamines by using a routine method, some of the time-consuming and costly steps for collection and processing of blood samples can be eliminated.

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Table 1. Methods of Collection, Processing, and Analysis for Norepinephrine (NE) Compared

Ref. no.	Technique	Collection and processing	Authors' comments on NE stability
Here	HPLC-ECD	At room temperature	Stable in whole blood and plasma for 5 h or more at room temp.
5	Radioenzymatic	At room temperature	Stable in whole blood and plasma for 22 h or more at room temp.
3	Radioenzymatic	Ice-chilled tubes; centrifugation at 4 °C; prompt processing and storage	Unstable, easily degraded in whole blood at room temp.
4	Fluorometric	Antioxidants added; centrifugation and prompt sepn. of plasma from whole blood, subsequent freezing	Very unstable, easily degraded in whole blood at room temp.

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Specific Conductivity of Urine and Sensitivity of Enzyme Immunoassay Methods of Analysis for Drugs of Abuse

Ole Andersen and Peter Bonne Eriksen

We studied the sensitivity of the EMIT® assays of amphetamine, benzodiazepines (diazepam), methadone, opiates (morphine), and propoxyphene at different specific conductivities in urine. The specific conductivity was varied by adding NaCl. For a sensitivity of 0.5 mg of drug per liter, the urine must have a specific conductivity of less than about 35 mS/cm in all these assays except that for benzodiazepine, for which it must be less than about 20 mS/cm.

In our laboratory we screen urine from addicts by means of the Enzyme Multiplied Assay Technique (EMIT®; Syva, Palo Alto, Calif. 94394) drug-abuse urine assays and finally identify the drugs in samples that are positive by thin-layer chromatographic methods. Addition of NaCl to urine decreases the sensitivity in the EMIT assays (*1*), probably because of an increase in ionic strength. To avoid falsely negative results in the EMIT assays, we studied the relation between specific conductivity of the urine and detection limits for the following drugs: amphetamine, benzodiazepines (diazepam), methadone, opiates (morphine), and propoxyphene.

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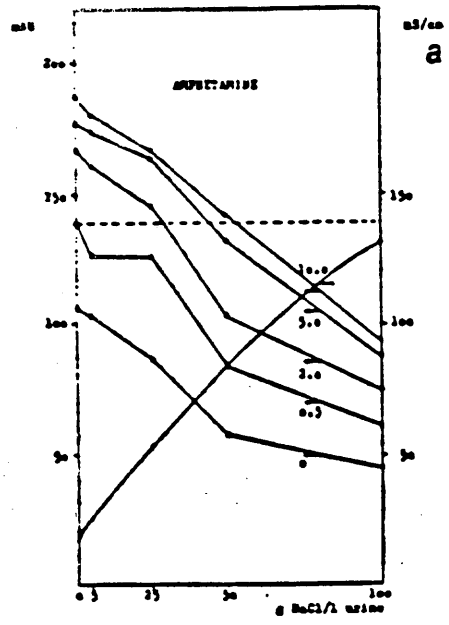
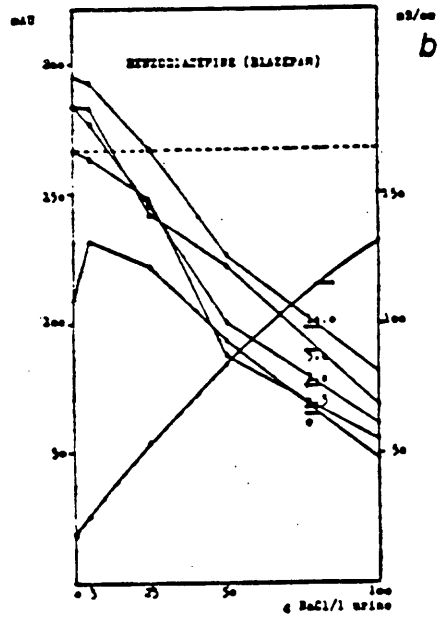
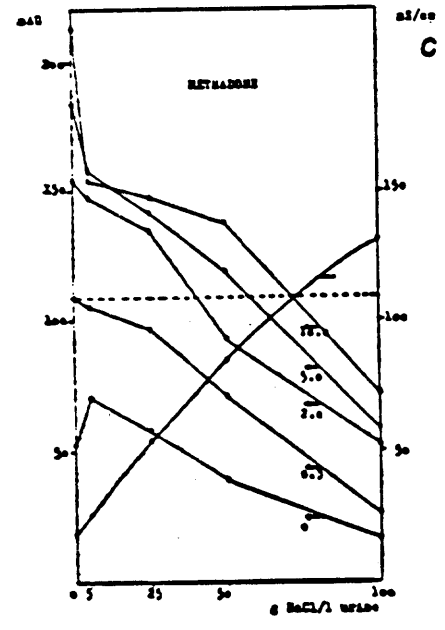
Materials and Methods

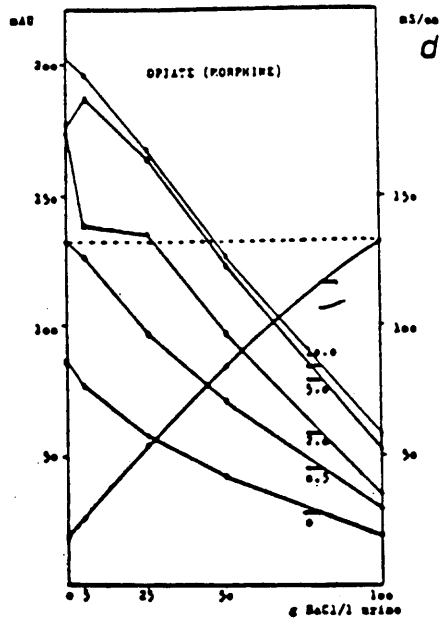
Apparatus

We measured the specific conductivity at 25 °C on a conductivity meter (Type CDM, with a CDC 304 electrode; Radiometer, Copenhagen). The EMIT drug-abuse urine assays were done according to the procedure by Schneider et al. (*2*) with a Gilford-300 spectrometer equipped with a Model 3017 thermocuvette thermostated at 37 °C. The change in absorbance during the first minute was measured with a recorder connected to the spectrometer.









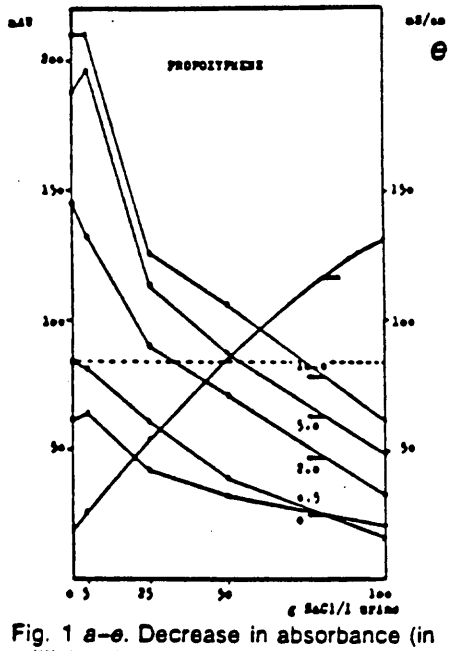


Fig. 1 *a–e*. Decrease in absorbance (in milliabsorbance units) at different drug concentrations (mg/liter of urine), and specific conductivity (mS/cm), as functions of added amounts of NaCl (g/liter of urine)

The dashed lines are drawn at the points that corresponds to absorbance decrease of urine containing no additional NaCl and a drug concentration of 0.5 mg/liter

Reagents

The urine specimens were collected from laboratory personnel and blood donors.

Drugs were added to a pooled sample of drug-free urine to give the following concentrations: 0, 0.5, 2.0, 5.0, and 10.0 mg per liter of urine. To each of these was added NaCl at the following concentrations: 0, 5, 25, 50, or 100 g/liter of urine; thus there were 25 different samples for each drug. Stock solutions of amphetamine, benzodiazepine (diazepam), methadone, opiates (morphine), and propoxyphene were 5.0 g/liter of methanol.

All reagents for the EMIT assays were those commercially available from Syva.

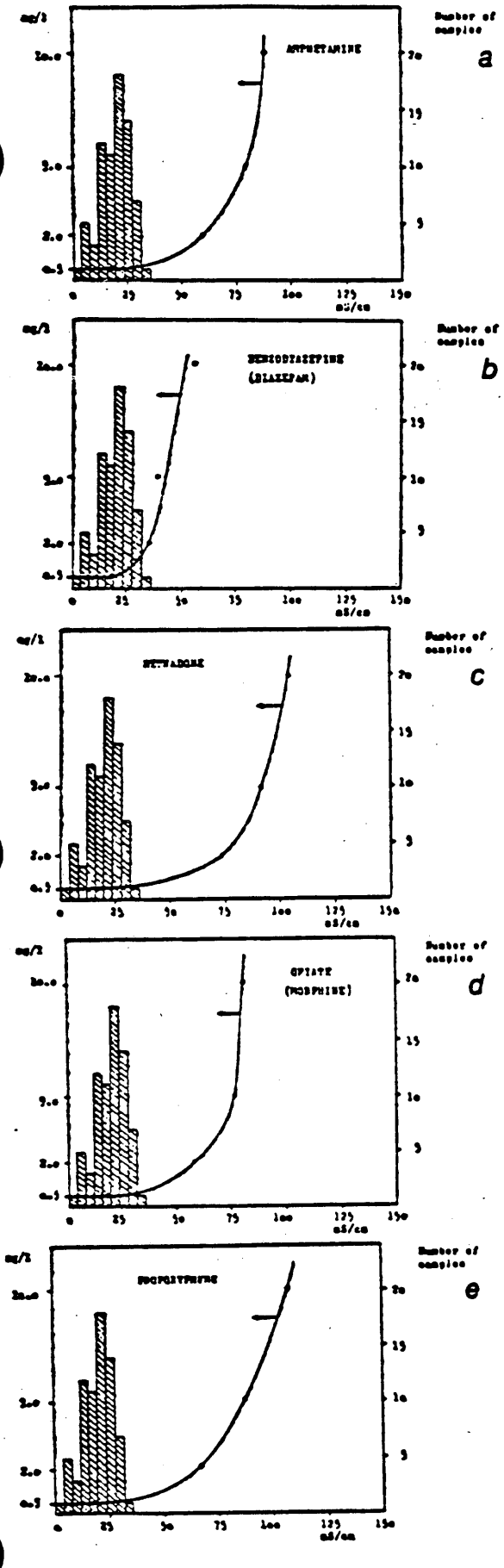


Fig. 2 *a–e*. Distribution of specific conductivities for urines from normal subjects, and minimal detectable concentration of drug (mg/liter) as a function of specific conductivity (mS/cm)

Results

Single determinations of the 5 × 5 × 5 experiment (five drugs, five drug concentrations, and five NaCl concentrations) were performed in one run, starting with the first drug at the lowest NaCl concentration, five determinations with increasing drug concentration, then at the next NaCl concentration, and so on, ending with the last drug. The results are presented graphically in Figure 1 *a–e*. The same urine pool from five normal persons was used for all five drugs. In the same figure is shown the specific conductivity vs. the added amount of NaCl. The dashed lines are drawn at the points that corresponds to absorbance decrease of urine containing no additional NaCl and a drug concentration of 0.5 mg/liter. We use this urine as our reference. If the absorbance change of the sample was smaller than that of the reference, the sample was considered negative. Where the dashed line in Figure 1 intercepts the curves corresponding to higher drug concentrations, we have read the NaCl amount on the abscissa and then converted this value into a specific conductivity from the Figure. In this way Figure 2 *a–e* was constructed. Points below the curves represent samples that will be considered negative, points above the curves represent positive samples in the EMIT assays. Furthermore, the conductivity distribution of urines from 28 women and 43 men is shown in Figure 2 *a–e*. The readings have been summarized in classes with a width of 4 mS/cm, starting with the class 0–4 mS/cm. The readings were to the first decimal place.

Discussion

We assume that the decreased sensitivity of the EMIT assays is a result of inactivation of the lysing enzyme because of the increasing ionic strength, and not a specific NaCl effect. In our experiment we varied the specific conductivity with NaCl, but common inorganic salts have similar specific conductivities (*3*). We chose NaCl because it is the predominant salt in urine, and is easily available for one attempting to escape the detection of drugs of abuse. From our results we conclude that the sensitivity of the EMIT assays strongly depends on the specific conductivity in urine. In our laboratory we want to maintain a sensitivity of about 0.5 mg of drug/liter of urine. Figure 2 *a–e* shows that by the EMIT technique we can obtain this sensitivity in urines with specific conductivities of less than about 35 mS/cm in assays of amphetamine, methadone, opiates, and propoxyphene, and about 20 mS/cm in the benzodiazepine assay. The specific conductivity in urine from normal subjects is such that the sensitivity of the EMIT assays will be adequate in most cases, but if the specific conductivity exceeds these values we directly analyze the urine sample by a thin-layer chromatographic method (*4*), which is not affected by high ionic strength.

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Comparison of the EMIT (Enzyme Multiplied Immunoassay Technique) Opiate Assay and a Gas-Chromatographic–Mass-Spectrometric Determination of Morphine and Codeine in Urine

E. P. J. van der Slooten and H. J. van der Helm

We examined 124 urine samples with the EMIT opiate assay kit and with a gas-chromatographic–mass-spectrometric determination (I) for morphine and codeine. With a cut-off value between positive and negative results at 0.5 mg (morphine equivalents) per liter for both methods, the EMIT assay gave 4.0% false positives and 5.6% false negatives when compared with I. Lowering of the cut-off value for I to 0.1 mg/liter resulted in a decrease of false-positives to 1.6% and an increase of false-negatives to 6.4%, seemingly satisfactory for screening purposes.

Additional Keyphrases: *double-beam spectrophotometers in EMIT technique • inter-method comparison • abused drugs • "kit" methods*

Because of its high sensitivity and relative ease, the EMIT drug-abuse urine assay is widely used. However, the method has inherent disadvantages because of possible interferences of other drugs and urine constituents (e.g., enzyme inhibitors, salts, H^+, or OH^- ions). These difficulties have been recognized and led to comparisons of the EMIT assay with other methods, such as radioimmunoassay (*1–3*), hemagglutination inhibition (*2*), fluorometry (*2*), and thin-layer chromatography (*1–3*).

All these methods also have their limitations with respect to specificity or sensitivity. For this reason it is desirable to compare results by the EMIT assay with those from a sensitive and specific method. We therefore decided to compare the EMIT assay for morphine with a gas-chromatographic–mass-spectrometric (GC-MS) determination, because this technique combines high sensitivity and specificity (*4, 5*).

Materials and Methods

The GC-MS combination was a model JMS-07 S instrument (JEOL Ltd., Tokyo, Japan) with multiple ion detection capabilities. The conditions were: 1 m × 3 mm (i.d.) glass column filled with 3% OV 17 on Chromosorb W-HP, 80–100 mesh; injection temperature, 260 °C; column oven temperature, 230 °C; temperature of connection to mass spectrometer, 260 °C; helium flow, 40 ml/min; electron impact energy, 30 eV.

As the recommended automatic instrumentation for the EMIT opiate assay was not available to us, measurements were made on a Shimadzu UV-200 double-beam recording spectrophotometer with thermostated cuvette holder (Shimadzu Seisakusha Ltd., Tokyo, Japan).

EMIT opiate kits were obtained from Syva Corp., Palo Alto, Calif. 94304.

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Urines were obtained from outpatients attending a center for treatment of drug addicts (111 samples) and from inpatients of a general hospital (13 samples). The latter group of patients were receiving various medications, but no opiates.

EMIT Assay

Urine samples were, when necessary, centrifuged and the pH adjusted to 5.5–8.0.

The EMIT assay was slightly modified as follows. The bacterial suspension, prepared according to the EMIT procedure, was diluted by addition of 75 ml of EMIT buffer solution to 20 ml of suspension. Into a semi-micro cuvette (optical pathlength of 1.00 cm and 1.5 ml volume) were pipetted 0.95 ml of the diluted bacteria suspension, 0.10 ml of sample, and 0.05 ml of reagent A (antibody solution). After equilibration at 37 °C for 5 min, 50 μl of reagent B (enzyme solution) was added and the decrease in absorbance at 436 nm during the interval 10 to 50 s after this addition was measured from the recorder trace. The reference cell contained a similar cuvette filled with water.

The concentration of morphine equivalents was read from a calibration curve, prepared with EMIT standards in the same way. Urine samples giving a reading of more than 50 mg/liter were diluted with EMIT buffer and redetermined. On samples giving a reading of more than 0.5 mg/liter a blank lysozyme determination was performed, and if necessary the original reading was corrected accordingly. The within-run precision (CV) of the EMIT assay was 7% (n=38), the day-to-day precision 21% (n=29), determined in the range 0.5 to 50 mg/liter.

GC-MS Assay

The samples were hydrolyzed by adding to 15 ml of urine 1.5 ml of hydrochloric acid (8 mol/liter) and autoclaving for 30 min. The extraction and clean-up procedure were as described before (*6*). The dry residue was dissolved in 300 μl of methanol containing 3 mg of akineton (1-piperidino-1-phenyl-bicycloheptenyl-propanol-1) per milliliter as internal standard. Of this solution, 3 μl was injected into the GC-MS combination. The ions at *m/e* 294, 299, and 285 were monitored for akineton, codeine, and morphine, respectively. From the peak heights of these ions and calibration curves we calculated the concentration of codeine and morphine in the sample.

Akineton was chosen as internal standard because its retention time (.74) relative to morphine (1.00) and codeine (1.14) made it well suited for the production of a chromatogram containing three nicely discrete peaks, and because its mass spectrum contained an abundant fragment ion at *m/e* 294, well within range of the abundant molecular ions *m/e* 285 and *m/e* 299 from the spectrum of morphine and codeine, respectively.

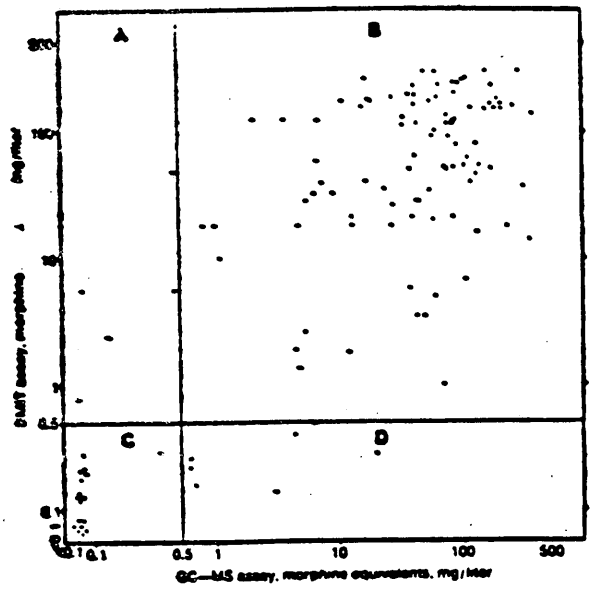

Fig. 1. Comparison of results by the EMIT method and the GC-MS method

Cut-off value between positives and negatives at 0.5 mg/liter (morphine-equivalents). Area *B* (95 samples) and *C* (17 samples): results by both methods positive and negative, respectively; area *A* (5 samples): EMIT positive, GC-MS negative; area *D* (7 samples): EMIT negative, GC-MS positive

We first checked the specificity of the method by injecting 13 blank samples; we saw no increase in the monitored ions. Next, 15 positive samples were re-injected, and the *m/e* ions 244, 229, and 215 (for akineton, codeine, and morphine) were monitored. The concentration of morphine and codeine, calculated from the peak heights of these fragments, agreed with the results of the first determination within the limits that could be expected from the variance of the method. Because the EMIT opiate assay measures both morphine and codeine, but with different sensitivity, results of the GC-MS codeine determinations were converted into morphine equivalents by using the data supplied by Syva Corp. The within-run precision (CV) of the GC-MS assay was 5% (n = 25), the day-to-day precision 7% (n = 21).

Results and Discussion

Figure 1 summarizes our results. Notwithstanding the fact that the precision of each method is reasonable, the correlation between them is poor—not unexpectedly, since several factors influence the accuracy of the results, such as:

- conjugated morphine and codeine are determined completely after hydrolysis by the GC-MS method; the EMIT method is less sensitive for these conjugated forms than for the free substances;
- the EMIT method has no absolute specificity, so cross-reactions with other substances present in urine may be possible;
- the antigen–antibody coupling or the lysozyme activity may be influenced by substances present in urine;
- preparation of samples for the GC-MS determination causes a loss of morphine and codeine; for morphine this loss is 6–15% (15 recovery determinations), for codeine 4–12% (15 recovery determinations); and
- dilution of urine samples when EMIT readings exceed 50 mg/liter may introduce some error (e.g., by changing the electrolyte content or the concentration of other substances in the sample).

For practical purposes only the results in terms of positive-negative are of interest. If a cut-off level of 0.5 mg/liter, as recommended for EMIT, is selected for both methods, and the results of the GC-MS method are accepted as true, area *A* of Figure 1 contains the falsely positive EMIT readings and area *D* the falsely negative. Expressed as percentage of the total number of determinations this amounts to 4.0% false-positives and 5.6% false-negatives.

It is not practical to select a much lower cut-off value for EMIT, because the difference in absorbance between negatives and low positives then becomes very small. For the GC-MS method it is possible, and also desirable, to select a lower value, because the presence of even a very small amount of morphine gives a positive result. With an arbitrarily chosen cut-off level of 0.1 mg/liter the falsely positive results decrease to 1.6%, the falsely negative increase to 6.4%.

Because in many practical situations a falsely positive result has more consequences than a falsely negative, and especially makes confirmation by another method necessary, one will generally try to limit the number of false-positives, even at the cost of an increased number of false-negatives. Thus, one may conclude from the results of the examined series that the EMIT method can be useful for the surveillance of drug abuse.

We thank Miss C. J. M. Leupers for her interest and excellent technical assistance.

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Specificity of the EMIT Drug Abuse Urine Assay Methods

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ABSTRACT

An investigation was conducted to determine the specificity of the EMIT DAU method of drugs of abuse analysis. Drug-free urine, from healthy volunteers, was individually spiked at 1000, 100, 10, and 1 μg/mL concentrations with each of 162 different drug substances. These spiked samples were analyzed with the EMIT DAU assay for amphetamines, barbiturates, benzodiazepine metabolites, cocaine metabolites, methadone, opiates, and propoxyphene. Although several of the test methods yielded positive results at a concentration of 1000 μg/mL, many drugs will probably not reach that concentration in the urine. The number of drugs giving a false positive at a concentration of 100 μg/mL was very low. The assay for cocaine metabolites gave no false positive results at any of the concentrations studied while the assay for methadone gave the largest number of false positive results. When interpreting the results of this investigation, one must consider that in many cases drug metabolites will exist in the urine, salt forms of the drugs studied were used, and ionic strength and pH effects can interfere with the lysozyme enzyme system used in the EMIT DAU assays. In summary, the proper utilization of specificity information may assist the analyst in explaining unusual

values obtained in the laboratory, particularly when the subject is concurrently using prescription or nonprescription medication.

INTRODUCTION

The EMIT DAU drug abuse urine assays have been proven to be of value as rapid, semiquantitative immunochemical tests for certain classes of drugs of abuse. Both performance of the assay and interpretation of the assay results are rapid, simple, and subject to relatively few sources of error. The primary sources of error in the performance of the assay appear to be due to:

1. Variations in the composition of unknown samples
2. Reproducibility of the measurements of sample and reagent volumes
3. Instrumental accuracy and reproducibility

There is another potential source of error in the interpretation of the results: the occurrence of false positive results. This is estimated to occur with an incidence of 3 to 5%. Although some of this can be related to "carry over" following positive samples, another source of false positives is the presence of other drug substances in the urine of the subjects. The purpose of this investigation was to study the incidence of false positives induced by spiking the urine of drug-free subjects with one of 162 drugs and subjecting this urine to the EMIT Drug Abuse Urine Assay. The results of this investigation would assist in determining the specificity of these assays and enable the analyst to explain some of the false positive results obtained in the laboratory.

MATERIALS AND METHODS

Drug substances were obtained from the manufacturer, either in pure form or as a labeled dilution (Table 1). One milligram equivalent of each pure drug was weighed using an electronic balance (Cahn Model 26, Cahn Instruments, Cerritos, California 90701) and placed in a 12 × 75 glass disposable culture tube (No. T12853, Scientific Products, McGray Park, Illinois 60085). Pooled urine from four healthy drug-free volunteers was assayed to assure negative values on each EMIT DAU assay. Exactly 1 mL of this urine was added to the drug substances in the test tubes. The tubes were vortexed and allowed to sit 24 h in a refrigerator prior to use. One hour before assaying, the tubes were removed from the refrigerator, vortexed, and allowed to return to room temperature. These urines were then analyzed with the EMIT DAU assays for amphetamines, barbiturates, benzodiazepine metabolites, cocaine metabolites, methadone, opiates, and propoxyphene (Tables 1 and 2) using a semiautomated pipettor/

TABLE 1. List of Drugs Used in Study

Generic name/brand name	Manufacturer/lot number	Lowest concentration giving a false positive result (μg/mL) (M = 1000, C = 100, X = 10)[a]						
		Am	Ba	Be	Co	Me	Op	Pr
Acetaminophen Tylenol	McNeil (7802739)							
Acetazolamide Diamox	Lederle (0363-A9549)							
Acetophenetidin	Mallinkrodt (PSJ1)							
Allopurinol Zyloprim	Burroughs-Wellcome (810179)							
Aminophylline	Merrell (NA)							
Amitriptyline HCl Elavil	MSD (L-720,101-01X22)				C	M	M	
Ammonium chloride	Mallinkrodt (JJZ)							
Amoxicillin trihydrate Amoxil	Beecham (821026)				M			
Amphotericin B Fungizone	Squibb (22-380-94498-005)							

(continued)

TABLE 1 (continued)

Generic name/brand name	Manufacturer/lot number	Lowest concentration giving a false positive result (μg/mL) (M = 1000, C = 100, X = 10)[a]						
		Am	Ba	Be	Co	Me	Op	Pr
Troleandomycin TAO	Pfizer (7D066-76QCS)							
Warfarin Na Coumadin	Endo (78-223)			M				

[a] Am = Amphetamines.
Ba = Barbiturates.
Be = Benzodiazepines.
Co = Cocaine.
Me = Methadone.
Op = Opiates.
Pr = Propoxyphene.

TABLE 2. Commercial Kits and Supplies Used[a]

Kit	Lot
Amphetamine DAU	J01
Barbiturate DAU	H02
Benzodiazepine DAU Assay	J02
Cocaine DAU Assay	H01
Methadone DAU Assay	H01
Opiate DAU Assay	H01A
Propoxyphene DAU Assay	J02
Bacteria Suspension	H101D
EMIT-DAU Buffer	H03
EMIT-DAU Negative Calibrator	H01B
EMIT-DAU Low Calibrator	H02B

[a]SYVA, 3181 Porter Drive, Palo Alto, California 94304.

diluter and spectrophotometer-microprocessor (Syva EMIT/LAB 5000, Syva, Palo Alto, California 94303). Negative and low calibrators were included periodically in the assay procedures. The results were interpreted and recorded.

A dilution of the aforementioned 1000 μg/mL sample for which positive results were obtained was made by taking 0.1 mL of the drug-urine mixture and adding 0.9 mL of drug-free urine. The concentration of the resulting urine-drug solution was 100 μg/mL. This procedure was followed to also obtain 10 and 1 μg/mL concentrations. The EMIT DAU assay [1] was performed and the results recorded.

RESULTS AND DISCUSSION

In the EMIT DAU assay the drug is labeled with an enzyme which, when bound to an antibody against the drug, reduces the activity of the enzyme. Since free drug in a sample competes with the enzyme-labeled drug for the antibody, the process of enzyme-inactivation is inhibited. Enzyme activity correlates with the concentration of free drug introduced and is measured by an absorbance change resulting from the enzyme's catalytic action on a substrate. There are numerous factors which can alter the results of the EMIT DAU assays as well as other enzymatic reactions. These include pH, high salt con-

centration, the presence of endogenous enzyme (lysozyme), and interfering drugs. The pH range specified for these assays is in the range of 5.5 to 8.0. In most instances the buffer supplied will be sufficient to bring the urine samples into the proper pH range. Approximately 2 to 4% of all urine samples contain sufficient lysozyme to produce false positive results [1]. This situation can be corrected by running suitable blanks. High salt concentrations, greater than 50 mg/mL NaCl, will result in false negative assay results and will necessitate an alternative method of analysis, i.e., TLC, HPLC, or GC [2]. The presence of interfering drugs will be discussed later.

In general, a false positive test result has greater impact on the status of the subject than a false negative test result. EMIT DAU assays are subject to a 3 to 5% incidence of false positives.

False positive test results can result from (1) contamination of calibrators or lysozyme in the reagents; (2) contamination or dilution of the low calibrator, resulting in a lower cutoff value: (3) contamination of the sample with saliva (which contains lysozyme); (4) carry-over following a high positive sample which results in a slight elevation of the subsequent assay: and (5) the presence of a drug or substance which cross-reacts with the enzyme-labeled drug for the antibody. False negative test results can arise from (1) adulteration of the urine sample, (2) the patient drinking excessively large quantities of water to dilute the urine, (3) adding salt to the urine, and (4) a urine with a pH range outside 5.5 to 8.0.

This investigation was concerned with the occurrence of false positive test results due to the presence of interfering drug substances. The results, tabulated and summarized in Table 1, use the average of the low calibrator values for the respective test as the cutoff value: everything greater than that value was interpreted as positive.

It was found that the cocaine metabolite assay yields the fewest false positives and the methadone assay the greatest. Also, there are several instances where one drug substance affects several assays, e.g., amitriptyline hydrochloride, brompheniramine maleate, desipramine hydrochloride, imipramine hydrochloride, indomethacin, methoxyphenamine hydrochloride, orphenadrine citrate, promethazine hydrochloride, propranolol hydrochloride, triethyperazine maleate, and tripelennamine. The antihistamines and tricyclic antidepressants are cross-reactants in numerous cases.

The amphetamine assay primarily detects amphetamine and methamphetamine. The manufacturer states that a small percentage of false positives may be observed in urines containing a high concentration of phenylpropanolamine and ephedrine. Other cross-reactants listed include phentermine, mephentermine, nylidrin, isoxsuprine, and methylphenidate. These correlate well with the results of the current investigation which expands the list to include other drugs, including additional sympathomimetic amines.

The barbiturate assay is designed to detect secobarbital, phenobarbital, butabarbital, pentobarbital, and amobarbital. A listed cross-

reactant is glutethimide which was confirmed in this study. Other cross-reactants found were several anticonvulsants and anti-inflammatory agents.

The benzodiazepine assay detects oxazepam in the urine and is utilized for diazepam and other benzodiazepines excreted as oxazepam. The manufacturer states that cross-reactivity with nonbenzodiazepine substances has not been observed. Twenty-six drugs were found that cross-reacted with this assay, as listed in Table 1, including several antihistamines and antispasmodics.

Benzoyl ecgonine is the substance detected in the cocaine metabolite assay. The product literature lists the belladonna alkaloids, barbiturates, and amphetamines as cross-reactants at levels at least 1000 μg/mL and greater. No cross-reactants were found for the cocaine metabolite assay in this investigation.

Methadone is detected as the parent compound in the urine. Cross-reactions with nonmethadone substances are usually not observed, according to the manufacturer: occasional exceptions are high concentrations of chlorpromazine, promethazine, and dextromethorphan. Thirty-six drug substances, as shown in Table 1, demonstrated the ability to provide false positive test results for the methadone assay, including 11 of the same compounds that yielded a false positive for the benzodiazepine assay.

The opiate assay is designed to detect morphine and morphine glucuronide, in addition to codeine, nalorphine, and meperidine in higher concentrations. Cross-reactants listed are chlorpromazine, naloxone, dextromethorphan, and methadone. The current study adds 19 additional cross-reactants, including numerous antihistamines and several tricyclic antidepressants. The low cut-off value (low calibrator) is adjusted by the manufacturer such that 95% of positive samples will be positive and 95% of negative samples will be negative. It can be altered to meet the specific requirements of a laboratory. One study [3] demonstrated a 4.0% incidence of false positives and a 5.6% incidence of false negatives for the opiate assay. By decreasing the low cut-off value from 0.5 μg (morphine equivalent)/mL to 0.1 μg/mL, the incidence of false positives decreased to 1.6% and the incidence of false negatives rose to 6.4%.

The propoxyphene assay is sensitive to propoxyphene and the major metabolite, N-demethyldextropropoxyphene (norpropoxyphene). Cross-reacting substances enumerated by the manufacturer include high concentrations of morphine, codeine, methadone, barbiturates, amphetamines, benzoyl ecgonine, chlorpromazine, oxazepam, and dextromethorphan. The current study provides eight more cross-reacting drugs, mostly antihistamines and tricyclic antidepressants.

The exact mechanism of the dynamics of cross-reactivity has not been explained: for example, what is the quantitative effect of one drug as compared to another on a specific EMIT DAU assay. One study [4] involved the effect of adding codeine to morphine samples analyzed by both enzyme immunoassay and radioimmunoassay. The results were not the simple weighted mean of the morphine and codeine concentra-

tions but were much higher. The presence of naloxone in another sample also gave a positive but unequal result. No attempt is made in this report to elucidate the cross-reactivity mechanism.

It should be noted that many of the drugs tested are salt forms of the parent drugs, and it has already been mentioned that ionic strength effects can alter assay results. However, the effect of increasing ionic strength by the addition of NaCl (at least 50 mg) is an increase in the incidence of false negative results [2]. The salts of the drugs utilized do not approach this concentration and false positive results were obtained, not false negative.

It is important to keep in perspective that most drugs will probably never accumulate to a concentration of 1000 μg/mL in the urine. The concentration a drug achieves in the urine is a function of many variables (e.g., dose, route of administration, metabolism, half-life, state of hydration of the patient, urinary volume, kidney function, and fluid intake). Many drugs will be present in the urine in the form of their metabolites as well as in their parent form.

Much more needs to be done to further enhance the interpretation of the EMIT DAU assays, including:

1. Studying the specificity of the assay in the presence of any of several hundred other drug substances
2. Studying the specificity of the assay in the presence of any of the metabolites of the hundreds of drugs used today
3. Studying the incidence of false negatives utilizing spiked urine containing drugs of abuse (positive samples) and any of the several hundred drugs commonly used in medical practice today
4. As above but using the metabolites of commonly used prescription drugs

In addition to the work on the EMIT DAU assays, the effects of commonly used prescription and nonprescription drugs on the EMIT assay results for serum levels should be investigated.

ACKNOWLEDGMENTS

The authors thank SYVA for furnishing the EMIT materials used in this study. Appreciation is also extended to the drug manufacturers listed in Table 1 for their generous supplies of the drug substances.

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Letters

A Quality-Control Solution for Use in "ΔA_{450}" Determination of Amniotic Fluid

To the Editor:

It has been well established that the bilirubin concentration in amniotic fluid is a good indicator of increased hemoglobin degradation after fetal rhesus isoimmunization (*1*). Frequently the bilirubin concentration is not measured directly, but instead the absorbance change at 450 nm ("ΔA_{450}"), and this value is used as an indicator of bilirubin concentration. The technique used to measure the absorbance change is generally standardized (*2*), except for minor modifications. However, difficulties do arise when one attempts to implement a quality-control program.

The main problem stems from the instability of the bilirubin in amniotic fluid, which makes this material unsuitable for use as a quality control. The determination requires no reagents, so the primary reason for using a control is to provide a check on analytical technique. For this purpose, a fluid is needed that has a stable spectral response similar to that of amniotic fluid. A 2.34 × 10^{-3} mol/liter solution of 8-hydroxyquinoline in water (340 mg/liter; molecular mass 145.16) meets this need. Such a solution is close to the limit of solubility at room temperature (22 °C), but the solubility can be enhanced by adding a little hydrochloric acid or by using salts, such as the hemi-sulfate of 8-hydroxyquinoline. However, this is undesirable because of a spectral shift and decreased stability of the solution. We have found that the aqueous solution of 8-hydroxyquinoline is stable for at least one year at room temperature if precautions are taken to avoid excessive exposure to light (amber-colored bottle, stored away from direct sunlight). During two years use, we have established a ΔA_{450} value of 0.087 ± 0.004 (mean ± 2 SD; n = 300) for the 8-hydroxyquinoline solution. The spectral patterns of the 8-hydroxyquinoline solution and amniotic fluid so closely resemble one another that a "bilirubin" concentration can be calculated by applying a formula such as the one of Bjerre et al. (*3*).

Figure 1 shows the spectral tracings for a representative amniotic fluid and for the 8-hydroxyquinoline solution, Figure 2 the derivations of the ΔA_{450} values.

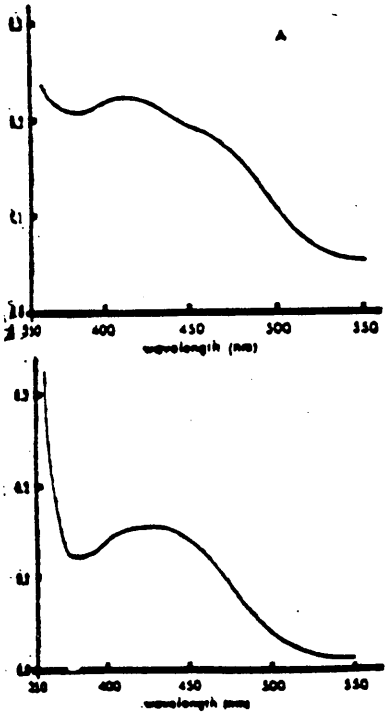

Fig. 1. Spectral tracing for an amniotic fluid specimen (*A*) and a 2.34 × 10^{-3} mol/liter solution of 8-hydroxyquinoline

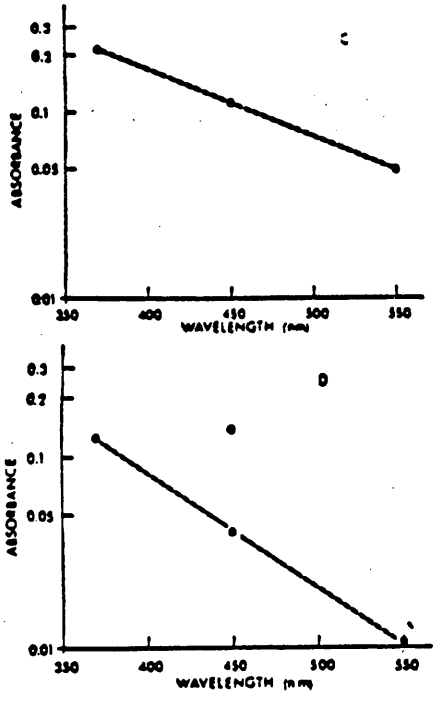

Fig. 2. Derivation of "ΔA_{450}" value for amniotic fluid specimen (*C*) and the 2.34 × 10^{-3} mol/liter solution of 8-hydroxyquinoline (*D*)

Absorbance values are plotted on a logarithmic scale, wavelength on a linear scale, at 370, 450, and 550 nm. A straight line is drawn between the 370-nm and 55-nm points. The derived absorbance value obtained from this line at 450 nm is the "baseline" absorbance at 450 nm. The difference between this and the measured absorbance at 450 nm is the ΔA_{450}

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Interference by NaCl with the EMIT Method of Analysis for Drugs of Abuse

To the Editor:

In our Toxicology Laboratory, we encounter schemes used by drug addicts on methadone detoxification programs to avoid our detection of drugs of abuse (*1*). Such efforts have included incorporation of a plastic bag filled with another's urine, concealed under the addict's clothing, connected with a long piece of plastic tubing running along the trunk of the body, and, on clinic visit, substituted for his own specimen. Another stratagem is to consume large quantities of fluids 2 to 4 h before urination, in the hope of diluting the urine to the point where the drug concentration may fall below the sensitivity of the method and thus escape detection. Methadone may be there in large quantities and may not be affected significantly by the dilution effect; thus this second scheme has limited success with both the thin-layer chromatographic or the EMIT (Syva, Palo Alto, Calif. 94304) methods for analysis for drugs of abuse.

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Recently, a urine specimen to be analyzed for morphine, barbiturates, and methadone tested negative by EMIT, but positive for all three drugs by thin-layer chromatography. Further investigation revealed that the patient had added sodium chloride to the urine specimen. We undertook a preliminary investigation on the EMIT system by supplementing urine specimens known to be positive for morphine, barbiturates, and methadone with sodium chloride to concentrations up to 200 g/liter. When concentrations exceeded 50 g/liter, all specimens became negative. Thus, one should be alert for the possibility of addicts clandestinely placing salt in their urines to escape detection. Fortunately, the added salt appears to nullify all EMIT tests, so that all drugs tested will be negative, which in itself may be suspicious. Thin-layer chromatographic results are not affected (*2*).

pH and ionic strength play a definite role in the mechanism of enzymatic reactions (*3*), a role that becomes more complex in the case of EMIT (*4*). The effect we report here is probably attributable to an increase in ionic strength to above a critical point, at which so many ions congregate at one or more charged sites that they prevent the necessary interactions. If so, the effect is nonspecific and we would expect any salt solution that contributes a high ionic strength to work in a similar manner.

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Thin-Layer Chromatographic Detection of Quinine, Morphine, and Poly-Drugs

To the Editor:

We read with great interest the letter [*Clinical Chemistry* 22, 393 (1976)] by Wilkinson et al. in which they discussed the findings of a service laboratory that had mistakenly reported the presence of morphine and cocaine in an individual's urine. We believe that the authors' point with regard to the use of more than one analytical procedure for confirming positive results was a valid one. Another article, by McIntyre and Armande, which appeared in the same issue, discussed their ability to detect free morphine at a sensitivity of at least 0.5 mg/liter.

We wish to call the attention of readers of this journal to the thin-layer chromatographic technique used in this laboratory. It is capable of detecting free morphine in a concentration of 100–190 µg/liter of urine. It is used to analyze 3000 urine specimens per week for opiates (morphine, codeine, methadone, and quinine), and more than 1000 specimens for poly-drugs (15 drugs: opiates plus amphetamine, methamphetamine, phenmetrazine, methylphenidate, phenothiazines, sedatives, and hypnotics). The technique has been detailed elsewhere (*1*, *2*). The following modifications have been introduced: (*a*) urine containing ion-paper is shaken for 20–30 min, (*b*) ratio of chloroform and isopropanol used is 5:2, and (*c*) drugs are extracted by shaking for 20 min. The sensitivity of this ion-exchange paper technique was described at the Sixth International Congress of Pharmacology (*3*).

The use of this single-step extraction and two-stage thin-layer development system enables us to measure the entire array of drugs of abuse in urine concomitantly in the following minimum concentrations (mg/liter, expressed as base): morphine, 0.1 (volume of urine, 50 ml) and 0.15–0.19 (volume urine, 20 ml); amphetamine, 0.87; methamphetamine, 0.4; phenmetrazine, 0.41; methylphenidate, 0.87; codeine, 0.35; methadone, 0.45–0.9; phenobarbital, 0.5; secobarbital, 0.36; propoxyphene, 0.90; and cocaine, 0.89. The volume of urine required for these sensitivities is 20–50 ml. We recommend that positive results be obtained for barbiturates be confirmed by respotting the residue and developing in another solvent. A technician can analyze 120 urine specimens for opiates and 80–90 specimens for poly-drugs per day. The cost of analysis for performing at least 4–5 tests (opiates) per urine specimen is $0.58 and for performing 9–15 tests (poly-drugs) is $0.82 per specimen (*4*), including labor, chemicals, and supplies. Our current total cost of analysis, including supervisory and administrative salaries (one chief toxicologist, one laboratory manager, one chief chemist), chemicals and supplies, laboratory rental, technical and support services, is $1.38 per specimen for monitoring 3500–4000 specimens per week. Set-up costs of a toxicology laboratory facility with thin-layer chromatography and various detection procedures currently used in drug-abuse screening programs are discussed elsewhere (*5*, *6*).

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NATIONAL INSTITUTE ON DRUG ABUSE

URINALYSIS COLLECTION HANDBOOK FOR FEDERAL DRUG TESTING PROGRAMS

For Implementation
of the
Mandatory Guidelines
for Federal Workplace Drug Testing Programs

September 1988

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES
Public Health Service
Alcohol, Drug Abuse, and Mental Health Administration

URINE SPECIMEN COLLECTION

OVERVIEW

The urine specimen collector plays a key role in each Agency's drug testing component of the Agency Plan. As specimen collector, you may be the only Agency official in the program with whom employees come into direct contact. Individuals subject to testing hold a variety of positions within the Agency with varying levels of responsibility. Your professionalism, sensitivity, and compassion can greatly affect their attitudes and the credibility of your program. Treat them with the respect and dignity you would expect for yourself.

SCOPE OF RESPONSIBILITY

Specimen collection is the most vulnerable part of any drug testing program. The agency must be able to tie the result of a urinalysis drug test to a specific individual. Chain of custody is the term that refers to the process of ensuring and providing documentation of proper sample identification from time of collection to the receipt of laboratory results.

In order for the results of a particular specimen to withstand legal scrutiny, it is necessary to demonstrate:

- No adulteration or tampering has taken place
- Documentation of all personnel who handled the specimen
- No unauthorized access to the specimen was possible
- Specimen was handled in a secure manner
- Specimen belongs to the individual whose information is printed on the label

Since an individual normally provides a specimen in the privacy of a stall or other partitioned area that allows for individual privacy, there is an opportunity for drug users to subvert the collection process. For example, individuals may use one of the following methods to avoid detection of drug use:

A. Substitution - Liquids such as soda, tea, apple juice and clean urine (i.e., store bought, drug-free) are substituted for their own urine.

B. Adulteration - Addition into the urine specimen of foreign material that is known or thought to invalidate the test. Common substances include soap, household cleaners, salt, bleach, and drain cleaner. The effect of each of these adulterants varies with the test methods used. Adulterants are often detectable at the collection site by visual inspection of the specimen, or by smell and abnormal temperatures caused by the chemicals.

C. Dilution - Efforts to reduce the drug concentration in the urine to the point that it will not be reported by the drug testing laboratory. This may be done by adding water after the specimen is provided.

NATIONAL INSTITUTE ON DRUG ABUSE

MEDICAL REVIEW OFFICER MANUAL:

A GUIDE TO EVALUATING URINE DRUG ANALYSIS

For Implementation
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SUPPLEMENTAL AND BACKGROUND INFORMATION

In some agencies the MRO may have a broader role as an active consultant to management. This section is included to assist in that role.

False Negative Reports

Errors in handling or analysis, as discussed above, could result in false negative reports. Drug abusers also can generate false negatives by substituting another person's urine for their own. Containers of urine may be concealed in boots, in voluminous skirts, and elsewhere around the body. Sophisticated male drug abusers, expecting direct observation of their urination, have concealed IV-solution bags in the axilla with the IV tube running inside the sleeve to the hand. Without extremely close observation, the drug abuser then can hold the penis as if for normal urination, apply pressure with the arm at the axilla, and deliver a stream of someone else's urine into the cup. Some drug abusers who expect close monitoring apparently have emptied their own bladders, instilled another person's urine into the bladder with a catheter, and then have urinated that sample in the observer's presence.

These experiences highlight the intensity of drug-related deception among persons heavily involved with drugs. The strong drive to continue taking drugs may lead to elaborate efforts to conceal the use. Such deception, not uncommon in drug treatment clinics, does not necessarily indicate that the deceiver is a "bad" person or a "bad" employee; rather, it underscores the powerful behavioral effects of some drugs. Those who engage in such deception often respond well to treatment and rehabilitation.

In most cases the collector in the Federal urinalysis program does not directly observe the urination; most employees might consider such observation too demeaning. But it is difficult (although not impossible) for a drug abuser to maintain a urine sample at body temperature outside of the body. Thus, urine collectors measure sample temperature immediately upon delivery. Urine samples must range from 32.5°-37.7°C (90.5°-99.8°F) within 4 minutes of urination. If a sample is not in that range, the collector obtains another specimen under direct observation, and both are forwarded to the laboratory.

An employee also might produce a false negative test through intentional dilution or contamination of a sample. A large amount of salt added to a sample can invalidate an assay, or extensive tap water dilution of a sample may reduce the concentration of drug below measurable levels. Safeguards against these sources of false negatives include the collector's careful inspection for sample color and temperature. If dilution is suspected, measurement of creatinine content and osmolarity in the laboratory can provide the MRO with additional information; the latter procedures reveal either dilution or salting.

Elimination Rates

Additional problems may arise in the interpretation of urinary data. First, drug abusers may eliminate some drugs more rapidly from their systems by changing urinary pH. For example, the renal clearance of phencyclidine increases 4- to 5-fold when urinary pH is below 5. Accordingly, patients overdosed with phencyclidine or amphetamines sometimes are treated with ammonium chloride (NH_4Cl) to hasten detoxification. An apparently intoxicated employee, directed to produce a urine sample "for cause," may delay for several days and make dietary changes resulting in more acidic urine. This hastens elimination of basic drugs, and may avoid detection. Employees who misunderstand this effect may add acid to a urine sample; pH below the physiological range suggests that manipulation.

Urination "On Demand"

Employees may have difficulty initiating a urinary stream "on demand." Anxiety about urine testing really does impede urinary release in some people. Certain medical conditions may cause urinary retention or difficulty in initiating micturition. Drug-abusing employees may attempt to defer urination almost indefinitely. Not infrequently prescription and over-the-counter medications possessing anticholinergic properties may also prolong the process. However, an employee who cannot urinate when first requested to do so should remain in the test area, consuming liquids until able to do so. Eight ounces of water every thirty minutes will generally produce urination in even the most reluctant subject within 2-3 hours. There should be a firm policy that samples must be produced on the scheduled day, coupled with sympathetic recognition that this may be difficult for some anxious people.

Proffered Explanations

Among the many striking explanations offered for drug-positive urines is passive inhalation of marijuana smoke. "I have never smoked marijuana, but I was in a car with some guys who did"; "I know that the man across the hall from me smokes marijuana, and I had my door open last night."

Several studies have examined the detection of THC (tetrahydrocannabinol, the major psychoactive constituent of marijuana) among those passively exposed to marijuana smoke (Levine, 1983; Law et al., 1984; Morland et al., 1985; Cone et al., 1987).

While THC urine concentrations have been produced experimentally at sufficient levels, e.g., 100 ng/ml, to be detected in the Federal testing program, the smoke conditions of the room were extreme and not typical of social environmental conditions. Moreover, all subjects under these conditions have subjective psychoactive effects as well. Thus the claim of <u>innocent</u> passive inhalation in a confined area as an explanation for a positive urine test result is not acceptable.

Destroying the myth - " Creatinine: an ineffective tool for adulteration detection."

Renal Function Tests

Clinical Laboratory Procedures and Diagnosis

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tenth day. The subject with the smallest variation (CV = 5%), represented in the upper portion of Figure 1–2, excreted 90 percent of the mean on the sixth day and 113 percent on the twentieth day. Shown in the middle portion of Figure 1–2 is the subject with the average variation (CV = 11%), who excreted 129 percent of the mean on the second day and 81 percent on the twenty-first day.

This study indicates that the daily urinary excretion of creatinine can vary significantly not only among different subjects but also in the same subject from one day to another. Identical results [31, 50] have been reported by others, and they indicate that the daily urinary excretion of creatinine cannot be used as a reliable index of the completeness of urine collection.

Creatinine in Uremia and Creatinine Deficit

In acute renal failure [38], the plasma concentration of creatinine increases at a daily rate of 2 to 3 mg/dl in direct proportion to the amount of creatinine that is retained in the body and to the reduction in renal function. In chronic renal failure, on the contrary [30], the urinary excretion of creatinine decreases as plasma concentration rises, and the rate of daily increase in plasma concentration of creatinine [38] is only one-half to one-third of what is expected from the creatinine retained as a result of the fall in GFR. This creatinine deficit becomes apparent at plasma concentrations of creatinine higher than 6 mg/dl and cannot be accounted for entirely by a reduction in endogenous production [30]. It has been estimated that 16 to 66 percent of the creatinine formed in uremia is metabolized or excreted extrarenally [30]. The existence of routes of creatinine excretion and metabolism other than the kidneys have been investigated in uremic patients.

Creatinine is uniformly distributed throughout body water [59] and, like urea and uric acid [39], diffuses into the gut. At a normal plasma concentration the amount of creatinine entering the gut is negligible, but in uremia it becomes significant [38]. The bacterial proliferation (streptococci and enterococci) [62] that develops in the upper gastrointestinal tract of chronically uremic patients [40] plays an important role in the induction of a creatininase system that is related to the degradation of creatinine. Metabolites of creatinine [40] have been identified in the lumen of the gut, plasma, urine, and expired air in uremic patients, thus providing evidence that creatinine is metabolized in the gut and recycled. The recognition of this important secondary route of metabolism and excretion of creatinine in uremic patients explains the significant variations in urinary excretion, plasma concentration, and clearance of creatinine in some patients with renal disease and gives reason to question seriously the validity of creatinine as a reliable test of renal function in uremia [40].

If the release of creatinine from muscle stores continues unchanged after the onset of renal failure, and if creatinine is a specific and sensitive method for the estimation of GFR, it is to be expected that plasma creatinine will rise in proportion to the decrease in creatinine clearance. However, as previously demonstrated by others [18, 25] and as shown in Figure 1–3, when different levels of plasma creatinine concentration are related to their corresponding creatinine clearance, a linear relationship fails to develop. The results of studies correlating plasma concentration with creatinine clearance in 253 males are shown in Figure 1–3A; the results for 223 females are given in Figure 1–3B. The protocols that were followed for these studies of 1-hour creatinine clearance and the methods that were used for the analytical determinations of the samples are described in Chapter 3. In agreement with studies reported by others [18, 25], the following observations can be made by examining Figures 1–3A and 1–3B from right to left: First, in the region in which results consistent with marked reductions in renal function (as indicated by significant elevations in plasma concentration of creatinine and decreases in creatinine clearance) are plotted, with small fluctuations in creatinine clearance there are correspondingly large variations in plasma creatinine concentrations. Next, in the intermediate area of Figures 1–3A and 1–3B, where plasma creatinine levels range from 6 to 2 mg/dl, there is a transitional zone in which a linear relationship between plasma concentration and clearance of creatinine becomes apparent. Finally, as shown in the left portion of Figures 1–3A and 1–3B and corresponding to values consistent with normal levels of renal function, the linear relationship is again lost, and in this area small variations in plasma creatinine relate to significantly wide changes in creatinine clearance.

To determine the adequacy of the changes in plasma concentration of creatinine as they relate to creatinine clearance, a scattergram was constructed by separating the values illustrated in Figures 1–3A and 1–3B into four main categories. The results are illustrated in Figures 1–4A and 1–4B. If values of 1.2 mg/dl and 0.9 mg/dl are taken as the highest normal plasma concentration of creatinine for males and females, respectively, and 80 ml/min as the lowest normal clearance of creatinine for both sexes, it can be appreciated that in approximately 76 percent of the values in the male population and in 74 percent of the females there was an adequate correlation between plasma concentration and clearance of creatinine, that is, either normal levels of plasma creatinine corresponded to normal levels of creatinine clearance (left upper quadrant in Figures 1–4A and 1–4B), or abnormally elevated levels of plasma creatinine were related to reduced levels of creatinine clearance (right lower quadrant in Figures 1–4A and 1–4B). In approximately 23 percent of males and 25 percent of females, however, plasma creatinine levels were not appropriate when related to creatinine clearance, that is, either normal levels of plasma creatinine corresponded to decreased creatinine clearance (left lower quadrant in Figures 1–4A and 1–4B), or elevated levels of plasma creatinine were related to normal values of creatinine clearance (right upper quadrant in Figures 1–4A and 1–4B).

Several attempts have been made to develop reliable methods that will allow

formation may be obtained by relating the BUN to the plasma concentration of creatinine or the clearance of urea to the clearance of creatinine.

The normal BUN-plasma creatinine concentration ratio of 10:1 [19, 20, 68] is usually maintained in uremia but can be disrupted in some other clinical conditions. This ratio may rise [19, 20, 68] as a result of an increase in BUN in catabolic states, in prerenal azotemia, in uremic patients after a high protein intake, by absorption of blood from the gut after gastrointestinal bleeding, when urinary tract obstruction causes renal reabsorption of urea, or when, as a consequence of the implantation of the ureters into the lumen of the gut, urea is absorbed from the gastrointestinal tract.

The ratio of BUN to plasma creatinine may be lower [20] as BUN decreases as a result of starvation, after a low protein intake, in advanced liver failure, or as a result of an increase in plasma creatinine as seen after muscular breakdown in muscular subjects. Creatinine dialyzes less well than urea [20, 68], and patients in chronic dialysis may have plasma creatinine levels that are proportionately higher than the BUN.

In advanced renal failure [44] at levels of GFR of 20 ml/min and less, as the remaining nephrons undergo an osmotic diuresis, the reabsorption of urea by the renal tubules diminishes and the urea clearance, which is usually lower than the GFR, approximates the clearance of inulin. Similarly, as a tubular maximum secretory rate for creatinine is exceeded at these levels of renal insufficiency [1, 44], creatinine clearance, which at higher levels of GFR overestimates the clearance of inulin, decreases toward the GFR. Therefore, the mean values of urea and creatinine clearance correspond more closely to the clearance of inulin at such low levels of GFR [44], and this measurement has been recommended for the evaluation of the progression of renal failure in patients in terminal uremia.

Summary

As the automated method for creatinine determination is being adopted by most institutions, the measurement of creatinine is gaining in accuracy and reliability, and it is now possible to obtain more uniform information on the use of creatinine as an index of renal function. Although the technical difficulties of creatinine determination have been overcome to a large extent, there are still significant limitations on the validity of creatinine for the evaluation of GFR. These problems are exemplified by the uncertainties that have been introduced by the existence of a secretory mechanism in the renal handling of creatinine; by the effects of various factors, such as diet and exercise, on creatinine metabolism; by the shifting in the ratios of plasma true creatinine-non-creatinine chromogens and of creatinine clearance-inulin clearance in progressive renal failure; and, more significantly, by the induction of an extrarenal mechanism of creatinine metabolism and excretion in uremia.

In spite of all these disadvantages, however, creatinine is the only known substance in endogenous concentration in the body of which the clearance approximates the clearance of inulin, thus making its use for the estimate of GFR both practical and economical. If a lack of availability of a more reliable method makes the use of creatinine necessary for the evaluation of renal function, creatinine clearance is preferred over plasma creatinine concentration because the former correlates better with inulin clearance. Because of the difficulties inherent in prolonged urine collections, the ability of the patient to cooperate is critical in deciding among a 1-hour creatinine clearance, a 24-hour creatinine clearance, and a plasma creatinine determination. A single measurement of creatinine can be misleading in evaluating renal function, but serial determinations are helpful in detecting the direction of changes in renal disease.

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46. Dean, R. F. A., and McCance, R.A. Inulin, diodone, creatinine and urea clearances in newborn infants. J. Physiol. (London) 106:431, 1947.

3M Government R&D Contracts

3M Center Bldg. 224-2S-25
St. Paul, MN 55144-1000
612/733 1110

3M

August 14, 1992

Mrs. Linda W. Neilson, Procurement Analyst
Defense Acquisition Regulations System
3062 Defense Pentagon
Washington, DC 20301-3062

SUBJECT: Proposed Final Rule on Drug-Free Work Force

Dear Mrs. Neilson:

Thank you for the opportunity to comment on the proposed final rule on the requirement for a drug-free work force. It is our opinion the proposed final rule is so much more burdensome, so much more costly to implement, so much more apt to lead to law suits, and so much more likely to discourage the sale of commercial products to the Government that it should be abandoned and the interim final rule published September 28, 1988 should be adopted as the final rule.

The bases for this opinion include the following:

- The proposed rule greatly expands the types of employees subject to its requirements. While the interim rule applies only to employees granted access to classified information and employees in other positions that the contractor determines involve national security, health or safety, or functions requiring a high degree of trust and confidence, the proposed rule requires random drug testing of all employees whose duties can reasonably be expected to affect health, safety, or national security. The new language will undoubtedly lead to disputes as to which employees are covered by the proposed rule; it will greatly increase the number of employees tested; and it will, therefore, be much more expensive to implement. Such results run directly contrary to the Administration's goals to reduce regulatory burdens as documented in the President's moratorium on new regulations, to eliminate budget deficits, and to assist U.S. companies to be more competitive in the global marketplace.

- The interim rule states that its requirements pertaining to drug testing programs do not apply if they are inconsistent with an existing collective bargaining agreement. The proposed rule is silent on this matter. Such silence may result in contractors having to attempt to reopen existing collective bargaining agreements, and that action may lead to costly labor disputes. Failure to negotiate union bargaining agreements which are consistent with the proposed rule may prevent companies from receiving contracts.

- The interim rule refers to the "Mandatory Guidelines for Federal Workplace Drug Testing Programs," (53 FR 11980 (April 11, 1988)), issued by the Department of Health and Human Services, merely as a source for identifying the illegal drugs a contractor must test for. However, the proposed rule requires that a contractor's drug testing program "shall conform" to those Mandatory Guidelines. Thus the proposed rule appears to mandate compliance with all of the very specific requirements of the Guidelines, including requirements that the designated collection site be "secure," that chain of custody standardized forms executed by authorized collection site personnel be used upon receipt of specimens, that toilet bluing agents be used and no other source of water, etc., etc.

While the interim rule gives a contractor flexibility in devising a testing program, the proposed rule imposes very specific, very rigid requirements on contractors. This will make the devising and implementing of a testing program unnecessarily costly.

- The proposed rule introduces a requirement, not found in the interim rule, that a contractor must obtain a Contracting Officer's approval before permitting an employee to return to work in a sensitive position on a DoD contract following a violation of DoD's drug policy or a criminal drug statute. This requirement conflicts with established statutes, regulations, personnel practices, and labor agreements and will result in unnecessary costs in its implementation.

- In DFARS Section 223.7504 of the interim rule, it is stated explicitly that the clause at DFARS 252.223-7500 is not to be included in contracts for commercial or commercial-type products, other than contracts involving access to classified information. That provision has been deleted from the proposed rule. Instead the proposed rule provides that the proposed clause shall be used in all contracts that require contractor employees to perform in sensitive positions, and the definition of "sensitive positions" has been broadened so much in the proposed rule that many contracts for commercial or commercial-type products will be subject to the requirements of the proposed rule. This will necessitate drug testing of additional people at additional cost, which will make U.S. products less competitive.

  It may be difficult or impossible to segregate from a contractor's established line for production of commercial products those particular items of such products that are sold to the Government. A contractor faced with the possibility of becoming less competitive in commercial sales because of the costs of drug testing may decide not to make any future sales to the Government.

For all of these reasons, we recommend that the proposed rule be abandoned and the interim rule made the final rule.

If you have any questions on these matters, please do not hesitate to call on me. My telephone number is 612-733-6723.

Sincerely,

Robert C. Spreng
Operations Manager

RCS/bjf
F:20814.bjf

International Brotherhood of Electrical Workers, Local 108

International Brotherhood of Boilermakers, Iron Shipbuilders, Blacksmiths, Forgers and Helpers, [redacted]807

International Association of Sheet Metal Workers, Local 15

United Association of Journeymen Plumbers and Steamfitters of America and Canada, Local 726

Tampa Metal Trades Council

(AFL-CIO)

United Brotherhood of Carpenters and Joiners of America, Local 140

Brotherhood of Painters and Allied Trades, District Council 66

Construction Shipyard and General Laborers, Local 1207

International Association of Machinists and Aerospace Workers, Local 570

International Union of Operating Engineers, Local 925

August 23, 1992

From:
Bob Betterton
President
c/o I.A.M.& A.W. Lodge 570
4020 80th Avenue North
Pinellas Park,Florida 34665

Subject:
Random Drug Testing DAR Case 88-083
United States Navy Contract
Procurement Language

To:
The Defense Acquisition Regulations Council
Attn: Mrs. Linda W. Nelson, OUSD (A)
3062 Defense Pentagon
Washington D.C. 20301-3062

Dear Council,

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1.) It is a unreasonable and unacceptable invasion of privacy.(ie; body fluids)
2.) It is unfair to force the added financial burden on employers particularly at this time,when most if not all shipyards in the United States are struggling to survive a dormant market in repairs and new ship construction.
3.) It has never been determined that a problem of drug abuse is at a level in our shipyards (ie; The American Ship Building Co., Tampa Shipyards Inc.)that warrants random vs. probable cause.
4.) It is our intention to see money spent that we as the work force, in partnership with our management,have determined to be real problems and a threat to our health and safety.

In conclusion,we feel that it would be a perfidious act for any agency or department of the United States Government to mandate randon drug testing to private shipbuilding and repair yards.

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c/o I.A.M.& A.W. Lodge 570
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United States Navy Contract
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3062 Defense Pentagon
Washington D.C. 20301-3062

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Sincerely,

Bob Betterton

Bob Betterton

Spectra Diode Laboratories, Inc.

80 Rose Orchard Way
San Jose, CA 95134-1356
(408) 943-9411
FAX: (408) 943-1070

September 8, 1992

Defense Acquisition Regulations Systems
3062 Defense Pentagon
Washington, DC 20301-3062

Attention: Mrs. Linda W. Neilson

Subject: Regulatory Flexibility Act - DAR Case 88-083

Reference: Federal Register Notice Dated 7/23/92

Dear Mrs. Neilson:

Spectra Diode Laboratories, Inc. is a small business doing defense work with the U. S. Government. We find the proposed rule for a Drug Free Work Force to be an economic and administrative burden to our company. SDL proposes the Regulatory Flexibility Act be amended to state that small businesses with DoD contracts are excluded from compliance with this proposed rule.

If you have any questions, please contact me.

Sincerely,

SPECTRA DIODE LABORATORIES, INC.

John P. Melton
Vice President, Business Operations

TAMPA SHIP

TAMPA SHIPYARDS INCORPORATED

P.O. BOX 1277 • TAMPA, FLORIDA 33601 • (813) 247-1183

August 26, 1992

Defense Acquisition Regulations Council
Attn: Mrs. Linda W. Neilson, OUSD (A)
3062 Defense Pentagon
Washington, D.C. 20301 - 3062

RE: DAR Case 88-083
Navy Random Drug Testing Requirements

Dear Mrs. Neilson,

Tampa Shipyards, Inc. supports the proposed DOD requirements for random drug testing in it's acquisition regulations.

We believe that random testing would be an effective, efficient, and economical way to achieve a truly drug free workplace.

The requirement should be extended to sub-contractors at all tiers as well.

Very Truly Yours,

Fred Turner
Director of Labor Relations

Shipbuilders Council of America
Suite 330
4301 N. Fairfax Drive
Arlington, Virginia 22203
Tel: 703-276-1700 Fax: 703-276-1707

August 31, 1992

To: Ms. Linda W. Neilson
OUSD (A)
Defense Acquisition Regulations Council
3062 Defense
The Pentagon
Washington, DC 20301-3062

Subject: Drug Free Work Force (DAR Case 88-083)

On behalf of the Shipbuilders Council of America, the national trade association which represents American shipyards and suppliers of marine equipment and services, I wish to submit the following comments on the proposed revisions to the Defense Federal Acquisition Regulation Supplement interim rule for a Drug Free Work Place.

Redundancy:

What is seemingly overlooked is the fact that all responsible contractors recognize the importance of a Drug Free Work Place and its impact on productivity and profit. Accordingly, we believe that the need for either the proposed regulation or the interim final regulation now in effect is redundant. In this regard, the coverage of the Federal Acquisition Regulation (FAR) on the subject of Drug-Free Work Place is adequate and provides the contractor with the required flexibility for an effective program. Furthermore, adequate direction is now provided in the FAR on the responsibility of contractors; and when contractors are found deficient, a finding of non-responsibility can be made under the FAR Regulations to eliminate contractors that ignore proper management of their companies with regard to maintaining a Drug-Free Work Place.

Random Testing:

Although the many thousands of responsible DoD contractors are diverse organizations with different needs, they all support a Drug Free Work Place policy. However, it is grossly inefficient to adopt a "one rule fits all" policy, without regard to a company's organizational structure which permits each contractor to tailor its program in a manner that optimizes costs, while at the same time ensuring that the ultimate goal of a Drug Free Work Place is met. Accordingly, we recommend that the proposed regulation and contract clause be carefully worded in order to permit the contractor to determine who should be tested and how many should be tested. By analogy, DoD statistics reflect that random testing of officers reveal a

much smaller incidence of drug abuse than among young enlisted personnel. Likewise, a company that dedicates extra resources to refining its employment screening process will result in a higher caliber of a work force and a lower likelihood of drug abuse. Such contractor initiatives often are more effective at accomplishing the Drug Free Work Place goal than random testing, and should be factored into an overall program that balances need with cost effective safeguards.

Testing:

For initial testing, contractors should be permitted to use their own laboratories. To confirm positive tests, the contractor should be permitted to select any certified laboratory in order to control costs that invariably escalate when some certified laboratories are summarily excluded. In short, "certified" should be the only criteria.

Cost:

All costs associated with a mandated testing program should be specifically identified as an allowable cost under the Regulation. Furthermore, all litigation expenses associated with enforcing mandatory requirements should also be specifically identified as an allowable cost.

Thank you for this opportunity to provide our comments which support a Drug Free Work Place while eliminating unnecessary costs that add no substantive value or additional safeguards that would preclude drug abuse by a work force that produces products or services for the Department of Defense, as well as for all commercial customers which expect and have every right to expect services or products to be provided in a drug free environment.

Sincerely,

John J. Stocker
President

Mission Research Corporation

SANTA BARBARA

735 STATE STREET
P.O. DRAWER 719
SANTA BARBARA
CALIFORNIA 93102-0719
(805) 963-8761
(805) 962-8530 FAX

September 10, 1992

Defense Acquisition Regulations Council
3062 Defense Pentagon
Washington, DC 20301-3062

Attn: Mrs. Linda W. Nelson, OUSD(A)

re: DAR Case 88-083

Dear Mrs. Nelson:

I am writing in opposition to the adoption of a rule that would require our company to implement drug testing. A defense contractor, Mission Research Corporation has downsized from 450 to 320 employees in the past three years. Overhead cost reductions have included the layoff of many staff members. We simply do not have the staff required to handle the additional burden of implementing and maintaining a drug testing program and we do not want to add staff, cost allowability notwithstanding.

In our current and future efforts to penetrate non-defense business areas, we greatly fear the handicap of excessive costs and a cumbersome bureaucracy. Also, given the post cold war environment, it is our opinion that additional security measures, such as mandated random drug testing, are highly questionable.

Steven L. Gutsche

Steven L. Gutsche
President

cc: Congressman Robert J. Lagomarsino

TAMPA BAY AREA LODGE NO. 570

INTERNATIONAL ASSOCIATION of MACHINISTS and AEROSPACE WORKERS

August 24, 1992

From:
Bob Betterton
President
4020 80th Avenue
Pinellas Park, Fl. 34665

To:
The Defense Acquisition Regulations Council
Attn.: Mrs. Linda W. Nelson, OUSED (A)
3062 Defense Pentagon
Washington, D.C. 20301-3062

Dear Council,

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In conclusion, we feel that it would be a perfidious act for any agency or department of the United States Government to mandate random drug testing to private shipbuilding and repair yards.

Sincerely,

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BB/kw
cc:file
E. House
G. Kourpias
R. Cox

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August 24, 1992

From:
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Subj: Random Drug Testing
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United States Navy Contract
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INSPECTOR GENERAL
DEPARTMENT OF DEFENSE
400 ARMY NAVY DRIVE
ARLINGTON, VIRGINIA 22202-2884

Audit Policy
and Oversight

AUG 18 1992

MEMORANDUM FOR DIRECTOR, DEFENSE ACQUISITION REGULATIONS COUNCIL

SUBJECT: Defense Acquisition Regulatory Case 88-083

The Office of the Inspector General, Department of Defense, does not wish to comment on Defense Acquisition Regulatory Case 88-083 (Drug-Free Work Force). We appreciate the opportunity to review the case.

Donald E. Davis
Deputy Assistant Inspector General
for Audit Policy and Oversight

G
C A
N

Government Contractor's Assistance Network

Post Office Box 28944
Santa Ana, CA 92799-8944
(714) 542-2710
FAX: (714) 542-6814

September 14, 1992

Defense Acquisition Regulation Council
Attention: Mrs. Linda W. Neilson, OUSD (A)
3062 Defense Pentagon
Washington, DC 20301-3062

Subject: Drug-Free Work Force Policy

Reference: DAR Case 88-083, 57 FR 32769

Dear Mrs. Neilson:

In response to your solicitation for comments on the subject and referenced DAR Case, we are pleased to submit the following:

1. No issue is taken with the proposed clause as written.

2. It is our contention that the area that requires revision is the application. It is generally understood that some seventy percent (70%) of the dollars expended today on Department of Defense (DoD) contracts flow through the prime contractor to subcontractors and suppliers. Although our review of the legislative history leading to the Drug-Free Work Place Act reveals no proscription as to the flow down, neither the Federal Acquisition Regulation (FAR) or Department of Defense Federal Acquisition Regulation Supplement (DFARS) implementation of the Act provides for its flow down to subsequent tiers. Almost every other socio-economic clause requires flow down and places the burden on the prime contractor to monitor and ensure compliance and reporting.

3. The final clause should also establish and implement a program of compliance review to ensure ; (1) contractor implements a Drug-Free Program ; (2) contractor identifies employee's in sensitive positions which , and (3) establish the required re-habilitation programs for employee's who test positive.

Finally, in April of this year we addressed our concerns and recommendations to the Office of National Drug Control Policy and the DoD; reference the FAR clause.

Thank you for your cooperation in this matter; it is greatly appreciated.

Sincerely,

GOVERNMENT CONTRACTOR'S ASSISTANCE NETWORK

H. W. McCoy

Herbert W. McCoy, CPPM, CF
Principal

DCS CORPORATION 1330 Braddock Place * Alexandria, Virginia 22314 * (703) 683-8430

August 5, 1992

Defense Acquisition Regulations Council
Attn: Mrs. Linda W. Neilson
OUSD A1. 3062 Defense Pentagon
Washington, D.C. 20301-3062

Re: DAR Case 88-083

Dear Mrs. Neilson:

In response to your request for comments regarding the Drug-Free Workforce Act, I would like to inform you of some of the difficulties we are encountering in establishing our random testing program:

1. Because the rule requires random testing for all "employees in a sensitive position", it is necessary for us to include employees who are located in our small offices, at least one of which is located in a rather remote location. We have several of these small offices scattered throughout the U.S. and it is difficult to find and make arrangements for collection sites which conform to the requirements you specify we must meet as stated in the "Mandatory Guidelines." I have not yet finished my research, but wonder what may happen if I am unable to find such sites? Could offices with less than (?) employees be exempted from the ruling, or could companies be allowed to deviate from the mandatory guidelines in selecting a collection site if unable to find one which meets all the guideline criteria?

2. Part of the mandatory guidelines [2.5 (d) (2)] stipulates that each agency must submit blind performance test specimens to its contract laboratories. The percentage of samples that must be submitted seems inordinately high given:

    a) The number of agencies using each approved laboratory;

    b) The quality assurance and quality control measures placed upon the laboratories and;

c) The expense to companies for the purchase of the specimens and payment for the testing to comply with this directive.

Since these costs are "allowable", contractors will be including them during the proposal process as part of their O/H expense, further adding to the government's cost of doing business. I do not believe the cost is justified and could be minimized by lowering the percentage of samples which must be submitted.

3. Despite the prominence of the MRO's function in the drug testing/verification process, the mandatory guidelines which we are required to follow place no "quality controls" on the MRO other than he/she be a "licensed physician with knowledge of substance abuse disorders." Since doctors, themselves, have a high percentage of substance abuse problems, this apparent lack of "quality control" over these physicians is somewhat troubling.

4. Finally, by whose authority does the DoD final ruling "take precedence over any state and local laws"?

Sincerely,

DCS CORPORATION

Barbara J. Napier
Human Resources Manager

BJN/mjw

OFFICE OF THE UNDER SECRETARY OF DEFENSE

WASHINGTON, DC 20301-3000

ACQUISITION

October 1, 1992

DP(DARS)

MEMORANDUM FOR SHIRLEY CURRY, OASD(PA)(DFOI & SR)

SUBJECT: DAR Case 88-083, Drug Free Work Force

Please discard the partial set of 14 public comments forwarded to your office on September 18, 1992, Drug Free Work Force.

Attached is a complete listing and 44 public comments received on the proposed rule of subject case published in the Federal Register on July 23, 1992, (57FR32769). This case involves revisions to DFARS Parts 223 and 252, Drug Free Work Force.

These comments are provided for the public's review or request for copies. Our case manager is Mrs. Linda Neilson, at 697-7266.

Linda E. Greene

Linda E. Greene
Deputy Director,
Defense Acquisition
Regulations Council

Attachments

DAR Case 88-083, Drug-Free Work Force
Public Comments

Alliant Techsystems	2 pgs
Canning, Donald T. (Atty)	5 pgs
Caterpillar, Inc.	4 pgs
*Chimera Research & Chemical, Inc.	3 pgs
*Brown, Catherine S., Ph.D.	1 pg
*Cater, Frank B.	1 pg
*Cole, Robert A.	1 pg
*K_____, Edward J.	1 pg
*Knight, Henderson W., AF Ret	1 pg
*Roberts, David F., Ph.D.	1 pg
*Keystone Laboratories	1 pg
*Waldon, Gary	1 pg
Chimera Research & Chemical, Inc.	57 pgs
Council of Defense & Space Industry Associations (CODSIA)	13 pgs
DCS Corporation	2 pgs
Employee Assistance Professionals Association, Inc.	3 pgs
Enzymatics, Inc.	2 pgs
Government Contractor's Assistance Network	1 pg
Grumman Corporation	3 pgs
Inspector General, Department of Defense	1 pg
International Association of Machinists & Aerospace Workers/Office of General Vice President	7 pgs
International Association of Machinists & Aerospace Workers/Lodge No. 389	2 pgs
International Association of Machinists & Aerospace Workers/Lodge No. 570	1 pg
Ironworkers/Local Union No. 627	1 pg
Litton Industries, Inc.	6 pgs
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National Steel and Shipbuilding Co.	3 pgs
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Seattle Professional Engineering Employees Ass'n (SPEEA)	12 pgs
Shipbuilders Council of America	2 pgs
Spectra Diode Laboratories, Inc.	1 pg
STI Optronics	2 pgs
Tampa Shipyards Incorporated	1 pg
Tampa Metal Trades Council	1 pg
3-M Corporation	2 pgs
University of California	9 pgs
Washington Headquarters Services, DoD	1 pg
41 Commenters	**213 pgs**

centration, the presence of endogenous enzyme (lysozyme), and interfering drugs. The pH range specified for these assays is in the range of 5.5 to 8.0. In most instances the buffer supplied will be sufficient to bring the urine samples into the proper pH range. Approximately 2 to 4% of all urine samples contain sufficient lysozyme to produce false positive results [1]. This situation can be corrected by running suitable blanks. High salt concentrations, greater than 50 mg/mL NaCl, will result in false negative assay results and will necessitate an alternative method of analysis, i.e., TLC, HPLC, or GC [2]. The presence of interfering drugs will be discussed later.

In general, a false positive test result has greater impact on the status of the subject than a false negative test result. EMIT DAU assays are subject to a 3 to 5% incidence of false positives.

False positive test results can result from (1) contamination of calibrators or lysozyme in the reagents; (2) contamination or dilution of the low calibrator, resulting in a lower cutoff value: (3) contamination of the sample with saliva (which contains lysozyme); (4) carry-over following a high positive sample which results in a slight elevation of the subsequent assay: and (5) the presence of a drug or substance which cross-reacts with the enzyme-labeled drug for the antibody. False negative test results can arise from (1) adulteration of the urine sample, (2) the patient drinking excessively large quantities of water to dilute the urine, (3) adding salt to the urine, and (4) a urine with a pH range outside 5.5 to 8.0.

This investigation was concerned with the occurrence of false positive test results due to the presence of interfering drug substances. The results, tabulated and summarized in Table 1, use the average of the low calibrator values for the respective test as the cutoff value: everything greater than that value was interpreted as positive.

It was found that the cocaine metabolite assay yields the fewest false positives and the methadone assay the greatest. Also, there are several instances where one drug substance affects several assays, e.g., amitriptyline hydrochloride, brompheniramine maleate, desipramine hydrochloride, imipramine hydrochloride, indomethacin, methoxyphenamine hydrochloride, orphenadrine citrate, promethazine hydrochloride, propranolol hydrochloride, triethyperazine maleate, and tripelennamine. The antihistamines and tricyclic antidepressants are cross-reactants in numerous cases.

The amphetamine assay primarily detects amphetamine and methamphetamine. The manufacturer states that a small percentage of false positives may be observed in urines containing a high concentration of phenylpropanolamine and ephedrine. Other cross-reactants listed include phentermine, mephentermine, nylidrin, isoxsuprine, and methylphenidate. These correlate well with the results of the current investigation which expands the list to include other drugs, including additional sympathomimetic amines.

The barbiturate assay is designed to detect secobarbital, phenobarbital, butabarbital, pentobarbital, and amobarbital. A listed cross-

reactant is glutethimide which was confirmed in this study. Other cross-reactants found were several anticonvulsants and anti-inflammatory agents.

The benzodiazepine assay detects oxazepam in the urine and is utilized for diazepam and other benzodiazepines excreted as oxazepam. The manufacturer states that cross-reactivity with nonbenzodiazepine substances has not been observed. Twenty-six drugs were found that cross-reacted with this assay, as listed in Table 1, including several antihistamines and antispasmodics.

Benzoyl ecgonine is the substance detected in the cocaine metabolite assay. The product literature lists the belladonna alkaloids, barbiturates, and amphetamines as cross-reactants at levels at least 1000 μg/mL and greater. No cross-reactants were found for the cocaine metabolite assay in this investigation.

Methadone is detected as the parent compound in the urine. Cross-reactions with nonmethadone substances are usually not observed, according to the manufacturer: occasional exceptions are high concentrations of chlorpromazine, promethazine, and dextromethorphan. Thirty-six drug substances, as shown in Table 1, demonstrated the ability to provide false positive test results for the methadone assay, including 11 of the same compounds that yielded a false positive for the benzodiazepine assay.

The opiate assay is designed to detect morphine and morphine glucuronide, in addition to codeine, nalorphine, and meperidine in higher concentrations. Cross-reactants listed are chlorpromazine, naloxone, dextromethorphan, and methadone. The current study adds 19 additional cross-reactants, including numerous antihistamines and several tricyclic antidepressants. The low cut-off value (low calibrator) is adjusted by the manufacturer such that 95% of positive samples will be positive and 95% of negative samples will be negative. It can be altered to meet the specific requirements of a laboratory. One study [3] demonstrated a 4.0% incidence of false positives and a 5.6% incidence of false negatives for the opiate assay. By decreasing the low cut-off value from 0.5 μg (morphine equivalent)/mL to 0.1 μg/mL, the incidence of false positives decreased to 1.6% and the incidence of false negatives rose to 6.4%.

The propoxyphene assay is sensitive to propoxyphene and the major metabolite, N-demethyldextropropoxyphene (norpropoxyphene). Cross-reacting substances enumerated by the manufacturer include high concentrations of morphine, codeine, methadone, barbiturates, amphetamines, benzoyl ecgonine, chlorpromazine, oxazepam, and dextromethorphan. The current study provides eight more cross-reacting drugs, mostly antihistamines and tricyclic antidepressants.

The exact mechanism of the dynamics of cross-reactivity has not been explained: for example, what is the quantitative effect of one drug as compared to another on a specific EMIT DAU assay. One study [4] involved the effect of adding codeine to morphine samples analyzed by both enzyme immunoassay and radioimmunoassay. The results were not the simple weighted mean of the morphine and codeine concentra-

tions but were much higher. The presence of naloxone in another sample also gave a positive but unequal result. No attempt is made in this report to elucidate the cross-reactivity mechanism.

It should be noted that many of the drugs tested are salt forms of the parent drugs, and it has already been mentioned that ionic strength effects can alter assay results. However, the effect of increasing ionic strength by the addition of NaCl (at least 50 mg) is an increase in the incidence of false negative results [2]. The salts of the drugs utilized do not approach this concentration and false positive results were obtained, not false negative.

It is important to keep in perspective that most drugs will probably never accumulate to a concentration of 1000 μg/mL in the urine. The concentration a drug achieves in the urine is a function of many variables (e.g., dose, route of administration, metabolism, half-life, state of hydration of the patient, urinary volume, kidney function, and fluid intake). Many drugs will be present in the urine in the form of their metabolites as well as in their parent form.

Much more needs to be done to further enhance the interpretation of the EMIT DAU assays, including:

1. Studying the specificity of the assay in the presence of any of several hundred other drug substances
2. Studying the specificity of the assay in the presence of any of the metabolites of the hundreds of drugs used today
3. Studying the incidence of false negatives utilizing spiked urine containing drugs of abuse (positive samples) and any of the several hundred drugs commonly used in medical practice today
4. As above but using the metabolites of commonly used prescription drugs

In addition to the work on the EMIT DAU assays, the effects of commonly used prescription and nonprescription drugs on the EMIT assay results for serum levels should be investigated.

ACKNOWLEDGMENTS

The authors thank SYVA for furnishing the EMIT materials used in this study. Appreciation is also extended to the drug manufacturers listed in Table 1 for their generous supplies of the drug substances.

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4/2

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Letters

A Quality-Control Solution for Use in "ΔA_{450}" Determination of Amniotic Fluid

To the Editor:

It has been well established that the bilirubin concentration in amniotic fluid is a good indicator of increased hemoglobin degradation after fetal rhesus isoimmunization (*1*). Frequently the bilirubin concentration is not measured directly, but instead the absorbance change at 450 nm ("ΔA_{450}"), and this value is used as an indicator of bilirubin concentration. The technique used to measure the absorbance change is generally standardized (*2*), except for minor modifications. However, difficulties do arise when one attempts to implement a quality-control program.

The main problem stems from the instability of the bilirubin in amniotic fluid, which makes this material unsuitable for use as a quality control. The determination requires no reagents, so the primary reason for using a control is to provide a check on analytical technique. For this purpose, a fluid is needed that has a stable spectral response similar to that of amniotic fluid. A 2.34 × 10^{-3} mol/liter solution of 8-hydroxyquinoline in water (340 mg/liter; molecular mass 145.16) meets this need. Such a solution is close to the limit of solubility at room temperature (22 °C), but the solubility can be enhanced by adding a little hydrochloric acid or by using salts, such as the hemi-sulfate of 8-hydroxyquinoline. However, this is undesirable because of a spectral shift and decreased stability of the solution. We have found that the aqueous solution of 8-hydroxyquinoline is stable for at least one year at room temperature if precautions are taken to avoid excessive exposure to light (amber-colored bottle, stored away from direct sunlight). During two years use, we have established a ΔA_{450} value of 0.087 ± 0.004 (mean ± 2 SD; n = 300) for the 8-hydroxyquinoline solution. The spectral patterns of the 8-hydroxyquinoline solution and amniotic fluid so closely resemble one another that a "bilirubin" concentration can be calculated by applying a formula such as the one of Bjerre et al. (*3*).

Figure 1 shows the spectral tracings for a representative amniotic fluid and for the 8-hydroxyquinoline solution, Figure 2 the derivations of the ΔA_{450} values.

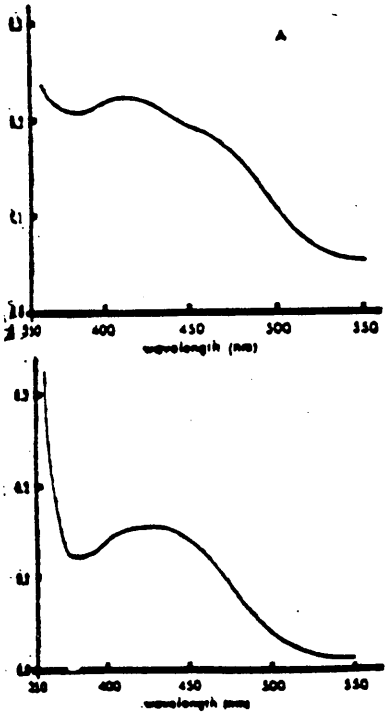

Fig. 1. Spectral tracing for an amniotic fluid specimen (*A*) and a 2.34 × 10^{-3} mol/liter solution of 8-hydroxyquinoline

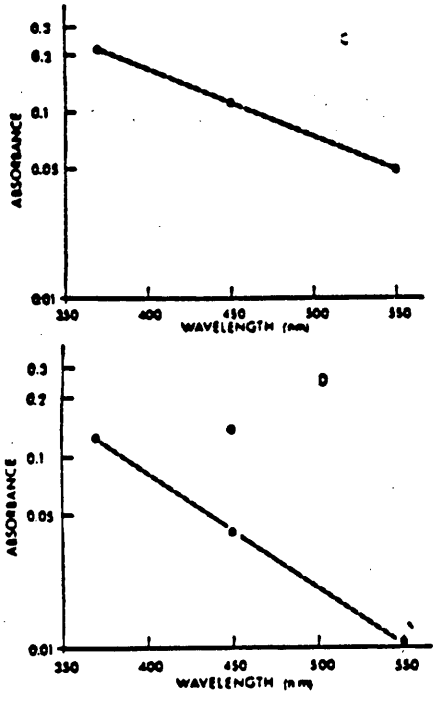

Fig. 2. Derivation of "ΔA_{450}" value for amniotic fluid specimen (*C*) and the 2.34 × 10^{-3} mol/liter solution of 8-hydroxyquinoline (*D*)

Absorbance values are plotted on a logarithmic scale, wavelength on a linear scale, at 370, 450, and 550 nm. A straight line is drawn between the 370-nm and 55-nm points. The derived absorbance value obtained from this line at 450 nm is the "baseline" absorbance at 450 nm. The difference between this and the measured absorbance at 450 nm is the ΔA_{450}

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Interference by NaCl with the EMIT Method of Analysis for Drugs of Abuse

To the Editor:

In our Toxicology Laboratory, we encounter schemes used by drug addicts on methadone detoxification programs to avoid our detection of drugs of abuse (*1*). Such efforts have included incorporation of a plastic bag filled with another's urine, concealed under the addict's clothing, connected with a long piece of plastic tubing running along the trunk of the body, and, on clinic visit, substituted for his own specimen. Another stratagem is to consume large quantities of fluids 2 to 4 h before urination, in the hope of diluting the urine to the point where the drug concentration may fall below the sensitivity of the method and thus escape detection. Methadone may be there in large quantities and may not be affected significantly by the dilution effect; thus this second scheme has limited success with both the thin-layer chromatographic or the EMIT (Syva, Palo Alto, Calif. 94304) methods for analysis for drugs of abuse.

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Recently, a urine specimen to be analyzed for morphine, barbiturates, and methadone tested negative by EMIT, but positive for all three drugs by thin-layer chromatography. Further investigation revealed that the patient had added sodium chloride to the urine specimen. We undertook a preliminary investigation on the EMIT system by supplementing urine specimens known to be positive for morphine, barbiturates, and methadone with sodium chloride to concentrations up to 200 g/liter. When concentrations exceeded 50 g/liter, all specimens became negative. Thus, one should be alert for the possibility of addicts clandestinely placing salt in their urines to escape detection. Fortunately, the added salt appears to nullify all EMIT tests, so that all drugs tested will be negative, which in itself may be suspicious. Thin-layer chromatographic results are not affected (*2*).

pH and ionic strength play a definite role in the mechanism of enzymatic reactions (*3*), a role that becomes more complex in the case of EMIT (*4*). The effect we report here is probably attributable to an increase in ionic strength to above a critical point, at which so many ions congregate at one or more charged sites that they prevent the necessary interactions. If so, the effect is nonspecific and we would expect any salt solution that contributes a high ionic strength to work in a similar manner.

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Thin-Layer Chromatographic Detection of Quinine, Morphine, and Poly-Drugs

To the Editor:

We read with great interest the letter [*Clinical Chemistry* 22, 393 (1976)] by Wilkinson et al. in which they discussed the findings of a service laboratory that had mistakenly reported the presence of morphine and cocaine in an individual's urine. We believe that the authors' point with regard to the use of more than one analytical procedure for confirming positive results was a valid one. Another article, by McIntyre and Armande, which appeared in the same issue, discussed their ability to detect free morphine at a sensitivity of at least 0.5 mg/liter.

We wish to call the attention of readers of this journal to the thin-layer chromatographic technique used in this laboratory. It is capable of detecting free morphine in a concentration of 100–190 µg/liter of urine. It is used to analyze 3000 urine specimens per week for opiates (morphine, codeine, methadone, and quinine), and more than 1000 specimens for poly-drugs (15 drugs: opiates plus amphetamine, methamphetamine, phenmetrazine, methylphenidate, phenothiazines, sedatives, and hypnotics). The technique has been detailed elsewhere (*1*, *2*). The following modifications have been introduced: (*a*) urine containing ion-paper is shaken for 20–30 min, (*b*) ratio of chloroform and isopropanol used is 5:2, and (*c*) drugs are extracted by shaking for 20 min. The sensitivity of this ion-exchange paper technique was described at the Sixth International Congress of Pharmacology (*3*).

The use of this single-step extraction and two-stage thin-layer development system enables us to measure the entire array of drugs of abuse in urine concomitantly in the following minimum concentrations (mg/liter, expressed as base): morphine, 0.1 (volume of urine, 50 ml) and 0.15–0.19 (volume urine, 20 ml); amphetamine, 0.87; methamphetamine, 0.4; phenmetrazine, 0.41; methylphenidate, 0.87; codeine, 0.35; methadone, 0.45–0.9; phenobarbital, 0.5; secobarbital, 0.36; propoxyphene, 0.90; and cocaine, 0.89. The volume of urine required for these sensitivities is 20–50 ml. We recommend that positive results be obtained for barbiturates be confirmed by respotting the residue and developing in another solvent. A technician can analyze 120 urine specimens for opiates and 80–90 specimens for poly-drugs per day. The cost of analysis for performing at least 4–5 tests (opiates) per urine specimen is $0.58 and for performing 9–15 tests (poly-drugs) is $0.82 per specimen (*4*), including labor, chemicals, and supplies. Our current total cost of analysis, including supervisory and administrative salaries (one chief toxicologist, one laboratory manager, one chief chemist), chemicals and supplies, laboratory rental, technical and support services, is $1.38 per specimen for monitoring 3500–4000 specimens per week. Set-up costs of a toxicology laboratory facility with thin-layer chromatography and various detection procedures currently used in drug-abuse screening programs are discussed elsewhere (*5*, *6*).

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NATIONAL INSTITUTE ON DRUG ABUSE

URINALYSIS COLLECTION HANDBOOK FOR FEDERAL DRUG TESTING PROGRAMS

For Implementation
of the
Mandatory Guidelines
for Federal Workplace Drug Testing Programs

September 1988

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES
Public Health Service
Alcohol, Drug Abuse, and Mental Health Administration

URINE SPECIMEN COLLECTION

OVERVIEW

The urine specimen collector plays a key role in each Agency's drug testing component of the Agency Plan. As specimen collector, you may be the only Agency official in the program with whom employees come into direct contact. Individuals subject to testing hold a variety of positions within the Agency with varying levels of responsibility. Your professionalism, sensitivity, and compassion can greatly affect their attitudes and the credibility of your program. Treat them with the respect and dignity you would expect for yourself.

SCOPE OF RESPONSIBILITY

Specimen collection is the most vulnerable part of any drug testing program. The agency must be able to tie the result of a urinalysis drug test to a specific individual. Chain of custody is the term that refers to the process of ensuring and providing documentation of proper sample identification from time of collection to the receipt of laboratory results.

In order for the results of a particular specimen to withstand legal scrutiny, it is necessary to demonstrate:

- No adulteration or tampering has taken place
- Documentation of all personnel who handled the specimen
- No unauthorized access to the specimen was possible
- Specimen was handled in a secure manner
- Specimen belongs to the individual whose information is printed on the label

Since an individual normally provides a specimen in the privacy of a stall or other partitioned area that allows for individual privacy, there is an opportunity for drug users to subvert the collection process. For example, individuals may use one of the following methods to avoid detection of drug use:

A. Substitution - Liquids such as soda, tea, apple juice and clean urine (i.e., store bought, drug-free) are substituted for their own urine.

B. Adulteration - Addition into the urine specimen of foreign material that is known or thought to invalidate the test. Common substances include soap, household cleaners, salt, bleach, and drain cleaner. The effect of each of these adulterants varies with the test methods used. Adulterants are often detectable at the collection site by visual inspection of the specimen, or by smell and abnormal temperatures caused by the chemicals.

C. Dilution - Efforts to reduce the drug concentration in the urine to the point that it will not be reported by the drug testing laboratory. This may be done by adding water after the specimen is provided.

NATIONAL INSTITUTE ON DRUG ABUSE

MEDICAL REVIEW OFFICER MANUAL:

A GUIDE TO EVALUATING URINE DRUG ANALYSIS

For Implementation
of the
Mandatory Guidelines
for Federal Workplace Drug Testing Programs

September 1988

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES
Public Health Service
Alcohol, Drug Abuse, and Mental Health Administration

SUPPLEMENTAL AND BACKGROUND INFORMATION

In some agencies the MRO may have a broader role as an active consultant to management. This section is included to assist in that role.

False Negative Reports

Errors in handling or analysis, as discussed above, could result in false negative reports. Drug abusers also can generate false negatives by substituting another person's urine for their own. Containers of urine may be concealed in boots, in voluminous skirts, and elsewhere around the body. Sophisticated male drug abusers, expecting direct observation of their urination, have concealed IV-solution bags in the axilla with the IV tube running inside the sleeve to the hand. Without extremely close observation, the drug abuser then can hold the penis as if for normal urination, apply pressure with the arm at the axilla, and deliver a stream of someone else's urine into the cup. Some drug abusers who expect close monitoring apparently have emptied their own bladders, instilled another person's urine into the bladder with a catheter, and then have urinated that sample in the observer's presence.

These experiences highlight the intensity of drug-related deception among persons heavily involved with drugs. The strong drive to continue taking drugs may lead to elaborate efforts to conceal the use. Such deception, not uncommon in drug treatment clinics, does not necessarily indicate that the deceiver is a "bad" person or a "bad" employee; rather, it underscores the powerful behavioral effects of some drugs. Those who engage in such deception often respond well to treatment and rehabilitation.

In most cases the collector in the Federal urinalysis program does not directly observe the urination; most employees might consider such observation too demeaning. But it is difficult (although not impossible) for a drug abuser to maintain a urine sample at body temperature outside of the body. Thus, urine collectors measure sample temperature immediately upon delivery. Urine samples must range from 32.5°-37.7°C (90.5°-99.8°F) within 4 minutes of urination. If a sample is not in that range, the collector obtains another specimen under direct observation, and both are forwarded to the laboratory.

An employee also might produce a false negative test through intentional dilution or contamination of a sample. A large amount of salt added to a sample can invalidate an assay, or extensive tap water dilution of a sample may reduce the concentration of drug below measurable levels. Safeguards against these sources of false negatives include the collector's careful inspection for sample color and temperature. If dilution is suspected, measurement of creatinine content and osmolarity in the laboratory can provide the MRO with additional information; the latter procedures reveal either dilution or salting.

Elimination Rates

Additional problems may arise in the interpretation of urinary data. First, drug abusers may eliminate some drugs more rapidly from their systems by changing urinary pH. For example, the renal clearance of phencyclidine increases 4- to 5-fold when urinary pH is below 5. Accordingly, patients overdosed with phencyclidine or amphetamines sometimes are treated with ammonium chloride (NH_4Cl) to hasten detoxification. An apparently intoxicated employee, directed to produce a urine sample "for cause," may delay for several days and make dietary changes resulting in more acidic urine. This hastens elimination of basic drugs, and may avoid detection. Employees who misunderstand this effect may add acid to a urine sample; pH below the physiological range suggests that manipulation.

Urination "On Demand"

Employees may have difficulty initiating a urinary stream "on demand." Anxiety about urine testing really does impede urinary release in some people. Certain medical conditions may cause urinary retention or difficulty in initiating micturition. Drug-abusing employees may attempt to defer urination almost indefinitely. Not infrequently prescription and over-the-counter medications possessing anticholinergic properties may also prolong the process. However, an employee who cannot urinate when first requested to do so should remain in the test area, consuming liquids until able to do so. Eight ounces of water every thirty minutes will generally produce urination in even the most reluctant subject within 2-3 hours. There should be a firm policy that samples must be produced on the scheduled day, coupled with sympathetic recognition that this may be difficult for some anxious people.

Proffered Explanations

Among the many striking explanations offered for drug-positive urines is passive inhalation of marijuana smoke. "I have never smoked marijuana, but I was in a car with some guys who did"; "I know that the man across the hall from me smokes marijuana, and I had my door open last night."

Several studies have examined the detection of THC (tetrahydrocannabinol, the major psychoactive constituent of marijuana) among those passively exposed to marijuana smoke (Levine, 1983; Law et al., 1984; Morland et al., 1985; Cone et al., 1987).

While THC urine concentrations have been produced experimentally at sufficient levels, e.g., 100 ng/ml, to be detected in the Federal testing program, the smoke conditions of the room were extreme and not typical of social environmental conditions. Moreover, all subjects under these conditions have subjective psychoactive effects as well. Thus the claim of <u>innocent</u> passive inhalation in a confined area as an explanation for a positive urine test result is not acceptable.

Destroying the myth - " Creatinine: an ineffective tool for adulteration detection."

Renal Function Tests

Clinical Laboratory Procedures and Diagnosis

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Little, Brown and Company
Boston

tenth day. The subject with the smallest variation (CV = 5%), represented in the upper portion of Figure 1–2, excreted 90 percent of the mean on the sixth day and 113 percent on the twentieth day. Shown in the middle portion of Figure 1–2 is the subject with the average variation (CV = 11%), who excreted 129 percent of the mean on the second day and 81 percent on the twenty-first day.

This study indicates that the daily urinary excretion of creatinine can vary significantly not only among different subjects but also in the same subject from one day to another. Identical results [31, 50] have been reported by others, and they indicate that the daily urinary excretion of creatinine cannot be used as a reliable index of the completeness of urine collection.

Creatinine in Uremia and Creatinine Deficit

In acute renal failure [38], the plasma concentration of creatinine increases at a daily rate of 2 to 3 mg/dl in direct proportion to the amount of creatinine that is retained in the body and to the reduction in renal function. In chronic renal failure, on the contrary [30], the urinary excretion of creatinine decreases as plasma concentration rises, and the rate of daily increase in plasma concentration of creatinine [38] is only one-half to one-third of what is expected from the creatinine retained as a result of the fall in GFR. This creatinine deficit becomes apparent at plasma concentrations of creatinine higher than 6 mg/dl and cannot be accounted for entirely by a reduction in endogenous production [30]. It has been estimated that 16 to 66 percent of the creatinine formed in uremia is metabolized or excreted extrarenally [30]. The existence of routes of creatinine excretion and metabolism other than the kidneys have been investigated in uremic patients.

Creatinine is uniformly distributed throughout body water [59] and, like urea and uric acid [39], diffuses into the gut. At a normal plasma concentration the amount of creatinine entering the gut is negligible, but in uremia it becomes significant [38]. The bacterial proliferation (streptococci and enterococci) [62] that develops in the upper gastrointestinal tract of chronically uremic patients [40] plays an important role in the induction of a creatininase system that is related to the degradation of creatinine. Metabolites of creatinine [40] have been identified in the lumen of the gut, plasma, urine, and expired air in uremic patients, thus providing evidence that creatinine is metabolized in the gut and recycled. The recognition of this important secondary route of metabolism and excretion of creatinine in uremic patients explains the significant variations in urinary excretion, plasma concentration, and clearance of creatinine in some patients with renal disease and gives reason to question seriously the validity of creatinine as a reliable test of renal function in uremia [40].

If the release of creatinine from muscle stores continues unchanged after the onset of renal failure, and if creatinine is a specific and sensitive method for the estimation of GFR, it is to be expected that plasma creatinine will rise in proportion to the decrease in creatinine clearance. However, as previously demonstrated by others [18, 25] and as shown in Figure 1–3, when different levels of plasma creatinine concentration are related to their corresponding creatinine clearance, a linear relationship fails to develop. The results of studies correlating plasma concentration with creatinine clearance in 253 males are shown in Figure 1–3A; the results for 223 females are given in Figure 1–3B. The protocols that were followed for these studies of 1-hour creatinine clearance and the methods that were used for the analytical determinations of the samples are described in Chapter 3. In agreement with studies reported by others [18, 25], the following observations can be made by examining Figures 1–3A and 1–3B from right to left: First, in the region in which results consistent with marked reductions in renal function (as indicated by significant elevations in plasma concentration of creatinine and decreases in creatinine clearance) are plotted, with small fluctuations in creatinine clearance there are correspondingly large variations in plasma creatinine concentrations. Next, in the intermediate area of Figures 1–3A and 1–3B, where plasma creatinine levels range from 6 to 2 mg/dl, there is a transitional zone in which a linear relationship between plasma concentration and clearance of creatinine becomes apparent. Finally, as shown in the left portion of Figures 1–3A and 1–3B and corresponding to values consistent with normal levels of renal function, the linear relationship is again lost, and in this area small variations in plasma creatinine relate to significantly wide changes in creatinine clearance.

To determine the adequacy of the changes in plasma concentration of creatinine as they relate to creatinine clearance, a scattergram was constructed by separating the values illustrated in Figures 1–3A and 1–3B into four main categories. The results are illustrated in Figures 1–4A and 1–4B. If values of 1.2 mg/dl and 0.9 mg/dl are taken as the highest normal plasma concentration of creatinine for males and females, respectively, and 80 ml/min as the lowest normal clearance of creatinine for both sexes, it can be appreciated that in approximately 76 percent of the values in the male population and in 74 percent of the females there was an adequate correlation between plasma concentration and clearance of creatinine, that is, either normal levels of plasma creatinine corresponded to normal levels of creatinine clearance (left upper quadrant in Figures 1–4A and 1–4B), or abnormally elevated levels of plasma creatinine were related to reduced levels of creatinine clearance (right lower quadrant in Figures 1–4A and 1–4B). In approximately 23 percent of males and 25 percent of females, however, plasma creatinine levels were not appropriate when related to creatinine clearance, that is, either normal levels of plasma creatinine corresponded to decreased creatinine clearance (left lower quadrant in Figures 1–4A and 1–4B), or elevated levels of plasma creatinine were related to normal values of creatinine clearance (right upper quadrant in Figures 1–4A and 1–4B).

Several attempts have been made to develop reliable methods that will allow

formation may be obtained by relating the BUN to the plasma concentration of creatinine or the clearance of urea to the clearance of creatinine.

The normal BUN-plasma creatinine concentration ratio of 10:1 [19, 20, 68] is usually maintained in uremia but can be disrupted in some other clinical conditions. This ratio may rise [19, 20, 68] as a result of an increase in BUN in catabolic states, in prerenal azotemia, in uremic patients after a high protein intake, by absorption of blood from the gut after gastrointestinal bleeding, when urinary tract obstruction causes renal reabsorption of urea, or when, as a consequence of the implantation of the ureters into the lumen of the gut, urea is absorbed from the gastrointestinal tract.

The ratio of BUN to plasma creatinine may be lower [20] as BUN decreases as a result of starvation, after a low protein intake, in advanced liver failure, or as a result of an increase in plasma creatinine as seen after muscular breakdown in muscular subjects. Creatinine dialyzes less well than urea [20, 68], and patients in chronic dialysis may have plasma creatinine levels that are proportionately higher than the BUN.

In advanced renal failure [44] at levels of GFR of 20 ml/min and less, as the remaining nephrons undergo an osmotic diuresis, the reabsorption of urea by the renal tubules diminishes and the urea clearance, which is usually lower than the GFR, approximates the clearance of inulin. Similarly, as a tubular maximum secretory rate for creatinine is exceeded at these levels of renal insufficiency [1, 44], creatinine clearance, which at higher levels of GFR overestimates the clearance of inulin, decreases toward the GFR. Therefore, the mean values of urea and creatinine clearance correspond more closely to the clearance of inulin at such low levels of GFR [44], and this measurement has been recommended for the evaluation of the progression of renal failure in patients in terminal uremia.

Summary

As the automated method for creatinine determination is being adopted by most institutions, the measurement of creatinine is gaining in accuracy and reliability, and it is now possible to obtain more uniform information on the use of creatinine as an index of renal function. Although the technical difficulties of creatinine determination have been overcome to a large extent, there are still significant limitations on the validity of creatinine for the evaluation of GFR. These problems are exemplified by the uncertainties that have been introduced by the existence of a secretory mechanism in the renal handling of creatinine; by the effects of various factors, such as diet and exercise, on creatinine metabolism; by the shifting in the ratios of plasma true creatinine-non-creatinine chromogens and of creatinine clearance-inulin clearance in progressive renal failure; and, more significantly, by the induction of an extrarenal mechanism of creatinine metabolism and excretion in uremia.

In spite of all these disadvantages, however, creatinine is the only known substance in endogenous concentration in the body of which the clearance approximates the clearance of inulin, thus making its use for the estimate of GFR both practical and economical. If a lack of availability of a more reliable method makes the use of creatinine necessary for the evaluation of renal function, creatinine clearance is preferred over plasma creatinine concentration because the former correlates better with inulin clearance. Because of the difficulties inherent in prolonged urine collections, the ability of the patient to cooperate is critical in deciding among a 1-hour creatinine clearance, a 24-hour creatinine clearance, and a plasma creatinine determination. A single measurement of creatinine can be misleading in evaluating renal function, but serial determinations are helpful in detecting the direction of changes in renal disease.

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3M Government R&D Contracts

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August 14, 1992

Mrs. Linda W. Neilson, Procurement Analyst
Defense Acquisition Regulations System
3062 Defense Pentagon
Washington, DC 20301-3062

SUBJECT: Proposed Final Rule on Drug-Free Work Force

Dear Mrs. Neilson:

Thank you for the opportunity to comment on the proposed final rule on the requirement for a drug-free work force. It is our opinion the proposed final rule is so much more burdensome, so much more costly to implement, so much more apt to lead to law suits, and so much more likely to discourage the sale of commercial products to the Government that it should be abandoned and the interim final rule published September 28, 1988 should be adopted as the final rule.

The bases for this opinion include the following:

- The proposed rule greatly expands the types of employees subject to its requirements. While the interim rule applies only to employees granted access to classified information and employees in other positions that the contractor determines involve national security, health or safety, or functions requiring a high degree of trust and confidence, the proposed rule requires random drug testing of all employees whose duties can reasonably be expected to affect health, safety, or national security. The new language will undoubtedly lead to disputes as to which employees are covered by the proposed rule; it will greatly increase the number of employees tested; and it will, therefore, be much more expensive to implement. Such results run directly contrary to the Administration's goals to reduce regulatory burdens as documented in the President's moratorium on new regulations, to eliminate budget deficits, and to assist U.S. companies to be more competitive in the global marketplace.

- The interim rule states that its requirements pertaining to drug testing programs do not apply if they are inconsistent with an existing collective bargaining agreement. The proposed rule is silent on this matter. Such silence may result in contractors having to attempt to reopen existing collective bargaining agreements, and that action may lead to costly labor disputes. Failure to negotiate union bargaining agreements which are consistent with the proposed rule may prevent companies from receiving contracts.

- The interim rule refers to the "Mandatory Guidelines for Federal Workplace Drug Testing Programs," (53 FR 11980 (April 11, 1988)), issued by the Department of Health and Human Services, merely as a source for identifying the illegal drugs a contractor must test for. However, the proposed rule requires that a contractor's drug testing program "shall conform" to those Mandatory Guidelines. Thus the proposed rule appears to mandate compliance with all of the very specific requirements of the Guidelines, including requirements that the designated collection site be "secure," that chain of custody standardized forms executed by authorized collection site personnel be used upon receipt of specimens, that toilet bluing agents be used and no other source of water, etc., etc.

While the interim rule gives a contractor flexibility in devising a testing program, the proposed rule imposes very specific, very rigid requirements on contractors. This will make the devising and implementing of a testing program unnecessarily costly.

- The proposed rule introduces a requirement, not found in the interim rule, that a contractor must obtain a Contracting Officer's approval before permitting an employee to return to work in a sensitive position on a DoD contract following a violation of DoD's drug policy or a criminal drug statute. This requirement conflicts with established statutes, regulations, personnel practices, and labor agreements and will result in unnecessary costs in its implementation.

- In DFARS Section 223.7504 of the interim rule, it is stated explicitly that the clause at DFARS 252.223-7500 is not to be included in contracts for commercial or commercial-type products, other than contracts involving access to classified information. That provision has been deleted from the proposed rule. Instead the proposed rule provides that the proposed clause shall be used in all contracts that require contractor employees to perform in sensitive positions, and the definition of "sensitive positions" has been broadened so much in the proposed rule that many contracts for commercial or commercial-type products will be subject to the requirements of the proposed rule. This will necessitate drug testing of additional people at additional cost, which will make U.S. products less competitive.

  It may be difficult or impossible to segregate from a contractor's established line for production of commercial products those particular items of such products that are sold to the Government. A contractor faced with the possibility of becoming less competitive in commercial sales because of the costs of drug testing may decide not to make any future sales to the Government.

For all of these reasons, we recommend that the proposed rule be abandoned and the interim rule made the final rule.

If you have any questions on these matters, please do not hesitate to call on me. My telephone number is 612-733-6723.

Sincerely,

Robert C. Spreng
Operations Manager

RCS/bjf
F:20814.bjf

International Brotherhood of Electrical Workers, Local 108

International Brotherhood of Boilermakers, Iron Shipbuilders, Blacksmiths, Forgers and Helpers, [redacted]807

International Association of Sheet Metal Workers, Local 15

United Association of Journeymen Plumbers and Steamfitters of America and Canada, Local 726

Tampa Metal Trades Council

(AFL-CIO)

United Brotherhood of Carpenters and Joiners of America, Local 140

Brotherhood of Painters and Allied Trades, District Council 66

Construction Shipyard and General Laborers, Local 1207

International Association of Machinists and Aerospace Workers, Local 570

International Union of Operating Engineers, Local 925

August 23, 1992

From:
Bob Betterton
President
c/o I.A.M.& A.W. Lodge 570
4020 80th Avenue North
Pinellas Park,Florida 34665

Subject:
Random Drug Testing DAR Case 88-083
United States Navy Contract
Procurement Language

To:
The Defense Acquisition Regulations Council
Attn: Mrs. Linda W. Nelson, OUSD (A)
3062 Defense Pentagon
Washington D.C. 20301-3062

Dear Council,

It is our opinion and belief that the drug-free work force clause of [redacted]ptember 1988 should NOT be changed to accommodate randon drug testing [redacted]r the following reasons:

1.) It is a unreasonable and unacceptable invasion of privacy.(ie; body fluids)
2.) It is unfair to force the added financial burden on employers particularly at this time,when most if not all shipyards in the United States are struggling to survive a dormant market in repairs and new ship construction.
3.) It has never been determined that a problem of drug abuse is at a level in our shipyards (ie; The American Ship Building Co., Tampa Shipyards Inc.)that warrants random vs. probable cause.
4.) It is our intention to see money spent that we as the work force, in partnership with our management,have determined to be real problems and a threat to our health and safety.

In conclusion,we feel that it would be a perfidious act for any agency or department of the United States Government to mandate randon drug testing to private shipbuilding and repair yards.

Sincerely,

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Sincerely,

Bob Betterton

Bob Betterton

Spectra Diode Laboratories, Inc.

80 Rose Orchard Way
San Jose, CA 95134-1356
(408) 943-9411
FAX: (408) 943-1070

September 8, 1992

Defense Acquisition Regulations Systems
3062 Defense Pentagon
Washington, DC 20301-3062

Attention: Mrs. Linda W. Neilson

Subject: Regulatory Flexibility Act - DAR Case 88-083

Reference: Federal Register Notice Dated 7/23/92

Dear Mrs. Neilson:

Spectra Diode Laboratories, Inc. is a small business doing defense work with the U. S. Government. We find the proposed rule for a Drug Free Work Force to be an economic and administrative burden to our company. SDL proposes the Regulatory Flexibility Act be amended to state that small businesses with DoD contracts are excluded from compliance with this proposed rule.

If you have any questions, please contact me.

Sincerely,

SPECTRA DIODE LABORATORIES, INC.

John P. Melton
Vice President, Business Operations

TAMPA SHIP

TAMPA SHIPYARDS INCORPORATED

P.O. BOX 1277 • TAMPA, FLORIDA 33601 • (813) 247-1183

August 26, 1992

Defense Acquisition Regulations Council
Attn: Mrs. Linda W. Neilson, OUSD (A)
3062 Defense Pentagon
Washington, D.C. 20301 - 3062

RE: DAR Case 88-083
Navy Random Drug Testing Requirements

Dear Mrs. Neilson,

Tampa Shipyards, Inc. supports the proposed DOD requirements for random drug testing in it's acquisition regulations.

We believe that random testing would be an effective, efficient, and economical way to achieve a truly drug free workplace.

The requirement should be extended to sub-contractors at all tiers as well.

Very Truly Yours,

Fred Turner
Director of Labor Relations

Shipbuilders Council of America
Suite 330
4301 N. Fairfax Drive
Arlington, Virginia 22203
Tel: 703-276-1700 Fax: 703-276-1707

August 31, 1992

To: Ms. Linda W. Neilson
OUSD (A)
Defense Acquisition Regulations Council
3062 Defense
The Pentagon
Washington, DC 20301-3062

Subject: Drug Free Work Force (DAR Case 88-083)

On behalf of the Shipbuilders Council of America, the national trade association which represents American shipyards and suppliers of marine equipment and services, I wish to submit the following comments on the proposed revisions to the Defense Federal Acquisition Regulation Supplement interim rule for a Drug Free Work Place.

Redundancy:

What is seemingly overlooked is the fact that all responsible contractors recognize the importance of a Drug Free Work Place and its impact on productivity and profit. Accordingly, we believe that the need for either the proposed regulation or the interim final regulation now in effect is redundant. In this regard, the coverage of the Federal Acquisition Regulation (FAR) on the subject of Drug-Free Work Place is adequate and provides the contractor with the required flexibility for an effective program. Furthermore, adequate direction is now provided in the FAR on the responsibility of contractors; and when contractors are found deficient, a finding of non-responsibility can be made under the FAR Regulations to eliminate contractors that ignore proper management of their companies with regard to maintaining a Drug-Free Work Place.

Random Testing:

Although the many thousands of responsible DoD contractors are diverse organizations with different needs, they all support a Drug Free Work Place policy. However, it is grossly inefficient to adopt a "one rule fits all" policy, without regard to a company's organizational structure which permits each contractor to tailor its program in a manner that optimizes costs, while at the same time ensuring that the ultimate goal of a Drug Free Work Place is met. Accordingly, we recommend that the proposed regulation and contract clause be carefully worded in order to permit the contractor to determine who should be tested and how many should be tested. By analogy, DoD statistics reflect that random testing of officers reveal a

much smaller incidence of drug abuse than among young enlisted personnel. Likewise, a company that dedicates extra resources to refining its employment screening process will result in a higher caliber of a work force and a lower likelihood of drug abuse. Such contractor initiatives often are more effective at accomplishing the Drug Free Work Place goal than random testing, and should be factored into an overall program that balances need with cost effective safeguards.

Testing:

For initial testing, contractors should be permitted to use their own laboratories. To confirm positive tests, the contractor should be permitted to select any certified laboratory in order to control costs that invariably escalate when some certified laboratories are summarily excluded. In short, "certified" should be the only criteria.

Cost:

All costs associated with a mandated testing program should be specifically identified as an allowable cost under the Regulation. Furthermore, all litigation expenses associated with enforcing mandatory requirements should also be specifically identified as an allowable cost.

Thank you for this opportunity to provide our comments which support a Drug Free Work Place while eliminating unnecessary costs that add no substantive value or additional safeguards that would preclude drug abuse by a work force that produces products or services for the Department of Defense, as well as for all commercial customers which expect and have every right to expect services or products to be provided in a drug free environment.

Sincerely,

John J. Stocker
President

Mission Research Corporation

SANTA BARBARA

735 STATE STREET
P.O. DRAWER 719
SANTA BARBARA
CALIFORNIA 93102-0719
(805) 963-8761
(805) 962-8530 FAX

September 10, 1992

Defense Acquisition Regulations Council
3062 Defense Pentagon
Washington, DC 20301-3062

Attn: Mrs. Linda W. Nelson, OUSD(A)

re: DAR Case 88-083

Dear Mrs. Nelson:

I am writing in opposition to the adoption of a rule that would require our company to implement drug testing. A defense contractor, Mission Research Corporation has downsized from 450 to 320 employees in the past three years. Overhead cost reductions have included the layoff of many staff members. We simply do not have the staff required to handle the additional burden of implementing and maintaining a drug testing program and we do not want to add staff, cost allowability notwithstanding.

In our current and future efforts to penetrate non-defense business areas, we greatly fear the handicap of excessive costs and a cumbersome bureaucracy. Also, given the post cold war environment, it is our opinion that additional security measures, such as mandated random drug testing, are highly questionable.

Steven L. Gutsche

Steven L. Gutsche
President

cc: Congressman Robert J. Lagomarsino

TAMPA BAY AREA LODGE NO. 570

INTERNATIONAL ASSOCIATION of MACHINISTS and AEROSPACE WORKERS

August 24, 1992

From:
Bob Betterton
President
4020 80th Avenue
Pinellas Park, Fl. 34665

To:
The Defense Acquisition Regulations Council
Attn.: Mrs. Linda W. Nelson, OUSED (A)
3062 Defense Pentagon
Washington, D.C. 20301-3062

Dear Council,

It is our opinion and belief that the drug-free work force clause of September, 1988 should NOT be changed to accommodate random drug testing for the following reasons:

1.) It is an unreasonable and unacceptable invasion of privacy. (i.e.; body fluids)

2.) It is unfair to force the added financial burden on employers particularly at this time when most if not all shipyards in the United States are struggling to survive a dormant market in repairs and new ship construction.

3.) It has never been determined that a problem of drug abuse is at a level at our shipyards (i.e. The American Ship Building Co., Tampa Shipyards, Inc.) that warrants random vs. probable cause.

4.) It is our intention to see money spent that we as the work force, in partnership with our management, have determined to be real problems and a threat to our health and safety.

In conclusion, we feel that it would be a perfidious act for any agency or department of the United States Government to mandate random drug testing to private shipbuilding and repair yards.

Sincerely,

Bob Betterton

BB/kw
cc:file
E. House
G. Kourpias
R. Cox

TAMPA BAY AREA LODGE NO. 570

INTERNATIONAL ASSOCIATION of MACHINISTS and AEROSPACE WORKERS

August 24, 1992

From:
Bob Betterton
President
4020 80th Avenue
Pinellas Park, Fl. 34665

Subj: Random Drug Testing
DAR Case 88-083
United States Navy Contract
Procurement Language

To:
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3062 Defense Pentagon
Washington, D.C. 20301-3062

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E. House
G. Kourpias
R. Cox

INSPECTOR GENERAL
DEPARTMENT OF DEFENSE
400 ARMY NAVY DRIVE
ARLINGTON, VIRGINIA 22202-2884

Audit Policy
and Oversight

AUG 18 1992

MEMORANDUM FOR DIRECTOR, DEFENSE ACQUISITION REGULATIONS COUNCIL

SUBJECT: Defense Acquisition Regulatory Case 88-083

The Office of the Inspector General, Department of Defense, does not wish to comment on Defense Acquisition Regulatory Case 88-083 (Drug-Free Work Force). We appreciate the opportunity to review the case.

Donald E. Davis
Deputy Assistant Inspector General
for Audit Policy and Oversight

G
C A
N

Government Contractor's Assistance Network

Post Office Box 28944
Santa Ana, CA 92799-8944
(714) 542-2710
FAX: (714) 542-6814

September 14, 1992

Defense Acquisition Regulation Council
Attention: Mrs. Linda W. Neilson, OUSD (A)
3062 Defense Pentagon
Washington, DC 20301-3062

Subject: Drug-Free Work Force Policy

Reference: DAR Case 88-083, 57 FR 32769

Dear Mrs. Neilson:

In response to your solicitation for comments on the subject and referenced DAR Case, we are pleased to submit the following:

1. No issue is taken with the proposed clause as written.

2. It is our contention that the area that requires revision is the application. It is generally understood that some seventy percent (70%) of the dollars expended today on Department of Defense (DoD) contracts flow through the prime contractor to subcontractors and suppliers. Although our review of the legislative history leading to the Drug-Free Work Place Act reveals no proscription as to the flow down, neither the Federal Acquisition Regulation (FAR) or Department of Defense Federal Acquisition Regulation Supplement (DFARS) implementation of the Act provides for its flow down to subsequent tiers. Almost every other socio-economic clause requires flow down and places the burden on the prime contractor to monitor and ensure compliance and reporting.

3. The final clause should also establish and implement a program of compliance review to ensure ; (1) contractor implements a Drug-Free Program ; (2) contractor identifies employee's in sensitive positions which , and (3) establish the required re-habilitation programs for employee's who test positive.

Finally, in April of this year we addressed our concerns and recommendations to the Office of National Drug Control Policy and the DoD; reference the FAR clause.

Thank you for your cooperation in this matter; it is greatly appreciated.

Sincerely,

GOVERNMENT CONTRACTOR'S ASSISTANCE NETWORK

H. W. McCoy

Herbert W. McCoy, CPPM, CF
Principal

DCS CORPORATION 1330 Braddock Place * Alexandria, Virginia 22314 * (703) 683-8430

August 5, 1992

Defense Acquisition Regulations Council
Attn: Mrs. Linda W. Neilson
OUSD A1. 3062 Defense Pentagon
Washington, D.C. 20301-3062

Re: DAR Case 88-083

Dear Mrs. Neilson:

In response to your request for comments regarding the Drug-Free Workforce Act, I would like to inform you of some of the difficulties we are encountering in establishing our random testing program:

1. Because the rule requires random testing for all "employees in a sensitive position", it is necessary for us to include employees who are located in our small offices, at least one of which is located in a rather remote location. We have several of these small offices scattered throughout the U.S. and it is difficult to find and make arrangements for collection sites which conform to the requirements you specify we must meet as stated in the "Mandatory Guidelines." I have not yet finished my research, but wonder what may happen if I am unable to find such sites? Could offices with less than (?) employees be exempted from the ruling, or could companies be allowed to deviate from the mandatory guidelines in selecting a collection site if unable to find one which meets all the guideline criteria?

2. Part of the mandatory guidelines [2.5 (d) (2)] stipulates that each agency must submit blind performance test specimens to its contract laboratories. The percentage of samples that must be submitted seems inordinately high given:

    a) The number of agencies using each approved laboratory;

    b) The quality assurance and quality control measures placed upon the laboratories and;

c) The expense to companies for the purchase of the specimens and payment for the testing to comply with this directive.

Since these costs are "allowable", contractors will be including them during the proposal process as part of their O/H expense, further adding to the government's cost of doing business. I do not believe the cost is justified and could be minimized by lowering the percentage of samples which must be submitted.

3. Despite the prominence of the MRO's function in the drug testing/verification process, the mandatory guidelines which we are required to follow place no "quality controls" on the MRO other than he/she be a "licensed physician with knowledge of substance abuse disorders." Since doctors, themselves, have a high percentage of substance abuse problems, this apparent lack of "quality control" over these physicians is somewhat troubling.

4. Finally, by whose authority does the DoD final ruling "take precedence over any state and local laws"?

Sincerely,

DCS CORPORATION

Barbara J. Napier
Human Resources Manager

BJN/mjw

OFFICE OF THE UNDER SECRETARY OF DEFENSE

WASHINGTON, DC 20301-3000

ACQUISITION

October 1, 1992

DP(DARS)

MEMORANDUM FOR SHIRLEY CURRY, OASD(PA)(DFOI & SR)

SUBJECT: DAR Case 88-083, Drug Free Work Force

Please discard the partial set of 14 public comments forwarded to your office on September 18, 1992, Drug Free Work Force.

Attached is a complete listing and 44 public comments received on the proposed rule of subject case published in the Federal Register on July 23, 1992, (57FR32769). This case involves revisions to DFARS Parts 223 and 252, Drug Free Work Force.

These comments are provided for the public's review or request for copies. Our case manager is Mrs. Linda Neilson, at 697-7266.

Linda E. Greene

Linda E. Greene
Deputy Director,
Defense Acquisition
Regulations Council

Attachments

DAR Case 88-083, Drug-Free Work Force
Public Comments

Alliant Techsystems	2 pgs
Canning, Donald T. (Atty)	5 pgs
Caterpillar, Inc.	4 pgs
*Chimera Research & Chemical, Inc.	3 pgs
*Brown, Catherine S., Ph.D.	1 pg
*Cater, Frank B.	1 pg
*Cole, Robert A.	1 pg
*K_____, Edward J.	1 pg
*Knight, Henderson W., AF Ret	1 pg
*Roberts, David F., Ph.D.	1 pg
*Keystone Laboratories	1 pg
*Waldon, Gary	1 pg
Chimera Research & Chemical, Inc.	57 pgs
Council of Defense & Space Industry Associations (CODSIA)	13 pgs
DCS Corporation	2 pgs
Employee Assistance Professionals Association, Inc.	3 pgs
Enzymatics, Inc.	2 pgs
Government Contractor's Assistance Network	1 pg
Grumman Corporation	3 pgs
Inspector General, Department of Defense	1 pg
International Association of Machinists & Aerospace Workers/Office of General Vice President	7 pgs
International Association of Machinists & Aerospace Workers/Lodge No. 389	2 pgs
International Association of Machinists & Aerospace Workers/Lodge No. 570	1 pg
Ironworkers/Local Union No. 627	1 pg
Litton Industries, Inc.	6 pgs
Litton Ingalls Shipbuilding	36 pgs
McDonnell Douglas Corporation	2 pgs
McKenna & Cuneo	10 pgs
Mission Research Corporation	1 pg
Motorola Inc.	7 pgs
National Steel and Shipbuilding Co.	3 pgs
Olin Corporation	2 pgs
Seattle Professional Engineering Employees Ass'n (SPEEA)	12 pgs
Shipbuilders Council of America	2 pgs
Spectra Diode Laboratories, Inc.	1 pg
STI Optronics	2 pgs
Tampa Shipyards Incorporated	1 pg
Tampa Metal Trades Council	1 pg
3-M Corporation	2 pgs
University of California	9 pgs
Washington Headquarters Services, DoD	1 pg
41 Commenters	**213 pgs**

ALLIANTTECHSYSTEMS

Alliant Techsystems Inc.
5901 Lincoln Drive
Edina, MN 55436

Telephone: 612 939-2000

September 21, 1992

Defense Acquisition Regulations Council
Attn: Mrs. Linda Neilson
OUSD (A)
3062 Defense Pentagon
Washington, D.C. 20301-3062

Re: DAR Case 88-083

Dear Mrs. Neilson

On Friday, September 18, 1992, the Council of Defense and Space Industry Associations advised you of its position that, absent a demonstrated problem peculiar to the defense contractor work force justifying more intrusive drug programs than already exist, the interim DFARS seems to suffice. CODSIA also stated that if DoD is resolved to pursue the approach taken in its proposed rule, then DoD respectfully consider the CODSIA comments and the proposed CODSIA revisions to the DoD proposed rule.

The purpose of this letter is to support the CODSIA position, and provide several supplementary comments.

Alliant Techsystems' businesses have supplied high-quality defense products and systems to the U.S. government and its allies for more than 50 years. We currently rank as the largest munitions supplier to the U.S. Department of Defense. We employ 5,633 people, in Minnesota, Washington, Illinois, Maryland and Pennsylvania, Hawaii, New Jersey, and Virginia. Revenues for the year ending in March of 1992 totaled $1.2 billion.

Alliant Techsystems supports the September 18 CODSIA letter, however we wish the record to be unquestionably clear that there is no information demonstrating that drug use in the defense industry is greater than other industry subject to the regulations. Absent a particular problem, there would appear to be no reason to require additional regulations specific to our industry.

Should DoD prefer defense specific regulations, we wish you to know that Alliant Techsystems is in support of the very thoughtful alternative rules, with explanatory comments, proposed by CODSIA.

We are also advised that DoD has estimated the industry cost of compliance to be $185 million. Nationally, we are seeing a dramatic downsizing of defense industrial base employment. Alliant Techsystems is no exception. Retaining a competent workforce in an environment of declining defense expenditures is increasingly difficult. Diversion of additional costs to a program for which there is no demonstrated need will make retention of employees in critical capabilities all the more difficult.

We therefore concur with CODSIA Sec. (F)(2), permitting the direct and associated costs of compliance to be fully allowable. In our case, the cost of the test defined by DFAR is $71 per person per test. In addition, the procedure requires blind performance testing up to 10% of samples submitted to a laboratory up to a maximum of 250 per quarter. Further, since the term "random testing" is not defined in DFAR, the number and frequency of testing cannot be determined. If, for example, DFAR were to adopt the Department of Transportation random testing standard of 50% per year, it is possible that 2,600 employees per year would be tested. Costs of compliance will therefore be likely to exceed $300,000 per year.

We also specifically concur with that portion of CODSIA Sec. (F)(2) which would permit allowability of all costs, fines and penalties incurred by contractors acting in good faith to implement the final rule.

Thank you for the opportunity to be heard on this most important matter.

Sincerely,

Wayne E. Gilbert
Director, Government Relations

August 5, 1992

11208 Harbor Court
Reston, VA 22091

Defense Acquisition Regulation Council
ATTN: Mrs. Linda W. Neilson
OUSD(A) 3063 Defense
Pentagon
Washington DC. 20301-3062

Reference: Proposed Rule, DoD Drug-Free Work-force
DAR Case 88-083

Dear Mrs. Neilson:

I submit the following comments regarding the "Proposed Rule and Request For Comments" on Department of Defense (DoD) regulations implementing the Drug-Free Workplace Act. See 57 Fed. Reg. 32769. In short, the regulation imposes unreasonable cost and administrative burdens upon contractors; imposes significant litigation risks on both contractors and DoD; fundamentally misconstrues DoD's ability to preempt state law by regulation; and ignores the impact on contractor employee morale. Each of these subjects is treated below.

I. COST AND ADMINISTRATIVE BURDENS

This implementing regulation will place, in fact already has placed, a significant burden on DoD contractors, both large and small. While the text of the regulation does not appear on its face to require great time or effort, the reality is quite different. The following are steps which contractors must, prudently, undertake to comply with the regulation as proposed:

(A) Promulgate a Policy Statement: The regulation clearly requires a written policy statement, and its dissemination to employees. All company policy statements, particularly those which arguably involve an intrusion into employees' privacy, require review by legal counsel. The state of the law in this area is in extreme flux, making legal review all the more critical.

The Supreme Court has upheld random drug testing only of public employees engaged in safety-sensitive positions, drug interdiction, or where firearms are used in job performance (see NTEU v. Von Raab, 489 U.S. 656 (1989) and Skinner v. RLEA,

489 U.S. 602 (1989)). The U.S. Court of Appeals for the D.C. Circuit struck down the random drug testing portions of the Department of Justice's drug testing program as it applied to all employees with access to grand jury proceedings (Harmon v. Thornberg, 878 F.2d 484 (D.C. Cir. 1989)). The Court only upheld the program's application to personnel required to maintain Top Secret security clearances. See also NTEU v. Yeutter, 918 F.2d 968 (D.C. Cir. 1990) and AFGE v. Cheney, 944 F.2d 503 (9th Cir. 1991).

If the government cannot constitutionally subject broadly based groups of its own employees to such intrusion, neither can it force its contractors to subject their employees to similar treatment. Governmental action (e.g., implementing procurement regulations) cannot be transformed into purely private conduct between employer and employee so easily and transparently. More on this subject below.

Given the state of the law and the propensity of disgruntled former employees to assert wrongful termination claims, professional advice in drafting the policy statement is a necessity for any prudent business person. If the employer is without the benefit of inside legal counsel versed in this obtuse area, the cost for competent counsel will likely be on the order of $10,000 to $15,000.

(B) "Supervisory Training": Without the benefit of further guidance or definition, the contractor is required to "train supervisors to identify and assist" employees with drug problems. While these terms are obviously not self-defining, the prudent contractor will assume, at a minimum, that it must engage the services of a physician or qualified substance abuse counselor to conduct seminars to teach supervisors these subjects. Very few DoD contractors have this resource in-house. While the cost (and the quality) of such services certainly vary greatly, the costs can reasonably be expected to be something on the order of $10,000 per year, including the cost of the supervisors' time to attend such training seminars.

(C) The Testing Program: The regulation requires contractors to institute a program of random drug use testing of employees in "sensitive positions" (as that term is defined in the regulation, and which definition goes well beyond those holding Top Secret security clearances). It is perfectly safe to assume that no (or only a very few) DoD contractors maintain NIDA approved laboratories in-house. The cost of collection, laboratory fees, medical review of results, and reporting is approximately $100 per test, based upon my survey of the market. The total cost to the contractor is, of course, completely dependent upon the number of tests performed per year. This variable is, in turn, completely dependent upon the overall size of the work-force, the number of employees in sensitive positions, and the percentage of sensitive position - employees the contractor decides to test. The regulations provide not one whit of guidance on these question, thus an estimation of actual cost is not possible.

Quantifying the total costs of implementing the mandated program is impossible given the differing sizes of DoD contractors, the lack of definition (or even guidance)

contained within the regulation itself about important details (e.g., random testing sample size, frequency of random testing, frequency of supervisors' training, etc.), and varying in-house resources contractors posses. It is reasonable to conclude, however, that for a contractor with 75 to 100 employees, the start-up and first year running costs of the Drug-Free Workplace program under this regulation will be on the order of $50,000. In all fairness, costs should decrease substantially in following years.

II. LITIGATION RISKS

The regulation appears to proceed from an assumption that either: (1) As a private employer, the contractor may randomly test employees without regard to legal prohibitions or litigation risk rooted in tort law and/or constitutional search and seizure constraints, or (2) The contractor is immunized from such legal risk by virtue the last sentence of the regulation which reads: "The requirements of this clause take precedence over any State [sic] or local laws to the contrary." Neither assumption is tenable.

A survey of the case law regarding wrongful termination and invasion of privacy is well beyond the scope of this comment. It should be pointed out, however, that an employer (public or private) is not normally privileged to conduct inquiry into the private, non-job related conduct of its employees. Failure to observe this principle can, and has, resulted in significant civil judgments against employers.

Perhaps the best way to illustrate this risk, both to the contractor and DoD, is to pose a few hypothetical (although by no means worst-case) scenarios.

Scenario (1): Employee A , whose hiring predates this regulation and who has excellent performance reviews, is in a sensitive position (as defined by the regulation). Employee A does not hold a Top Secret security clearance. Employer has no reason to believe he is a drug user, on or off-duty. After the drug testing program has been published in Employer's policy statement and has been running for several months without incident, Employee A is randomly selected for testing.

Employee A refuses to be tested, and challenges Employer to demonstrate any factual predicate (or reason to believe) he does, or ever has used illegal drugs, and/or that his work was thereby affected. Employer cannot make this demonstration, but nonetheless terminates his employment. Employee A sues Employer, in federal court, alleging a deprivation of civil rights under the Civil Rights Act (42 USC 1983), a Fourth Amendment violation, ERISA violations (arguing his termination was a pretextual firing to prevent him from becoming fully vested in Employer's retirement plan), and attaches pendent state law causes of action for wrongful termination, invasion of privacy, slander, and whatever else he can think of. As to the claims based upon federal statutes, Employer impleads the United States, arguing that if its

(Employer's) actions were wrongful as to Employee, it did so only because it was forced to by DoD.

Scenario (2): Prospective Employee B, a resident of California (or any other state or local jurisdiction which prohibits no-cause random drug testing) applies to Employer, doing business in California, for employment in a sensitive position (as defined by the regulation). Her education, work experience, and subjective ratings clearly place her as the candidate of choice. She holds a Secret security clearance, which can be transferred to Employer without administrative difficulty. She is offered the position contingent upon passing a drug test as required by Employer's policy statement (supplied to her). She refuses testing, and Employer rescinds its employment offer.

Prospective Employee B sues Employer in state court alleging a violation of the state statute, and simultaneously files against both Employer and the United States in federal court under the Civil Rights Act and the Fourth Amendment.

Other scenarios, involving botched testing or poorly conceived administrative procedures (both of which were rampant in the early years of the testing programs for military personnel) could be postulated. All scenarios present real world nightmares for contractors.

DoD has not agreed to indemnify contracts from losses incurred when (not if) some of these scenarios play out. No doubt it cannot without Congressional authorization. Instead, it carries forward the transparent fiction that the mandated testing program is a private matter between employers and employees, untouched by federal action with its attendant statutory and constitutional constraints.

III. THE PREEMPTION QUESTION

The last sentence of the proposed regulation purports to preempt "State [sic] and local law to the contrary." Federal *legislation* can preempt state law (both statutory and common law) by virtue of the Supremacy Clause of the U.S. Constitution. However, federal preemption is not assumed merely from the existence of a conflict between federal and state *statutes*, much less from a conflict between state statute and federal *regulation*.

To establish preemption by federal *statute*, the following must be shown: (1) A clear Congressional intent to preempt state law; (2) Pervasive federal activity within the substantive area; (3) An overriding federal, as opposed to state, interest in the subject matter, requiring national uniformity; and (4) A danger of a conflict between state and federal programs (see Pennsylvania v. Nelson, 350 U.S. 497 (1956)). See also Hillsborough County v. Automated Medical Labs 471 U.S. 707 (1985) and Pacific Gas & Electric v. Energy Resources Comm'n, 461 U.S. 190 (1983). The Drug-Free Workplace Act, under which this proposed regulation is promulgated, contains none of

these elements. The *regulation's* one sentence recital of intent to preempt state and local law could not be more beside the point.

The proposed regulation puts contractors in states and localities which have statutes or ordinances prohibiting non-cause random drug testing at greatest legal risk. The argument that the regulation preempts state law is not only a transparent fiction, it is just plain silly.

IV. EMPLOYEE MORALE CONCERNS

The majority of DoD contractors' employees are not fresh from the military where random drug testing is standard operating procedure. Nor are they aircraft pilots or train engineers. Most are civilians who have never been assumed to be wrongdoers, and who will resent being required to prove that they do not use illegal drug. There is a cost (however non-quantifiable) to this type of intrusion, both to the employer and, ultimately, to DoD.

V. SUMMARY

The proposed rule will place a significant financial and administrative burden on contractors, both large and small, and will adversely affect the morale of the work-force. There is not the slightest empirical evidence that DoD contractor employees, as a class, have a drug use problem, nor that a random drug testing program will advance the public interest by protecting national security. DoD appears to be attempting to cloth its desire to extend random drug testing into the civilian community with the imprimatur of private employer, voluntary action. It thus hopes to avoid statutory and constitutional constraints applicable to governmental action.

The proposed regulation is ill conceived, overly broad as to the work-force covered, and is poorly drafted. I would recommend that it be withdrawn completely before it engenders yet another round of drug testing litigation.

As we say in Virginia, this dog of a regulation won't hunt.

Respectfully Submitted,

Donald T. Canning
Attorney at Law

CATERPILLAR

Caterpillar Inc.

100 NE Adams Street
Peoria, Illinois 61629

Caterpillar, Inc
100 N.E. Adams Street
Peoria, Illinois 61629

Defense Acquisition Regulation Council
Attention: Mrs. Linda W. Neilson
OUSD(A)
3062 Defense Pentagon
Washington, D.C. 20301-3062

Dear Mrs. Neilson:

Subject: Proposed Final DoD Drug-free Workforce Rule - DAR Case 88-083

The proposed final DoD rule on a drug free workforce would be a significant departure from the current DoD position as described in the 1988 interim rule. Caterpillar Inc. is concerned that DoD attempted to force the new rule into effect and appears to inappropriately be moving into an area of management of its current and prospective contractors. The proposed final rule is seriously flawed and places an unwarranted burden on industry. Additionally, there appears to be an attitude of "pass the costs" to the contractor - particularly for those contractors who deal primarily in commercial type product. There are four (4) specific areas of the proposed rule of concern:

1. Lack <u>of exemption</u> of contracts <u>for commercial products</u>,
2. <u>Expanded definition</u> of an employee working in a sensitive position,
3. Required <u>random drug tests</u>, and
4. A statement that the proposed rule would preempt <u>state and local laws</u> to the contrary.

<u>Exemption for commercial products</u>:

Based on the fact that Caterpillar participates in providing DoD product that is, for the most part, commercial product, our first concern is that the DoD has elected to change direction on the drug free workforce issue without regard to the costs or how those costs will be paid. Major defense contractors, like those who do 70-80% or more of their total business with the federal government (or even DoD), can recover costs for mandated requirements fairly readily. Smaller (commercial) contractors, including those who do less than 5% of their total business with the government, sometimes require as much as several years to recover just a portion of those same costs because of the way G&A is calculated. No rationale has been provided by DoD to indicate why this change in position might be appropriate. If this rule continues to be, we recommend this part of the rule be worded to approximate that noted in the interim rule - that is, to exempt purchases for commercial type product.

Expanded definition:

The proposed rule elicits two specific concerns in this area: first, the simple expansion of persons potentially involved; and second, the lack of guidance or direction as to the handling of persons charged with offenses, persons convicted of a drug related crime, and persons who successfully complete a rehabilitation program.

The desire to have such a rule for contractors offering a major weapon system like a tank, airplane, ship, or other tactical weapon is understandable. Because of the sensitive nature of even the components of some of these systems, contractor employees at all levels "could" be in sensitive positions. Even here, however, a single, all encompassing definition is inappropriate. But in situations where a contractor is providing commercial product - or even modified commercial product, we see no need to expand the definition beyond those involved in the execution of the contract and who must have access to classified materials. Or said another way, we see no reason for application of the proposed rule in purchases of commercial product if there is no classified information or sensitive materials involved in the product or contract.

Next, the rule is mute on the issue of what a contractor can (or should) do with employees who have been charged with a drug related crime (but are awaiting trial), as well as employees who are undergoing (or have completed) a drug rehabilitation program. For example, if all employees of a given plant are in "sensitive positions", a contractor is hard pressed to replace one employee from another plant and then at some later date send the "convicted but rehabilitated employee" to the plant of the second employee. This could easily be complicated by the existence of two or more contracts for commercial product involving more than one plant. And, can a rehabilitated employee from one plant be sent to another plant where all the positions are "sensitive" ? Again the rule is mute on how this potentially significant cost driver can or should be handled.

The ambiguity of the wording would leave contractors, particularly commercial type contractors, at the mercy of the interpretation of their contracting officer with no assurance that some other interpretation might be imposed at some later date by either a strained relationship or a replacement contracting officer or even as the result of the delegation of responsibilities from a procuring contracting officer (PCO) to an administrative contracting officer (ACO).

Random drug tests:

No rationale has been provided by DoD to indicate why random drug tests are preferred over employment entry tests or any other method of identifying those who use illegal substances. Likewise, the frequency of testing and coverage of testing is left to question. If random testing is the mandated method for all businesses in all parts of the U.S., what are acceptable or desired parameters? For example, should 100% of the required workforce be

tested once a year, semiannually or quarterly? Should a worker be subjected to a drug test more than once during a cycle (harassed in the eyes of the worker) - or should that worker be dropped from the random selection for some specified period of time following selection? What action must the employer take if tests indicate the presence of drugs - how quickly ? These and similar questions are unanswered by DoD. No discussion or rationale has been provided that would allow a (commercial) contractor to quantify or determine realistic costs for such an efforts (if that can be done at all).

State and local laws:

While the proposed rule is clear that it would preempt any state or local law to the contrary, no legislative requirement for random drug testing presently exists. Such a rule would place contractors in direct confrontation with existing state and local laws. And there is no clear authority to disregard them. It begins to become unclear as to how strong a position the DoD (or federal government ?) would take if litigation were to result. In that "the government" will sit alongside or behind the contractor in litigation, the contractor is still in jeopardy, let alone still bearing the burden of additional expenses. This is an untested rule and its application could harm the relationship(s) a contractor has worked to establish within its local community. It is inappropriate for the DoD to create such a situation. Differences between federal, state and local governing bodies should be resolved before such rules are imposed on contractors.

Caterpillar Position

Caterpillar is a high-quality manufacturer of commercial products. Product quality is utmost in Caterpillar philosophy. At no time in the history of the company has there been any indication that drug use (or abuse) by our employees has affected the quality of our end product. We have a very active chemical dependency program with ongoing employee and dependent education. This results in referral by supervision, self-referral, and referral by dependents of employees who have substance abuse problems. We also follow up on these cases and involve appropriate management in the educational, discovery, and treatment process.

The average age of our work force is 47 - 48 years of age; or higher than the age of high drug usage in the working population. Most of our plants are located in the Midwest, agricultural areas, not in large metropolitan areas where the instance of drug abuse is high.

The cost of seeking out drug abusers would be very high for the return. It would be extremely difficult to identify the employees who will be working on defense-designated commercial products, when the percentage of DoD units is quite low (less than 3%).

At least one model for drug testing indicates that drug testing costs alone could exceed the profits from our defense contracting for that year. Passing drug testing costs of DoD regulations on to the remainder of our customers would not enhance the value of our product and would result in making Caterpillar less competitive in the commercial market place.

This proposed action is contrary to federal efforts to remove barriers to the integration of commercial and military industrial bases. It could result in commercial contractors refusing to sell to the government.

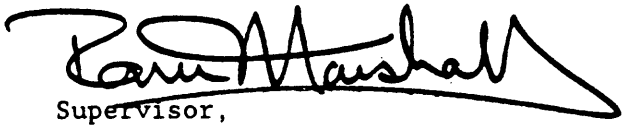
Summary:

In summary, Caterpillar is opposed to the change in direction which no longer excludes contracts for commercial products. We feel the definition provided for sensitive positions is inappropriate, particularly for commercial type contractors. We feel the wording for random testing is inadequate and that the method of testing should be left up to the contractor - perhaps subject to approval and acceptance of the contracting officer as a condition of award. And finally, we feel it is inappropriate to place contractors between governing bodies for non-resolved issues.

Our recommendation is that the DoD discontinue any effort to rewrite the proposed rule. Rather, it should concentrate on working with contractors to assure that contractors make conscientious efforts to eliminate drugs from the workplace. Application of the current interim rule is sufficient for major defense contractors. A simple alternate to that rule could be written that would include commercial product if access to classified data is required in order for the contractor to fulfill the contract obligations.

If you have any questions regarding this letter or the subjects it addresses, please do not hesitate to contact the undersigned.

Very truly yours,



Supervisor,
Contract Administration, Engineering & ILS
Machine Product Division
Defense and Federal Products Dept.

RPMarshall
Telephone: (309) 675-6978
rpm\drugs1

cc: D. J. Crane - Caterpillar, Medical
E. J. Guth - MAPI, 1200 18th St. NW, Washington DC 20036
R. K. Heisel - Caterpillar, Defense & Federal Products
T. R. Johnson - Caterpillar, Legal, AB7310
R. S. Meinig - Caterpillar, Human Resources, AB4225
E. R. McKenny - Caterpillar, Defense & Federal Products
E. F. Wilson - Caterpillar, Defense & Federal Products

CHIMERA RESEARCH & CHEMICAL, Inc.

Defense Acquisition Regulations Council
c/o Mrs. Linda W. Neilson
OUSD(A)
3062 Defense Pentagon
Washington, DC 20301

RE: DAR CASE 88-083

Mrs Neilson,

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Any drug testing program that does not address the issue of adulteration will FAIL to unmask the serious and savvy drug user. If the DOD is dedicated to eliminating illicit drug use in the workplace it is imperative that it require an effective adulteration detection program that includes pH and Specific Gravity.

Sincerely,

ASK ED

continued from page 50

FLOWERING CYCLE

After a plant has begun to bud, is it OK to switch the photo-period back to continuous light? Also—will this have an adverse effect on bud development?

Dr. U Bud
Maryland

No. It is not OK to interrupt the dark cycle once budding has started. Doing so will result in smaller, runny buds and hermaphroditism. Turning the cycle back to continuous light after the buds have started forming will cause plants to revert back to vegetative growth. Buddage will be reduced, not increased.

DYNOGEN

I used some Dynogen which was advertised in the *Farmer's Almanac*. Within two weeks of the first spraying, new shoots started growing all over. In late January, the snow was covering my skylight. We have no insulation and normally a plant would freeze, since it is very cold here.

Pot Lover
Hoopa, CA

Dynogen's active ingredient is a plant hormone, gibberellin, which has profound effects on plant growth. It is known to induce stretching, increase yields of some plants, especially fruiting ones, and also has been known to induce male flowers in female plants. The effects you reported, of preventing death from freeze and of inducing new growth on early buds, are very interesting.

BONSAI PLANT

In June of 1989 I saw two bonsai pot plants in the Ask Ed column. How would I go about raising them

HIGH TIMES MAGAZINE
AUGUST 1992
PAGE 70

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Defense Acquisition Regulations Council
c/o Mrs. Linda W. Neilson
OUSD(A)
3062 Defense Pentagon
Washington, DC 20301

RE: DAR CASE 88-083

Mrs Neilson,

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Any drug testing program that does not address the issue of adulteration will FAIL to unmask the serious and savvy drug user. If the DOD is dedicated to eliminating illicit drug use in the workplace it is imperative that it require an effective adulteration detection program that includes pH and Specific Gravity.

Sincerely,

Catherine S Brown

CATHERINE S BROWN, Ph D.
Assistant DIRECTOR, NIDA Laboratory
NATIONAL Psychopharmacology LABORATORY, Inc.
9320 PARK West Blvd.
Knoxville, TN 37923

Defense Acquisition Regulations Council
c/o Mrs. Linda W. Neilson
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Sincerely,

Frank Cater

Defense Acquisition Regulations Council
c/o Mrs. Linda W. Neilson
OUSD(A)
3062 Defense Pentagon
Washington, DC 20301

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Sincerely,

Robert A. Cole

Operations Engineer.
Chevron Corp.

Defense Acquisition Regulations Council
c/o Mrs. Linda W. Neilson
OUSD(A)
3062 Defense Pentagon
Washington, DC 20301

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Sincerely,

Edward J. K

Defense Acquisition Regulations Council
c/o Mrs. Linda W. Neilson
OUSD(A)
3062 Defense Pentagon
Washington, DC 20301

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Sincerely, Henderson N. Knight, A F. Ret
(30 years of Military Service).

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Washington, DC 20301

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Any drug testing program that does not address the issue of adulteration will FAIL to unmask the serious and savvy drug user. If the DOD is dedicated to eliminating illicit drug use in the workplace it is imperative that it require an effective adulteration detection program that includes pH and Specific Gravity.
for examine

Sincerely,

David A. Roberts, PhD

Defense Acquisition Regulations Council
c/o Mrs. Linda W. Neilson
OUSD(A)
3062 Defense Pentagon
Washington, DC 20301

RE: DAR CASE 88-083

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Sincerely,

Marianne Smith
Keystone Laboratories

Defense Acquisition Regulations Council
c/o Mrs. Linda W. Neilson
OUSD(A)
3062 Defense Pentagon
Washington, DC 20301

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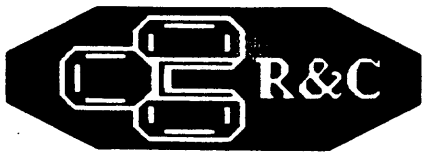
Sincerely,

Gary Waldron



CHIMERA RESEARCH & CHEMICAL, Inc.

Defense Acquisition Regulations Council
c/o Mrs. Linda W. Neilson
OUSD(A)
3062 Defense Pentagon
Washington, DC 20301

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Sincerely,

Jesse Carter, V.P. Tech. Sales

Specimen Adulteration in Drug Urinalysis

J. T. Cody
Air Force Drug Testing Laboratory
Brooks AFB, TX 78235-5000

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1042-7201/02-01-90/63-75/$6.50 •

A. In Vivo Adulteration

In vivo adulteration refers to substances individuals administer to themselves for the purpose of altering drug testing results. These adulterants fall into several general categories. One of the most popular idea is that there is a "magic" potion that a drug abuser can take to mask the presence of the drug in the urine or flush the drug out of their system before the test.

1. "Magic" Potions

A variety of substances have been reputed to interfere with the drug testing process when taken by the drug abuser prior to providing a sample for testing purposes. Many of these myths are perpetuated by the fact that a drug user who is taking substance "X" is given a drug test and is reported as negative. The fact that the drug was no longer in the system or perhaps present but below established cutoff limits is inconsequential to the drug user.

Not all advice given to the drug user is worthless. A fairly extensive treatment of methods to avoid detection of drug use has been reported by Hoffman [8]. Many of the technical issues discussed in this reference are incorrect, but much of the advice from this reference, along with magazines generally associated with the drug community, have much advice for the drug user to follow.

Simple dilution of the urine by self administration of large volumes of fluid can cause the concentration of the drug to be significantly lowered. In addition, some of the substances can, as a consequence of taking large amounts, alter urine pH to some extent. The excretion profile of some drugs can be altered by shifts in urinary pH as exemplified by the amphetamines excretion patterns reported by Beckett and Rowland and others [1,2,7,27]. With an alkaline pH, the excretion rate of amphetamines is slower, and the time the drug can be detected in urine is longer; at the same time, the concentration is lower than if excretion is completed in a shorter period of time. Done [6] also reported an enhanced phencyclidine (PCP) excretion pattern by acidification of the urine. Thus, knowing when a sample will be taken becomes the most crucial factor.

Some substances which are reputed to have caused urine to test negative, regardless of whether or not the drug is actually present, are vitamin C, vinegar, a variety of acidic fruit juices, and golden seal root either in capsule form or, less frequently, brewed as a tea. As reported by Morgan [20], golden seal root gained its reputation in the urine drug testing arena due to the presence of alkaloids in the plant material that interfere with the thin layer chromatography (TLC) tests for opiates. Schwartz and Bogema [26] have demonstrated, however, that the interfering effect can be avoided by the use of current test methodologies. Nevertheless, the specific drug class and test methodology associated with this adulterant seem to have been forgotten, and it has been continuously considered effective in causing negative test results for several drug categories. Although there is little scientific data to prove that in vivo adulteration does not work, this fact is accepted in the scientific community [15,19,25] and recognized in drug culture publications [8,18].

Brunk [4] reported that ibuprofen may cause false negative results in the confirmation analysis of the marijuana metabolite, 11-nor-Δ^9-tetrahydrocannabinoid-9-carboxylic acid (THC-COOH). This report would make self administration of large doses of ibuprofen a desirable step for marijuana users. It is interesting to note that ibuprofen has been reported by Blanke [3], McBay [16], and Warner [32] as the cause of false positive results in the EMIT screening assay. Despite the fact that Syva Company [28] has eliminated this problem by the use of a different enzyme in the assay system, the rumor still persisted that ibuprofen caused false positive results for the marijuana assay. Similarly, Larsen and Fogerson [12] reported that with fluorescent polarization immunoassay (FPIA) false positives of benzodiazepine and barbiturate can result from the presence of nonsteroidal anti-inflammatory drugs ibuprofen and fenoprofen, and naproxen, respectively. In a recent study, however, Rollins et al. [23] reported that subjects using the nonsteroidal anti-inflammatory drugs ibuprofen, naproxen and fenoprofen in both acute and chronic doses were not found to be positive for cannabinoids, benzodiazepines, or barbiturates using either the EMIT or FPIA assay systems. While there were some unconfirmed positive samples in this study, they did not occur in samples which contained the highest concentrations of the drugs/metabolites indicating the possibility that the positive result was most likely due to some other influence.

2. Diuretics

While studies conducted by Podkowik et al. [22] indicated that the diuretic itself typically would not interfere with the test, it was also reported by Manno [15] that it might have the capability of diluting the concentration of the drug to a level which is either not detectable or is below the established administrative cutoff limits. Some diuretics are very potent and fast acting. These can be used to cause significant dilution of the drug in the urine in a very short time. Some over-the-counter "water loss" pills do have some diuretic effect as do some commonly encountered foodstuffs like tea. If the individual has access to potent prescription diuretics, the impact can be substantial. Diuresis induced by simply ingesting large volumes of liquids can cause dilution of

very near the "normal" range. It should be noted that the potential for punitive action to be taken against an individual who has been identified as having adulterated a sample brings a significant burden on either the collection site personnel or laboratory who identifies the sample as being adulterated; thus, the identification of some suspicious samples may go unreported to avoid defending observations that may be considered inconclusive.

A. Collection Site

The first place adulteration of a sample can be detected is at the collection site. At the time the sample is provided, there are a number of measures which may provide signs of adulteration that cannot be monitored even a short time after the sample was collected. It is unusual for a collection site to have the capability to carry out many tests on the sample; but even the look, smell, and temperature of freshly voided urine can give clues to some forms of adulteration.

The Mandatory Guidelines [14] which describe collection in the federal civilian employee drug program call for denying access to water or other chemicals which could be used for dilution or adulteration, removal of excess clothing (i.e., coats), and allows the individual to provide the specimen in privacy. The temperature of the voided sample is to be tested within four minutes of collection and must be within the range of 32.5-37.7 °C (90.5-99.8 °F). If there is any indication of substitution, dilution or adulteration, the individual is requested to provide another sample under direct observation. It is also required that both the suspect sample and the sample taken under observation are sent to the laboratory for testing. In a study concerning the use of temperature measurement as an alternative to observed collection, Judson et al. [9] indicated that a temperature range of 32.5-36.7 °C would include 99% of the population based on a sample of 782 urine specimens taken from individuals in a drug treatment program. This same study evaluated the potential for deception by taking water heated to body temperature (37 °C), placed into condoms, and held under the arms of 12 persons for a period of one hour. The water was then dispensed into a urine collection bottle and the temperature measured. The results showed an average temperature of 33.9 °C and all twelve samples fell within the acceptable limits. This clearly demonstrated that the use of temperature measurement is helpful but will not eliminate dilution or substitution of a sample as described above by Hoffman [8].

The appearance of a sample can give an indication of many forms of adulteration, as can the smell. Some adulterants, even salt, may not completely dissolve if too

Table 1. Effect of adulterants on urine pH and specific gravity (Reprinted with permission from *J Anal Toxicol* 13:277; 1989.)

Adulterant		pH			Specific[e]
Name	Conc. (%)[a]	Day 1[b]	Day 2[c]	Day 7[d]	Gravity
Ammonia	1	6.4	6.5	6.5	1.021
	5	8.8	7.9	7.8	1.021
	10	9.5	9.0	8.8	1.020
Ascorbic acid	1	4.2	4.3	4.5	1.025
	5	3.5	3.6	3.7	1.035
	10	3.1	3.2	3.3	1.035
Bleach	1	6.0	6.1	6.2	1.021
	5	6.0	6.1	6.2	1.022
	10	6.1	6.2	6.2	1.025
Blood	0.1	6.0	6.1	6.1	1.020
	1	6.0	6.0	6.1	1.020
	5	6.3	6.3	6.3	1.020
	10	6.4	6.5	6.4	1.021
Detergent (ionic)	1	6.1	6.4	6.4	1.020
	5	8.1	7.8	7.7	1.021
	10	9.5	9.3	9.1	1.022
Drano®	5	13.4	13.3	12.9	1.035
	10	13.5	13.4	13.1	1.035
Golden seal root	0.009	6.0	6.0	6.1	1.021
	0.090	6.0	6.0	6.1	1.021
	0.450	6.0	6.0	6.5	1.022
	0.900	6.0	6.0	7.0	1.022
Lemon juice	10	3.5	3.5	3.7	1.022
Lime-A-Way®	1	4.4	4.5	4.7	1.021
	5	2.1	2.2	2.3	1.024
	10	1.8	1.9	2.0	1.027
Methanol	10	6.0	6.0	6.0	1.025
Salt	1	6.0	5.9	5.9	1.025
	5	5.7	5.8	5.9	1.035
	10	5.5	5.7	5.8	1.035
Soap	1	6.0	6.0	6.1	1.022
	5	6.0	6.1	6.1	1.024
	10	5.9	6.0	6.1	1.026
Sodium phosphate (tribasic)	1	8.7	8.6	8.5	1.020
	5	11.5	11.3	11.1	1.029
	10	12.0	11.9	11.8	1.035
Vanish®	1	4.2	4.4	4.5	1.020
	5	1.8	1.9	2.0	1.031
	10	1.4	1.5	1.7	1.035
Vinegar	1	5.6	5.7	5.8	1.021
	5	4.9	5.0	5.1	1.021
	10	4.4	4.7	4.9	1.020
Visine®	1	6.0	6.0	6.1	1.021
	5	6.0	6.1	6.1	1.020
	10	6.0	6.1	6.0	1.020
	25	6.0	6.1	6.1	1.017
pH 13[f]		13.0	12.8	12.7	NT[g]
Control		6.0	6.1	6.1	1.020

[a]Weight:weight.
[b]Day of preparation of adulterated sample.
[c]One day after addition.
[d]Six days after addition.
[e]Measured on day one.
[f]pH adjusted but not buffered.
[g]Not tested.

detergents, but they too are not designed for testing urine samples. Some adaptation of these testing procedures may be developed, but currently the most effective methods are several general clinical parameters including pH, specific gravity, sodium and chloride and creatinine contents. Although interpretation of the results may be complicated in old samples, they can still be useful tools.

IV. IMPACT OF ADULTERANTS

A. Screening Procedures

The screening procedure is more sensitive to the impact of adulterants than is the typical confirmatory test like gas chromatography/mass spectrometry (GC/MS). Although a wide variety of screening procedures are available and used, the most commonly used methodology is immunoassay, including enzyme multiplied immunoassay (EMIT), fluorescent polarization immunoassay (FPIA), and radioimmunoassay (RIA). Each system is vulnerable from the standpoint of the antibody protein. Any substance which will bind with or disrupt the structure of the antibody will have a potentially significant impact on the test results. In the case of the enzyme or fluorescent immunoassays, the possibility also exists for adulterants to impact the coupled reaction for the enzyme system, or to cause absorbance in the range used by either system to measure the presence of the drug. Radioimmunoassay is less sensitive to the influence on the measurement step of the assay procedure, because none of the common adulterants would be expected to interfere with normal radioactive decay or its measurement.

The impact of adulterants also depends on the drug involved and the test being used. Published data show the immunoassay tests for the marijuana metabolite, THC-COOH, are most likely to be impacted by the presence of a variety of adulterants [5,17,21,31]. As observed by this author [5] and Warner [31], the effect might be a positive rather than a negative one, just opposite to the intended purpose. In some cases, whether the end result is positive or negative depends upon which immunoassay system is utilized. For example, detergent caused a false negative result in the EMIT assay [10,17,24,30,31] but caused samples to appear to have significantly higher concentrations of drug in the RIA assay [5].

A variety of different substances have been used in an attempt to circumvent drug-testing programs. Many have no documented effects; most that do are not obtained under stringent scientific investigation. There are many stories in the forensic community about the use of various substances which have been discovered in "urine" samples, unfortunately, little of that information has made it into the literature. While in vitro data are not wide spread, data from in vivo studies are virtually nonexistent. Table 2 is a summary of the few available references concerning the effects of various adulterants on common drug testing methodologies.

Table 2. Summary of references showing analytical data associated with adulterants and assays

Compound	Assay[a] RIA	EMIT	FPIA
Alcohol	5,31	31	31
Ammonia	5		
Ascorbic acid	5	26	
Bleach	5,31	17,24,31	31
Blood	5	24	
Detergent	5,31	24,31	31
Drano®	5	17	
Golden seal root	5	17,26	
Lemon juice	5	17,24	
Lime-a-way®	5		
Peroxide	31	31	31
Salt	5,31	10,17,24, 30,31	31
Soap	5	17,30	
Sodium phosphate (tribasic)	5		
Vanish®	5		
Vinegar	5		
Visine®	5	17,21	
pH 13[b]	5		

[a]Data from GC/MS and TLC described in text.
[b]pH adjusted but not buffered.

1. Alcohol

When tested by RIA in this author's laboratory [5], the presence of methanol at a concentrations of up to 10% showed no influence on the results of positive (150% of the cutoff level as define by the Mandatory Guidelines [14]) or negative samples for amphetamine, barbiturates, benzoylecgonine (cocaine metabolite), opiates, PCP, or THC-COOH.

Addition of ethanol, isopropanol, and ethylene glycol showed no effect on the EMIT assay system. A small effect of these alcohols was reported by Warner [31] for the RIA and FPIA assay systems, but in no case did they cause a false positive or false negative result.

2. Ammonia

In the RIA system, the presence of ammonia at concentrations of 5 and 10% caused benzoylecgonine positive samples to be negative after seven days. Al-

7. Drano®

At a concentration of 10%, Drano® produced the most dramatic and consistent results of any of the adulterants on the RIA system. All samples, both positive and negative, showed counts which were consistent with a high concentration positive sample. The THC-COOH, morphine, amphetamine, PCP, and barbiturate assays were likewise effected at the 5% level. The benzoylecgonine negative sample, although still negative, showed a significant change in apparent concentration. At the opposite extreme, at a concentration of 1%, the benzoylecgonine assay gave a false negative result. In this case, results obtained from the positive samples and the negative controls were indistinguishable [5].

False negative results for positive drug samples were seen with the EMIT assay system for amphetamine, benzodiazepine, barbiturate, benzoylecgonine, opiates, and THC-COOH. Drano® showed a concentration dependent impact on several of the assays; but in other assays, the EMIT system gave false negative results regardless of the concentration of the drug. In all cases, the effect of Drano® on the EMIT system was to cause a false negative result [17].

8. Golden Seal Root

In the RIA system, golden seal root, as an in vitro adulterant at a concentration of 0.9%, had no influence on the results of either positive or negative samples for any of the drug classes tested except for the THC-COOH assay. The effect on the positive THC-COOH samples was to cause the apparent concentration to be lowered; but there was no measurable effect on the negative THC-COOH samples. At lower concentrations of the adulterant, there was a measurable, but less marked, effect. At 0.45% the positive sample was at the cutoff level after one day, and showed clearly negative results after seven days. At the highest concentration, equivalent to the contents of one capsule in a 60-mL sample of urine (0.9%), the results were clearly negative on both days. At each level, there was an apparent decrease in concentration between day one and day seven. The difference between these ratios was larger with the increasing concentrations of the adulterant [5].

A study which used tea brewed from the golden seal plant material as the in vitro adulterant showed a concentration dependent effect on the EMIT THC-COOH assay [17]. In that study, concentrations of golden seal at 30 mg/mL caused samples containing over 100 ng/mL of the drug to give a false negative result. In an in vivo study [26], five subjects each smoked a marijuana cigarette and then consumed 1,560 mg of golden seal root in capsule form one and a half hours later. Several hours later, a urine sample was collected from each individual with a subsequent sample taken at a later time. Test results for all samples from all subjects were positive by the EMIT assay system and by GC/MS.

9. Lemon Juice

The presence of lemon juice at a concentration of 10% had no influence on the results of either positive or negative samples for amphetamines, barbiturates, benzoylecgonine, opiates, PCP, or marijuana when tested with the RIA system [5].

Lemon juice and its effect on the EMIT assay system was evaluated and shown to effect only urine samples supplemented with drugs, and even then only at an adulterant concentration of 500 mL/L [17]. Samples from actual marijuana, amphetamine, barbiturate, cocaine, or opiate users were not affected.

10. Lime-A-Way®

In the RIA assay system, the presence of Lime-A-Way® (a strong household cleaner) in urine samples caused both the amphetamine and morphine positive samples to read at the cutoff level. The THC-COOH assay showed no effect with an adulterant concentration of 1%, but there was a substantial effect at the 5% and 10% levels, with the 10% sample reading at the cutoff level for the negative samples [5].

11. Peroxide (H_2O_2)

Adulteration of urine samples with hydrogen peroxide caused an apparent increase in the apparent concentration for both positive and negative benzodiazepine samples tested by the FPIA system; these increases were not significant enough to caused false positives. The RIA and FPIA THC-COOH assays showed an apparent increase in concentration for positive samples but those that contained no drug were not effected [31].

12. Salt

The presence of salt at 10% showed no influence on negative samples for amphetamines, barbiturates, benzoylecgonine, opiates, PCP, or marijuana when tested with RIA. Likewise, there was no effect on positive samples except for THC-COOH samples which showed an apparent decrease in concentration to the cutoff level [5].

The impact of salt on the EMIT assay system has been the subject of several studies [10,17, 24,30,31]. It was reported by Kim and Cerceo [10] that, at a levels of 50 g/L, salt caused the EMIT assay to produce false negative

Although consumption of large amounts of vinegar is reputed to cause false negatives, there is no scientific evidence to support this claim. Even *High Times* magazine acknowledges that there is no evidence that any substance, including vinegar, will cause a false negative drug test. In an interesting comment regarding the use of vinegar to defeat drug tests, Montague [18] reported that individuals that were sick due to the consumption of a large amount of vinegar, in an attempt to foil an employer's urine drug testing program, had virtually no chance of success suing their employers for damages.

17. Visine®

Except for the THC-COOH positive samples, the presence of Visine® at concentrations of up to 10% had no influence on the results of either positive or negative samples for amphetamines, barbiturates, benzoylecgonine, opiates, PCP, or marijuana when tested with RIA. Analysis of samples positive for THC-COOH showed results at the cutoff level at Visine® concentrations of 1, 5, 10, and 25% after only one day [5].

Visine® was also shown to affect the EMIT analysis of benzodiazepines and THC-COOH by causing false negative results [17]. A mechanism for the action of Visine® on the THC-COOH EMIT assay was proposed as the effect of benzalkonium chloride micelles interacting with the THC-COOH in the samples. The borate buffer also seemed to have an additive effect with the benzalkonium chloride. GC/MS analysis conducted by Pearson et al. [21] indicated that the drug was not chemically altered; the adulterant presumably impacted the assays by affecting the solubility and binding to the vessel wall resulting in the lowering of detectable concentration in the specimen.

18. pH Variation

Evaluation of the RIA system showed that adjusting the urine pH to 13 had no influence on the results of either positive or negative samples for PCP, amphetamine, barbiturate, and morphine. The benzoylecgonine assay showed no effect on negative samples, but positive samples gave the same result as the negative control after only one day. The same result was seen on day seven. THC-COOH analysis showed only a slight apparent increase in concentration for the positive samples; however, the negative samples were at the cutoff level on day one and gave positive results on day seven [5]. While this was the only study which directly investigated the effect of high pH, several other studies attributed the effects of some adulterants to the effect of the pH on the assay rather than a direct action of the adulterant. In the RIA assay, adulterants which raised the pH to around 10 were associated with positive results. Likewise adulterants which dropped the pH to less than 4 caused negative samples to read at the cutoff level [5].

The effect of the pH of a urine sample on the assay is dependent on the buffering capacity of the urine sample and the reagent mixture. The THC-COOH assay was shown to be more readily affected by samples which had extreme pH values than other RIA assays tested. This was most likely due to the larger amount of urine used in the THC-COOH assay and the lower buffering capacity of the reagent mixture [5].

B. Confirmation Procedures

The confirmation of the presence of a drug or its metabolite in urine samples is most often carried out using a sophisticated analytical procedure and instrumentation like GC/MS. With the absolute specificity of a properly conducted assay using this methodology, it is rare for an adulterant to interfere with the testing process. The entire analytical procedure must be sufficiently robust to prevent extremes of pH to affect extraction, or loss of a derivatizing reagent due to reaction with a high concentration of an adulterant. An example of interference with a confirmation assay is the impact of high concentrations of ibuprofen on a THC-COOH assay as reported by Brunk [4]. Use of a deuterated internal standard or addition of sufficient derivatizing reagent would eliminate or at least detect this kind of interference. This same impact would be expected with a number of other acidic drugs which might be found in urine.

The adulterants which actually cause a change to the drug, as is seen with benzoylecgonine at high pH, will indirectly affect the confirmation test because the system will correctly show there is little or no drug present in the sample due to degradation. The decreased benzoylecgonine, unfortunately, does not correctly reflect the actual sample status when it was provided. There is little or nothing that can be done about this situation unless the samples are tested for pH at the collection site or are tested as soon as they enter the laboratory. In situations where the time between collection and testing is extended, changes in pH may not necessarily be attributed to adulteration.

V. CONCLUSION

There is little doubt that with the increased use of urine drug testing, particularly in the American workplace, there will be an increased probability that urine specimens will be adulterated. Samples collected without direct observation are far more susceptible to this possibility. In

CORRECTIONS

Vol.	No.	Page	Location	Information to be added
1	2	149	Figure 5	(Reproduced with permission from *Forensic Sci Int* 24:183; 1984.)
1	2	151	Figure 6	(Reproduced with permission from *Forensic Sci Int* 24:183; 1984.)
1	2	153	Figure 7	(Reproduced with permission from *Forensic Sci Int* 24:183; 1984.)
1	2	153	Figure 8	(Reproduced with permission from *J. Forensic Sci Soc* 27:247; 1987.)
1	2	157	Figure 9	(Reproduced with permission from *Forensic Sci Int* 37:177; 1988.)
1	2	159	Figure 10	(Reproduced with permission from *Forensic Sci Int* 43:183; 1989.)
1	2	157	Table 3	(Reproduced with permission from *Forensic Sci Int* 40:131; 1989.)
1	2	158	Table 4	(Reproduced with permission from *Forensic Sci Int* 43:183; 1989.)

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Drug Urinalysis-Related Review Articles Published in Forensic Science Review

Title	Author(s)	Vol/Issue	Publication Date
Morphine and Codeine in Biological Fluids: Approaches to Source Differentiation	ElSohly MA & Jones AB	1/1	June, 1989
Urinary Excretion of Commonly Abused Drugs Following Unconventional Means of Administration	Cone EJ & Huestis MA	1/2	Dec., 1989
Specimen Adulteration in Drug Urinalysis	Cody JT	2/1	June, 1990
Stability of Drugs of Abuse in Biological Specimens	Levine B & Smith ML	2/2	Dec., 1990
The Interaction of Ethanol and Drugs	Havier RG	3/1	June, 1991
Applications of Solid-Phase Extraction to Drug Urinalysis	Platoff GE & Gere JA	3/2	Dec., 1991

Should Adulteration testing be performed on urines for drugs of abuse? Are Drug testing laboratories taking the necessary steps to detect Adulterated urines?

The following booklet includes articles, monographs, and excerpts from journals and federal government publications that affirm the need for testing for **adulteration** as part of a complete urine drug testing program. Analysis for **pH** and **specific gravity** will detect in **VITRO** (in test tube) and in **VIVO** (in living body) adulteration that can mask the presence of drugs of abuse.

Is knowledge of how to adulterate urine readily obtainable by the average drug abuser? The answer is **yes**. There are publications (e.g. High Times, etc.) available to the general public as well as 900 phone services that disseminate this information to the general public. Many adulterants are easily obtainable (table salt, diet salt, liquid hand soap, bleach, vinegar, Visine®, sodium bicarb., Goldseal Tea®, Drano®, soft drinks, hydrogen peroxide, etc.). Use of some, but not all in **VITRO** adulterants can be eliminated by direct observation of the subject during the collection process. Direct observation, however, is not acceptable in most cases. In **VIVO** adulterants present an additional problem because they must be consumed several hours or days prior to testing and can only be detected in the laboratory.

In conclusion, a complete and thorough analysis for drugs of abuse must include tests for **adulteration**. Evidence shows that the most effective indicators of adulteration are **pH** and **specific gravity**. NOTE: **Creatinine is not a substitute for specific gravity.** As stated by Dr. C.G. Duarte in Renal Function Tests, " daily urinary excretion of creatinine can not be used as a reliable index of the completeness of urine collection." A random urine can be diluted by a factor of 5 and still contain sufficient creatinine to test normal. Therefore, creatinine testing is a poor indicator of dilution. In Fact, some soft drinks will test normal for creatinine. College of American Pathologists and National Institute of Drug Abuse (primary national drug testing regulatory agencies) recommend adulteration testing be performed by drug testing labs.

BOTTOM LINE:

A drug testing laboratory that is not doing pH and specific gravity as part of their drug testing program for adulteration, should not perform urine drug testing for drugs of abuse!

All of the following articles acknowledge that adulteration of positive specimens using household items is possible. These adulterants can affect all three screening methods (**FPIA, EIA, RIA**, and etc.). In some cases false positives are also produced. These false positives can also be very costly to the laboratory because of the labor-intensive nature of GC/MS confirmation testing, and the ensuing delays in reporting results.

The **NIDA** monograph enclosed refers to the in vivo acidification of the urine. This process speeds up elimination of basic drugs (such as cocaine, opiates, amphetamines, PCP, etc.) thereby possibly avoiding detection. In order to be successful, in **VIVO** acidfication must occur some hours in advance of collection. The only means of detection for the technique is urine **pH** testing. All of the enclosed references point out that testing each specimen for **pH** and **Specific Gravity** is the best way to detect adulterated specimens, and thereby preventing false negatives.

THE FOLLOWING IS A SYNOPSIS OF THE ENCLOSED FINDINGS IN A CONVENIENT FORMAT:

FALSE NEGATIVES							
ADULTERANT	TEST						
	Amp	Ba	Bz	Coc	THC	Op	PCP
NaCl [B]	E	E	E	E	E	E	E
Bleach [A]	E/F/R	E	E	E	E/F	E/F/R	E/F/R
Drano [A,1,2]	E	E	E	E	E	E	
Soap [A,C]		E	E		E		E
Sodium Bicarb. [A]						E	E
Vinegar [A,1,2]					E		
Visine [1,2]					E		
GoldSeal Tea [D,1,2]					E		
FALSE POSITIVES							
	Amp	Ba	Bz	Coc	THC	Op	PCP
Sodium Bicarb.	R	R				R	
Soap	F	F	F/R		F/R		
Bleach			F				
H_2O_2			F				

A= Detected by pH
B= Detected by Specific Gravity
C= Detected by ionic strength
D= Detected by color
1= Not tested on FPIA, RIA assays
2= Not tested on any PCP assay
E= EIA
F= FPIA
R= RIA

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Booklet provided by: *CHIMERA RESEARCH & CHEMICAL, Inc.*

PREFACE and ACKNOWLEDGMENTS:

We at Chimera Research & Chemical would like to thank all of the researchers whom provided the information for the Journals (Clinical Chemistry, Forensic Toxicology, etc.) and booklets (NIDA, etc.) from which we obtained our information. We hope that this booklet will provide a valuble reference source for all drug testing adulteration programs.

CLIN. CHEM. 34/11, 2333–2336 (1988)

Adulterants Causing False Negatives in Illicit Drug Testing

Stephen L. Mikkelsen[1] and K. Owen Ash[2]

Illicit-drug users may attempt to falsify results by in vitro adulteration of specimens. We investigated eight additives (NaCl, Visine™, handsoap, Drano™, bleach, vinegar, golden-seal tea, and lemon juice) claimed by drug users to invalidate enzyme immunoassay (EIA) drug assays. We also analyzed adulterated urine specimens to determine if they could be identified, adding adulterants at several concentrations to 222 EIA-positive specimens confirmed by gas chromatography and mass spectrometry (GC/MS) to contain illicit drugs. To identify adulterated urines, we monitored pH, relative density, and urine color and turbidity at adulterant concentrations that falsified EIA results. Specimens contaminated with NaCl had relative densities >1.035. Liquid Drano™, bleach, and vinegar shifted urine pH outside the physiological range. Golden-seal tea caused a dark appearance, and specimens containing liquid soap were unusually cloudy. Lemon juice had no effect on the assays. Visine™ was the only adulterant not detected. The adulterants interfered somewhat differently with each of the drug assays. EIA assays for illicit drugs can be invalidated by specimen adulteration producing false-negative results. Therefore, if urine drug testing is to be conducted, pH, relative density, and appearance should be assessed and suspect specimens should be rejected. Not all adulterants can be detected, so observed collection is strongly recommended.

Growing public concern over the use of illicit drugs in the workplace has led to analysis of urine as a way to detect and deter drug use (*1*). Testing for illicit drugs has been implemented for many prospective and current employees in industry; personnel of the armed forces; parolees and bail seekers in civilian court systems; workers in the transportation industry; and some role models, such as athletes (*2*). Two factors have led to widespread testing for illicit drugs: technical advances, e.g., the development of the Syva EMIT d.a.u. procedures (*3*), and the growing demand for drug testing by industry (*4*). Society is becoming increasingly aware of the negative impact of drug use on public safety and the high costs of drug abuse in industry owing to related absenteeism, decreased safety, and lost productivity. Annual costs have been estimated at $33 billion in the United States (*3*).

The entire procedure must withstand vigorous legal scrutiny. Therefore, drug-testing laboratories are required to implement extensive precautions to ensure that their results include no false positives. However, adequate methods to secure the data from false-negative results are generally not in place.

Several methods of interference claimed to produce false-negative results are common knowledge to many individuals who undergo testing for illicit drugs (*6–9*). However, those subject to illicit drug testing are usually required to provide a urine sample with little or no advance notice, so they have little opportunity to do in vivo specimen manipulation. The present study is limited to in vitro urine adulteration. From the literature search and during interviews with admitted drug abusers, drug-abuse treatment-center personnel, and clinical toxicologists, eight substances were identified as additives being used by drug users to contaminate their urine specimens in the hope of avoiding detection of illicit drugs. These suspected interferents include household vinegar (*6*), table salt (*6*), liquid laundry bleach (*6*), concentrated lemon juice (*7*), caustic household cleansers (*7*), golden-seal tea (*8*), liquid handsoap (*9*) from rest-room dispensers, and Visine™ eyedrops. Salt concentrations >50 mg/mL (*10*), commercial soap concentrations of >10 mL/L (*9*), and solutions changing the urine pH to <5 or >8 are reported (*5*) to produce false-negative results with Syva EMIT assays. Ionic strength, pH, and relative density (specific gravity) measurements have been suggested as ways to screen for adulterated specimens (*11*).

Here we report an investigation of eight readily available substances claimed to cause false-negative results when added to urine that would otherwise test positive by the EIA screening assays for illicit drugs.[3] We also attempted to identify effective means of detecting urine specimens that are contaminated so that an unadulterated specimen may be obtained.

Materials and Methods

Morphine sulfate, benzoylecognine, and 11-nor-delta-9-THC-9-COOH were obtained from Alltech Associated Applied Science, Deerfield, IL. Amphetamine sulfate was obtained from Smith-Kline, Philadelphia, PA. Oxazepam was obtained from Wyeth Laboratories, Philadelphia, PA. Secobarbital was from Eli Lilly & Co., Indianapolis, IN. The interferents were purchased from a local supermarket or health-food store (golden-seal tea). EIA- and GC/MS-confirmed positive urine specimens (n = 222) were from Associated Regional and University Pathologists, Inc. The EMIT d.a.u. assay reagents and calibrators were from the Syva Co., Palo Alto, CA.

EIA analyses were done in a Hitachi 704 Analyzer from Boehringer Mannheim Diagnostics, Indianapolis, IN. Other instrumentation included a Beckman Expandomatic SS-2 pH meter and a Reichert TS meter.

Supplemented Urine Preparation

Solutions of the purified drugs (metabolite or standards) in isotonic saline were added to aliquots of urine from a healthy drug-free volunteer to achieve concentrations somewhat higher than the cutoff for a positive result. Amphetamine sulfate, benzoylecgonine, secobarbital, oxazepam, and morphine sulfate were added to give a final concentration, after a 1:1 dilution with normal saline, of 0.5 mg/L; 11-nor-

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[1] This investigation was in partial fulfillment of requirements for the M.S. degree in Medical Laboratory Science.

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[3] Nonstandard abbreviations: EIA, enzyme immunoassay; GC/MS, gas chromatography/mass spectrometry; THC, tetrahydrocannibinol.

delta-9-THC-9-COOH was added to 0.06 mg/L. The "positive" cutoff value for amphetamines, barbiturates, cocaine, benzodiazepines, and opiates was 0.3 mg/L. For marijuana, we selected a cutoff of 0.05 mg/L. Thus, 1:1 dilutions of supplemented urine with the potential interferents yielded drug concentrations exceeding the positive "cutoff" limits. Aliquots of the supplemented urines diluted 1:1 with isotonic saline were assayed to confirm the EIA-positive results on the diluted specimens before testing the interferents.

Adulterant Preparation

Before mixing with the drug-supplemented urine specimens, the potential interferents (e.g., liquid "Clorox" bleach, Heinz household vinegar, Vestal medicated liquid handsoap, liquid "Drano", "Visine" eye drops, "Real Lemon" concentrated lemon juice, Morton's table salt, and "Natural Brand" golden-seal tea) were added to saline to give concentrations thought to adversely affect drug-testing results (*5, 9, 10*). Isotonic saline, used because it approximates the ionic strength of physiological fluids, was the diluent for all interferent solutions. The golden seal was prepared as a tea by dissolving 120 mg of golden seal (ground leaves and stem) in 1.0 mL of isotonic saline at 37 °C. The tea was covered and allowed to sit overnight at 4 °C before filtering to remove undissolved residue. Liquid Clorox bleach contained sodium hypochlorite, 52.6 g/L; Drano contained 17 g of NaOH and 60 g of sodium hypochlorite per liter; Visine contained 1 g of EDTA, 500 mg of tetrahydrozaline hydrochloride and 100 mg of benzalkonium chloride per liter. Two ingredients of the golden seal that might interfere were hydrastine and berberine. Equivolume dilutions of the interferent solutions were added to the drug-supplemented urine to determine the minimum amount of interferent that would cause false-negative results.

Standard Enzyme Assay

The EMIT d.a.u. assays were performed according to the manufacturer's specified procedures. After we mixed the test urines with the potential interferents, the specimens were vortex-mixed and allowed to sit for 2 h at room temperature before analysis in the Hitachi 704 with the EMIT d.a.u. assays for six illicit drugs. Positive and negative (drug-free urine) controls were included in each run.

Urine specimens previously confirmed positive for each drug by EIA and GC/MS procedures were assayed to obtain baseline absorbance values, which were then used to estimate the drug concentrations in each specimen. These assays were conducted on 100-μL aliquots of positive urine mixed with 100 μL of drug-free urine. Absorbance readings for known drug or metabolite concentrations were plotted on semilogarithmic graph paper for semiquantification of the drugs in each positive urine specimen. The pH, relative density, and appearance of each test specimen were noted before the analysis for drugs.

Results

Drug-Supplemented Urines

The minimum adulterant concentrations required to produce a false-negative result for at least one of the test drugs were: NaCl, 50 g/L; vinegar, 85 mL/L; liquid bleach, 12 mL/L; liquid Drano, 12 mL/L; liquid handsoap, 12 mL/L; Visine, 500 mL/L; lemon juice concentrate, 500 mL/L; golden-seal tea, 15 g/L.

The interferent concentrations causing false-negative results for the drug-supplemented urines served as starting concentrations for investigation of specimens containing more-representative drug and metabolite concentrations, i.e., urine specimens that were confirmed positive by EIA and GC/MS procedures.

Adulterant Effects

The range of each drug concentration as estimated from the EIA absorbance values is given in the legends for Figures 1–6, which summarize the false-negative results caused by the adulterants.

Amphetamines: Two adulterants caused false-negative amphetamine results (Figure 1). Urines containing amphetamines up to 1.42 mg/L tested falsely negative at NaCl concentrations of 75 g per liter of urine. Drano (or bleach), the second adulterant, caused concentration-dependent interference. Positive urines containing amphetamine up to 0.52 mg/L tested negative at a Drano or bleach concentration of 12 mL per liter of urine, whereas drug concentrations up to 1.80 mg/L became negative when the Drano or bleach was increased to 23 mL/L. The false-negative results caused by Drano and bleach extended to amphetamine concentrations up to 4.65 mg/L. No effective interferent concentrations were found for the other five adulterants.

Barbiturates: Three adulterants caused false-negative results at low barbiturate concentrations (Figure 2). Urines containing barbiturates up to 0.38 mg/L tested negative at 75 g of NaCl per liter. Liquid handsoap and Drano (or bleach) at 125 mL/L altered all EIA tests for barbiturate concentrations <1.45 mg/L. None of the adulterants interfered when barbiturate concentrations exceeded 1.45 mg/L.

Benzodiazepines: Visine, handsoap, and Drano (or bleach) caused false-negative tests for benzodiazepines. Urines containing benzodiazepines up to 0.78 mg/L were falsely negative with Visine at 107 mL/L (Figure 3). Drano (or bleach) at 125 mL/L interfered when drug concentrations were <3.0 mg/L, and soap at 42 mL/L interfered at drug concentrations <6.5 mg/L. No effective concentrations of the other adulterants produced false-negative results.

Cocaine: Drano (or bleach) and NaCl caused concentration-dependent interference with the cocaine assay (Figure 4). Results for urines containing benzoylecgonine, the primary metabolite of cocaine, up to 1.18 mg/L were altered by Drano (or bleach) at 42 mL/L. This interference was extended to 1.82 mg/L by increasing the Drano (or bleach) concentration to 125 mL/L. No effective concentrations of the other interferents caused false-negative results.

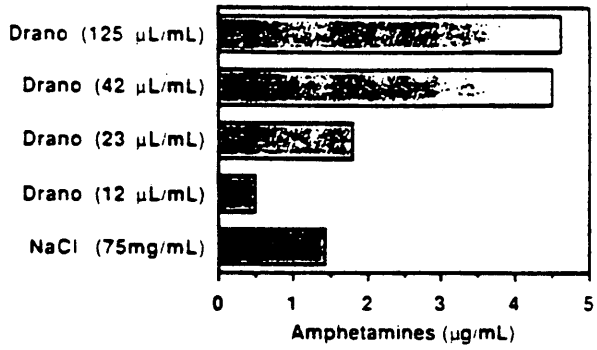

Fig. 1. False-negative amphetamines

Positive urines (n = 40) containing 0.34 to 4.72 mg of amphetamine per liter were tested with eight adulterants. Drano (or bleach) and NaCl caused false-negative tests for amphetamines. In Figures 1–6, adulterant concentrations specified on the *ordinate* caused false-negative results for the drug concentrations indicated by the *horizontal bars*

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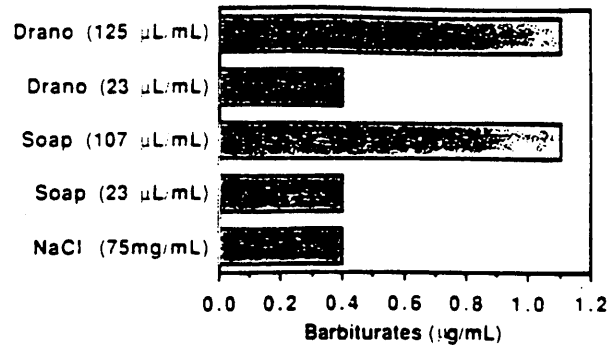

Fig. 2. False-negative barbiturates

Positive urines (n = 20) containing 0.38 to 2.90 µg of barbiturates per milliliter were tested with eight adulterants. NaCl, soap, and Drano (or bleach) caused false-negative tests for barbiturates

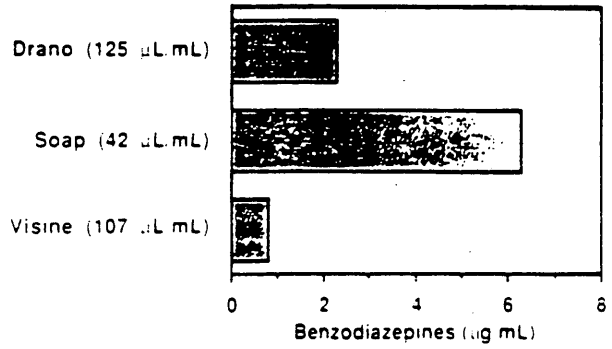

Fig. 3. False-negative benzodiazepines

Positive urines (n = 40) containing 0.38 to >6.50 mg of benzodiazepines per liter were tested with eight adulterants. Visine, Drano (or bleach), and soap caused false-negative results

Opiates: Drano (or bleach) and NaCl interfered with the EIA test for opiates (Figure 5). Urines with opiates up to 2.7 mg/L tested negative in the presence of 125 mL of Drano (or bleach) per liter. NaCl interfered only for drug concentrations <0.78 mg/L.

Marijuana: The test for THC was most sensitive to manipulation. Seven of the eight additives caused false-negative results (Figure 6). NaCl (25 g/L), Visine (125 mL/L), soap (12 mL/L), and Drano or bleach (12 mL/L) interfered at all drug concentrations investigated (31–122 µg/L). Golden seal and vinegar exhibited concentration-dependent interference. Lemon juice had no effect on any of the positive urine specimens regardless of the levels introduced; it did, however, interfere with the supplemented samples.

Urinalysis

All urines that contained sufficient NaCl to cause false-negative results had relative densities >1.035, outside the range for unadulterated urines (Table 1). Urines to which bleach, Drano, or liquid handsoap were added were alkaline. Conversely, urines containing vinegar were more acidic than unadulterated urines. Urines containing sufficient handsoap to affect the EIA assays adversely exhibited abnormal turbidity, and urines contaminated with golden-seal tea were obvious because of their brownish color. The only additive that gave urinalysis results physiologically similar to uncontaminated urine was Visine, which was not detected by routine urinalysis (Table 1).

Discussion

Four important conclusions are supported by the results of this investigation.

First, urine specimens can be adulterated to produce false-negative results. In vitro addition of NaCl, bleach, Drano, liquid handsoap, Visine, golden-seal tea, or vinegar can cause false-negative results when added to urines before testing for illicit drugs.

Second, the concentration of adulterants required to cause the false-negative results generally depends on the drug concentration in the urine, and is different for the positive urine samples than for the drug-free urines supplemented with parent drugs or metabolites. This suggests that interference may result from reactions between the adulterants and the drugs or metabolites. In contrast to the negative urines supplemented with a single drug or metabolite, the positive urine specimens probably contain several drug metabolites, any or all of which might react with the adulterants. The concentration effect is especially evident when bleach or Drano is added. However, the interference might also be explained by oxidation of NADH, which

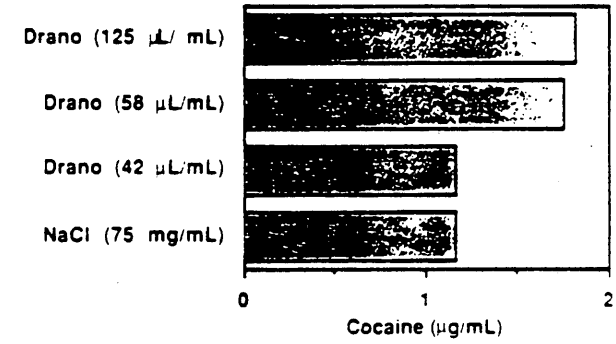

Fig. 4. False-negative cocaines

Positive urines (n = 40) containing 0.30 to >2.70 mg of benzoylecgonine, the primary cocaine metabolite, per liter were tested with eight adulterants. NaCl and Drano (or bleach) caused false-negative tests for cocaine

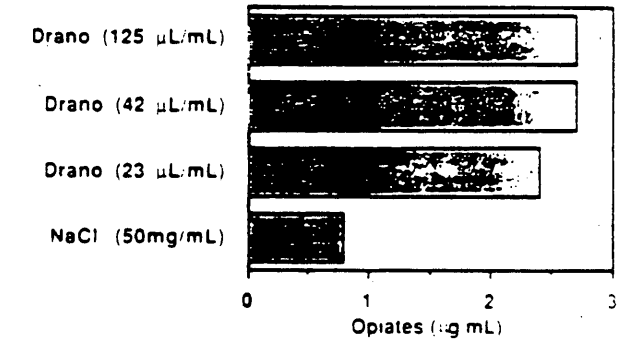

Fig. 5. False-negative opiates

Positive urines (n = 40) containing 0.31 to >2.70 mg of opiates per liter were tested with eight adulterants. NaCl and Drano (or bleach) caused false-negative results for opiates

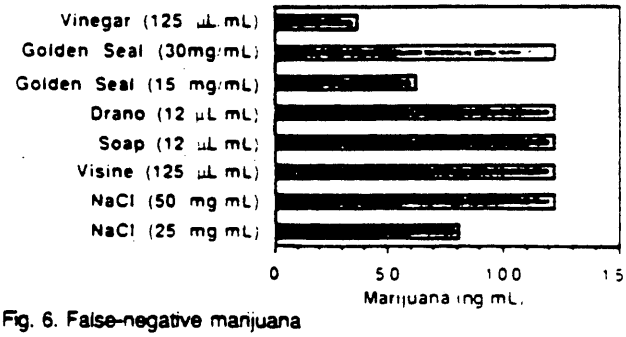

Fig. 6. False-negative marijuana

Urines (n = 42) containing 31–122 µg of 11-nor-9-carboxy-delta-9-tetrahydrocannabinol, the primary marijuana metabolite, per liter were tested with eight adulterants. All except lemon juice caused false-negative results for marijuana

Table 1. Urinalysis Results

	pH	Rel. density	Abnormal appearance
Unadulterated urines	5–7	1.005–1.030	
NaCl			
25–75 g/L	5.5	1.035	
Liquid Drano			
12–23 mL/L	6–7	1.018–1.019	
42–125 mL/L	8–11	1.020–1.028	
Liquid handsoap			
12–42 mL/L	6–7	1.018–1.021	Cloudy to turbid
107 mL/L	8	1.033	Cloudy to turbid
Visine			
107–125 mL/L	7	1.016–1.018	
Vinegar			
125 mL/L	4	1.018	
Golden seal			
15–30 g/L	6	1.022–1.024	Brown

provides the signal in the assay reaction. When the oxidizing capacity of the interferent is used up, NADH would accumulate and the result would be positive.

Third, consistent results are obtained with increasing concentrations of drugs, suggesting that the metabolites in the positive specimens had similar reactivity in the assay.

Finally, the adulterants interfere somewhat differently with the testing for separate drugs. Figures 1–6 show the minimum concentrations of adulterants causing false-negative results in authentic specimens with increasing drug concentrations. Because a continuum of drug concentrations was not tested, the upper value for a false negative for a given drug at any level of adulterant could differ somewhat from those shown. The mechanisms of interference appear to be related to the uniqueness of each drug's chemical and physical properties. The concentration of interferents causing false-negative results depends on both the specific drug and its concentration, because other components of the assay system are held constant. The THC assay, which is sensitive to seven of the eight adulterants, is the most easily manipulated to produce false-negative results.

In selecting the adulterants to investigate, we used three criteria.

First, the dilution must not be the cause of the false-negative results. Accordingly, the positive urine specimens were diluted 1:1 with isotonic saline and re-analyzed to verify that the diluted specimens remained positive.

Second, the quantities of the interferents that cause false-negative results must be small enough to be hidden on one's person. If illicit drug users intended to adulterate their urine for the purpose of avoiding detection, they must avoid detection as they transport the interferent into the collection room.

Third, the added interferent could not leave an obvious precipitate or residue in the urine specimen container, which would make the adulteration obvious. Typically, about 60 mL of urine is submitted to the drug-testing laboratory. Based on a 60-mL urine volume, the minimum amounts of the adulterants required to cause false-negative results ranged from 0.7 to 7.5 mL for the liquid interferents, the amount of solid interferents from 0.9 to 4.5 g. However, the quantities of interferents required to alter drug testing results depend not only on the specific drug but also on the drug and metabolite concentrations, so individuals intent on adulterating their urine specimen would not know how much adulterant would be required.

Determination of the mechanisms by which the adulterants can alter drug-testing results was beyond the scope of this study. Unfortunately, the specimens giving false-negative results were not available for GC/MS analysis. However, detailed investigation of several possible interference mechanisms is underway, including GC/MS analysis after introduction of the adulterants. Several different mechanisms could be involved. For example, the increased ionic strength due to addition of NaCl could alter protein structures to affect drug binding or enzyme activities. The high salt concentration conceivably could cause drugs to precipitate before sampling. The acidic pH caused by vinegar and the alkaline pH caused by liquid bleach and Drano could alter binding, reaction rates, or drug solubilities; changes in pH per se could not account for the interference. Liquid bleach and Drano probably affect the drug assays by oxidation reactions. Adding liquid bleach or Drano to NADH oxidizes it, decreasing the absorbance at 340 nm. Soap may interfere by a combination of pH and ionic strength or may remove the drug by forming an insoluble complex. Soaps may also increase drug-binding sites on the antibody, resulting in decreased activity in the assay reaction. The optical properties of the adulterated urine specimens may also interfere with absorbance measurements. With golden seal, the active ingredients are claimed to be hydrastine and, to a lesser extent, berberine. Future studies are planned to elucidate the mechanisms by which the adulterants interfered so that further measures can be taken to avoid false-negative results.

We recommend that testing for illicit drugs include assessment of pH, relative density, and urine appearance. Suspect urine specimens should be rejected and new specimens obtained. Because urine specimens can be successfully adulterated and not all adulterants can be detected, observed collection is strongly recommended.

Ed. note: See also Arch Pathol Lab Med 1988;112:769. This letter says that large doses of ascorbic acid do not interfere with cannabinoid testing.

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Interference of Common Household Chemicals in Immunoassay Methods for Drugs of Abuse

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I report how some adulterants affect results for drugs of abuse in urine as measured by Roche RIA, Syva EMIT d.a.u., and Abbott TDx FPIA (fluorescence polarization immunoassay) for the following drugs: amphetamines, barbiturates, benzodiazepines, cannabinoids, cocaine, opiates, and phencyclidine (PCP). Sodium chloride interfered negatively with all of these drugs when assayed by EMIT and caused a slight decrease in measured benzodiazepine concentration by FPIA. Drug concentrations were also decreased by added H_2O_2 (EMIT: benzodiazepine), Joy® detergent (EMIT: cannabinoid, benzodiazepines, PCP), $NaHCO_3$ (EMIT: opiate; FPIA: PCP), or $NaHClO_4$ (EMIT, RIA, FPIA: amphetamines, opiates, PCP; EMIT, FPIA: cannabinoid; EMIT: benzodiazepines). False-positive results were caused by H_2O_2 (FPIA: benzodiazepines) and Joy (RIA, FPIA: benzodiazepine, cannabinoid; FPIA: barbiturate, amphetamine). Sodium bicarbonate causes a suspiciously high pH in the urine, $NaHClO_4$ an apparently low pH (using pH paper).

A major issue in programs for testing urine for drugs of abuse is the development of a collection process that will ensure the integrity of the specimen. In no other type of laboratory testing does the person being tested have both the opportunity and the incentive to alter the collected specimen. Because of the opposition to witnessed collection, other approaches are needed to eliminate specimen switching or adulteration.

Procedures for identifying or eliminating specimen tampering at the collection site include requiring removal of all outer bulky garments and purses, or use of an examining gown; coloring of the water in the toilet; and collecting the specimen directly into a cup containing a temperature-sensitive material, after which the collection-site person pours the specimen into the transport container.

Use of a collection device such as the Franklin Collector (Franklin Diagnostics, Inc., 60 Franklin St., Morristown, NJ 07960) not only can assist in identifying specimens that may not be the subject's urine (urine kept in a plastic bag taped to the body will not achieve the normal temperature range of 96.4–100.4 °F), but also makes it difficult for the subject to add liquid adulterants, because it takes 1–2 min for the temperature to equilibrate. Further, the size of the container, approximately 85 mL, precludes adding solid adulterants and easily getting them into solution. At the time the collection person pours the urine into the transport container, adulterants such as isopropanol or sodium hypochlorite can be detected by smell, even if they have not already interfered with the temperature reading. Use of solid adulterants may be detected by the presence of residues in the container. Pre-analytical checks of pH and relative density will identify samples adulterated with sodium chloride, sodium hypochlorite, and sodium bicarbonate.

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However, given the desperation and cunning of many drug users and the potential for improper collection and lack of adulteration testing, I examined the effect of several common chemicals on immunoassay methods in case they escaped detection in pre-analytical examinations. Some of these chemicals have been recommended for use as potential adulterants (*1*).

Materials and Methods

Drug-free normal human urine collected at different times but from a single individual was used for all testing. To separate portions of the urine I added a single drug to give a concentration that would yield a positive result at or near the cutoff value for the assay, after diluting the sample with the adulterant. Table 1 lists the drugs studied, their approximate final concentrations, and the assay methods used. I added 1 volume of liquid adulterants to 4 volumes of drug-containing urine, using an automatic dilutor (Micromedic Systems, Horsham, PA).

Cannabinoid specimens, so diluted, gave results that indicated that the drug was being absorbed by the plastic tubing as the drug-containing urine passed through the dilutor. Some additional testing of an unadulterated specimen containing the same cannabinoid metabolite, divided into different types of storage containers, including glass and several types of plastic, verified that drug concentrations were decreased after contact with some of the plastics used, but not with glass, and that ethanol could partly reverse the process. Thus, for this study, all the dilutions were done with glass pipets.

Liquid adulterants used were ethanol (950 mL/L), isopropanol, ethylene glycol, sodium hypochlorite (52.5 mL/L, as Clorox®), hydrogen peroxide (30 mL/L), and Joy® detergent (10-fold predilution). Solid adulterants used were sodium chloride (250 g/L final concentration) and sodium bicarbonate (200 g/L final concentration). Drug-free urine, 1 mL, was added to samples adulterated with sodium chloride and sodium bicarbonate, to equalize the drug concentrations in all samples to be tested. An unadulterated sample was prepared containing the same concentration of drug as the adulterated samples. Results for all samples were then compared with those for the unadulterated specimen.

The sodium hypochlorite caused vigorous fizzing the first few minutes after addition; and sodium bicarbonate, at the concentration tested, gave a saturated solution, with some residue present. Otherwise, none of the adulterants caused any changes in the appearance or turbidity of the urine.

I tested each set of specimens by RIA (Roche Diagnostics, Nutley, NJ), the EMIT d.a.u. enzyme immunoassay (Syva Co., Palo Alto, CA) in an Hitachi 705 (BMD, Indianapolis, IN), and fluorescence polarization immunoassay (FPIA) in the TDx (Abbott Laboratories, N. Chicago, IL). I evaluated the results of these assays to determine if the adulterated specimens produced changes in counts per min, absorbance, or net polarization, respectively, when compared with unadulterated specimens containing the same concentration of drug. A second set of adulterated specimens, containing either no drug or a drug other than the one being assayed, was evaluated along with the samples containing the drug of interest. Samples were tested in duplicate in the RIA and singly in the EMIT and FPIA assays.

Table 1. Drugs and Concentrations Tested, and Cutoff Values for Each

Drug added	Drug concn, ng/mL[a]	Cutoff concn for positive result, ng/mL		
		EMIT	RIA	FPIA
Amphetamine · HCl	530, 600	300	1000	300
Benzoylecgonine · $4H_2O$	570, 500	300	300	300
Morphine sulfate · $5H_2O$	336, 300	300	300	200
Oxazepam	351, 250	300	—	200
Phencyclidine · HCl	75, 100	75	25	75
Secobarbital	510, 800	300	200	500
9-Carboxy-11-nor-delta-9-THC	38, 38	20	100[b]	25

[a] The final concentrations in the samples evaluated by EMIT and FPIA are in the first column, those by RIA are in the second column.
[b] Control with a concentration of 30 ng/mL included here.

Results

Drug concentrations that fell within the linear portion of the assay curves were used so that the effects caused by the adulterants could more readily be observed, because I was mainly interested in relative results for adulterated specimens as compared with unadulterated specimens containing the same concentration of drug.

The results are summarized in Tables 2, 3, and 4. I anticipated that solvents such as ethanol, isopropanol, and ethylene glycol might affect viscosity and thus the accurate pipetting of samples, but I observed no effects with these solvents except in the case of the cannabinoid-containing specimens, and this may have had more to do with an effect on solubility or adherence of the drug to the containers used. For unknown reasons, this effect was not observed with the EMIT assay.

The effect of NaCl in the EMIT assays has been previously reported (*2–4*). I also noted that the absorbance changes in drug-free samples containing NaCl were decreased com-

Table 2. Effect of Adulterants on Immunoassay Results When Drug Being Tested Is Present[a]

Assays	H_2O_2			NaCl			$NaHCO_3$			JOY®			$NaHClO_4$		
	EMIT, A	RIA, C	FPIA, P	EMIT, A	RIA, C	FPIA, P	EMIT, A	RIA, C	FPIA, P	EMIT, A	RIA, C	FPIA, P	EMIT, A	RIA, C	FPIA, P
Amphetamine	—	—	—	−13[b]	—	—	—	+18	—	—	—	+10	−31[b]	−19[b]	−14[b]
Barbiturate	—	—	—	−13[b]	—	—	+8	+14	—	+8	—	−38	—	+14	—
Benzodiazepine	−6	—	+19	−16[b]	—	−6	—	—	—	−10[b]	+69	+19	−16[b]	—	—
Cocaine	—	—	—	−12[b]	—	—	—	—	—	—	—	—	—	—	—
Opiates[c]	—	—	—	−26[b]	—	—	−6[b]	+60	—	—	—	—	−40[b]	−100[b]	−57[b]
Phencyclidine	—	—	—	−35[b]	—	—	—	—	−14[b]	−10[b]	—	—	−12[b]	−29[b]	−35[b]

[a] % change in absorbance (A), counts/min (C), or polarization units (P) observed for the adulterated sample, in comparison with that for the unadulterated sample. The sign indicates effect on drug concentration. Only changes >5% (EMIT, FPIA) or >10% (RIA) are shown. [b] Change sufficient to cause a false negative at the concentration of drug tested and the cutoff value used. [c] Results reported previously (*5*).

Table 3. Effect of Adulterants on Immunoassay Results When Drug Being Tested Is Absent[a]

	H_2O_2			NaCl			$NaHCO_3$			JOY®			$NaHClO_4$		
Assays	EMIT, A	RIA, C	FPIA, P	EMIT, A	RIA, C	FPIA, P	EMIT, A	RIA, C	FPIA, P	EMIT, A	RIA, C	FPIA, P	EMIT, A	RIA, C	FPIA, P
Amphetamine	—	—	—	−13	—	—	—	+9	—	—	—	+9	—	—	—
Barbiturate	—	—	—	—	—	—	—	+16	—	—	—	+43	—	—	—
Benzodiazepine	—	—	+22	−14	—	—	—	—	—	−9	+71	+72	—	—	+10[b]
Cocaine	—	—	—	−21	—	—	—	—	—	—	—	—	—	—	—
Opiates	—	—	—	−12	—	—	—	+9	—	—	—	—	—	—	—
Phencyclidine	—	—	—	−13	—	—	—	—	—	—	—	—	—	—	—

[a] % change in absorbance (A), counts/min (C), or polarization units (P) observed for the adulterated sample, in comparison with that for the unadulterated sample. The sign indicates effect on drug concentration. Only changes >5% (EMIT, FPIA) or >10% (RIA) are shown, and only positive changes resulting in a false-positive result are reported. [b] Apparent concentrations were 117–176 (cutoff vaue, 200 ng/mL).

Table 4. Effect of Adulteration on the Cannabinoid Assay

	Cannabinoid present			Cannabinoid absent		
	EMIT, A	RIA, C	FPIA, P	EMIT, A	RIA, C	FPIA, P
Adulterant	% Change[a]					
Ethanol	—	+38	+29	—	—	—
Isopropanol	—	+45	+31	—	—	—
Ethylene glycol	—	+14	+19	—	—	—
$NaHClO_4$	−25[b]	—	−14[b]	—	—	—
H_2O_2	—	+34	+14	—	—	—
Joy®	−34[b]	+70	+38	−23	+61[c]	+14[c]
NaCl	−20[b]	—	—	−20	—	—
$NaHCO_3$	—	−38	—	—	+17[d]	—

[a] Reported as in Tables 2 and 3. [b] Sufficient change for specimen to be less than the cutoff (falsely negative). [c] Sufficient change for sample to be greater than the cutoff (falsely positive) [d] C was decreased, indicating increased concentration; however, result was strongly negative.

pared with normal drug-free urine, adding evidence that the effect of NaCl is on the EMIT assay reagents. Sodium chloride did not affect RIA, and only a slight effect was noted with one of the FPIA assays.

I expected that pH extremes would have a negative effect, and strongly basic specimens ($NaHCO_3$) actually yielded increased values for some of the RIA assays, with the same effect for drug-free specimens, indicating that pH per se is affecting assay reagents. Sodium bicarbonate depressed apparent concentrations for one EMIT and one FPIA assay.

Handsoap reportedly is an effective adulterant for the EMIT benzodiazepine, barbiturate, and cannabinoid assays (*4*). Using the liquid detergent, Joy, I found these same three assays were affected; however, barbiturates demonstrated increased rather than decreased concentrations. The effect of Joy on the EMIT assays was found in both drug-free and drug-containing specimens. The most interesting effect of Joy, however, is that it causes false-positive results for three of the FPIA and one of the RIA assays, along with increased concentrations for drug-containing specimens for these same assays.

The effect of $NaHClO_4$ on all three immunoassays for several of the drugs, coupled with the fact that drug-free specimens were not affected, suggests that $NaHClO_4$, a strong oxidizing agent, may react with the drugs or antibody and interfere with the antibody reaction. Harder to explain are the effects on the FPIA benzodiazepine and RIA barbiturate assays, and the fact that the EMIT and FPIA cannabinoid assays give decreased concentrations but the RIA does not. The finding of benzodiazepine (by FPIA) in the drug-free specimen is coupled with a slight decrease in concentration of the drug-containing sample. These may be off-setting effects, with actual drug reacting with $NaHClO_4$ to give a decreased value coupled to a positive effect on the assay as a whole. The increased apparent concentrations observed for the barbiturate and cannabinoid RIA may be due to pH, because these assays also gave increased results in the presence of (basic) $NaHCO_3$.

Hydrogen peroxide, on the other hand, is acidic, and may be exerting a pH effect upon the FPIA benzodiazepine assay, because increased apparent concentrations were observed in both drug-containing and drug-free specimens. The diluent-well solution was bright yellow in the presence of peroxide. The RIA and FPIA for cannabinoids gave enhanced results for the drug-containing specimens with no effect observed in the drug-free samples.

Although the cannabinoid assay seems particularly sensitive to adulterants, with at least one type of immunoassay affected by every one of the adulterants tested, overall only four of the 15 effects observed resulted in decreased concentrations, and therefore successful adulteration with these chemicals to achieve a negative result will be difficult. The RIA was affected by six of the eight adulterants, all of the effects being in a positive direction. The only false-positive results was the Joy (RIA, FPIA). If a specimen containing Joy is confirmed by use of the Toxi-Lab TLC system (Marion Scientific, St. Louis, MO), the extraction will be very messy even when the three-extraction clean-up procedure is used. A weak but definite positive, compared with the unadulterated specimen, was observed for a drug-containing specimen.

Evidently adulteration is a two-edged sword, with the possibility of producing a false negative outweighed, in many cases, by the specter of false positives.

Discussion

At least some of the advice being given to drug users on how to adulterate urine samples successfully will not be totally effective if immunoassay is used for screening—with some notable exceptions.

The most effective of the adulterants I tested is sodium chloride, which will be a concern only for laboratories that use the EMIT technology. This and other studies indicate that the minimum amount of sodium chloride that must be added to produce a negative result varies with different assays, but it is substantial. The effective amounts used in this study would be difficult to store (e.g., under fingernails) and require time and stirring for solution to be complete. Others have reported that amounts from 50 to 75 g/L are effective in producing false negatives, depending upon the assay and drug concentration used (*3–5*). I found that 50 g/L was insufficient to affect the EMIT cannabinoid assay. Sufficient sodium chloride to produce falsely negative results will result in a residue (which can be noted by the collection-site person), a high relative-density reading, and a delta absorbance value less than the negative calibrator.

Other adulterants that might be problematic include $NaHClO_4$, which should be readily recognized by its smell (even one adulterated sample in a group is easily detected) and its reaction with pH paper. Although $NaHClO_4$ is basic and a urine treated with it will give a pH reading of ~10 with a pH meter, if pH paper is used, a bright-red (but rapidly fading) color indicative of an acid pH of ~1 is produced.

Other false negatives of concern are those caused by dilute Joy and $NaHCO_3$. Sodium bicarbonate in the concentration tested will not go completely into solution and will result in a pH of 8–9, which should be considered abnormal by the laboratory and should result in a request for a fresh sample. Joy did not cause any changes in appearance, pH, or relative density, but can be detected by vigorously shaking a small amount of the urine. More copious, longer-lasting bubbles are formed compared with normal urine, and when held to the light they refract it to give the typical rainbow appearance of soap bubbles.

A major drawback, for the subject, to the use of Joy or $NaHCO_3$ is the fact that these compounds also cause false-positive results in several assays, hardly the result desired by the subject adding adulterants to ensure a negative result.

Of the two assays currently of most interest, cocaine and cannabinoids, the cocaine assay was found to be a robust one, with only NaCl producing a decreased result with the EMIT assay. The cannabinoid assay appears to be very sensitive to adulterants, yielding both decreased and increased results, depending upon the adulterant and immunoassay method used; however, most of these effects were in the positive rather than the negative direction.

These results indicate that specimen adulteration is complicated for the subject by the fact that some adulterants shown to cause falsely lowered results can be readily detected by either trained collection-site personnel or by simple laboratory procedures such as temperature, pH, relative density, residue checks, and shake and sniff tests. In addition, the undesired result of an enhanced or false positive, produced by a number of potential adulterants, makes their use less attractive as a mechanism for producing a false-negative result. The laboratory needs to assess, based upon the methods used for screening, what preanalytical tests for detection of adulterants are necessary. This study was designed to serve as a starting point in making such decisions.

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Serum Creatine Kinase Isoenzyme BB Is a Poor Index to the Size of Various Brain Lesions

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We divided patients with brain lesions into three groups: (*a*) patients with primary or metastatic brain cancer, (*b*) brain infarctions, and (*c*) brain contusion(s). We analyzed each patient's sera for creatine kinase isoenzyme BB (CK-BB), using a monoclonal antibody kit (Impres-BB; International Immunoassay Laboratories). Computerized axial tomography (CAT) scans were performed on each patient. The size of the various lesions was measured from the CAT scan and recorded in milliliters. Total CK, CK-BB, and their ratios were compared with the volume of damaged brain tissue. We found no correlation between any of the variables and the various brain lesions. We attribute this lack of correlation to an intact blood–brain barrier, the rapid elimination or inactivation of CK-BB, or some combination of these factors.

Biochemical diagnosis of brain injury has traditionally been confined to analysis of cerebrospinal fluid. No specific blood test has been available, and there has been uncertainty whether such a test could be devised because of the blood–brain barrier.

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curve fitting methods. However, procedure *d* and the procedures of Jones (*2*) and Loo and Brien (*4*) resulted in peaks eluting with vitamin D that were more than twice the size of the peaks in procedures *a* to *c*. Moreover, the thin-layer chromatograms show that lipid removal is improved by increasing the number or volume of successive washes.

The liquid-chromatographic results show a similar picture. Specifically, fewer lipids are eluted when gentle pressure is applied than when the solvent simply drips through the cartridge. With the drip procedure, backward diffusion may be occurring within the cartridge, whereas the use of injected washes under pressure overcomes these effects by allowing a more rapid transport of solvent through the column.

C18 cartridges have been used in this role by several other workers (*6–8*). Turnbull et al. (*7*) used one wash with 3 mL of methanol/water (7/3 by vol), and both Kohl and Schaefer (*8*) and Kao and Hesser (*6*) used one wash with 10 mL of methanol/water (7/3 by vol). Our experiments support the effectiveness of the latter procedure. Jones (*2*) based his extraction on an earlier reported method that extracted all the lipids. The further filtration steps clarified the sample efficiently, but did not separate or decrease the lipids; consequently, his extraction must be considered unsatisfactory. The procedure of Loo and Brien (*4*) was much quicker, but again it yielded an unsatisfactory, lipid-rich extract.

We conclude that: A single extraction, as used by Traba et al. (*3*), leaves substantial amounts of lipid on the cartridge. Both the Jones (*2*) and Loo and Brien (*4*) extracts are lipid rich. The cartridge-washing system described by Kohl and Schaefer (*8*) is satisfactory, as is that of Traba et al. (*3*) when two additional washes are performed. A decrease in lipids may be demonstrated by the peak area or by the presence of lipids in the cartridge wash.

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EMIT® Tests for Drugs of Abuse: Interference by Liquid Soap Preparations

To the Editor:

The EMIT (Syva, Palo Alto, CA 94304) enzyme immunoassay technique is widely used in screening for drugs of abuse in urine. Addicts resort to any stratagem to avoid positive results: substitution, dilution, addition of extraneous compounds to the urine. When several drugs are regularly screened for, negative results for all may sometimes arouse suspicion: when their urine is to be sampled, some addicts attempt any new trick to cause it to test negative. The analysis usually is directed to detection of a single drug; e.g., in this country, screening for opiates is only a recommended procedure for those addicts who are on a treatment program. Non-experienced personnel may perform drug determinations in a physician's office, and toxicological laboratories commonly are asked to assay urine but are given no insight into the sampling precautions.

Interference by NaCl with EMIT tests for drugs of abuse has been described (*1*). Liquid soaps such as those found in restrooms or used for dish washing and bathing can also interfere. They dissolve quickly, leaving the appearance of the urine specimen unchanged. We report some laboratory experiments to investigate this interference.

Urine samples supplemented with drugs were tested with four different-purpose commercial liquid-soap preparations. All EMIT determinations were done with the semi-automatic Gilford Stasar System 101.

Typical results are summarized in Table 1 for one liquid soap. A positive ΔE value corresponds to a positive urine. We confirmed these observations, using authentic positive urine samples containing the excreted drugs.

The effect occurs when less than 1 mL of liquid soap is present per deciliter of urine, and it affects all EMIT-DAU tests in which the labeled enzyme is lysozyme and the enzyme substrate is the *M. lateus* bacterial suspension. It occurs at 3 mL/dL with all EMIT-St single tests in which the labeled enzyme is malate dehydrogenase or glucose-6-phosphate dehydrogenase and the substrates are, respectively, malate and glucose 6-phosphate in the presence of NAD^+.

The sodium concentrations of the liquid soaps we tested, determined by flame photometry, are in the range of 2 to 3 mmol for every 1 mL/dL, 10-fold less than the concentration indicated in ref. *1*, in which the effect is attributed to NaCl and its role in modifying the ionic strength. Normal drug-free urine contains 90 mmol/L.

Unless the ionic strength is measured, there is no evidence that there is interference by soap with the EMIT tests. The neutralizing effect of NaCl is drug-concentration dependent. At 3 mol of NaCl per liter a positive urine can remain positive. Comparatively the effect of liquid soaps is greater for EMIT-DAU.

pH is an important factor in any enzymic reaction, but the measured pH of the urines remain unchanged before the EMIT buffer is added, throughout the indicated (Table 1) soap concentrations.

The hemagglutination inhibition test for opiates ("Agglutex"; Roche Diagnostics, Nutley, 07110 NJ) does not show negative results until the concentration of liquid soap exceeds 10

Table 1. Interference of Liquid Soap and NaCl with Methadone EMIT-DAU Tests

Liquid soap, mL/dL	NaCl, mol/L	ΔE
Negative		
0		−18
*Positive, 0.5 μg/mL**		
0		+42
0.1		+40
0.5		−7
Positive, 2 μg/mL		
0		+79
15		−56
0.5		−8
0.1		+7
Positive, 2 μg/mL		
	0	+106
	1	+83
	3	+10
	4	−20

*Methadone HCl added.

mL/dL. Radioimmunoassays (Roche Diagnostics) of positive urines to which liquid soaps were added up to 15 mL/dL remained positive; negative urines remained negative.

Those involved in urine collection and laboratory personnel should be aware of this kind of interference; 0.5 mL of liquid soaps per deciliter is just two drops in the typical urine sample!

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Stability of Norepinephrine in Blood

To the Editor:

Measurement of plasma catecholamines has become more important because increasingly it is used as an index to overall activity of the sympathetic nervous system (*1*). However, the assay techniques can be tedious and capricious and the concentrations being measured in plasma are extremely small.

Zuspan (*2*) reports that the conditions under which blood is taken and the validity of the control groups used are important considerations in interpreting plasma norepinephrine concentrations. However, Rubin et al. (*3*), using radioenzymatic techniques, go further, saying that norepinephrine is unstable in plasma and is easily degraded in whole blood at room temperature. They also indicate that special procedures such as transferring the blood to chilled tubes and immediate centrifugation at 4 °C are necessary. Carruthers et al. (*4*), who used fluorometry, found that plasma catecholamines were either rapidly degraded or taken up by erythrocytes, or both, so that even slight delays in separating the plasma become important.

By contrast, Pettersson et al. (*5*) found that catecholamines in plasma, as measured by a radioenzymatic method, were markedly stable in either plasma or whole blood. They found that storage of whole blood for several hours at room temperature did not result in any losses of plasma catecholamines, but that these were swiftly degraded when stored in buffer solutions in the absence of thiols. Moreover, human erythrocytes possess an active transport system for both norepinephrine and epinephrine uptake (*6*). However, the efficiency of the transport system depends critically on the surrounding temperature, and it is only induced at temperatures that substantially exceed room temperature (*6*).

These differing reports (*3*, *5*, *6*), together with the problems associated with collecting blood specimens from hospital wards, prompted us to check the apparent stability of norepinephrine in plasma and whole blood. We found that whole blood could be left standing at room temperature for as long as 5 h or more before removing the plasma for extraction without detectable loss of norepinephrine. Details of the experiment were as follows.

We collected 40 mL of whole blood from six normal, recumbent subjects into heparinized tubes at room temperature. Ten milliliters of the specimen was centrifuged and two 2-mL samples of plasma were extracted without delay. Three 10-mL samples of the blood specimens were left standing at room temperature for 1, 2, and 5 h, respectively, before we separated the plasma (two 2-mL samples each time) for extraction. For the assay we used a modification of a "high-performance" liquid-chromatographic assay with electrochemical detection (*7*). The extractions with alumina were carried out by customary procedures (*7*), except that we found antioxidants and special arrangements for blood collection and processing such as chilled tubes and refrigerated centrifuges were not required. Using a two-way analysis of variance, we saw no significant difference, within experimental error, between the plasma norepinephrine concentrations measured at each time for a given subject (zero-time values ranged from 96.5 to 208.0 ng/L for the six subjects).

These findings are in agreement with the results of Pettersson et al. (*5*) and Danon and Sapira (*6*), but are clearly at variance with those of other workers (*3*, *4*). Our findings and those of others (*5*, *6*), who used radioenzymatic methods, suggest that catecholamines are stable in plasma and whole blood. Results obtained by the older, less sensitive and specific methods of fluorometry, together with the well-known observation that catecholamines are unstable when stored in buffers, may account for the belief that catecholamines are unstable and are easily degraded in whole blood and plasma at room temperature (*3*). Table 1 summarizes the differing reports on this subject.

Although precautions regarding sampling and processing of blood specimens used for plasma catecholamine determinations should not be neglected, we believe that, when one may check the stability of catecholamines by using a routine method, some of the time-consuming and costly steps for collection and processing of blood samples can be eliminated.

The study was supported by a grant from the Medical Research Advisory Committee of The Australian Associated Brewers.

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Table 1. Methods of Collection, Processing, and Analysis for Norepinephrine (NE) Compared

Ref. no.	Technique	Collection and processing	Authors' comments on NE stability
Here	HPLC-ECD	At room temperature	Stable in whole blood and plasma for 5 h or more at room temp.
5	Radioenzymatic	At room temperature	Stable in whole blood and plasma for 22 h or more at room temp.
3	Radioenzymatic	Ice-chilled tubes; centrifugation at 4 °C; prompt processing and storage	Unstable, easily degraded in whole blood at room temp.
4	Fluorometric	Antioxidants added; centrifugation and prompt sepn. of plasma from whole blood, subsequent freezing	Very unstable, easily degraded in whole blood at room temp.

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CLIN. CHEM. 23/4, 751–753 (1977)

Specific Conductivity of Urine and Sensitivity of Enzyme Immunoassay Methods of Analysis for Drugs of Abuse

Ole Andersen and Peter Bonne Eriksen

We studied the sensitivity of the EMIT® assays of amphetamine, benzodiazepines (diazepam), methadone, opiates (morphine), and propoxyphene at different specific conductivities in urine. The specific conductivity was varied by adding NaCl. For a sensitivity of 0.5 mg of drug per liter, the urine must have a specific conductivity of less than about 35 mS/cm in all these assays except that for benzodiazepine, for which it must be less than about 20 mS/cm.

In our laboratory we screen urine from addicts by means of the Enzyme Multiplied Assay Technique (EMIT®; Syva, Palo Alto, Calif. 94394) drug-abuse urine assays and finally identify the drugs in samples that are positive by thin-layer chromatographic methods. Addition of NaCl to urine decreases the sensitivity in the EMIT assays (*1*), probably because of an increase in ionic strength. To avoid falsely negative results in the EMIT assays, we studied the relation between specific conductivity of the urine and detection limits for the following drugs: amphetamine, benzodiazepines (diazepam), methadone, opiates (morphine), and propoxyphene.

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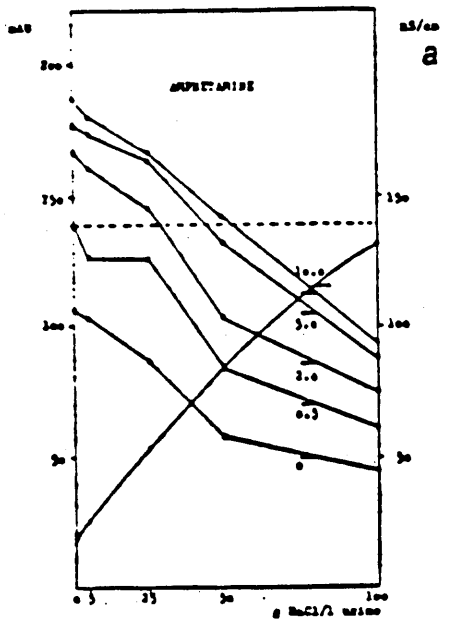
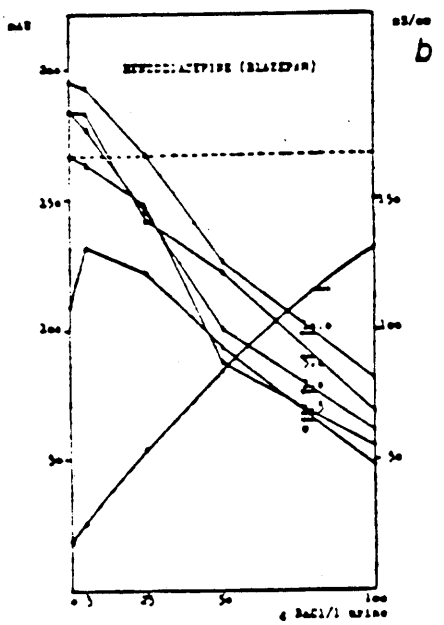
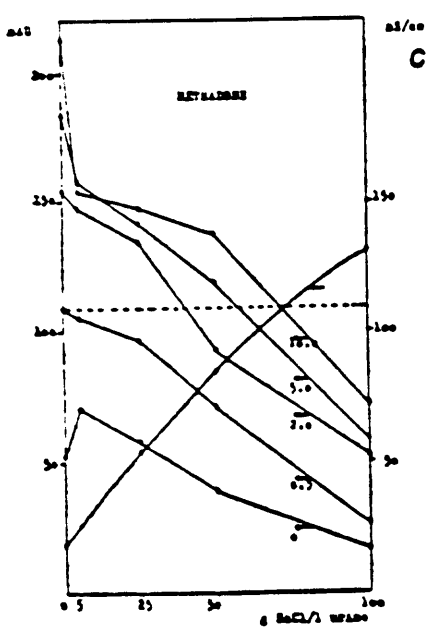
Materials and Methods

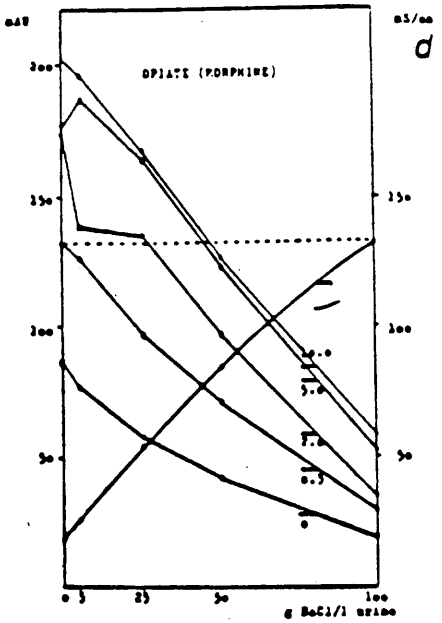
Apparatus

We measured the specific conductivity at 25 °C on a conductivity meter (Type CDM, with a CDC 304 electrode; Radiometer, Copenhagen). The EMIT drug-abuse urine assays were done according to the procedure by Schneider et al. (*2*) with a Gilford-300 spectrometer equipped with a Model 3017 thermocuvette thermostated at 37 °C. The change in absorbance during the first minute was measured with a recorder connected to the spectrometer.









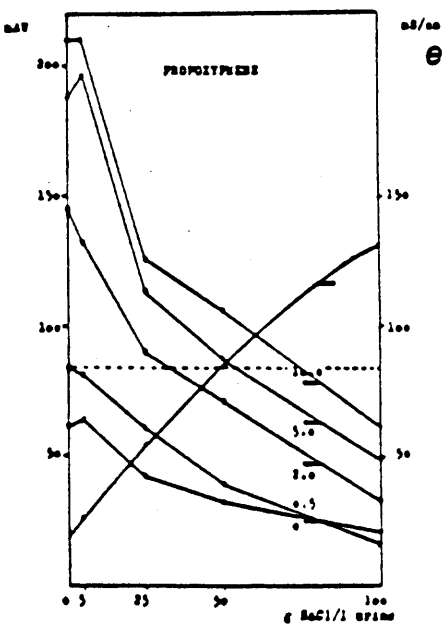


Fig. 1 *a–e*. Decrease in absorbance (in milliabsorbance units) at different drug concentrations (mg/liter of urine), and specific conductivity (mS/cm), as functions of added amounts of NaCl (g/liter of urine)

The dashed lines are drawn at the points that corresponds to absorbance decrease of urine containing no additional NaCl and a drug concentration of 0.5 mg/liter

Reagents

The urine specimens were collected from laboratory personnel and blood donors.

Drugs were added to a pooled sample of drug-free urine to give the following concentrations: 0, 0.5, 2.0, 5.0, and 10.0 mg per liter of urine. To each of these was added NaCl at the following concentrations: 0, 5, 25, 50, or 100 g/liter of urine; thus there were 25 different samples for each drug. Stock solutions of amphetamine, benzodiazepine (diazepam), methadone, opiates (morphine), and propoxyphene were 5.0 g/liter of methanol.

All reagents for the EMIT assays were those commercially available from Syva.

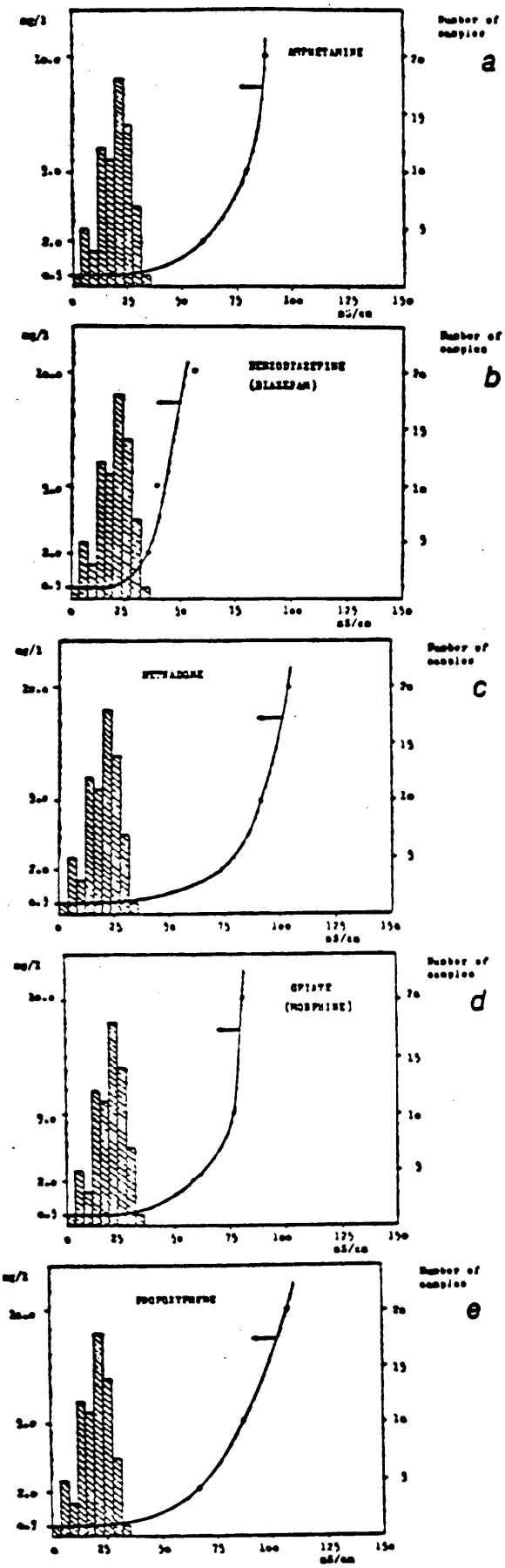


Fig. 2 *a–e*. Distribution of specific conductivities for urines from normal subjects, and minimal detectable concentration of drug (mg/liter) as a function of specific conductivity (mS/cm)

Results

Single determinations of the 5 × 5 × 5 experiment (five drugs, five drug concentrations, and five NaCl concentrations) were performed in one run, starting with the first drug at the lowest NaCl concentration, five determinations with increasing drug concentration, then at the next NaCl concentration, and so on, ending with the last drug. The results are presented graphically in Figure 1 *a–e*. The same urine pool from five normal persons was used for all five drugs. In the same figure is shown the specific conductivity vs. the added amount of NaCl. The dashed lines are drawn at the points that corresponds to absorbance decrease of urine containing no additional NaCl and a drug concentration of 0.5 mg/liter. We use this urine as our reference. If the absorbance change of the sample was smaller than that of the reference, the sample was considered negative. Where the dashed line in Figure 1 intercepts the curves corresponding to higher drug concentrations, we have read the NaCl amount on the abscissa and then converted this value into a specific conductivity from the Figure. In this way Figure 2 *a–e* was constructed. Points below the curves represent samples that will be considered negative, points above the curves represent positive samples in the EMIT assays. Furthermore, the conductivity distribution of urines from 28 women and 43 men is shown in Figure 2 *a–e*. The readings have been summarized in classes with a width of 4 mS/cm, starting with the class 0–4 mS/cm. The readings were to the first decimal place.

Discussion

We assume that the decreased sensitivity of the EMIT assays is a result of inactivation of the lysing enzyme because of the increasing ionic strength, and not a specific NaCl effect. In our experiment we varied the specific conductivity with NaCl, but common inorganic salts have similar specific conductivities (*3*). We chose NaCl because it is the predominant salt in urine, and is easily available for one attempting to escape the detection of drugs of abuse. From our results we conclude that the sensitivity of the EMIT assays strongly depends on the specific conductivity in urine. In our laboratory we want to maintain a sensitivity of about 0.5 mg of drug/liter of urine. Figure 2 *a–e* shows that by the EMIT technique we can obtain this sensitivity in urines with specific conductivities of less than about 35 mS/cm in assays of amphetamine, methadone, opiates, and propoxyphene, and about 20 mS/cm in the benzodiazepine assay. The specific conductivity in urine from normal subjects is such that the sensitivity of the EMIT assays will be adequate in most cases, but if the specific conductivity exceeds these values we directly analyze the urine sample by a thin-layer chromatographic method (*4*), which is not affected by high ionic strength.

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CLIN. CHEM. 22/7, 1110–1111 (1976)

Comparison of the EMIT (Enzyme Multiplied Immunoassay Technique) Opiate Assay and a Gas-Chromatographic–Mass-Spectrometric Determination of Morphine and Codeine in Urine

E. P. J. van der Slooten and H. J. van der Helm

We examined 124 urine samples with the EMIT opiate assay kit and with a gas-chromatographic–mass-spectrometric determination (I) for morphine and codeine. With a cut-off value between positive and negative results at 0.5 mg (morphine equivalents) per liter for both methods, the EMIT assay gave 4.0% false positives and 5.6% false negatives when compared with I. Lowering of the cut-off value for I to 0.1 mg/liter resulted in a decrease of false-positives to 1.6% and an increase of false-negatives to 6.4%, seemingly satisfactory for screening purposes.

Additional Keyphrases: *double-beam spectrophotometers in EMIT technique • inter-method comparison • abused drugs • "kit" methods*

Because of its high sensitivity and relative ease, the EMIT drug-abuse urine assay is widely used. However, the method has inherent disadvantages because of possible interferences of other drugs and urine constituents (e.g., enzyme inhibitors, salts, H^+, or OH^- ions). These difficulties have been recognized and led to comparisons of the EMIT assay with other methods, such as radioimmunoassay (*1–3*), hemagglutination inhibition (*2*), fluorometry (*2*), and thin-layer chromatography (*1–3*).

All these methods also have their limitations with respect to specificity or sensitivity. For this reason it is desirable to compare results by the EMIT assay with those from a sensitive and specific method. We therefore decided to compare the EMIT assay for morphine with a gas-chromatographic–mass-spectrometric (GC-MS) determination, because this technique combines high sensitivity and specificity (*4, 5*).

Materials and Methods

The GC-MS combination was a model JMS-07 S instrument (JEOL Ltd., Tokyo, Japan) with multiple ion detection capabilities. The conditions were: 1 m × 3 mm (i.d.) glass column filled with 3% OV 17 on Chromosorb W-HP, 80–100 mesh; injection temperature, 260 °C; column oven temperature, 230 °C; temperature of connection to mass spectrometer, 260 °C; helium flow, 40 ml/min; electron impact energy, 30 eV.

As the recommended automatic instrumentation for the EMIT opiate assay was not available to us, measurements were made on a Shimadzu UV-200 double-beam recording spectrophotometer with thermostated cuvette holder (Shimadzu Seisakusha Ltd., Tokyo, Japan).

EMIT opiate kits were obtained from Syva Corp., Palo Alto, Calif. 94304.

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Urines were obtained from outpatients attending a center for treatment of drug addicts (111 samples) and from inpatients of a general hospital (13 samples). The latter group of patients were receiving various medications, but no opiates.

EMIT Assay

Urine samples were, when necessary, centrifuged and the pH adjusted to 5.5–8.0.

The EMIT assay was slightly modified as follows. The bacterial suspension, prepared according to the EMIT procedure, was diluted by addition of 75 ml of EMIT buffer solution to 20 ml of suspension. Into a semi-micro cuvette (optical pathlength of 1.00 cm and 1.5 ml volume) were pipetted 0.95 ml of the diluted bacteria suspension, 0.10 ml of sample, and 0.05 ml of reagent A (antibody solution). After equilibration at 37 °C for 5 min, 50 µl of reagent B (enzyme solution) was added and the decrease in absorbance at 436 nm during the interval 10 to 50 s after this addition was measured from the recorder trace. The reference cell contained a similar cuvette filled with water.

The concentration of morphine equivalents was read from a calibration curve, prepared with EMIT standards in the same way. Urine samples giving a reading of more than 50 mg/liter were diluted with EMIT buffer and redetermined. On samples giving a reading of more than 0.5 mg/liter a blank lysozyme determination was performed, and if necessary the original reading was corrected accordingly. The within-run precision (CV) of the EMIT assay was 7% (n=38), the day-to-day precision 21% (n=29), determined in the range 0.5 to 50 mg/liter.

GC-MS Assay

The samples were hydrolyzed by adding to 15 ml of urine 1.5 ml of hydrochloric acid (8 mol/liter) and autoclaving for 30 min. The extraction and clean-up procedure were as described before (*6*). The dry residue was dissolved in 300 µl of methanol containing 3 mg of akineton (1-piperidino-1-phenyl-bicycloheptenyl-propanol-1) per milliliter as internal standard. Of this solution, 3 µl was injected into the GC-MS combination. The ions at *m/e* 294, 299, and 285 were monitored for akineton, codeine, and morphine, respectively. From the peak heights of these ions and calibration curves we calculated the concentration of codeine and morphine in the sample.

Akineton was chosen as internal standard because its retention time (.74) relative to morphine (1.00) and codeine (1.14) made it well suited for the production of a chromatogram containing three nicely discrete peaks, and because its mass spectrum contained an abundant fragment ion at *m/e* 294, well within range of the abundant molecular ions *m/e* 285 and *m/e* 299 from the spectrum of morphine and codeine, respectively.

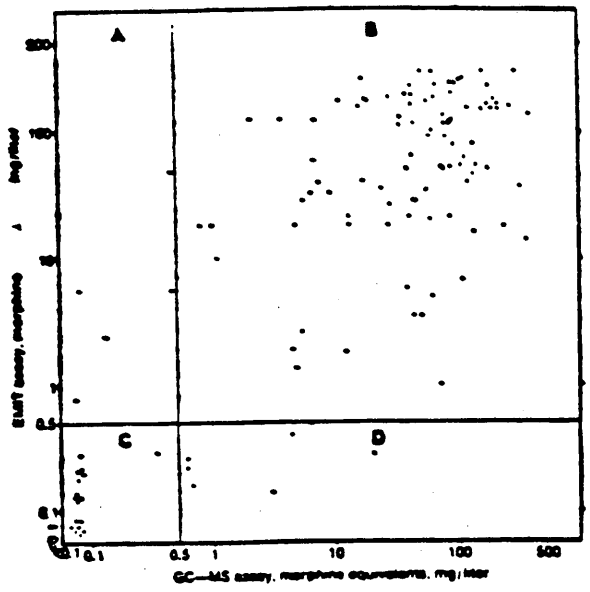

Fig. 1. Comparison of results by the EMIT method and the GC-MS method

Cut-off value between positives and negatives at 0.5 mg/liter (morphine-equivalents). Area *B* (95 samples) and *C* (17 samples): results by both methods positive and negative, respectively; area *A* (5 samples): EMIT positive, GC-MS negative; area *D* (7 samples): EMIT negative, GC-MS positive

We first checked the specificity of the method by injecting 13 blank samples; we saw no increase in the monitored ions. Next, 15 positive samples were re-injected, and the *m/e* ions 244, 229, and 215 (for akineton, codeine, and morphine) were monitored. The concentration of morphine and codeine, calculated from the peak heights of these fragments, agreed with the results of the first determination within the limits that could be expected from the variance of the method. Because the EMIT opiate assay measures both morphine and codeine, but with different sensitivity, results of the GC-MS codeine determinations were converted into morphine equivalents by using the data supplied by Syva Corp. The within-run precision (CV) of the GC-MS assay was 5% (n = 25), the day-to-day precision 7% (n = 21).

Results and Discussion

Figure 1 summarizes our results. Notwithstanding the fact that the precision of each method is reasonable, the correlation between them is poor—not unexpectedly, since several factors influence the accuracy of the results, such as:

- conjugated morphine and codeine are determined completely after hydrolysis by the GC-MS method; the EMIT method is less sensitive for these conjugated forms than for the free substances;
- the EMIT method has no absolute specificity, so cross-reactions with other substances present in urine may be possible;
- the antigen–antibody coupling or the lysozyme activity may be influenced by substances present in urine;
- preparation of samples for the GC-MS determination causes a loss of morphine and codeine; for morphine this loss is 6–15% (15 recovery determinations), for codeine 4–12% (15 recovery determinations); and
- dilution of urine samples when EMIT readings exceed 50 mg/liter may introduce some error (e.g., by changing the electrolyte content or the concentration of other substances in the sample).

For practical purposes only the results in terms of positive-negative are of interest. If a cut-off level of 0.5 mg/liter, as recommended for EMIT, is selected for both methods, and the results of the GC-MS method are accepted as true, area *A* of Figure 1 contains the falsely positive EMIT readings and area *D* the falsely negative. Expressed as percentage of the total number of determinations this amounts to 4.0% false-positives and 5.6% false-negatives.

It is not practical to select a much lower cut-off value for EMIT, because the difference in absorbance between negatives and low positives then becomes very small. For the GC-MS method it is possible, and also desirable, to select a lower value, because the presence of even a very small amount of morphine gives a positive result. With an arbitrarily chosen cut-off level of 0.1 mg/liter the falsely positive results decrease to 1.6%, the falsely negative increase to 6.4%.

Because in many practical situations a falsely positive result has more consequences than a falsely negative, and especially makes confirmation by another method necessary, one will generally try to limit the number of false-positives, even at the cost of an increased number of false-negatives. Thus, one may conclude from the results of the examined series that the EMIT method can be useful for the surveillance of drug abuse.

We thank Miss C. J. M. Leupers for her interest and excellent technical assistance.

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Specificity of the EMIT Drug Abuse Urine Assay Methods

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ABSTRACT

An investigation was conducted to determine the specificity of the EMIT DAU method of drugs of abuse analysis. Drug-free urine, from healthy volunteers, was individually spiked at 1000, 100, 10, and 1 μg/mL concentrations with each of 162 different drug substances. These spiked samples were analyzed with the EMIT DAU assay for amphetamines, barbiturates, benzodiazepine metabolites, cocaine metabolites, methadone, opiates, and propoxyphene. Although several of the test methods yielded positive results at a concentration of 1000 μg/mL, many drugs will probably not reach that concentration in the urine. The number of drugs giving a false positive at a concentration of 100 μg/mL was very low. The assay for cocaine metabolites gave no false positive results at any of the concentrations studied while the assay for methadone gave the largest number of false positive results. When interpreting the results of this investigation, one must consider that in many cases drug metabolites will exist in the urine, salt forms of the drugs studied were used, and ionic strength and pH effects can interfere with the lysozyme enzyme system used in the EMIT DAU assays. In summary, the proper utilization of specificity information may assist the analyst in explaining unusual

values obtained in the laboratory, particularly when the subject is concurrently using prescription or nonprescription medication.

INTRODUCTION

The EMIT DAU drug abuse urine assays have been proven to be of value as rapid, semiquantitative immunochemical tests for certain classes of drugs of abuse. Both performance of the assay and interpretation of the assay results are rapid, simple, and subject to relatively few sources of error. The primary sources of error in the performance of the assay appear to be due to:

1. Variations in the composition of unknown samples
2. Reproducibility of the measurements of sample and reagent volumes
3. Instrumental accuracy and reproducibility

There is another potential source of error in the interpretation of the results: the occurrence of false positive results. This is estimated to occur with an incidence of 3 to 5%. Although some of this can be related to "carry over" following positive samples, another source of false positives is the presence of other drug substances in the urine of the subjects. The purpose of this investigation was to study the incidence of false positives induced by spiking the urine of drug-free subjects with one of 162 drugs and subjecting this urine to the EMIT Drug Abuse Urine Assay. The results of this investigation would assist in determining the specificity of these assays and enable the analyst to explain some of the false positive results obtained in the laboratory.

MATERIALS AND METHODS

Drug substances were obtained from the manufacturer, either in pure form or as a labeled dilution (Table 1). One milligram equivalent of each pure drug was weighed using an electronic balance (Cahn Model 26, Cahn Instruments, Cerritos, California 90701) and placed in a 12 × 75 glass disposable culture tube (No. T12853, Scientific Products, McGray Park, Illinois 60085). Pooled urine from four healthy drug-free volunteers was assayed to assure negative values on each EMIT DAU assay. Exactly 1 mL of this urine was added to the drug substances in the test tubes. The tubes were vortexed and allowed to sit 24 h in a refrigerator prior to use. One hour before assaying, the tubes were removed from the refrigerator, vortexed, and allowed to return to room temperature. These urines were then analyzed with the EMIT DAU assays for amphetamines, barbiturates, benzodiazepine metabolites, cocaine metabolites, methadone, opiates, and propoxyphene (Tables 1 and 2) using a semiautomated pipettor/

TABLE 1. List of Drugs Used in Study

Generic name/brand name	Manufacturer/lot number	Lowest concentration giving a false positive result (μg/mL) (M = 1000, C = 100, X = 10)[a]						
		Am	Ba	Be	Co	Me	Op	Pr
Acetaminophen Tylenol	McNeil (7802739)							
Acetazolamide Diamox	Lederle (0363-A9549)							
Acetophenetidin	Mallinkrodt (PSJ1)							
Allopurinol Zyloprim	Burroughs-Wellcome (810179)							
Aminophylline	Merrell (NA)							
Amitriptyline HCl Elavil	MSD (L-720,101-01X22)				C	M	M	
Ammonium chloride	Mallinkrodt (JJZ)							
Amoxicillin trihydrate Amoxil	Beecham (821026)				M			
Amphotericin B Fungizone	Squibb (22-380-94498-005)							

(continued)

TABLE 1 (continued)

Generic name/brand name	Manufacturer/lot number	Lowest concentration giving a false positive result (μg/mL) (M = 1000, C = 100, X = 10)[a]						
		Am	Ba	Be	Co	Me	Op	Pr
Troleandomycin TAO	Pfizer (7D066-76QCS)							
Warfarin Na Coumadin	Endo (78-223)			M				

[a] Am = Amphetamines.
Ba = Barbiturates.
Be = Benzodiazepines.
Co = Cocaine.
Me = Methadone.
Op = Opiates.
Pr = Propoxyphene.

TABLE 2. Commercial Kits and Supplies Used[a]

Kit	Lot
Amphetamine DAU	J01
Barbiturate DAU	H02
Benzodiazepine DAU Assay	J02
Cocaine DAU Assay	H01
Methadone DAU Assay	H01
Opiate DAU Assay	H01A
Propoxyphene DAU Assay	J02
Bacteria Suspension	H101D
EMIT-DAU Buffer	H03
EMIT-DAU Negative Calibrator	H01B
EMIT-DAU Low Calibrator	H02B

[a]SYVA, 3181 Porter Drive, Palo Alto, California 94304.

diluter and spectrophotometer-microprocessor (Syva EMIT/LAB 5000, Syva, Palo Alto, California 94303). Negative and low calibrators were included periodically in the assay procedures. The results were interpreted and recorded.

A dilution of the aforementioned 1000 μg/mL sample for which positive results were obtained was made by taking 0.1 mL of the drug-urine mixture and adding 0.9 mL of drug-free urine. The concentration of the resulting urine-drug solution was 100 μg/mL. This procedure was followed to also obtain 10 and 1 μg/mL concentrations. The EMIT DAU assay [1] was performed and the results recorded.

RESULTS AND DISCUSSION

In the EMIT DAU assay the drug is labeled with an enzyme which, when bound to an antibody against the drug, reduces the activity of the enzyme. Since free drug in a sample competes with the enzyme-labeled drug for the antibody, the process of enzyme-inactivation is inhibited. Enzyme activity correlates with the concentration of free drug introduced and is measured by an absorbance change resulting from the enzyme's catalytic action on a substrate. There are numerous factors which can alter the results of the EMIT DAU assays as well as other enzymatic reactions. These include pH, high salt con-

centration, the presence of endogenous enzyme (lysozyme), and interfering drugs. The pH range specified for these assays is in the range of 5.5 to 8.0. In most instances the buffer supplied will be sufficient to bring the urine samples into the proper pH range. Approximately 2 to 4% of all urine samples contain sufficient lysozyme to produce false positive results [1]. This situation can be corrected by running suitable blanks. High salt concentrations, greater than 50 mg/mL NaCl, will result in false negative assay results and will necessitate an alternative method of analysis, i.e., TLC, HPLC, or GC [2]. The presence of interfering drugs will be discussed later.

In general, a false positive test result has greater impact on the status of the subject than a false negative test result. EMIT DAU assays are subject to a 3 to 5% incidence of false positives.

False positive test results can result from (1) contamination of calibrators or lysozyme in the reagents; (2) contamination or dilution of the low calibrator, resulting in a lower cutoff value; (3) contamination of the sample with saliva (which contains lysozyme); (4) carry-over following a high positive sample which results in a slight elevation of the subsequent assay; and (5) the presence of a drug or substance which cross-reacts with the enzyme-labeled drug for the antibody. False negative test results can arise from (1) adulteration of the urine sample, (2) the patient drinking excessively large quantities of water to dilute the urine, (3) adding salt to the urine, and (4) a urine with a pH range outside 5.5 to 8.0.

This investigation was concerned with the occurrence of false positive test results due to the presence of interfering drug substances. The results, tabulated and summarized in Table 1, use the average of the low calibrator values for the respective test as the cutoff value: everything greater than that value was interpreted as positive.

It was found that the cocaine metabolite assay yields the fewest false positives and the methadone assay the greatest. Also, there are several instances where one drug substance affects several assays, e.g., amitriptyline hydrochloride, brompheniramine maleate, desipramine hydrochloride, imipramine hydrochloride, indomethacin, methoxyphenamine hydrochloride, orphenadrine citrate, promethazine hydrochloride, propranolol hydrochloride, triethyperazine maleate, and tripelennamine. The antihistamines and tricyclic antidepressants are cross-reactants in numerous cases.

The amphetamine assay primarily detects amphetamine and methamphetamine. The manufacturer states that a small percentage of false positives may be observed in urines containing a high concentration of phenylpropanolamine and ephedrine. Other cross-reactants listed include phentermine, mephentermine, nylidrin, isoxsuprine, and methylphenidate. These correlate well with the results of the current investigation which expands the list to include other drugs, including additional sympathomimetic amines.

The barbiturate assay is designed to detect secobarbital, phenobarbital, butabarbital, pentobarbital, and amobarbital. A listed cross-

reactant is glutethimide which was confirmed in this study. Other cross-reactants found were several anticonvulsants and anti-inflammatory agents.

The benzodiazepine assay detects oxazepam in the urine and is utilized for diazepam and other benzodiazepines excreted as oxazepam. The manufacturer states that cross-reactivity with nonbenzodiazepine substances has not been observed. Twenty-six drugs were found that cross-reacted with this assay, as listed in Table 1, including several antihistamines and antispasmodics.

Benzoyl ecgonine is the substance detected in the cocaine metabolite assay. The product literature lists the belladonna alkaloids, barbiturates, and amphetamines as cross-reactants at levels at least 1000 μg/mL and greater. No cross-reactants were found for the cocaine metabolite assay in this investigation.

Methadone is detected as the parent compound in the urine. Cross-reactions with nonmethadone substances are usually not observed, according to the manufacturer: occasional exceptions are high concentrations of chlorpromazine, promethazine, and dextromethorphan. Thirty-six drug substances, as shown in Table 1, demonstrated the ability to provide false positive test results for the methadone assay, including 11 of the same compounds that yielded a false positive for the benzodiazepine assay.

The opiate assay is designed to detect morphine and morphine glucuronide, in addition to codeine, nalorphine, and meperidine in higher concentrations. Cross-reactants listed are chlorpromazine, naloxone, dextromethorphan, and methadone. The current study adds 19 additional cross-reactants, including numerous antihistamines and several tricyclic antidepressants. The low cut-off value (low calibrator) is adjusted by the manufacturer such that 95% of positive samples will be positive and 95% of negative samples will be negative. It can be altered to meet the specific requirements of a laboratory. One study [3] demonstrated a 4.0% incidence of false positives and a 5.6% incidence of false negatives for the opiate assay. By decreasing the low cut-off value from 0.5 μg (morphine equivalent)/mL to 0.1 μg/mL, the incidence of false positives decreased to 1.6% and the incidence of false negatives rose to 6.4%.

The propoxyphene assay is sensitive to propoxyphene and the major metabolite, N-demethyldextropropoxyphene (norpropoxyphene). Cross-reacting substances enumerated by the manufacturer include high concentrations of morphine, codeine, methadone, barbiturates, amphetamines, benzoyl ecgonine, chlorpromazine, oxazepam, and dextromethorphan. The current study provides eight more cross-reacting drugs, mostly antihistamines and tricyclic antidepressants.

The exact mechanism of the dynamics of cross-reactivity has not been explained: for example, what is the quantitative effect of one drug as compared to another on a specific EMIT DAU assay. One study [4] involved the effect of adding codeine to morphine samples analyzed by both enzyme immunoassay and radioimmunoassay. The results were not the simple weighted mean of the morphine and codeine concentra-

tions but were much higher. The presence of naloxone in another sample also gave a positive but unequal result. No attempt is made in this report to elucidate the cross-reactivity mechanism.

It should be noted that many of the drugs tested are salt forms of the parent drugs, and it has already been mentioned that ionic strength effects can alter assay results. However, the effect of increasing ionic strength by the addition of NaCl (at least 50 mg) is an increase in the incidence of false negative results [2]. The salts of the drugs utilized do not approach this concentration and false positive results were obtained, not false negative.

It is important to keep in perspective that most drugs will probably never accumulate to a concentration of 1000 μg/mL in the urine. The concentration a drug achieves in the urine is a function of many variables (e.g., dose, route of administration, metabolism, half-life, state of hydration of the patient, urinary volume, kidney function, and fluid intake). Many drugs will be present in the urine in the form of their metabolites as well as in their parent form.

Much more needs to be done to further enhance the interpretation of the EMIT DAU assays, including:

1. Studying the specificity of the assay in the presence of any of several hundred other drug substances
2. Studying the specificity of the assay in the presence of any of the metabolites of the hundreds of drugs used today
3. Studying the incidence of false negatives utilizing spiked urine containing drugs of abuse (positive samples) and any of the several hundred drugs commonly used in medical practice today
4. As above but using the metabolites of commonly used prescription drugs

In addition to the work on the EMIT DAU assays, the effects of commonly used prescription and nonprescription drugs on the EMIT assay results for serum levels should be investigated.

ACKNOWLEDGMENTS

The authors thank SYVA for furnishing the EMIT materials used in this study. Appreciation is also extended to the drug manufacturers listed in Table 1 for their generous supplies of the drug substances.

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Letters

Quality-Control Solution for Use in "ΔA_{450}" Determination of Amniotic Fluid

To the Editor:

It has been well established that the bilirubin concentration in amniotic fluid is a good indicator of increased hemoglobin degradation after fetal rhesus isoimmunization (*1*). Frequently the bilirubin concentration is not measured directly, but instead the absorbance change at 450 nm ("ΔA_{450}"), and this value is used as an indicator of bilirubin concentration. The technique used to measure the absorbance change is generally standardized (*2*), except for minor modifications. However, difficulties do arise when one attempts to implement a quality-control program.

The main problem stems from the instability of the bilirubin in amniotic fluid, which makes this material unsuitable for use as a quality control. The determination requires no reagents, so the primary reason for using a control is to provide a check on analytical technique. For this purpose, a fluid is needed that has a stable spectral response similar to that of amniotic fluid. A 2.34×10^{-3} mol/liter solution of 8-hydroxyquinoline in water (340 mg/liter; molecular mass 145.16) meets this need. Such a solution is close to the limit of solubility at room temperature (22 °C), but the solubility can be enhanced by adding a little hydrochloric acid or by using salts, such as the hemi-sulfate of 8-hydroxyquinoline. However, this is undesirable because of a spectral shift and decreased stability of the solution. We have found that the aqueous solution of 8-hydroxyquinoline is stable for at least one year at room temperature if precautions are taken to avoid excessive exposure to light (amber-colored bottle, stored away from direct sunlight). During two years use, we have established a ΔA_{450} value of 0.087 ± 0.004 (mean ± 2 SD; n = 300) for the 8-hydroxyquinoline solution. The spectral patterns of the 8-hydroxyquinoline solution and amniotic fluid so closely resemble one another that a "bilirubin" concentration can be calculated by applying a formula such as the one of Bjerre et al. (*3*).

Figure 1 shows the spectral tracings for a representative amniotic fluid and for the 8-hydroxyquinoline solution, Figure 2 the derivations of the ΔA_{450} values.

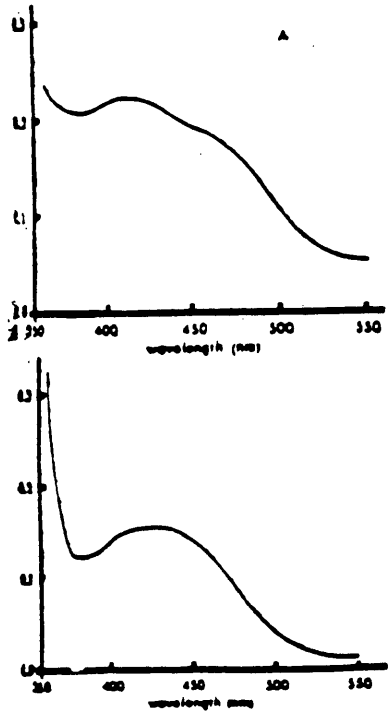

Fig. 1. Spectral tracing for an amniotic fluid specimen (*A*) and a 2.34×10^{-3} mol/liter solution of 8-hydroxyquinoline

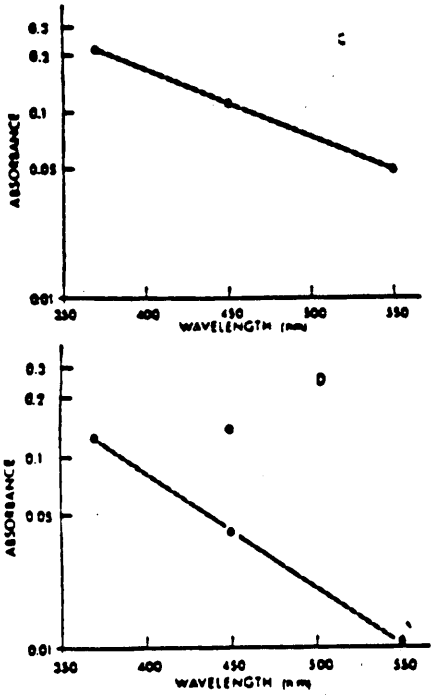

Fig. 2. Derivation of "ΔA_{450}" value for amniotic fluid specimen (*C*) and the 2.34×10^{-3} mol/liter solution of 8-hydroxyquinoline (*D*)

Absorbance values are plotted on a logarithmic scale, wavelength on a linear scale, at 370, 450, and 550 nm. A straight line is drawn between the 370-nm and 55-nm points. The derived absorbance value obtained from this line at 450 nm is the "baseline" absorbance at 450 nm. The difference between this and the measured absorbance at 450 nm is the ΔA_{450}

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Interference by NaCl with the EMIT Method of Analysis for Drugs of Abuse

To the Editor:

In our Toxicology Laboratory, we encounter schemes used by drug addicts on methadone detoxification programs to avoid our detection of drugs of abuse (*1*). Such efforts have included incorporation of a plastic bag filled with another's urine, concealed under the addict's clothing, connected with a long piece of plastic tubing running along the trunk of the body, and, on clinic visit, substituted for his own specimen. Another stratagem is to consume large quantities of fluids 2 to 4 h before urination, in the hope of diluting the urine to the point where the drug concentration may fall below the sensitivity of the method and thus escape detection. Methadone may be there in large quantities and may not be affected significantly by the dilution effect; thus this second scheme has limited success with both the thin-layer chromatographic or the EMIT (Syva, Palo Alto, Calif. 94304) methods for analysis for drugs of abuse.

Recently, a urine specimen to be analyzed for morphine, barbiturates, and methadone tested negative by EMIT, but positive for all three drugs by thin-layer chromatography. Further investigation revealed that the patient had added sodium chloride to the urine specimen. We undertook a preliminary investigation on the EMIT system by supplementing urine specimens known to be positive for morphine, barbiturates, and methadone with sodium chloride to concentrations up to 200 g/liter. When concentrations exceeded 50 g/liter, all specimens became negative. Thus, one should be alert for the possibility of addicts clandestinely placing salt in their urines to escape detection. Fortunately, the added salt appears to nullify all EMIT tests, so that all drugs tested will be negative, which in itself may be suspicious. Thin-layer chromatographic results are not affected (*2*).

pH and ionic strength play a definite role in the mechanism of enzymatic reactions (*3*), a role that becomes more complex in the case of EMIT (*4*). The effect we report here is probably attributable to an increase in ionic strength to above a critical point, at which so many ions congregate at one or more charged sites that they prevent the necessary interactions. If so, the effect is nonspecific and we would expect any salt solution that contributes a high ionic strength to work in a similar manner.

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Thin-Layer Chromatographic Detection of Quinine, Morphine, and Poly-Drugs

To the Editor:

We read with great interest the letter [*Clinical Chemistry* 22, 393 (1976)] by Wilkinson et al. in which they discussed the findings of a service laboratory that had mistakenly reported the presence of morphine and cocaine in an individual's urine. We believe that the authors' point with regard to the use of more than one analytical procedure for confirming positive results was a valid one. Another article, by McIntyre and Armande, which appeared in the same issue, discussed their ability to detect free morphine at a sensitivity of at least 0.5 mg/liter.

We wish to call the attention of readers of this journal to the thin-layer chromatographic technique used in this laboratory. It is capable of detecting free morphine in a concentration of 100–190 μg/liter of urine. It is used to analyze 3000 urine specimens per week for opiates (morphine, codeine, methadone, and quinine), and more than 1000 specimens for poly-drugs (15 drugs: opiates plus amphetamine, methamphetamine, phenmetrazine, methylphenidate, phenothiazines, sedatives, and hypnotics). The technique has been detailed elsewhere (*1, 2*). The following modifications have been introduced: (*a*) urine containing ion-paper is shaken for 20–30 min, (*b*) ratio of chloroform and isopropanol used is 5:2, and (*c*) drugs are extracted by shaking for 20 min. The sensitivity of this ion-exchange paper technique was described at the Sixth International Congress of Pharmacology (*3*).

The use of this single-step extraction and two-stage thin-layer development system enables us to measure the entire array of drugs of abuse in urine concomitantly in the following minimum concentrations (mg/liter, expressed as base): morphine, 0.1 (volume of urine, 50 ml) and 0.15–0.19 (volume urine, 20 ml); amphetamine, 0.87; methamphetamine, 0.4; phenmetrazine, 0.41; methylphenidate, 0.87; codeine, 0.35; methadone, 0.45–0.9; phenobarbital, 0.5; secobarbital, 0.36; propoxyphene, 0.90; and cocaine, 0.89. The volume of urine required for these sensitivities is 20–50 ml. We recommend that positive results so obtained for barbiturates be confirmed by respotting the residue and developing in another solvent. A technician can analyze 120 urine specimens for opiates and 80–90 specimens for poly-drugs per day. The cost of analysis for performing at least 4–5 tests (opiates) per urine specimen is $0.58 and for performing 9–15 tests (poly-drugs) is $0.82 per specimen (*4*), including labor, chemicals, and supplies. Our current total cost of analysis, including supervisory and administrative salaries (one chief toxicologist, one laboratory manager, one chief chemist), chemicals and supplies, laboratory rental, technical and support services, is $1.38 per specimen for monitoring 3500–4000 specimens per week. Set-up costs of a toxicology laboratory facility with thin-layer chromatography and various detection procedures currently used in drug-abuse screening programs are discussed elsewhere (*5, 6*).

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NATIONAL INSTITUTE ON DRUG ABUSE

URINALYSIS COLLECTION HANDBOOK FOR FEDERAL DRUG TESTING PROGRAMS

For Implementation
of the
Mandatory Guidelines
for Federal Workplace Drug Testing Programs

September 1988

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES
Public Health Service
Alcohol, Drug Abuse, and Mental Health Administration

URINE SPECIMEN COLLECTION

OVERVIEW

The urine specimen collector plays a key role in each Agency's drug testing component of the Agency Plan. As specimen collector, you may be the only Agency official in the program with whom employees come into direct contact. Individuals subject to testing hold a variety of positions within the Agency with varying levels of responsibility. Your professionalism, sensitivity, and compassion can greatly affect their attitudes and the credibility of your program. Treat them with the respect and dignity you would expect for yourself.

SCOPE OF RESPONSIBILITY

Specimen collection is the most vulnerable part of any drug testing program. The agency must be able to tie the result of a urinalysis drug test to a specific individual. Chain of custody is the term that refers to the process of ensuring and providing documentation of proper sample identification from time of collection to the receipt of laboratory results.

In order for the results of a particular specimen to withstand legal scrutiny, it is necessary to demonstrate:

- No adulteration or tampering has taken place
- Documentation of all personnel who handled the specimen
- No unauthorized access to the specimen was possible
- Specimen was handled in a secure manner
- Specimen belongs to the individual whose information is printed on the label

Since an individual normally provides a specimen in the privacy of a stall or other partitioned area that allows for individual privacy, there is an opportunity for drug users to subvert the collection process. For example, individuals may use one of the following methods to avoid detection of drug use:

A. Substitution - Liquids such as soda, tea, apple juice and clean urine (i.e., store bought, drug-free) are substituted for their own urine.

B. Adulteration - Addition into the urine specimen of foreign material that is known or thought to invalidate the test. Common substances include soap, household cleaners, salt, bleach, and drain cleaner. The effect of each of these adulterants varies with the test methods used. Adulterants are often detectable at the collection site by visual inspection of the specimen, or by smell and abnormal temperatures caused by the chemicals.

C. Dilution - Efforts to reduce the drug concentration in the urine to the point that it will not be reported by the drug testing laboratory. This may be done by adding water after the specimen is provided.

NATIONAL INSTITUTE ON DRUG ABUSE

MEDICAL REVIEW OFFICER MANUAL:

A GUIDE TO EVALUATING URINE DRUG ANALYSIS

For Implementation
of the
Mandatory Guidelines
for Federal Workplace Drug Testing Programs

September 1988

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES
Public Health Service
Alcohol, Drug Abuse, and Mental Health Administration

SUPPLEMENTAL AND BACKGROUND INFORMATION

In some agencies the MRO may have a broader role as an active consultant to management. This section is included to assist in that role.

False Negative Reports

Errors in handling or analysis, as discussed above, could result in false negative reports. Drug abusers also can generate false negatives by substituting another person's urine for their own. Containers of urine may be concealed in boots, in voluminous skirts, and elsewhere around the body. Sophisticated male drug abusers, expecting direct observation of their urination, have concealed IV-solution bags in the axilla with the IV tube running inside the sleeve to the hand. Without extremely close observation, the drug abuser then can hold the penis as if for normal urination, apply pressure with the arm at the axilla, and deliver a stream of someone else's urine into the cup. Some drug abusers who expect close monitoring apparently have emptied their own bladders, instilled another person's urine into the bladder with a catheter, and then have urinated that sample in the observer's presence.

These experiences highlight the intensity of drug-related deception among persons heavily involved with drugs. The strong drive to continue taking drugs may lead to elaborate efforts to conceal the use. Such deception, not uncommon in drug treatment clinics, does not necessarily indicate that the deceiver is a "bad" person or a "bad" employee; rather, it underscores the powerful behavioral effects of some drugs. Those who engage in such deception often respond well to treatment and rehabilitation.

In most cases the collector in the Federal urinalysis program does not directly observe the urination; most employees might consider such observation too demeaning. But it is difficult (although not impossible) for a drug abuser to maintain a urine sample at body temperature outside of the body. Thus, urine collectors measure sample temperature immediately upon delivery. Urine samples must range from 32.5°-37.7°C (90.5°-99.8°F) within 4 minutes of urination. If a sample is not in that range, the collector obtains another specimen under direct observation, and both are forwarded to the laboratory.

An employee also might produce a false negative test through intentional dilution or contamination of a sample. A large amount of salt added to a sample can invalidate an assay, or extensive tap water dilution of a sample may reduce the concentration of drug below measurable levels. Safeguards against these sources of false negatives include the collector's careful inspection for sample color and temperature. If dilution is suspected, measurement of creatinine content and osmolarity in the laboratory can provide the MRO with additional information; the latter procedures reveal either dilution or salting.

Elimination Rates

Additional problems may arise in the interpretation of urinary data. First, drug abusers may eliminate some drugs more rapidly from their systems by changing urinary pH. For example, the renal clearance of phencyclidine increases 4- to 5-fold when urinary pH is below 5. Accordingly, patients overdosed with phencyclidine or amphetamines sometimes are treated with ammonium chloride (NH_4Cl) to hasten detoxification. An apparently intoxicated employee, directed to produce a urine sample "for cause," may delay for several days and make dietary changes resulting in more acidic urine. This hastens elimination of basic drugs, and may avoid detection. Employees who misunderstand this effect may add acid to a urine sample; pH below the physiological range suggests that manipulation.

Urination "On Demand"

Employees may have difficulty initiating a urinary stream "on demand." Anxiety about urine testing really does impede urinary release in some people. Certain medical conditions may cause urinary retention or difficulty in initiating micturition. Drug-abusing employees may attempt to defer urination almost indefinitely. Not infrequently prescription and over-the-counter medications possessing anticholinergic properties may also prolong the process. However, an employee who cannot urinate when first requested to do so should remain in the test area, consuming liquids until able to do so. Eight ounces of water every thirty minutes will generally produce urination in even the most reluctant subject within 2-3 hours. There should be a firm policy that samples must be produced on the scheduled day, coupled with sympathetic recognition that this may be difficult for some anxious people.

Proffered Explanations

Among the many striking explanations offered for drug-positive urines is passive inhalation of marijuana smoke. "I have never smoked marijuana, but I was in a car with some guys who did"; "I know that the man across the hall from me smokes marijuana, and I had my door open last night."

Several studies have examined the detection of THC (tetrahydrocannabinol, the major psychoactive constituent of marijuana) among those passively exposed to marijuana smoke (Levine, 1983; Law et al., 1984; Morland et al., 1985; Cone et al., 1987).

While THC urine concentrations have been produced experimentally at sufficient levels, e.g., 100 ng/ml, to be detected in the Federal testing program, the smoke conditions of the room were extreme and not typical of social environmental conditions. Moreover, all subjects under these conditions have subjective psychoactive effects as well. Thus the claim of <u>innocent</u> passive inhalation in a confined area as an explanation for a positive urine test result is not acceptable.

Destroying the myth - " Creatinine: an ineffective tool for adulteration detection."

Renal Function Tests

Clinical Laboratory Procedures and Diagnosis

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tenth day. The subject with the smallest variation (CV = 5%), represented in the upper portion of Figure 1–2, excreted 90 percent of the mean on the sixth day and 113 percent on the twentieth day. Shown in the middle portion of Figure 1–2 is the subject with the average variation (CV = 11%), who excreted 129 percent of the mean on the second day and 81 percent on the twenty-first day.

This study indicates that the daily urinary excretion of creatinine can vary significantly not only among different subjects but also in the same subject from one day to another. Identical results [31, 50] have been reported by others, and they indicate that the daily urinary excretion of creatinine cannot be used as a reliable index of the completeness of urine collection.

Creatinine in Uremia and Creatinine Deficit

In acute renal failure [38], the plasma concentration of creatinine increases at a daily rate of 2 to 3 mg/dl in direct proportion to the amount of creatinine that is retained in the body and to the reduction in renal function. In chronic renal failure, on the contrary [30], the urinary excretion of creatinine decreases as plasma concentration rises, and the rate of daily increase in plasma concentration of creatinine [38] is only one-half to one-third of what is expected from the creatinine retained as a result of the fall in GFR. This creatinine deficit becomes apparent at plasma concentrations of creatinine higher than 6 mg/dl and cannot be accounted for entirely by a reduction in endogenous production [30]. It has been estimated that 16 to 66 percent of the creatinine formed in uremia is metabolized or excreted extrarenally [30]. The existence of routes of creatinine excretion and metabolism other than the kidneys have been investigated in uremic patients.

Creatinine is uniformly distributed throughout body water [59] and, like urea and uric acid [39], diffuses into the gut. At a normal plasma concentration the amount of creatinine entering the gut is negligible, but in uremia it becomes significant [38]. The bacterial proliferation (streptococci and enterococci) [62] that develops in the upper gastrointestinal tract of chronically uremic patients [40] plays an important role in the induction of a creatininase system that is related to the degradation of creatinine. Metabolites of creatinine [40] have been identified in the lumen of the gut, plasma, urine, and expired air in uremic patients, thus providing evidence that creatinine is metabolized in the gut and recycled. The recognition of this important secondary route of metabolism and excretion of creatinine in uremic patients explains the significant variations in urinary excretion, plasma concentration, and clearance of creatinine in some patients with renal disease and gives reason to question seriously the validity of creatinine as a reliable test of renal function in uremia [40].

If the release of creatinine from muscle stores continues unchanged after the onset of renal failure, and if creatinine is a specific and sensitive method for the estimation of GFR, it is to be expected that plasma creatinine will rise in proportion to the decrease in creatinine clearance. However, as previously demonstrated by others [18, 25] and as shown in Figure 1–3, when different levels of plasma creatinine concentration are related to their corresponding creatinine clearance, a linear relationship fails to develop. The results of studies correlating plasma concentration with creatinine clearance in 253 males are shown in Figure 1–3A; the results for 223 females are given in Figure 1–3B. The protocols that were followed for these studies of 1-hour creatinine clearance and the methods that were used for the analytical determinations of the samples are described in Chapter 3. In agreement with studies reported by others [18, 25], the following observations can be made by examining Figures 1–3A and 1–3B from right to left: First, in the region in which results consistent with marked reductions in renal function (as indicated by significant elevations in plasma concentration of creatinine and decreases in creatinine clearance) are plotted, with small fluctuations in creatinine clearance there are correspondingly large variations in plasma creatinine concentrations. Next, in the intermediate area of Figures 1–3A and 1–3B, where plasma creatinine levels range from 6 to 2 mg/dl, there is a transitional zone in which a linear relationship between plasma concentration and clearance of creatinine becomes apparent. Finally, as shown in the left portion of Figures 1–3A and 1–3B and corresponding to values consistent with normal levels of renal function, the linear relationship is again lost, and in this area small variations in plasma creatinine relate to significantly wide changes in creatinine clearance.

To determine the adequacy of the changes in plasma concentration of creatinine as they relate to creatinine clearance, a scattergram was constructed by separating the values illustrated in Figures 1–3A and 1–3B into four main categories. The results are illustrated in Figures 1–4A and 1–4B. If values of 1.2 mg/dl and 0.9 mg/dl are taken as the highest normal plasma concentration of creatinine for males and females, respectively, and 80 ml/min as the lowest normal clearance of creatinine for both sexes, it can be appreciated that in approximately 76 percent of the values in the male population and in 74 percent of the females there was an adequate correlation between plasma concentration and clearance of creatinine, that is, either normal levels of plasma creatinine corresponded to normal levels of creatinine clearance (left upper quadrant in Figures 1–4A and 1–4B), or abnormally elevated levels of plasma creatinine were related to reduced levels of creatinine clearance (right lower quadrant in Figures 1–4A and 1–4B). In approximately 23 percent of males and 25 percent of females, however, plasma creatinine levels were not appropriate when related to creatinine clearance, that is, either normal levels of plasma creatinine corresponded to decreased creatinine clearance (left lower quadrant in Figures 1–4A and 1–4B), or elevated levels of plasma creatinine were related to normal values of creatinine clearance (right upper quadrant in Figures 1–4A and 1–4B).

Several attempts have been made to develop reliable methods that will allow

5-2

formation may be obtained by relating the BUN to the plasma concentration of creatinine or the clearance of urea to the clearance of creatinine.

The normal BUN-plasma creatinine concentration ratio of 10:1 [19, 20, 68] is usually maintained in uremia but can be disrupted in some other clinical conditions. This ratio may rise [19, 20, 68] as a result of an increase in BUN in catabolic states, in prerenal azotemia, in uremic patients after a high protein intake, by absorption of blood from the gut after gastrointestinal bleeding, when urinary tract obstruction causes renal reabsorption of urea, or when, as a consequence of the implantation of the ureters into the lumen of the gut, urea is absorbed from the gastrointestinal tract.

The ratio of BUN to plasma creatinine may be lower [20] as BUN decreases as a result of starvation, after a low protein intake, in advanced liver failure, or as a result of an increase in plasma creatinine as seen after muscular breakdown in muscular subjects. Creatinine dialyzes less well than urea [20, 68], and patients in chronic dialysis may have plasma creatinine levels that are proportionately higher than the BUN.

In advanced renal failure [44] at levels of GFR of 20 ml/min and less, as the remaining nephrons undergo an osmotic diuresis, the reabsorption of urea by the renal tubules diminishes and the urea clearance, which is usually lower than the GFR, approximates the clearance of inulin. Similarly, as a tubular maximum secretory rate for creatinine is exceeded at these levels of renal insufficiency [1, 44], creatinine clearance, which at higher levels of GFR overestimates the clearance of inulin, decreases toward the GFR. Therefore, the mean values of urea and creatinine clearance correspond more closely to the clearance of inulin at such low levels of GFR [44], and this measurement has been recommended for the evaluation of the progression of renal failure in patients in terminal uremia.

Summary

As the automated method for creatinine determination is being adopted by most institutions, the measurement of creatinine is gaining in accuracy and reliability, and it is now possible to obtain more uniform information on the use of creatinine as an index of renal function. Although the technical difficulties of creatinine determination have been overcome to a large extent, there are still significant limitations on the validity of creatinine for the evaluation of GFR. These problems are exemplified by the uncertainties that have been introduced by the existence of a secretory mechanism in the renal handling of creatinine; by the effects of various factors, such as diet and exercise, on creatinine metabolism; by the shifting in the ratios of plasma true creatinine-noncreatinine chromogens and of creatinine clearance-inulin clearance in progressive renal failure; and, more significantly, by the induction of an extrarenal mechanism of creatinine metabolism and excretion in uremia.

In spite of all these disadvantages, however, creatinine is the only known substance in endogenous concentration in the body of which the clearance approximates the clearance of inulin, thus making its use for the estimate of GFR both practical and economical. If a lack of availability of a more reliable method makes the use of creatinine necessary for the evaluation of renal function, creatinine clearance is preferred over plasma creatinine concentration because the former correlates better with inulin clearance. Because of the difficulties inherent in prolonged urine collections, the ability of the patient to cooperate is critical in deciding among a 1-hour creatinine clearance, a 24-hour creatinine clearance, and a plasma creatinine determination. A single measurement of creatinine can be misleading in evaluating renal function, but serial determinations are helpful in detecting the direction of changes in renal disease.

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COUNCIL OF DEFENSE AND SPACE INDUSTRY ASSOCIATIONS

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September 18, 1992

Defense Acquisition Regulations Council
Attn: Mrs. Linda W. Neilson
OUSD(A)
3062 Defense Pentagon
Washington, D.C. 20301-3062

Dear Mrs. Neilson:

The undersigned associations of the Council of Defense and Space Industry Associations are pleased to respond to the July 23, 1992, Federal Register notice requesting comments on the proposed rule entitled, "Drug-Free Work Force," DAR Case 88-083. We strongly support Secretary Atwood's decision to reinstate the October 1988 interim rule and appreciate the opportunity to comment on this proposed rule.

We believe that contractors should be permitted to craft drug abatement programs tailored to their work force. These programs, to be effective, must be different at different locations because of varying demographics. Historically, however, most contractor programs provide, at a minimum, pre-employment testing, employee assistance programs, education and training, and appropriate drug testing.

Under these circumstances, an appropriate DoD rule would be one allowing flexibility for a contractor to design a program tailored to its particular situation. Such a program would be subject to governmental oversight and could include the option of random testing if a contractor so desired. The interim DFARS regulation, promulgated in 1988, and reinstated in July 1992, accomplishes the dual purposes of (1) requiring a program for achieving the objective of a drug-free work force, and (2) providing the flexibility for employer discretion as to the detailed elements of that program.

Therefore, absent a demonstrated problem peculiar to the defense contractor work force justifying more intrusive drug programs than already exist, the interim DFARS seems to suffice (without adding an addition annual cost of $185.5 million to a declining defense budget).

If DoD is resolved to pursue the approach taken in the proposed rule, then we respectfully request your careful consideration of the attached comments on the Federal Register proposal. Our point of contact is Patrick Sullivan, 202-371-8522.

We welcome the opportunity to discuss these comments further.

Sincerely,

Don Fuqua
President
Aerospace Industries Association

James R. Hogg
President
National Security Industrial Association

Dan C. Heinemeier
Vice President
Electronic Industries Association

Gary D. Engebretson
President
Contract Services Association

Bert M. Conklin
President
Professional Services Council

John J. Stocker
President
Shipbuilders Council of America

J. Richard Iverson
President
American Electronics Association

Enclosures: (1) Rationale
(2) Proposed Rule

DF:ps

ENCLOSURE (1)

RATIONALE

The following provides our rationale for the provisions included in the industry draft Drug free Work Force rule (Enclosure (2)) and our specific comments on the proposed rule:

(A) DEFINITIONS

(1)(i) "CONTROLLED SUBSTANCE". This definition is a modification of the definition of "illegal drugs" used in the 1988 rule, and the standards set out in (b)(4)(iv) of that rule. In our comments on the 1988 rule, we noted that NIDA has not established acceptable drug testing protocols for all of the drugs listed in Schedules I and II. Every variation of the DoD Drug-Free Work Force regulation (and this industry draft) require adherence to the "Mandatory Guidelines" issued by HHS. Particularly in light of the severe consequences for a finding of use of illegal drugs, we believe it essential that the government, the contractor and the employee have a uniform standard for determining violations.

We did not adopt the 1991 definition (which is also in the current FAR Drug-Free Work Place regulation) because the listing of all drugs on Schedules I through V would create an impossibility of performance for identification, testing and analysis. No NIDA protocols exist for drugs below Schedule II. It may be appropriate for the FAR rule to continue to cite Schedules I through V because that FAR rule does not provide for any testing requirements and only requires notice to employees and a statement of the contractor's enforcement policy for an employee found to be using drugs illegally.

(2) "EMPLOYEE IN A SENSITIVE POSITION". This key definition is a variation of the 1988 interim rule and the proposed rule. Our definition includes:

--an employee who has been "granted access to classified information at the secret or higher level". There has been confusion from the outset of the 1988 interim rule as to whether a contractor employee's access to "confidential" information was the type of access to "classified information" that should be automatically covered under the rule. In our view, only those employees with access to secret and higher levels of classification

should be automatically covered by the rule. We believe the contractor should be given the flexibility to determine whether an employee with only "confidential" access was in a "sensitive" position; under other provisions of the industry draft, the contractor would be able to make that determination.

--"EMPLOYEE IN ANY OTHER POSITION". This portion of the industry draft is taken from the 1988 interim rule. We agree with the formulation in the 1988 interim rule that the contractor is in the best position to determine which other employees are engaged in "national security, health or safety or functions...requiring a high degree of trust and confidence" such that the employee would be specifically brought within the scope of coverage of the rule.

--"SUCH OTHER POSITIONS". The 1991 final rule specifically listed categories of duties performed by contractor employees. By definition, all employees in those job classifications would be subject to the rule. In the industry draft, we have adopted many of those job categories (although not verbatim in each case) as illustrative of the minimum types of positions which the contractor should evaluate to determine whether employees in those job classifications were, in fact, engaged in "national security, health or safety or functions...requiring a high degree of trust and confidence" such that the employee should be, and therefore would be, specifically brought within the scope of coverage of the rule.

(B) POLICY

The statement of Policy in the industry draft is identical to the 1991 final rule. However, we have spelled out the specifics of the contractor's program in another section of our rule. We have retained the requirement for compliance with the Mandatory Guidelines issued by HHS in another section of our rule.

(C) PROGRAM

This section of the industry draft details the program that the contractor must have in order to be in compliance with the rule.

(1)(a). This paragraph requires the contractor to have a random drug testing program for employees in sensitive positions as part of the contractor's qualifying "program" to meet the requirements of our coverage. The requirement is taken from the clarification of the intended coverage of the 1988 interim rule, and provided for

explicitly in the 1991 final rule. We have, however, granted the contractor some flexibility in designing the specific elements of this mandatory random drug testing program (such as the criteria and test rate). These standards are taken directly from the 1988 interim rule.

(1)(b). This paragraph requires the contractor to have an employee assistance program and a program for self-referrals (or appropriate alternatives) as part of the contractor's qualifying "program" to meet the requirements of our coverage. This standard is taken directly from the 1988 interim rule.

(2) This paragraph also requires the contractor to have certain other forms of testing for employees in sensitive positions as part of the contractor's qualifying "program" to meet the requirements of our coverage. These other forms of testing are taken directly from the 1988 interim rule, with only minor word changes, and are consistent with the "no permission to work" policy standards in subsection (c)(1) of the 1991 final rule.

(3) This paragraph requires that any drug testing program carried out under this subsection, irrespective of the nature of the testing (i.e., random or for cause), must comply with the Mandatory Guidelines issued by HHS.

(D) NO PERMISSION TO WORK POLICY

This paragraph establishes the policy regarding when an employee must be removed from work in a "sensitive position". The three standards in our industry proposal are taken from the 1991 final rule, with only minor word changes.

(E) PERMISSION TO RETURN TO WORK POLICY

This paragraph establishes the policy regarding when an employee may be permitted to return to work in a sensitive position. The first requirement is that the contractor have an "established" procedure for making the determination of when an employee may otherwise return to work. This requirement is a reformulation of subsection (d) of the 1988 interim rule.

Our paragraph also establishes three additional specific criteria that the contractor must meet before permitting that employee to return to work in a sensitive position. The first criterion, that the employee can perform in the position, is taken from the 1988

interim rule. The second criterion, regarding compliance with the terms of a rehabilitation program, is a modification of the requirement used in the 1991 final rule. The third criterion, which requires the contractor to notify the contracting officer (or administrative contracting officer (ACO), if there is one) of the determination that the contractor has made to return an employee to work, is a new formulation.

In our view, this notification will provide the government with the visibility into the contractor's program and the actions taken specifically with respect to this employee that seem to be the basis for the requirement in the 1991 final rule for advance approval by the government. However, even with our formulation of a notice of action only, we remain extremely concerned about the legality of such notification. There are many who believe that even providing this minimal notification is, itself, a violation of the Privacy Act and other provisions of law. The implications for companies' trying to square compliance with our proposal and with provisions in the Americans with Disabilities Act and with privacy provisions in title 42 of the United States Code have also been raised.

Our industry proposal has not incorporated the provision from the 1991 final rule that requires the contracting officer to "approve" in advance whether the employee may return to work. As DoD officials acknowledge, the Department has no standards in place or contemplated to guide the contracting officer in making the determination; the contracting officer typically has no training or expertise to make those determinations; and the obligation for contract performance (including compliance with any version of this clause which is included in future contracts) rests with the contractor. For these, and other legal and policy reasons, we have not retained the requirement in the 1991 final rule for advance government approval before returning an employee to a sensitive position.

(F) PRECEDENCE

This key section of the industry proposal establishes the relationship between this DoD clause and other related obligations and limitations on implementation.

(1) Our proposal provides for an explicit precedence over any inconsistent state and local law, rule or regulation. This formulation is identical to the 1991 final rule. We opposed the

provision in the 1988 interim rule that permitted state and local laws to supersede this rule.

Our proposal also provides for an explicit precedence over any inconsistent collective bargaining agreement. This is a explicit reversal of the treatment of such agreements in the 1988 interim rule; the 1991 final rule was silent on its treatment of collective bargaining agreements, and we have interpreted such silence to infer a decision not to override such inconsistent collective bargaining agreements. We believe that the importance of this rule, coupled with the importance of achieving the greatest consistency in the compliance obligations with the rule, demand that inconsistent collective bargaining agreements be affirmatively superseded by this rule.

(2) Our proposal makes explicit that all costs, fines or penalties incurred by the contractor in carrying out this clause shall be fully allowable, to the extent reasonable, notwithstanding any other rule to the contrary. We recognize the uniqueness of writing in an affirmative allowability standard into a substantive rule rather than into a cost principle in Part 31. We have no objection to the location of the cost principle, and have incorporated it here for convenience. However, we feel strongly about the substance of the principle we have included here. It has been our position that in the absence of a cost principle to the contrary, the direct and associated costs of complying with the 1988 interim rule, the 1991 final rule, and even the essential elements of our industry proposal, would be "allowable" if otherwise meeting the traditional tests of allocability and reasonableness.

We do not believe it is enough to stop there, however. We are fully aware of the likelihood of significant legal challenges to contractors who seek, in good faith, to implement even the industry alternative, let alone the 1991 final rule. There will be costs associated with defending the contractor's actions, and the contractor may very well be held liable for fines and penalties for complying with the Department's rules. Therefore, we have provided for indemnification.

(3) Our proposal makes explicit in the clause that this clause does not apply to commercial products (as defined in FAR Part 11). This element is taken from the prescription of the 1988 interim rule, and we strongly support its retention. For unstated reasons, this exemption for commercial products was dropped from the 1991 final rule.

(4) Our proposal makes explicit in the clause that this clause does not apply to performance outside the United States. This is explicit in the FAR Drug-Free Workplace law and regulation, and was included in the prescription of the 1988 interim rule. For unstated reasons, this exemption for performance outside the United States was dropped from the 1991 final rule.

(5) Our proposal limits applicability of the clause to prime contracts only. This limitation is consistent with the application of the FAR Drug-Free Workplace regulation.

(6) Our proposal makes explicit in the clause that this clause does not apply to contracts below the small purchase threshold. This is explicit in the FAR Drug-Free Workplace law and regulation, and is consistent with other procurement policy actions by the Department of Defense.

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ENCLOSURE (2)

CODSIA PROPOSED
DRUG-FREE WORK FORCE CLAUSE

(A) DEFINITIONS

(1)(i) "Controlled substance" means a Schedule I and II drug, the possession of which is unlawful under law, and for which testing protocols established by the National Institute of Drug Abuse exist. The term does not include the use of a controlled substance pursuant to a valid prescription or other uses authorized by law.

(ii) "Employee" and "criminal drug statute" have the meanings given in the Drug-Free Workplace clause of this contract.

(2) "Employee in a sensitive position" as used in this clause, means, with respect to the performance of a contract with the Department of Defense, an employee who has been granted access to classified information at the secret or higher level of classification; and an employee in any other position that the contractor determines involves national security, health or safety, or functions other than the foregoing requiring a high degree of trust and confidence. Such other positions may include (i) possession or use of a firearm; (ii) design,

manufacture, test and evaluation of weapons, weapons systems, nuclear or toxic materials, or major components of the foregoing, which are directly contracted for by the Department of Defense; (iii) control or operation of items listed in (ii) above; (v) transportation, storage, or protection of toxic or nuclear materials, or munitions, or potentially dangerous materials (such as explosives or unstable chemicals) which are directly contracted for by the Department of Defense; (vi) direct treatment or rehabilitation of employees for unlawful use or abuse of controlled substances; or (vii) air traffic control. "Employee in a sensitive position" also means, at the discretion of the contractor, any other contractor personnel.

(B) POLICY
The contractor shall institute and maintain a program for achieving a drug-free work force as provided for in paragraph (C).

(C) PROGRAM
(1) The contractor's program shall include:
(a) random drug testing of employees in sensitive positions. The extent and frequency of, and criteria for, such testing shall be determined by the contractor based on the nature of the work performed, the employee's duties and the risk should the employee fail to adequately

perform his or her position; and

(b) the following, or appropriate alternatives:

(i) employee assistance programs, including contractor run, contractor sponsored, or contractor approved community based programs; and (ii) provisions for self-referrals and supervisory referrals.

(2) The contractor's program shall also include

(a) employee testing--

(i) upon reasonable suspicion that an employee uses a controlled substance;

(ii) when an employee has been involved in an on-the-job accident or unsafe practice;

(iii) as part of or as a follow-up to counselling or rehabilitation for illegal drug use.

(b) as part of a procedure of testing applicants for employment.

(3) Any drug testing program instituted under this clause shall conform to the "Mandatory Guidelines for Federal Workplace Drug Testing Programs" published by the Department of Health and Human Service (53 FR 11970), April 11, 1988.

(D) The Contractor shall not permit an employee to work in a sensitive position if

(1) the employee tests positive for the use of a controlled substance during a test pursuant to paragraphs (c)(1)(a) or (c)(2) of this clause;

(2) the use of a controlled substance is determined to be unlawful; or
(3) the employee is convicted of violating a criminal drug statute.

(E) The Contractor may permit an employee covered by paragraph (D) of this clause to work in a sensitive position in accordance with the contractor's established procedures only when--
(1) the contractor determines that the employee can adequately perform in his or her position;
(2) the employee is complying with any conditions or requirements of a rehabilitation program that the contractor requires; and
(3) the contractor notifies the contracting officer (or in the case of a contractor with a cognizant administrative contracting officer, such cognizant administrative contracting officer) of such determination.

(F)(1) This clause shall take precedence over any state or local law, rule or regulation or existing collective bargaining agreement to the contrary.
(2) "All costs incurred by the contractor in implementing this clause shall be fully allowable if otherwise reasonable, notwithstanding any rule to the contrary. The government agrees to indemnify the contractor for all other costs, including the costs of legal proceedings, fines, penalties,

judgments, and third party settlements concurred in by the government, if any, incurred by the contractor in carrying out this clause or defending any action brought against the contractor for complying with this clause."

(3) This clause shall not apply to commercial, or commercial-type products (See FAR 11.001).

(4) This clause shall not apply to a contract, or to that part of a contract, that is performed outside of the United States and its territories and possessions.

(5) This clause shall apply to the prime contract only.

(6) This clause shall not apply to any contract below the small purchase threshold (See FAR 13).

(end of clause)

DCS CORPORATION 1330 Braddock Place * Alexandria, Virginia 22314 * (703) 683-8430

August 5, 1992

Defense Acquisition Regulations Council
Attn: Mrs. Linda W. Neilson
OUSD A1. 3062 Defense Pentagon
Washington, D.C. 20301-3062

Re: DAR Case 88-083

Dear Mrs. Neilson:

In response to your request for comments regarding the Drug-Free Workforce Act, I would like to inform you of some of the difficulties we are encountering in establishing our random testing program:

1. Because the rule requires random testing for all "employees in a sensitive position", it is necessary for us to include employees who are located in our small offices, at least one of which is located in a rather remote location. We have several of these small offices scattered throughout the U.S. and it is difficult to find and make arrangements for collection sites which conform to the requirements you specify we must meet as stated in the "Mandatory Guidelines." I have not yet finished my research, but wonder what may happen if I am unable to find such sites? Could offices with less than (?) employees be exempted from the ruling, or could companies be allowed to deviate from the mandatory guidelines in selecting a collection site if unable to find one which meets all the guideline criteria?

2. Part of the mandatory guidelines [2.5 (d) (2)] stipulates that each agency must submit blind performance test specimens to its contract laboratories. The percentage of samples that must be submitted seems inordinately high given:

    a) The number of agencies using each approved laboratory;

    b) The quality assurance and quality control measures placed upon the laboratories and;

c) The expense to companies for the purchase of the specimens and payment for the testing to comply with this directive.

Since these costs are "allowable", contractors will be including them during the proposal process as part of their O/H expense, further adding to the government's cost of doing business. I do not believe the cost is justified and could be minimized by lowering the percentage of samples which must be submitted.

3. Despite the prominence of the MRO's function in the drug testing/verification process, the mandatory guidelines which we are required to follow place no "quality controls" on the MRO other than he/she be a "licensed physician with knowledge of substance abuse disorders." Since doctors, themselves, have a high percentage of substance abuse problems, this apparent lack of "quality control" over these physicians is somewhat troubling.

4. Finally, by whose authority does the DoD final ruling "take precedence over any state and local laws"?

Sincerely,

DCS CORPORATION

Barbara J. Napier
Human Resources Manager

BJN/mjw

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EAP ASSOCIATION

EMPLOYEE ASSISTANCE PROFESSIONALS ASSOCIATION, INC.

September 22, 1992

Defense Acquisition Regulations Council
ATTN: Mrs. Linda W. Neilson
OUSD(A)
3062 Defense Pentagon
Washington, DC 20301-3062

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Dear Mrs. Neilson:

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The Association's active membership represents most of the cumulative industry efforts to address workplace misuse and abuse of alcohol and other drugs. Additionally, we have a very active Department of Defense Special Interest Group which represents membership from all sizes of DoD contractor companies. As the spokesperson for these respective members, I would like to comment on the Department of Defense's request for comments notice printed in the July 23, 1992, *Federal Register*, **Defense Federal Acquisition; Regulation Supplement, Drug-Free Work Force.**

EAPA agrees illicit substance use and abuse has an adverse effect on the workplace. We do, however, maintain that the execution of a comprehensive drug-testing program alone is not the most effective way to deter substance abuse in the workplace. EAPA believes the implementation of a comprehensive Drug Free Workplace Program, utilizing employee assistance programs, as well as prevention programs and drug testing where appropriate, will more effectively respond to job performance and safety concerns at the workplace.

EAPA is concerned about the lack of a role for Employee Assistance Programs in the proposed rule. The notice proposes to incorporate by reference the "Mandatory Guidelines for Federal Workplace Drug Testing Programs; Final Guidelines," which require referral of a positive test result to an EAP. We believe that there should be an explicit reference to Employee Assistance Programs. Employees who test positive for illicit substances should immediately be referred to the employee assistance professional. This referral should be done regardless of disciplinary action taken by the employer, up to and including termination of the employee. Contractors, therefore, should be put on notice through an explicit reference in the rule to the requirement of an Employee Assistance Program.

The EAPA Board of Directors approved the following definition of an employee assistance program in 1988. This definition has been included in H.Rep. 102-522, which accompanied PL 102-321. To assist you in your efforts to appropriately include EAPs in the regulations, we recommend the following EAPA definition.

> ***An Employee Assistance Program (EAP) shall be a worksite-based program designed to assist in the identification and resolution of productivity problems associated with employees impaired by personal concerns, including, but not limited to: health, marital, family, financial, alcohol, drug, legal, emotional, stress, or other personal concerns that may adversely affect employee job performance.***
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We would also like to take this opportunity to comment on confidentiality. Employee Assistance Programs maintain a strict sense of confidentiality, including compliance with the U.S. Department of Health and Human Services, Title 42 CFR Part II: Confidentiality of Alcohol and Drug Abuse Patient Records; Final Rule, where applicable. From our perspective, confidentiality is the keystone of any successful employee assistance program, and if violated, would have negative repercussions throughout the industry. EAPA has developed *Standards for Employee Assistance Programs*. Included in the Standards is the following provision on confidentiality.

> ***The EAP Professional shall prepare and implement a written confidentiality policy consistent with all professional standards and ethics, and adhere to all other regulations that may apply to information in the possession of the EAP. Disclosures specified by government guidelines and EAP policy will be communicated to users of the EAP services. The limits of the confidentiality policy shall be disclosed in writing to those who use the EAP.***

EAPA is also concerned about the lack of supervisory training requirements in the proposed rule. As noted in the definition, an EAP provides appropriate ongoing training and education. The rule should include a provision for supervisory training to assist in identifying and addressing deteriorating job performance or judgement, or observation which may result from illegal drug use by an employee. In addition to supervisory training, we would suggest education on substance abuse.

On behalf of all of EAPA members, I would like to thank the U.S. Department of Defense for this opportunity to comment on this proposed regulation and contribute to a drug-free work environment.

Sincerely,

Michael L. Benjamin, MPH
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On behalf of all of EAPA members, I would like to thank the U.S. Department of Defense for this opportunity to comment on this proposed regulation and contribute to a drug-free work environment.

Sincerely,

Michael L. Benjamin, MPH
Chief Operating Officer

4601 North Fairfax Drive
Suite 1001
Arlington, VA 22203

Telephone (703) 522-6272
Fax (703) 522-4585

EAP · ASSOCIATION ·

EMPLOYEE ASSISTANCE PROFESSIONALS ASSOCIATION, INC.

September 22, 1992

Defense Acquisition Regulations Council
ATTN: Mrs. Linda W. Neilson
OUSD(A)
3062 Defense Pentagon
Washington, DC 20301-3062

Re: **DAR Case 88-083**

Dear Mrs. Neilson:

The Employee Assistance Professionals Association (EAPA) is the non-profit, international professional membership association representing individuals and organizations in the Employee Assistance Program (EAP) field. EAPA was founded in 1971 and presently has approximately 7,000 members and 85 chapters. It is governed by a voluntary Board of Directors and headquartered in Arlington, Virginia.

The Association's active membership represents most of the cumulative industry efforts to address workplace misuse and abuse of alcohol and other drugs. Additionally, we have a very active Department of Defense Special Interest Group which represents membership from all sizes of DoD contractor companies. As the spokesperson for these respective members, I would like to comment on the Department of Defense's request for comments notice printed in the July 23, 1992, *Federal Register*, **Defense Federal Acquisition; Regulation Supplement, Drug-Free Work Force.**

EAPA agrees illicit substance use and abuse has an adverse effect on the workplace. We do, however, maintain that the execution of a comprehensive drug-testing program alone is not the most effective way to deter substance abuse in the workplace. EAPA believes the implementation of a comprehensive Drug Free Workplace Program, utilizing employee assistance programs, as well as prevention programs and drug testing where appropriate, will more effectively respond to job performance and safety concerns at the workplace.

EAPA is concerned about the lack of a role for Employee Assistance Programs in the proposed rule. The notice proposes to incorporate by reference the "Mandatory Guidelines for Federal Workplace Drug Testing Programs; Final Guidelines," which require referral of a positive test result to an EAP. We believe that there should be an explicit reference to Employee Assistance Programs. Employees who test positive for illicit substances should immediately be referred to the employee assistance professional. This referral should be done regardless of disciplinary action taken by the employer, up to and including termination of the employee. Contractors, therefore, should be put on notice through an explicit reference in the rule to the requirement of an Employee Assistance Program.

The EAPA Board of Directors approved the following definition of an employee assistance program in 1988. This definition has been included in H.Rep. 102-522, which accompanied PL 102-321. To assist you in your efforts to appropriately include EAPs in the regulations, we recommend the following EAPA definition.

> ***An Employee Assistance Program (EAP) shall be a worksite-based program designed to assist in the identification and resolution of productivity problems associated with employees impaired by personal concerns, including, but not limited to: health, marital, family, financial, alcohol, drug, legal, emotional, stress, or other personal concerns that may adversely affect employee job performance.***
>
> ***The specific core activities of EAPs shall include both of the following: (1) Expert consultation and training to appropriate persons in the identification and resolution of job-performance issues related to the employee personal concerns listed above and (2) Programming characterized by confidential, appropriate, and timely problem assessment services; referrals for appropriate diagnosis, treatment, and assistance; establishment of linkages between workplace and community resources that provide such services; and follow-up activities for employees who use those services.***

We would also like to take this opportunity to comment on confidentiality. Employee Assistance Programs maintain a strict sense of confidentiality, including compliance with the U.S. Department of Health and Human Services, Title 42 CFR Part II: Confidentiality of Alcohol and Drug Abuse Patient Records; Final Rule, where applicable. From our perspective, confidentiality is the keystone of any successful employee assistance program, and if violated, would have negative repercussions throughout the industry. EAPA has developed *Standards for Employee Assistance Programs*. Included in the Standards is the following provision on confidentiality.

> ***The EAP Professional shall prepare and implement a written confidentiality policy consistent with all professional standards and ethics, and adhere to all other regulations that may apply to information in the possession of the EAP. Disclosures specified by government guidelines and EAP policy will be communicated to users of the EAP services. The limits of the confidentiality policy shall be disclosed in writing to those who use the EAP.***

EAPA is also concerned about the lack of supervisory training requirements in the proposed rule. As noted in the definition, an EAP provides appropriate ongoing training and education. The rule should include a provision for supervisory training to assist in identifying and addressing deteriorating job performance or judgement, or observation which may result from illegal drug use by an employee. In addition to supervisory training, we would suggest education on substance abuse.

On behalf of all of EAPA members, I would like to thank the U.S. Department of Defense for this opportunity to comment on this proposed regulation and contribute to a drug-free work environment.

Sincerely,

Michael L. Benjamin, MPH
Chief Operating Officer

Enzymatics, Inc.

500 Enterprise Road
Horsham, PA 19044
215-674-3288
Fax 215-674-3273
800-245-6845

September 14, 1992

Defense Acquisition Regulations Council
Attn: Mrs. Linda W. Neilson
OUSD(A), 3062 Defense Pentagon
Washington, D.C. 20301-3062

SUBJECT: DAR Case 88-083, Proposed Rule and Request for Comment

Dear Mrs. Neilson:

The purpose of this letter is to respond to the request for public comment concerning the Proposed Rule for implementing the Drug Free Workplace Regulation Supplement. It is our hope that the following information may be of assistance to the Department of Defense in promoting security and safety within the defense contractor-based workplace.

The preservation of National Security is obviously enhanced by a Drug-Free workplace. The Department of Defense, particularly the uniformed military services, have always been at the forefront of resolving troubling social issues in the United States. In the contractor/civilian-oriented drug-free workplace, however, the Departments of Energy and Transportation are setting the standard for excellence and rational thought by including alcohol in the concept for drug testing.

Promoting National Security and safety in the workplace are hollow concepts without including testing for the single most damaging drug in use in the United States: alcohol.

Since alcohol is the most abused drug in the United States, we recommend that the Department of Defense follow the leadership of the Departments of Energy and Transportation and amend Paragraph 223.570-1 Policy to read:

"...eliminating the unlawful use of any drug (to include alcohol) by employees whose duties affect health, safety, national security, or accomplishment of the DoD mission."

Further recommend that the Omnibus Transportation Employee Testing Act of 1991, established under Public Law 102-143, dated October 28, 1991 be viewed as a potential model for implementing alcohol testing DoD-wide within the contractor base. After all, the Transportation Industry is probably the single greatest asset in the United States promoting our collective National Security.

If the concept works for transportation, it should work for the defense contractors. From a practical point-of-view, it is less expensive to test for alcohol abuse, and the resultant savings in lives, injuries and so forth, is instantaneous because testing is real-time. Drug testing results, on the other hand, take days to receive while any damage done is to the National psyche and is usually a matter of historical record.

DoD must concentrate on solving real-time problems (alcohol abuse) with real-time impact on National Security on a real-time basis. Advanced technology now exists to address this problem of workplace drug abuse (alcohol abuse) in an economical and cost-effective manner. The same technology is being used widely in the military, and soon will be a part of the Transportation and Energy cultures.

Sincerely,

David E. Sanderson
Director of Government
Business Development

G
C A
N

Government Contractor's Assistance Network

Post Office Box 28944
Santa Ana, CA 92799-8944
(714) 542-2710
FAX: (714) 542-6814

September 14, 1992

Defense Acquisition Regulation Council
Attention: Mrs. Linda W. Neilson, OUSD (A)
3062 Defense Pentagon
Washington, DC 20301-3062

Subject: Drug-Free Work Force Policy

Reference: DAR Case 88-083, 57 FR 32769

Dear Mrs. Neilson:

In response to your solicitation for comments on the subject and referenced DAR Case, we are pleased to submit the following:

1. No issue is taken with the proposed clause as written.

2. It is our contention that the area that requires revision is the application. It is generally understood that some seventy percent (70%) of the dollars expended today on Department of Defense (DoD) contracts flow through the prime contractor to subcontractors and suppliers. Although our review of the legislative history leading to the Drug-Free Work Place Act reveals no proscription as to the flow down, neither the Federal Acquisition Regulation (FAR) or Department of Defense Federal Acquisition Regulation Supplement (DFARS) implementation of the Act provides for its flow down to subsequent tiers. Almost every other socio-economic clause requires flow down and places the burden on the prime contractor to monitor and ensure compliance and reporting.

3. The final clause should also establish and implement a program of compliance review to ensure ; (1) contractor implements a Drug-Free Program ; (2) contractor identifies employee's in sensitive positions which , and (3) establish the required re-habilitation programs for employee's who test positive.

Finally, in April of this year we addressed our concerns and recommendations to the Office of National Drug Control Policy and the DoD; reference the FAR clause.

Thank you for your cooperation in this matter; it is greatly appreciated.

Sincerely,

GOVERNMENT CONTRACTOR'S ASSISTANCE NETWORK

Herbert W. McCoy, CPPM, CF
Principal

Grumman Corporation
Bethpage, New York 11714-3582

CB&FP/CD-0992-17
18 September 1992

Defense Acquisition Regulations Council
Attn: Mrs. Linda W. Neilson, OUSD(A)
3062 Defense Pentagon
Washington, DC 20301-3062

Subject: DAR Case 88-083
Defense Federal Acquisition Regulation
Drug Free Work Force

Dear Mrs. Neilson:

The proposed final rule set forth at 57 Federal Register 32769-32770 makes three changes that together make this proposed rule burdensome and create serious legal issues. We suggest that the proposed rule be withdrawn.

The interim rule covers only employees granted access to classified information or other employees who the Contractor determines involve functions requiring a high degree of trust and confidence. The proposed final rule as defined would expand the coverage to almost every employee. Our analysis is that over eighty percent of our work force would fall into this category.

The interim rule gives the contractor considerable flexibility, both in establishing the criteria for a drug testing program and in dealing with those who are using drugs illegally. The proposed final rule would require that contractors start a random drug testing program for covered employees. The rule would further mandate that contractors "not permit" a covered employee to work on a DOD contract if he or she tests positive for illegal drug use.

Finally, the clause set forth in the interim rule specifically provides that the drug testing program "shall not apply" to the extent "inconsistent with State or local law." The clause set forth in the proposed final rule would provide that "the requirements of this clause take precedence over any State and local laws to the contrary."

Concerning the latter point, the kind of broadly-based compulsory random drug testing program contemplated by the proposed final rule is probably not valid under New York State law. See Fiorenza f. Grumman, 140 A.D. 2d 295, 527 NYS.2d 806 (1988). The final rule pre-empting of State and local legislation and possible individual rights of privacy considerations leaves the contractor vulnerable to Government and Personal Litigation.

The stipulation which requests the approval of the Contracting Officer before an employee can return to work after successfully completing a rehabilitation program conflicts with current employment practices. The responsibility for rehabilitation clearly rests with the employee and the employer. The final rule should not increase the administrative burden by interjecting the government into this process.

On the Federal level, there is considerable support for the proposition that this kind of broadly-based compulsory random drug testing program imposed by the Federal Government is unconstitutional. This is a violation of the right to protection against unreasonable searches and seizures provided by the Fourth Amendment to the U.S. Constitution. In the past, random drug testing programs have passed judicial muster when limited to such obviously critical employees as nuclear power plant employees or prison guards. A random sampling program aimed, according to the proposed final rule, at almost every employee involved in the manufacturing process, would very likely be held by the courts as constitutionally invalid. See Harmon v. Thornburgh, 878 F.2d 484 (D.C. Cir. 1989), cert. den. 110 S.Ct. 865 (1990).

Thank you for this opportunity to respond to the referenced proposed rule.

Very truly yours,

GRUMMAN CORPORATION
Corporate Operations

Ronald L. Smith
Director of Corporate Contracts
and Business Policy

RLS/es

cc: R. Fitzgerald
R. Foster
J. Groen
M. Polansky

ES-768

Grumman Corporate Operations
Bethpage New York 11714-3586

CB&FP/CD-0992-20
22 September 1992

Defense Acquisition Regulations Council
Attn: Mrs. Linda W. Neilson, OUSD(A)
3062 Defense Pentagon
Washington, DC 20301-3062

Subject: DAR Case 88-083
Defense Federal Acquisition Regulation
Drug Free Work Force

Reference: Grumman Corporation Letter
CB&FP/CD-0992-17 dated 18 September 1992

Dear Mrs. Neilson:

Per our above-referenced letter, the citation on page two, first paragraph, "Fiorenza f. Grumman," should be "Fiorenza v. Gunn."

I am sorry for this inconvenience.

Very truly yours,

GRUMMAN CORPORATION
Corporate Operations

for Ronald L. Smith
Director of Corporate Contracts
and Business Policy

RLS/es

ES-774

INSPECTOR GENERAL
DEPARTMENT OF DEFENSE
400 ARMY NAVY DRIVE
ARLINGTON, VIRGINIA 22202-2884

Audit Policy
and Oversight

AUG 18 1992

MEMORANDUM FOR DIRECTOR, DEFENSE ACQUISITION REGULATIONS COUNCIL

SUBJECT: Defense Acquisition Regulatory Case 88-083

The Office of the Inspector General, Department of Defense, does not wish to comment on Defense Acquisition Regulatory Case 88-083 (Drug-Free Work Force). We appreciate the opportunity to review the case.

Donald E. Davis
Deputy Assistant Inspector General
for Audit Policy and Oversight

International
Association of
Machinists and
Aerospace Workers

9000 Machinists Place
Upper Marlboro, Maryland 20772-2687

Area Code 301
967-4500

OFFICE OF THE GENERAL VICE PRESIDENT

GL 2 Legal Department

September 21, 1992

Defense Acquisitions Regulations Council
3062 Defense
Pentagon, Washington, DC 20301-3062

ATTENTION: Mrs. Linda W. Neilson, OUSD(A)

Subj: DAR CASE 88-083 - Comments of the International Association of Machinists and Aerospace Workers, AFL-CIO, and International Union of Electronic, Electrical, Salaried, Machine and Furniture Workers, AFL-CIO, in Response to the DOD's Proposed Rulemaking Concerning the Defense Federal Acquisition Regulation Supplemental Interim Rule for a Drug-Free Workplace

Dear Mrs. Neilson:

The International Association of Machinists and Aerospace Workers, AFL-CIO, and the International Union of Electronic, Electrical, Salaried, Machine and Furniture Workers, AFL-CIO, submit the enclosed Comments in response to the above-referenced proposed rule.

Sincerely yours,

Owen E. Herrnstadt
ASSOCIATE GENERAL COUNSEL
International Association of
Machinists and Aerospace Workers

OEH/bk

Enclosures

DAR CASE 88-083

COMMENTS OF THE INTERNATIONAL ASSOCIATION OF MACHINISTS AND AEROSPACE WORKERS, AFL-CIO, AND INTERNATIONAL UNION OF ELECTRONIC, ELECTRICAL, SALARIED, MACHINE AND FURNITURE WORKERS, AFL-CIO, IN RESPONSE TO THE DOD'S PROPOSED RULE-MAKING CONCERNING THE DEFENSE FEDERAL ACQUISITION REGULATION SUPPLEMENTAL INTERIM RULE FOR A DRUG-FREE WORKFORCE

The International Association of Machinists and Aerospace Workers, AFL-CIO, and International Union of Electronic, Electrical, Salaried, Machine and Furniture Workers, AFL-CIO, are labor unions representing employees in a variety of industries, including defense. Among other positions, IAM and IUE members employed in the defense industry include mechanics and related employees, machinists, tool and die makers, machine operators, helpers, production workers engaged in the manufacture of aircraft and other equipment and its component parts, and office and technical workers.

The proposed regulations depart from the DOD's interim rule issued in 1988 in several significant respects and could potentially result in random drug testing for tens of thousands of IAM and IUE represented workers. Perhaps the most significant departure is the vague and expansive definition of an employee in a "sensitive position." As proposed, the class of employees who will be required to undergo random testing would include virtually all employees engaged in the manufacture of defense equipment and its major component parts, regardless of whether the actual job functions of the employees are in any way "sensitive." In addition, the Notice does not address the potential costs of testing so many employees, nor the fact that defense contractors

will undoubtedly attempt to pass such costs on to the DOD and ultimately the American people.

The interim rule had stated that the clause's drug testing provisions were inapplicable to the extent they were inconsistent with an existing collective bargaining agreement. They also required the contractor to raise the inconsistencies in contract negotiations. The final regulations do not refer to collective bargaining at all. While we, of course, share the DOD's interest in safety, it is our view that the proposed rule is unsupported and concerns matters that should be resolved through labor-management negotiations rather than government-imposed regulations.

Thus, the Notice fails to document any need for the regulations it contains. This should not be surprising since no significant support for these regulations exist. Given this lack of basic information, there should be no effort to implement any type of drug testing program industry-wide until such time as there is hard evidence documenting industry-wide substance abuse problems that, in fact, are jeopardizing safety. In the event that there is such evidence, which at this time we doubt, then the problem should be addressed in the same manner that other problems of this nature have been dealt with in other industries -- through rehabilitation and drug awareness programs negotiated by employers and their unions.

If the DOD, nevertheless, insists on proceeding with industry-wide regulations concerning drug testing, then we strongly recommend that the regulations be in the form of guidelines for

those contractors who have documented substance abuse problems that are affecting safety. Such guidelines should encourage programs that have as their fundamental premise education and prevention of drug addiction. In addition DOD guidelines should require that any program fully protect employee privacy and provide nonpunitive, rehabilitation-oriented responses for those individuals whose drug addiction has, in fact, impaired their job performance.

With these basic principles in mind, any DOD guidelines regarding substance abuse programs also should include the following specific provisions:

1. Substance abuse is a treatable illness that will be viewed as any other long-term serious illness. In all cases, rehabilitation and education of affected employees will be the primary goal.

2. It will be recognized that while both contractors and employees have a proper interest in workplace safety and job performance, every employee has a right to his or her private life and no action shall be taken against an employee based on off-duty conduct unless it can be conclusively demonstrated that the employee's off-duty conduct is <u>specifically</u> and <u>directly</u> impairing his or her on-the-job performance.

3. It will follow then that the use of drug tests will be strictly limited to those situations where there is a

specific, objective reason to believe that the person who is to be tested is jeopardizing workplace safety or is not performing his or her job because of on-the-job intoxication and impairment. Random testing will not be permitted, nor may a contractor perform any test until the "reason to believe" the employee is impaired is documented in writing. This documentation will be by more than one management official and include someone who is not the employee's immediate supervisor. The employee's union representative shall be advised any time there is a request to submit to a drug test.

4. If and when drug tests are to be performed, there will be the maximum technological and procedural safeguards in place. Thus, only federally certified laboratory procedures will be utilized, and any laboratory selected must demonstrate that it observes the most rigorous quality control procedures, requires its technicians to be fully trained and experienced in the procedures being utilized, and has systems in place to assure a proper "chain of custody" of the samples taken. Furthermore, any employee who is required to take a drug test may, upon request, obtain a "split sample" to be tested by his or her own laboratory. The employee shall then have the right to challenge the accuracy of the employer's test results <u>prior</u> to any employer action.

a. DOD guidelines must further provide for retesting of any sample testing positive on an initial drug screen. This confirmation test shall be done using state-of-the-art gas chromatography and mass spectrometry. If a contractor fails to so confirm a positive test result, that test may not provide the basis for any adverse employment action, nor may any record of such an unconfirmed test be left in an employee's personnel file.

b. Any employee who tests negative or successfully challenges the accuracy of a positive result shall be compensated for the embarrassment, invasion of privacy, and mental duress involved in being required to submit to the process.

5. The DOD guidelines shall require that any employee who has a confirmed positive test will be referred to an agreed-upon rehabilitation program or Employer Assistance Plan established, where applicable, through the collective bargaining process. Rehabilitation shall be covered under established benefit plans and health insurance coverage. If it ever becomes necessary to impose discipline for on-the-job infractions that stem from substance induced impairment, discipline will be progressive and subject to challenge under the "just cause" provisions of any collective bargaining agreement.

* * * * * * * * * * *

We trust the foregoing responds to your request for comments. Where we have not commented, it is because the information is unavailable to us. Once again, we urge the DOD to move with great caution in this area so as to avoid unwarranted and unnecessary disruptions in the lives of our respective employees.

Thank you for considering our views.

Respectfully submitted,

George J. Kourpias

George J. Kourpias
INTERNATIONAL PRESIDENT
International Association of
Machinists and Aerospace Workers

William H. Bywater

William H. Bywater
INTERNATIONAL PRESIDENT
International Union of
Electronic, Electrical,
Salaried, Machine and
Furniture Workers

International Association of Machinists
and Aerospace Workers

LODGE NO. 389

AFFILIATED WITH DISTRICT NO. 50 AND CALIFORNIA STATE CONFERENCE OF MACHINISTS A. F. OF L.-C. I. O.

September 16, 1992

MACHINISTS UNION HALL
5150 KEARNY MESA ROAD
SAN DIEGO, CALIFORNIA 92111

PHONE 292-5150

Mrs. Linda W. Nelson, OUSED (A)
Defense Acquisition Regulations Council
3062 Defense Pentagon
Washington, D.C. 20301-3062

Subject: Proposed Random Drug Testing for US Navy Contract Procurement Language. (DAR Case 88-083)

Dear Mrs. Nelson:

In San Diego we represent over six hundred shipyard workers at National Steel and Shipbuilding Company (NASSCO), over one hundred shipyard workers at Campbell's Shipyard and a small number at several of the subcontractors on our waterfront.

Last May we received from NASSCO management a copy of the DOD's proposed new "Clause A, DRUG-FREE WORK FORCE (DEC 1991)" from its Federal Acquisition Regulations which states "as a minimum the program shall provide for the random drug testing of contractor employees working in sensitive positions."

Given the proposal's wide-ranging definition of "employee in a sensitive position" all of our production and maintenance workers in the shipyards plus many others working there would be subject to random drug testing. We think the proposal is very wrong and should not be adopted for the following reasons:

1. Random drug testing is an unreasonable invasion of our members' privacy absent any evidence of a particular problem of drug abuse in our shipyards. All of our employers on the waterfront have drug testing programs that include pre-hire screening, for cause testing and employee assistance programs to deal with what drug abuse problems we do have. No one has shown that these programs are inadequate.

2. Random drug testing in the eyes of many of our members means that they are suspected of drug abuse just because they happen to pull a wrench for a defense prime contractor. As veterans and loyal defense workers many of these people are insulted by such testing without cause. There is no real justification for singling them out from the rest of our population and subjecting them to random drug testing procedures. In fact they are less potentially dangerous to society than the car driver on the road.

3. The cost of the proposed random drug testing program on our shipbuilding and ship repair industry only adds to the current financial strains we are facing, especially in this period of

declining defense budgets. At a time when we must become competitive in the world market in order to survive, this proposal is but another cost disadvantage against foreign competitors who subsidize rather than punish their shipyards. It makes us less competitive not more competitive!

4. We are a partner in joint health and safety programs with most of our employers and believe that employee/employer cooperation and good OSHA laws and standards are the best tools to deal with health and safety issues in our shipyards. Random drug testing has never been an item on our or OSHA's agenda. We are the ones that work in these yards, who live and die with the health and safety problems we create. For an administration that preaches reducing government restrictions on business and reducing regulations, this proposal is going in the wrong direction.

5. Not only is this proposal unnecessary and unfair it is inconsistent because it does not require the same program for subcontractors. As a result in each shipyard subject to clause A there would be employees of the prime contractor who would be tested working along side employees of subcontractors who would not be subject to random drug testing. Is this fair or safe for the employees of the prime contractor? Is this fair to those shipyards who must bear the cost of the proposal while subcontractors do not? Is this bureaucratic nonsense or what?

Given these shortcomings the proposal we saw from DOD shows that the people who put it together are out of touch with the needs of the real world they are trying to make the rules for. Enough is enough. Please leave us alone. We have enough problems trying to survive without more hassles.

Sincerely,

Peter Zschiesche
Business Representative
PZ:lcb
opeiu-30

cc: Kourpias, Int'l Pres.
Poulin, GVP, NE Terr.
Ostro, GVP, West Terr.
Burnsky, MTD, AFL-CIO
Beck, Gen. Counsel
Batson, DBR
Hardin, Sec-Treas., PCMTDC
Maudlin, DBR
LL 389

TAMPA BAY AREA LODGE NO. 570

INTERNATIONAL ASSOCIATION of MACHINISTS and AEROSPACE WORKERS

August 24, 1992

From:
Bob Betterton
President
4020 80th Avenue
Pinellas Park, Fl. 34665

To:
The Defense Acquisition Regulations Council
Attn.: Mrs. Linda W. Nelson, OUSED (A)
3062 Defense Pentagon
Washington, D.C. 20301-3062

Dear Council,

It is our opinion and belief that the drug-free work force clause of September, 1988 should NOT be changed to accommodate random drug testing for the following reasons:

1.) It is an unreasonable and unacceptable invasion of privacy. (i.e.; body fluids)

2.) It is unfair to force the added financial burden on employers particularly at this time when most if not all shipyards in the United States are struggling to survive a dormant market in repairs and new ship construction.

3.) It has never been determined that a problem of drug abuse is at a level at our shipyards (i.e. The American Ship Building Co., Tampa Shipyards, Inc.) that warrants random vs. probable cause.

4.) It is our intention to see money spent that we as the work force, in partnership with our management, have determined to be real problems and a threat to our health and safety.

In conclusion, we feel that it would be a perfidious act for any agency or department of the United States Government to mandate random drug testing to private shipbuilding and repair yards.

Sincerely,

Bob Betterton

BB/kw
cc:file
E. House
G. Kourpias
R. Cox

TAMPA BAY AREA LODGE NO. 570

INTERNATIONAL ASSOCIATION of MACHINISTS and AEROSPACE WORKERS

August 24, 1992

From:
Bob Betterton
President
4020 80th Avenue
Pinellas Park, Fl. 34665

Subj: Random Drug Testing
DAR Case 88-083
United States Navy Contract
Procurement Language

To:
The Defense Acquisition Regulations Council
Attn.: Mrs. Linda W. Nelson, OUSED (A)
3062 Defense Pentagon
Washington, D.C. 20301-3062

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TAMPA BAY AREA LODGE NO. 570

INTERNATIONAL ASSOCIATION of MACHINISTS and AEROSPACE WORKERS

August 24, 1992

From:
Bob Betterton
President
4020 80th Avenue
Pinellas Park, Fl. 34665

Subj: Random Drug Testing
DAR Case 88-083
United States Navy Contract
Procurement Language

To:
The Defense Acquisition Regulations Council
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3062 Defense Pentagon
Washington, D.C. 20301-3062

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Sincerely,

Bob Betterton

BB/kw
cc:file
E. House
G. Kourpias
R. Cox

TAMPA BAY AREA LODGE NO. 570

INTERNATIONAL ASSOCIATION of MACHINISTS and AEROSPACE WORKERS

August 24, 1992

From:
Bob Betterton
President
4020 80th Avenue
Pinellas Park, Fl. 34665

Subj: Random Drug Testing
DAR Case 88-083
United States Navy Contract
Procurement Language

To:
The Defense Acquisition Regulations Council
Attn.: Mrs. Linda W. Nelson, OUSED (A)
3062 Defense Pentagon
Washington, D.C. 20301-3062

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Sincerely,

Bob Betterton

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cc:file
E. House
G. Kourpias
R. Cox

perform his or her position; and

(b) the following, or appropriate alternatives:

(i) employee assistance programs, including contractor run, contractor sponsored, or contractor approved community based programs; and (ii) provisions for self-referrals and supervisory referrals.

(2) The contractor's program shall also include

(a) employee testing--

(i) upon reasonable suspicion that an employee uses a controlled substance;

(ii) when an employee has been involved in an on-the-job accident or unsafe practice;

(iii) as part of or as a follow-up to counselling or rehabilitation for illegal drug use.

(b) as part of a procedure of testing applicants for employment.

(3) Any drug testing program instituted under this clause shall conform to the "Mandatory Guidelines for Federal Workplace Drug Testing Programs" published by the Department of Health and Human Service (53 FR 11970), April 11, 1988.

(D) The Contractor shall not permit an employee to work in a sensitive position if

(1) the employee tests positive for the use of a controlled substance during a test pursuant to paragraphs (c)(1)(a) or (c)(2) of this clause;

(2) the use of a controlled substance is determined to be unlawful; or
(3) the employee is convicted of violating a criminal drug statute.

(E) The Contractor may permit an employee covered by paragraph (D) of this clause to work in a sensitive position in accordance with the contractor's established procedures only when--
(1) the contractor determines that the employee can adequately perform in his or her position;
(2) the employee is complying with any conditions or requirements of a rehabilitation program that the contractor requires; and
(3) the contractor notifies the contracting officer (or in the case of a contractor with a cognizant administrative contracting officer, such cognizant administrative contracting officer) of such determination.

(F)(1) This clause shall take precedence over any state or local law, rule or regulation or existing collective bargaining agreement to the contrary.
(2) "All costs incurred by the contractor in implementing this clause shall be fully allowable if otherwise reasonable, notwithstanding any rule to the contrary. The government agrees to indemnify the contractor for all other costs, including the costs of legal proceedings, fines, penalties,

judgments, and third party settlements concurred in by the government, if any, incurred by the contractor in carrying out this clause or defending any action brought against the contractor for complying with this clause."

(3) This clause shall not apply to commercial, or commercial-type products (See FAR 11.001).

(4) This clause shall not apply to a contract, or to that part of a contract, that is performed outside of the United States and its territories and possessions.

(5) This clause shall apply to the prime contract only.

(6) This clause shall not apply to any contract below the small purchase threshold (See FAR 13).

(end of clause)

DCS CORPORATION 1330 Braddock Place * Alexandria, Virginia 22314 * (703) 683-8430

August 5, 1992

Defense Acquisition Regulations Council
Attn: Mrs. Linda W. Neilson
OUSD A1. 3062 Defense Pentagon
Washington, D.C. 20301-3062

Re: DAR Case 88-083

Dear Mrs. Neilson:

In response to your request for comments regarding the Drug-Free Workforce Act, I would like to inform you of some of the difficulties we are encountering in establishing our random testing program:

1. Because the rule requires random testing for all "employees in a sensitive position", it is necessary for us to include employees who are located in our small offices, at least one of which is located in a rather remote location. We have several of these small offices scattered throughout the U.S. and it is difficult to find and make arrangements for collection sites which conform to the requirements you specify we must meet as stated in the "Mandatory Guidelines." I have not yet finished my research, but wonder what may happen if I am unable to find such sites? Could offices with less than (?) employees be exempted from the ruling, or could companies be allowed to deviate from the mandatory guidelines in selecting a collection site if unable to find one which meets all the guideline criteria?

2. Part of the mandatory guidelines [2.5 (d) (2)] stipulates that each agency must submit blind performance test specimens to its contract laboratories. The percentage of samples that must be submitted seems inordinately high given:

    a) The number of agencies using each approved laboratory;

    b) The quality assurance and quality control measures placed upon the laboratories and;

c) The expense to companies for the purchase of the specimens and payment for the testing to comply with this directive.

Since these costs are "allowable", contractors will be including them during the proposal process as part of their O/H expense, further adding to the government's cost of doing business. I do not believe the cost is justified and could be minimized by lowering the percentage of samples which must be submitted.

3. Despite the prominence of the MRO's function in the drug testing/verification process, the mandatory guidelines which we are required to follow place no "quality controls" on the MRO other than he/she be a "licensed physician with knowledge of substance abuse disorders." Since doctors, themselves, have a high percentage of substance abuse problems, this apparent lack of "quality control" over these physicians is somewhat troubling.

4. Finally, by whose authority does the DoD final ruling "take precedence over any state and local laws"?

Sincerely,

DCS CORPORATION

Barbara J. Napier
Human Resources Manager

BJN/mjw

4601 North Fairfax Drive
Suite 1001
Arlington, VA 22203

Telephone (703) 522-6272
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EAP ASSOCIATION

EMPLOYEE ASSISTANCE PROFESSIONALS ASSOCIATION, INC.

September 22, 1992

Defense Acquisition Regulations Council
ATTN: Mrs. Linda W. Neilson
OUSD(A)
3062 Defense Pentagon
Washington, DC 20301-3062

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Dear Mrs. Neilson:

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The Association's active membership represents most of the cumulative industry efforts to address workplace misuse and abuse of alcohol and other drugs. Additionally, we have a very active Department of Defense Special Interest Group which represents membership from all sizes of DoD contractor companies. As the spokesperson for these respective members, I would like to comment on the Department of Defense's request for comments notice printed in the July 23, 1992, *Federal Register*, **Defense Federal Acquisition; Regulation Supplement, Drug-Free Work Force.**

EAPA agrees illicit substance use and abuse has an adverse effect on the workplace. We do, however, maintain that the execution of a comprehensive drug-testing program alone is not the most effective way to deter substance abuse in the workplace. EAPA believes the implementation of a comprehensive Drug Free Workplace Program, utilizing employee assistance programs, as well as prevention programs and drug testing where appropriate, will more effectively respond to job performance and safety concerns at the workplace.

EAPA is concerned about the lack of a role for Employee Assistance Programs in the proposed rule. The notice proposes to incorporate by reference the "Mandatory Guidelines for Federal Workplace Drug Testing Programs; Final Guidelines," which require referral of a positive test result to an EAP. We believe that there should be an explicit reference to Employee Assistance Programs. Employees who test positive for illicit substances should immediately be referred to the employee assistance professional. This referral should be done regardless of disciplinary action taken by the employer, up to and including termination of the employee. Contractors, therefore, should be put on notice through an explicit reference in the rule to the requirement of an Employee Assistance Program.

The EAPA Board of Directors approved the following definition of an employee assistance program in 1988. This definition has been included in H.Rep. 102-522, which accompanied PL 102-321. To assist you in your efforts to appropriately include EAPs in the regulations, we recommend the following EAPA definition.

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We would also like to take this opportunity to comment on confidentiality. Employee Assistance Programs maintain a strict sense of confidentiality, including compliance with the U.S. Department of Health and Human Services, Title 42 CFR Part II: Confidentiality of Alcohol and Drug Abuse Patient Records; Final Rule, where applicable. From our perspective, confidentiality is the keystone of any successful employee assistance program, and if violated, would have negative repercussions throughout the industry. EAPA has developed *Standards for Employee Assistance Programs*. Included in the Standards is the following provision on confidentiality.

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On behalf of all of EAPA members, I would like to thank the U.S. Department of Defense for this opportunity to comment on this proposed regulation and contribute to a drug-free work environment.

Sincerely,

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On behalf of all of EAPA members, I would like to thank the U.S. Department of Defense for this opportunity to comment on this proposed regulation and contribute to a drug-free work environment.

Sincerely,

Michael L. Benjamin, MPH
Chief Operating Officer

Enzymatics, Inc.

500 Enterprise Road
Horsham, PA 19044
215-674-3288
Fax 215-674-3273
800-245-6845

September 14, 1992

Defense Acquisition Regulations Council
Attn: Mrs. Linda W. Neilson
OUSD(A), 3062 Defense Pentagon
Washington, D.C. 20301-3062

SUBJECT: DAR Case 88-083, Proposed Rule and Request for Comment

Dear Mrs. Neilson:

The purpose of this letter is to respond to the request for public comment concerning the Proposed Rule for implementing the Drug Free Workplace Regulation Supplement. It is our hope that the following information may be of assistance to the Department of Defense in promoting security and safety within the defense contractor-based workplace.

The preservation of National Security is obviously enhanced by a Drug-Free workplace. The Department of Defense, particularly the uniformed military services, have always been at the forefront of resolving troubling social issues in the United States. In the contractor/civilian-oriented drug-free workplace, however, the Departments of Energy and Transportation are setting the standard for excellence and rational thought by including alcohol in the concept for drug testing.

Promoting National Security and safety in the workplace are hollow concepts without including testing for the single most damaging drug in use in the United States: alcohol.

Since alcohol is the most abused drug in the United States, we recommend that the Department of Defense follow the leadership of the Departments of Energy and Transportation and amend Paragraph 223.570-1 Policy to read:

"...eliminating the unlawful use of any drug (to include alcohol) by employees whose duties affect health, safety, national security, or accomplishment of the DoD mission."

Further recommend that the Omnibus Transportation Employee Testing Act of 1991, established under Public Law 102-143, dated October 28, 1991 be viewed as a potential model for implementing alcohol testing DoD-wide within the contractor base. After all, the Transportation Industry is probably the single greatest asset in the United States promoting our collective National Security.

If the concept works for transportation, it should work for the defense contractors. From a practical point-of-view, it is less expensive to test for alcohol abuse, and the resultant savings in lives, injuries and so forth, is instantaneous because testing is real-time. Drug testing results, on the other hand, take days to receive while any damage done is to the National psyche and is usually a matter of historical record.

DoD must concentrate on solving real-time problems (alcohol abuse) with real-time impact on National Security on a real-time basis. Advanced technology now exists to address this problem of workplace drug abuse (alcohol abuse) in an economical and cost-effective manner. The same technology is being used widely in the military, and soon will be a part of the Transportation and Energy cultures.

Sincerely,

David E. Sanderson
Director of Government
Business Development

G
C A
N

Government Contractor's Assistance Network

Post Office Box 28944
Santa Ana, CA 92799-8944
(714) 542-2710
FAX: (714) 542-6814

September 14, 1992

Defense Acquisition Regulation Council
Attention: Mrs. Linda W. Neilson, OUSD (A)
3062 Defense Pentagon
Washington, DC 20301-3062

Subject: Drug-Free Work Force Policy

Reference: DAR Case 88-083, 57 FR 32769

Dear Mrs. Neilson:

In response to your solicitation for comments on the subject and referenced DAR Case, we are pleased to submit the following:

1. No issue is taken with the proposed clause as written.

2. It is our contention that the area that requires revision is the application. It is generally understood that some seventy percent (70%) of the dollars expended today on Department of Defense (DoD) contracts flow through the prime contractor to subcontractors and suppliers. Although our review of the legislative history leading to the Drug-Free Work Place Act reveals no proscription as to the flow down, neither the Federal Acquisition Regulation (FAR) or Department of Defense Federal Acquisition Regulation Supplement (DFARS) implementation of the Act provides for its flow down to subsequent tiers. Almost every other socio-economic clause requires flow down and places the burden on the prime contractor to monitor and ensure compliance and reporting.

3. The final clause should also establish and implement a program of compliance review to ensure ; (1) contractor implements a Drug-Free Program ; (2) contractor identifies employee's in sensitive positions which , and (3) establish the required re-habilitation programs for employee's who test positive.

Finally, in April of this year we addressed our concerns and recommendations to the Office of National Drug Control Policy and the DoD; reference the FAR clause.

Thank you for your cooperation in this matter; it is greatly appreciated.

Sincerely,

GOVERNMENT CONTRACTOR'S ASSISTANCE NETWORK

Herbert W. McCoy, CPPM, CF
Principal

Grumman Corporation
Bethpage, New York 11714-3582

CB&FP/CD-0992-17
18 September 1992

Defense Acquisition Regulations Council
Attn: Mrs. Linda W. Neilson, OUSD(A)
3062 Defense Pentagon
Washington, DC 20301-3062

Subject: DAR Case 88-083
Defense Federal Acquisition Regulation
Drug Free Work Force

Dear Mrs. Neilson:

The proposed final rule set forth at 57 Federal Register 32769-32770 makes three changes that together make this proposed rule burdensome and create serious legal issues. We suggest that the proposed rule be withdrawn.

The interim rule covers only employees granted access to classified information or other employees who the Contractor determines involve functions requiring a high degree of trust and confidence. The proposed final rule as defined would expand the coverage to almost every employee. Our analysis is that over eighty percent of our work force would fall into this category.

The interim rule gives the contractor considerable flexibility, both in establishing the criteria for a drug testing program and in dealing with those who are using drugs illegally. The proposed final rule would require that contractors start a random drug testing program for covered employees. The rule would further mandate that contractors "not permit" a covered employee to work on a DOD contract if he or she tests positive for illegal drug use.

Finally, the clause set forth in the interim rule specifically provides that the drug testing program "shall not apply" to the extent "inconsistent with State or local law." The clause set forth in the proposed final rule would provide that "the requirements of this clause take precedence over any State and local laws to the contrary."

Concerning the latter point, the kind of broadly-based compulsory random drug testing program contemplated by the proposed final rule is probably not valid under New York State law. See Fiorenza f. Grumman, 140 A.D. 2d 295, 527 NYS.2d 806 (1988). The final rule pre-empting of State and local legislation and possible individual rights of privacy considerations leaves the contractor vulnerable to Government and Personal Litigation.

The stipulation which requests the approval of the Contracting Officer before an employee can return to work after successfully completing a rehabilitation program conflicts with current employment practices. The responsibility for rehabilitation clearly rests with the employee and the employer. The final rule should not increase the administrative burden by interjecting the government into this process.

On the Federal level, there is considerable support for the proposition that this kind of broadly-based compulsory random drug testing program imposed by the Federal Government is unconstitutional. This is a violation of the right to protection against unreasonable searches and seizures provided by the Fourth Amendment to the U.S. Constitution. In the past, random drug testing programs have passed judicial muster when limited to such obviously critical employees as nuclear power plant employees or prison guards. A random sampling program aimed, according to the proposed final rule, at almost every employee involved in the manufacturing process, would very likely be held by the courts as constitutionally invalid. See Harmon v. Thornburgh, 878 F.2d 484 (D.C. Cir. 1989), cert. den. 110 S.Ct. 865 (1990).

Thank you for this opportunity to respond to the referenced proposed rule.

Very truly yours,

GRUMMAN CORPORATION
Corporate Operations

Ronald L. Smith
Director of Corporate Contracts
and Business Policy

RLS/es

cc: R. Fitzgerald
R. Foster
J. Groen
M. Polansky

ES-768

Grumman Corporate Operations
Bethpage New York 11714-3586

CB&FP/CD-0992-20
22 September 1992

Defense Acquisition Regulations Council
Attn: Mrs. Linda W. Neilson, OUSD(A)
3062 Defense Pentagon
Washington, DC 20301-3062

Subject: DAR Case 88-083
Defense Federal Acquisition Regulation
Drug Free Work Force

Reference: Grumman Corporation Letter
CB&FP/CD-0992-17 dated 18 September 1992

Dear Mrs. Neilson:

Per our above-referenced letter, the citation on page two, first paragraph, "Fiorenza f. Grumman," should be "Fiorenza v. Gunn."

I am sorry for this inconvenience.

Very truly yours,

GRUMMAN CORPORATION
Corporate Operations

for Ronald L. Smith
Director of Corporate Contracts
and Business Policy

RLS/es

ES-774

INSPECTOR GENERAL
DEPARTMENT OF DEFENSE
400 ARMY NAVY DRIVE
ARLINGTON, VIRGINIA 22202-2884

Audit Policy
and Oversight

AUG 18 1992

MEMORANDUM FOR DIRECTOR, DEFENSE ACQUISITION REGULATIONS COUNCIL

SUBJECT: Defense Acquisition Regulatory Case 88-083

The Office of the Inspector General, Department of Defense, does not wish to comment on Defense Acquisition Regulatory Case 88-083 (Drug-Free Work Force). We appreciate the opportunity to review the case.

Donald E. Davis
Deputy Assistant Inspector General
for Audit Policy and Oversight

International
Association of
Machinists and
Aerospace Workers

9000 Machinists Place
Upper Marlboro, Maryland 20772-2687

Area Code 301
967-4500

OFFICE OF THE GENERAL VICE PRESIDENT

GL 2 Legal Department

September 21, 1992

Defense Acquisitions Regulations Council
3062 Defense
Pentagon, Washington, DC 20301-3062

ATTENTION: Mrs. Linda W. Neilson, OUSD(A)

Subj: DAR CASE 88-083 - Comments of the International Association of Machinists and Aerospace Workers, AFL-CIO, and International Union of Electronic, Electrical, Salaried, Machine and Furniture Workers, AFL-CIO, in Response to the DOD's Proposed Rulemaking Concerning the Defense Federal Acquisition Regulation Supplemental Interim Rule for a Drug-Free Workplace

Dear Mrs. Neilson:

The International Association of Machinists and Aerospace Workers, AFL-CIO, and the International Union of Electronic, Electrical, Salaried, Machine and Furniture Workers, AFL-CIO, submit the enclosed Comments in response to the above-referenced proposed rule.

Sincerely yours,

Owen E. Herrnstadt
ASSOCIATE GENERAL COUNSEL
International Association of
Machinists and Aerospace Workers

OEH/bk

Enclosures

DAR CASE 88-083

COMMENTS OF THE INTERNATIONAL ASSOCIATION OF MACHINISTS AND AEROSPACE WORKERS, AFL-CIO, AND INTERNATIONAL UNION OF ELECTRONIC, ELECTRICAL, SALARIED, MACHINE AND FURNITURE WORKERS, AFL-CIO, IN RESPONSE TO THE DOD'S PROPOSED RULE-MAKING CONCERNING THE DEFENSE FEDERAL ACQUISITION REGULATION SUPPLEMENTAL INTERIM RULE FOR A DRUG-FREE WORKFORCE

The International Association of Machinists and Aerospace Workers, AFL-CIO, and International Union of Electronic, Electrical, Salaried, Machine and Furniture Workers, AFL-CIO, are labor unions representing employees in a variety of industries, including defense. Among other positions, IAM and IUE members employed in the defense industry include mechanics and related employees, machinists, tool and die makers, machine operators, helpers, production workers engaged in the manufacture of aircraft and other equipment and its component parts, and office and technical workers.

The proposed regulations depart from the DOD's interim rule issued in 1988 in several significant respects and could potentially result in random drug testing for tens of thousands of IAM and IUE represented workers. Perhaps the most significant departure is the vague and expansive definition of an employee in a "sensitive position." As proposed, the class of employees who will be required to undergo random testing would include virtually all employees engaged in the manufacture of defense equipment and its major component parts, regardless of whether the actual job functions of the employees are in any way "sensitive." In addition, the Notice does not address the potential costs of testing so many employees, nor the fact that defense contractors

will undoubtedly attempt to pass such costs on to the DOD and ultimately the American people.

The interim rule had stated that the clause's drug testing provisions were inapplicable to the extent they were inconsistent with an existing collective bargaining agreement. They also required the contractor to raise the inconsistencies in contract negotiations. The final regulations do not refer to collective bargaining at all. While we, of course, share the DOD's interest in safety, it is our view that the proposed rule is unsupported and concerns matters that should be resolved through labor-management negotiations rather than government-imposed regulations.

Thus, the Notice fails to document any need for the regulations it contains. This should not be surprising since no significant support for these regulations exist. Given this lack of basic information, there should be no effort to implement any type of drug testing program industry-wide until such time as there is hard evidence documenting industry-wide substance abuse problems that, in fact, are jeopardizing safety. In the event that there is such evidence, which at this time we doubt, then the problem should be addressed in the same manner that other problems of this nature have been dealt with in other industries -- through rehabilitation and drug awareness programs negotiated by employers and their unions.

If the DOD, nevertheless, insists on proceeding with industry-wide regulations concerning drug testing, then we strongly recommend that the regulations be in the form of guidelines for

those contractors who have documented substance abuse problems that are affecting safety. Such guidelines should encourage programs that have as their fundamental premise education and prevention of drug addiction. In addition DOD guidelines should require that any program fully protect employee privacy and provide nonpunitive, rehabilitation-oriented responses for those individuals whose drug addiction has, in fact, impaired their job performance.

With these basic principles in mind, any DOD guidelines regarding substance abuse programs also should include the following specific provisions:

1. Substance abuse is a treatable illness that will be viewed as any other long-term serious illness. In all cases, rehabilitation and education of affected employees will be the primary goal.

2. It will be recognized that while both contractors and employees have a proper interest in workplace safety and job performance, every employee has a right to his or her private life and no action shall be taken against an employee based on off-duty conduct unless it can be conclusively demonstrated that the employee's off-duty conduct is <u>specifically</u> and <u>directly</u> impairing his or her on-the-job performance.

3. It will follow then that the use of drug tests will be strictly limited to those situations where there is a

specific, objective reason to believe that the person who is to be tested is jeopardizing workplace safety or is not performing his or her job because of on-the-job intoxication and impairment. Random testing will not be permitted, nor may a contractor perform any test until the "reason to believe" the employee is impaired is documented in writing. This documentation will be by more than one management official and include someone who is not the employee's immediate supervisor. The employee's union representative shall be advised any time there is a request to submit to a drug test.

4. If and when drug tests are to be performed, there will be the maximum technological and procedural safeguards in place. Thus, only federally certified laboratory procedures will be utilized, and any laboratory selected must demonstrate that it observes the most rigorous quality control procedures, requires its technicians to be fully trained and experienced in the procedures being utilized, and has systems in place to assure a proper "chain of custody" of the samples taken. Furthermore, any employee who is required to take a drug test may, upon request, obtain a "split sample" to be tested by his or her own laboratory. The employee shall then have the right to challenge the accuracy of the employer's test results <u>prior</u> to any employer action.

a. DOD guidelines must further provide for retesting of any sample testing positive on an initial drug screen. This confirmation test shall be done using state-of-the-art gas chromatography and mass spectrometry. If a contractor fails to so confirm a positive test result, that test may not provide the basis for any adverse employment action, nor may any record of such an unconfirmed test be left in an employee's personnel file.

b. Any employee who tests negative or successfully challenges the accuracy of a positive result shall be compensated for the embarrassment, invasion of privacy, and mental duress involved in being required to submit to the process.

5. The DOD guidelines shall require that any employee who has a confirmed positive test will be referred to an agreed-upon rehabilitation program or Employer Assistance Plan established, where applicable, through the collective bargaining process. Rehabilitation shall be covered under established benefit plans and health insurance coverage. If it ever becomes necessary to impose discipline for on-the-job infractions that stem from substance induced impairment, discipline will be progressive and subject to challenge under the "just cause" provisions of any collective bargaining agreement.

* * * * * * * * * * *

We trust the foregoing responds to your request for comments. Where we have not commented, it is because the information is unavailable to us. Once again, we urge the DOD to move with great caution in this area so as to avoid unwarranted and unnecessary disruptions in the lives of our respective employees.

Thank you for considering our views.

Respectfully submitted,

George J. Kourpias

George J. Kourpias
INTERNATIONAL PRESIDENT
International Association of
Machinists and Aerospace Workers

William H. Bywater

William H. Bywater
INTERNATIONAL PRESIDENT
International Union of
Electronic, Electrical,
Salaried, Machine and
Furniture Workers

International Association of Machinists
and Aerospace Workers

LODGE NO. 389

AFFILIATED WITH DISTRICT NO. 50 AND CALIFORNIA STATE CONFERENCE OF MACHINISTS A. F. OF L.-C. I. O.

September 16, 1992

MACHINISTS UNION HALL
5150 KEARNY MESA ROAD
SAN DIEGO, CALIFORNIA 92111

PHONE 292-5150

Mrs. Linda W. Nelson, OUSED (A)
Defense Acquisition Regulations Council
3062 Defense Pentagon
Washington, D.C. 20301-3062

Subject: Proposed Random Drug Testing for US Navy Contract Procurement Language. (DAR Case 88-083)

Dear Mrs. Nelson:

In San Diego we represent over six hundred shipyard workers at National Steel and Shipbuilding Company (NASSCO), over one hundred shipyard workers at Campbell's Shipyard and a small number at several of the subcontractors on our waterfront.

Last May we received from NASSCO management a copy of the DOD's proposed new "Clause A, DRUG-FREE WORK FORCE (DEC 1991)" from its Federal Acquisition Regulations which states "as a minimum the program shall provide for the random drug testing of contractor employees working in sensitive positions."

Given the proposal's wide-ranging definition of "employee in a sensitive position" all of our production and maintenance workers in the shipyards plus many others working there would be subject to random drug testing. We think the proposal is very wrong and should not be adopted for the following reasons:

1. Random drug testing is an unreasonable invasion of our members' privacy absent any evidence of a particular problem of drug abuse in our shipyards. All of our employers on the waterfront have drug testing programs that include pre-hire screening, for cause testing and employee assistance programs to deal with what drug abuse problems we do have. No one has shown that these programs are inadequate.

2. Random drug testing in the eyes of many of our members means that they are suspected of drug abuse just because they happen to pull a wrench for a defense prime contractor. As veterans and loyal defense workers many of these people are insulted by such testing without cause. There is no real justification for singling them out from the rest of our population and subjecting them to random drug testing procedures. In fact they are less potentially dangerous to society than the car driver on the road.

3. The cost of the proposed random drug testing program on our shipbuilding and ship repair industry only adds to the current financial strains we are facing, especially in this period of

declining defense budgets. At a time when we must become competitive in the world market in order to survive, this proposal is but another cost disadvantage against foreign competitors who subsidize rather than punish their shipyards. It makes us less competitive not more competitive!

4. We are a partner in joint health and safety programs with most of our employers and believe that employee/employer cooperation and good OSHA laws and standards are the best tools to deal with health and safety issues in our shipyards. Random drug testing has never been an item on our or OSHA's agenda. We are the ones that work in these yards, who live and die with the health and safety problems we create. For an administration that preaches reducing government restrictions on business and reducing regulations, this proposal is going in the wrong direction.

5. Not only is this proposal unnecessary and unfair it is inconsistent because it does not require the same program for subcontractors. As a result in each shipyard subject to clause A there would be employees of the prime contractor who would be tested working along side employees of subcontractors who would not be subject to random drug testing. Is this fair or safe for the employees of the prime contractor? Is this fair to those shipyards who must bear the cost of the proposal while subcontractors do not? Is this bureaucratic nonsense or what?

Given these shortcomings the proposal we saw from DOD shows that the people who put it together are out of touch with the needs of the real world they are trying to make the rules for. Enough is enough. Please leave us alone. We have enough problems trying to survive without more hassles.

Sincerely,

Peter Zschiesche
Business Representative
PZ:lcb
opeiu-30

cc: Kourpias, Int'l Pres.
Poulin, GVP, NE Terr.
Ostro, GVP, West Terr.
Burnsky, MTD, AFL-CIO
Beck, Gen. Counsel
Batson, DBR
Hardin, Sec-Treas., PCMTDC
Maudlin, DBR
LL 389

TAMPA BAY AREA LODGE NO. 570

INTERNATIONAL ASSOCIATION of MACHINISTS and AEROSPACE WORKERS

August 24, 1992

From:
Bob Betterton
President
4020 80th Avenue
Pinellas Park, Fl. 34665

To:
The Defense Acquisition Regulations Council
Attn.: Mrs. Linda W. Nelson, OUSED (A)
3062 Defense Pentagon
Washington, D.C. 20301-3062

Dear Council,

It is our opinion and belief that the drug-free work force clause of September, 1988 should NOT be changed to accommodate random drug testing for the following reasons:

1.) It is an unreasonable and unacceptable invasion of privacy. (i.e.; body fluids)

2.) It is unfair to force the added financial burden on employers particularly at this time when most if not all shipyards in the United States are struggling to survive a dormant market in repairs and new ship construction.

3.) It has never been determined that a problem of drug abuse is at a level at our shipyards (i.e. The American Ship Building Co., Tampa Shipyards, Inc.) that warrants random vs. probable cause.

4.) It is our intention to see money spent that we as the work force, in partnership with our management, have determined to be real problems and a threat to our health and safety.

In conclusion, we feel that it would be a perfidious act for any agency or department of the United States Government to mandate random drug testing to private shipbuilding and repair yards.

Sincerely,

Bob Betterton

BB/kw
cc:file
E. House
G. Kourpias
R. Cox

TAMPA BAY AREA LODGE NO. 570

INTERNATIONAL ASSOCIATION of MACHINISTS and AEROSPACE WORKERS

August 24, 1992

From:
Bob Betterton
President
4020 80th Avenue
Pinellas Park, Fl. 34665

Subj: Random Drug Testing
DAR Case 88-083
United States Navy Contract
Procurement Language

To:
The Defense Acquisition Regulations Council
Attn.: Mrs. Linda W. Nelson, OUSED (A)
3062 Defense Pentagon
Washington, D.C. 20301-3062

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August 24, 1992

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4020 80th Avenue
Pinellas Park, Fl. 34665

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United States Navy Contract
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August 24, 1992

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President
4020 80th Avenue
Pinellas Park, Fl. 34665

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DAR Case 88-083
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Procurement Language

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3062 Defense Pentagon
Washington, D.C. 20301-3062

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August 24, 1992

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4020 80th Avenue
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Bob Betterton

BB/kw
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E. House
G. Kourpias
R. Cox

IRONWORKERS

SHOPMEN'S LOCAL UNION NO. 627

International Association
of Bridge, Structural and
Ornamental Iron Workers
AFL-CIO

2957 54th Street
San Diego, California 92105
Telephone: 262-2431

September 18, 1992

Re: DAR Case 88-083

Mrs. Linda W. Neilson, OUSD(A)
Defense Acquisition Regulations Council
3062 Defense Pentagon
Washington, D.C. 20301-3062

Dear Mrs. Neilson:

I was very disturbed to find that DOD has published for comment a proposed clause putting onerous new requirements on defense contractors and their employees. This new clause specifies that drug-free workplace policies in the shipbuilding and ship repair industries shall "as a minimum . . . provide for the random drug testing of Contractor employees working in sensitive positions."

This labor organization represents some 1,500 skilled shipyard workers on the San Diego waterfront. The vast majority are involved is some phase of ship construction or repair under contract to the US Navy. Let me assure you, Mrs. Neilson, our members are not criminals or drug addicts. They are hard-working men and women with families and homes. They are good citizens and many are honorably-discharged veterans of the armed forces. Our members served to protect this country's precious heritage of individual liberties. Why shouldn't they now be allowed to enjoy the rights they fought to protect?

This proposed new rule is a completely unjustified invasion of the privacy rights of US citizens and taxpayers. No one has shown or even asserted that a generalized problem of drug abuse exists in our industry.

But our industry does have its problems. It is in precarious financial condition. It operates on the slimmest of profit margins in a world market in which it competes against foreign enterprises that are heavily subsidized by their governments. What sense does it make to burden our industry with yet another layer of expensive and unnecessary regulation?

Mrs. Neilson, this proposed rule is bad policy at its worst. It was proposed to remedy a problem that doesn't exist. It imposes a burdensome disadvantage upon a threatened strategic industry. And in doing so it offends and outrages the sensibilities of law-abiding citizens. Please don't carry out this plan.

Very truly yours,

Thomas J. McCammon

Thomas J. McCammon
President

Litton
Corporate

Litton Industries, Inc.
360 North Crescent Drive
Beverly Hills, California
90210-4867

Tel: 213 859-5960
Fax: 213 859-5940

John E. Preston
Vice President
Associate General Counsel

Via Federal Express

22 September 1992

Defense Acquisition Regulations Council (DARS)
Attn: Mrs. Linda W. Neilson
C-103 CAFRITZ Bldg.
1211 South Fern Street
Arlington, VA 22202

Re: Public Comment, DAR Case 83-083, "Drug Free Work Force Policy"

Dear Mrs. Neilson,

This responds to the Department of Defense Drug Free Work Force Policy proposed regulation announced in 57 Federal Register 32769 on 23 July 1992. That announcement invited public comment to assist in the formulation of the final rule. Per telephone call with Newton Lesh of my staff on 18 September 1992 you granted us a four day extension (to 25 September 1992) for submission of comments and provided us the above address to be used for Federal Express deliveries. This submission is within the extension period. Our comments below relate to the requirement for mandatory random drug testing.

We perceive substantial societal and economic benefit flowing to the nation by the adoption of a workable drug free policy. Litton Industries is committed to a drug free society and has established policies and guidelines to achieve that end among its employees. However, in designing and implementing our policies we have become aware of legal and administrative constraints which force us to tailor our policies to meet the requirements of state constitutional and statutory law as well as the federal constitution, and certain federal statutes concerning collective bargaining.

Indeed, all of our divisions that sell to the U. S. government comply with the Drug Free Workplace Act and its implementing regulation found in the Federal Acquisition Regulations. We also comply with the 1988 version of the DoD Drug Free Work Force Clause. Our divisions whose operations are regulated by a Department of Transportation (DOT) agency, (FAA, Coast Guard, Federal Highway Administration) conduct random drug testing as required under those Department of Transportation rules.

We recite this because we wish to contrast these rules, with which we have had experience, with the proposed DoD rule. We believe that the proposed DoD rule is fraught with compliance difficulties particularly in four respects.

1. No Preemption of State Law

The proposed rule purports to preempt contrary state constitutional and statutory law in those states which, like California, have and enforce constitutional and statutory protections against random drug testing of employees except in extremely limited circumstances.

In California, violation of privacy rights is against public policy and subjects the employer to punitive damages. For example, Article 1, Section 1, of the California Constitution guarantees each California resident the right of privacy from unwarranted intrusion into his or her private life, whether by government entities or California private businesses. This constitutional right has been the subject of appellate court decisions and opinion that prohibit a government contractor located in California from instituting random drug testing across a broad scope of job positions, such as required in the proposed DoD clause.

Unless the DoD drug testing requirement preempts existing California constitutional and common law, as well as similar laws of other states, DoD contractors will certainly be exposed to immense liability to employees who seek to enforce their state constitutional rights, by either refusing to submit a specimen when directed, or, by suing when discharged or removed from a sensitive position for such refusal or for failing to qualify for reinstatement after testing positive.

We are not aware of any ground upon which it can be argued that the DoD clause preempts state constitutional or statutory law to the contrary without express Federal statutory authority. Indeed, we have attempted to elicit rationale and statutory grounds from the DoD General Counsel's office without success. In addition, Mr. Mike Wermouth, Deputy Assistant Secretary of Defense for Drug Enforcement Policy, and other DoD officials, during public meetings with contractors, were unable to recite grounds for preemption.

It is well settled that an agency's authority must derive from a specific statute enacted by Congress that authorizes that agency to regulate in a particular manner. *Lyng v. Payne,* 90 L.Ed.2d 921, 933; *Burlington Truck Lines v. United States,* 9 L.Ed.2d 207, 215; *Civil Aeronautics Bd. v. Delta Airlines,* 6

L.Ed.2d 869, 874. We do not believe that the DoD can point to any statute as a basis for preemption. It should be noted that in 1988, when Congress considered the Drug Free Workplace Act, it expressly rejected language which would impose random drug testing upon employees of government contractors. Now, four years later, DoD seeks to implement by regulation the very same random drug testing that Congress had rejected.

This is in contrast to the clear statutory authority of the FAA to require random drug testing, not of those who sell to the FAA, but rather of those who conduct operations which are pervasively safety regulated by the FAA. The FAA's statutory basis for this pervasive regulation is contained in the Federal Aviation Act.

And, as stated above, our divisions that operate in that regulated industry, even those located in California, conduct random drug testing, but only for those employees who are clearly covered by the narrowly drawn scope of the FAA drug testing program. That program has been in effect for two years without challenge by employees because the FAA has the clear statutory authority to preempt state constitutional and statutory law. The FAA took great pains to design a requirement narrow in scope and clearly bottomed on its mandate to insure safety.

Although employee litigation based on state law will initially involve only the contractor, it can be expected that any contractor sued will quickly join the Department of Defense as a party to the law suit. In a similar vein, we perceive an ethical question regarding knowingly engaging in an unlawful act that may be raised by the proposed rule, both in the context of the absence of preemption of contrary state law and in the absence of preemption of the National Labor Relations Act and collective bargaining agreements thereunder (3 below). Therefore we recommend that the Department of Defense seek a formal opinion from the Department of Justice on the issue of preemption.

Consequently, until and unless Congress grants the DoD statutory authorization to invade the private workplace by instituting random drug testing, we believe that the random drug testing requirement must be deleted from the proposed rule.

2. Overbroad Scope of "Sensitive Position" (Fourth Amendment)

Only those in "sensitive positions" need be tested under either the 1988 or the current proposed version of the rule. However, the scope of the DoD

definition of "sensitive position" has been greatly expanded in the proposed rule from the narrow scope defined in the 1988 version. The proposed rule's broader scope raises serious U. S. Constitutional, Fourth Amendment questions concerning the need for random drug testing where health, safety or national security will not be immediately and directly impacted. The two leading Supreme Court cases in this area and their Appellate Court progeny (*International Brotherhood of Teamsters v. Dept. of Transportation*, 932 F.2d 1292 (9th Cir. 1991): *International Brotherhood of Electrical Workers v Skinner*, 913 F.2d 1454 (9th Cir. 1990); *Bluestein v Skinner*, 908 F.2d 451 (9th Cir. 1990); and *Taylor v. O'Grady*, 888 F.2d 1189 (7th Cir. 1989)) make it clear that unless there is a direct and immediate connection between the job function and its impact on the safety of others, any random drug testing requirement would violate the Fourth Amendment.

Thus in the 1988 version of the Drug Free Work Force Clause, the DoD correctly defined "sensitive position" as simply one occupied by an employee having access to classified information or other employee as determined by the contractor. The proposed rule greatly expands the scope of sensitive position to include those employees who, among others, design, manufacture, test and evaluate...aircraft, ships, vehicles and heavy equipment, munitions, toxic materials, weapons, weapon systems and potentially dangerous equipment...or major components. Under Supreme Court decisions interpreting the Fourth Amendment, an employee involved in the design, manufacture, test or evaluation of a product may not be required to submit to random testing unless the employee's function is directly and immediately related to the safety of operation by the end user, or others affected by its use.

Further in contrast with the proposed DoD rule, the FAA rule expressly excludes design, manufacture, test and evaluation functions from its random testing program. The FAA limited its scope of random drug testing to operators of aircraft (pilots, flight crew, flight attendants), airport security personnel, air traffic controllers and those who maintain the aircraft or its components (i.e., those functions having a direct and immediate effect on safety). Although it had preemptive authority, the FAA nevertheless was concerned that it not abuse the authority and be taken to court for overstepping its bounds established under the Fourth Amendment. We believe that the proposed rule's large scope of functions described in the Sensitive Position definition is overbroad and will subject DoD and its contractors to a flood of litigation on U.S. Constitutional grounds.

3. Violation of Existing Collective Bargaining Agreements

The proposed rule ignores the implications of existing collective bargaining agreements which may not allow the contractor to implement random drug testing. Contrast this with the 1988 version of the rule which allowed contractors to phase in drug testing by reaching agreement with the labor union in the next union contract renewal negotiation. No such recognition is apparent in the proposed rule.

Drug testing is a mandatory subject of bargaining under the National Labor Relations Act (NLRA). The Supreme Court in *Ford Motor Co. v. NLRB*, 441 U.S. 488 (1979) described mandatory subjects of bargaining as matters that are "plainly germane to the 'working environment'" and "... not among those 'managerial decisions which lie at the core of entrepreneurial control.'" Based upon that rationale the NLRB, in *Johnson-Bateman Co.*, 131 LRRM 1393, 1397 (1989), held that drug testing was a mandatory condition of bargaining. The Board noted that drug and alcohol testing:

> ...does not involve the commitment of investment capital and cannot otherwise be characterized as a decision taken with a view toward changing the scope of nature of the Respondent's enterprise. It is rather a more limited decision directed toward reducing workplace accidents and attendant insurance risks...

Accordingly, the Board held that Johnson-Bateman had violated Section 8(a)(5) of the NLRA by unilaterally implementing a drug-testing program.

Thus, any employer with an existing collective bargaining agreement that does not specifically allow drug testing would have three options if the proposed DoD regulation becomes effective:

1. Attempt to secure agreement from the union to allow the testing required by the regulations.

2. Failing to obtain such agreement, the contractor would be required to intentionally violate the NLRA or the collective bargaining agreement, or both if it elected to participate in a DoD contract.

3. Remove itself from consideration as a contractor.

4. Inclusion of Contracts for Commercial Items

The proposed rule does not exempt contracts for the procurement of commercial items or items from commercial vendors (as opposed to established defense contractors). Again, this is a departure from the 1988 version of the rule. The 1988 version exempted contracts for commercial or commercial type products that did not involve access to classified information. It would appear that imposing random drug testing on commercial companies who have been in business for years would discourage their participation in the DoD initiative toward more commercial acquisitions. As DoD already knows, there are many responsible commercial vendors who choose not to do business with the government because of the added cost of regulations and compliance. The proposed rule is another addition to that cost and burden.

In summary we believe the proposed clause must, at a minimum, be rewritten to satisfy the four points raised above. We believe that the 1988 version of the DoD Drug Free Work Force Clause accomplishes that result.

I am available to amplify the above comments, provide more detailed statutory and case citations or otherwise further discuss these issues. Please call me at (310) 859-5983 or Newton D. Lesh, II of my staff at (805) 378-2410.

Sincerely,

John E. Preston
Vice President and
Associate General Counsel

cc.: Defense Acquisition Regulations Council (DARS)
Attn.: **Ms. Linda W. Neilson**
OUSD (A)
3062 Defense
The Pentagon
Washington, D. C. 20301-3062 (by Federal Express)

Litton
Ingalls Shipbuilding

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DBM-92-115

17 September 1992

Defense Acquisition Regulations Council
Attn: Mrs. Linda W. Neilson
OUSD(A)
3062 Defense Pentagon
Washington, DC 20301-3062

RE: DAR Case 88-083
Comments on 252.223-7500 Drug Free Workforce

Dear Mrs. Neilson:

Enclosed are comments concerning the views of Ingalls Shipbuilding as they relate to Section 252.223-7500 of the Federal Acquisition Regulations Final Rule invoking Random Drug Testing.

Ingalls is extensively involved in drug testing and appreciates this opportunity to comment on this vital issue.

In support of our comments, we have taken the liberty of including a detailed description of our testing program.

Sincerely yours,

INGALLS SHIPBUILDING, INC.

D. F. Knecht
Vice President
Public/Industrial Relations

DFK/DBMJr/skm

Enclosures (as stated)

(b) The Contractor shall institute and maintain a program for achieving a drug-free workforce. As a minimum, the program shall provide for the random drug testing of Contractor employees working in sensitive positions. The Contractor's drug testing program shall conform to the "Mandatory Guidelines for Federal Workplace Drug Testing Programs" published by the Department of Health and Human Services (53 FR 11970), April 11, 1988.

COMMENT

Ingalls Shipbuilding does not agree that random drug testing is necessary to achieve a Drug-Free Work Force. This Company has had in place an extremely effective program of pre-employment testing as well as a program wherein all employees are subject to testing "for cause" or when involved in accidents causing injury or property damage. This program has proven to be effective, while at the same time withstanding a number of procedural challenges, including process through Federal District Court and U.S. Court of Appeals.

We also believe it's a matter of importance that in the process of bringing industry to the forefront of combating the drug problem by requiring contractors to conduct various forms of education and testing, that the Government not lose sight of other important elements of efficiently and effectively performing the requirements of a contract. Shipbuilding and many other industries, have a dynamic, constantly-changing workforce. The mix of skills required to perform the steel-preparation function differs from that required to assemble the components installed in a ship. The mix required to erect steel differs from that required to outfit the hull after it is assembled and erected. In order to assure that the right people are in the right place at the right time, our industry must, of necessity, hire in large numbers and in some cases temporarily lay-off and recall workers as the work flow dictates.

All of this personnel activity requires that our employment function react quickly in order to provide the workforce in the number and skills required.

To ensure that we can do this and at the same time comply with the Drug Free Workplace, Drug Free Workforce requirements imposed in 1988, we instituted an on-site testing program. The basic premise is that we perform an on-site initial screen using a Food and Drug Administration approved procedure. A split sample of any screen presumptive positive is sent to a National Institute on Drug Abuse (NIDA) approved laboratory for confirmation by Gas Chromotography/Mass Spectrometry (GC/MS).

There are two major pluses to a program which is operated in this fashion. (1) No final discipline is invoked on an employee or applicant until the presumptive test has (a) been GC/MS confirmed, (b) reviewed by our Medical Review Officer (MRO), and (c) the procedure has been reviewed by our Substance Abuse Review Committee. (2) Those testing negative at the time of the on-site processed screen can go directly to work with a minimum of delay. This on-site determination allows us to react to our manning requirements in a timely manner while at the same time providing our employees with well-paying jobs with a minimum of delay.

The invoking of the NIDA Guidelines in each and every testing program devised by the Government is placing a stranglehold on industries' ability to comply with the regulations while at the same time meeting the other obligations of its contract.

On-site initial screens backed by NIDA lab GC/MS confirmation of presumptive positives is a reasonable, timely and effective method of accomplishing a drug free environment.

We have attached a complete outline of our program in expectation that the Department of Defense might consider adopting these procedures throughout the defense industry. This program accomplishes effective drug detection and deterrence while simultaneously maintaining individual rights, and considering the need of business and industry to continue to conduct its business on behalf of the Department of Defense efficiently and effectively.

DRUG TESTING

AT

INGALLS SHIPBUILDING, INC.

This paper describes how on-site drug testing is performed in a large, defense oriented manufacturing facility.

Prepared by:

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SUBSTANCE ABUSE TESTING
AT
INGALLS SHIPBUILDING, INC.

INTRODUCTION

Ingalls Shipbuilding, located on the Gulf Coast in Pascagoula, Mississippi, builds, repairs and overhauls surface combatant ships for the United States Navy and others.

Current activity includes new construction of Ticonderoga Class Cruisers (CG 47), Arleigh Burke Class Destroyers (DDG 51), and General Purpose Amphibious Assault Ships (LHD 1) for the United States Navy. Ingalls is also building SA'AR 5 Class Corvettes for the Israeli Navy and overhauls a variety of ships. Ingalls also overhauled and returned to service the battleships Iowa and Wisconsin, and the Frigate Stark after it was damaged by an Iraqi missile.

Ingalls currently employs over 15,000 people and has a work backlog exceeding $4 billion. The production work force is unionized, and enjoys excellent labor management relations.

Ingalls' Drug Testing Program, which includes a rehabilitation phase prior to invoking discipline and confirmation of presumptive positives by a National Institute on Drug Abuse (NIDA) certified laboratory, is operating smoothly with a minimum of protests or grievances. The key to the program is conducting initial drug testing on-site. Ingalls' program is existing proof that these initial tests can be conducted by industry, on-site, in a technically proficient, courteous, dignified, and professional manner.

The following pages depict three (3) categories of presentation:

I. The Ingalls Method - A General Overview

- A. The Ingalls Program
- B. The Ingalls Process
- C. The Ingalls View

II. The On-Site Testing Aspects of the Ingalls Program

- A. Introduction
- B. Personnel
- C. Specimen Handling
- D. Security
- E. Drug Testing Methods
- F. Quality Control
- G. Proficiency
- H. Drug Testing Policies

III. Recommendations for the Regulation of On-Site Testing

I. THE INGALLS METHOD - A GENERAL OVERVIEW

A. THE INGALLS PROGRAM

In order to assure a safe, alcohol and drug-free environment and to comply with Public Law 100-690, The Drug-Free Work Place Act of 1988, and Federal Acquisition Regulation 252.223-7500, The Drug-Free Work Force Clause of Part 252 of the regulation regarding solicitation provisions and contract clauses, Ingalls instituted a Drug Testing Program on 03 April 1989, for Pre-employment and Recall reasons and extended it on 01 May 1989, to include For Cause and Accident events.

Final discipline is invoked only after an on-site determined presumptive positive is Gas Chromatography/Mass Spectrometry (GC/MS) confirmed by a NIDA certified laboratory and the employee has failed to meet the rehabilitative criteria of the program.

Ingalls' Employee Assistance Program Coordinator counsels, refers and tracks all employees who are positive in a directed test or who voluntarily seek help for a substance abuse problem.

During the nine month period from 03 April 1989, when the testing program went into effect, until 31 December 1989, the facility conducted 2,748 tests. Of this number, 278 (10%) were presumptive positive and required additional processing, while the 2,470 or 90%, who tested negative could be hired or returned to work immediately with a minimum of employment processing or work activity interruption. Likewise, for the period of January 1990 through December 1990, 5,452 tests were conducted, with 351 (7%) being presumptive positive, meaning that the 5,101 or 93%, who tested negative could be hired or restored to work immediately with a minimum of interruption. In this situation, on-site testing is an absolute necessity.

The calendar year 1991 experience shows that Ingalls conducted 7,017 tests, 317 or 5% of which were positive. On-site testing allowed the other 6,700 or 95% to go straight to their jobs without delay. This could not be done in the absence of on-site testing and in this case the delay would be costly for thousands of employees as well as the Company.

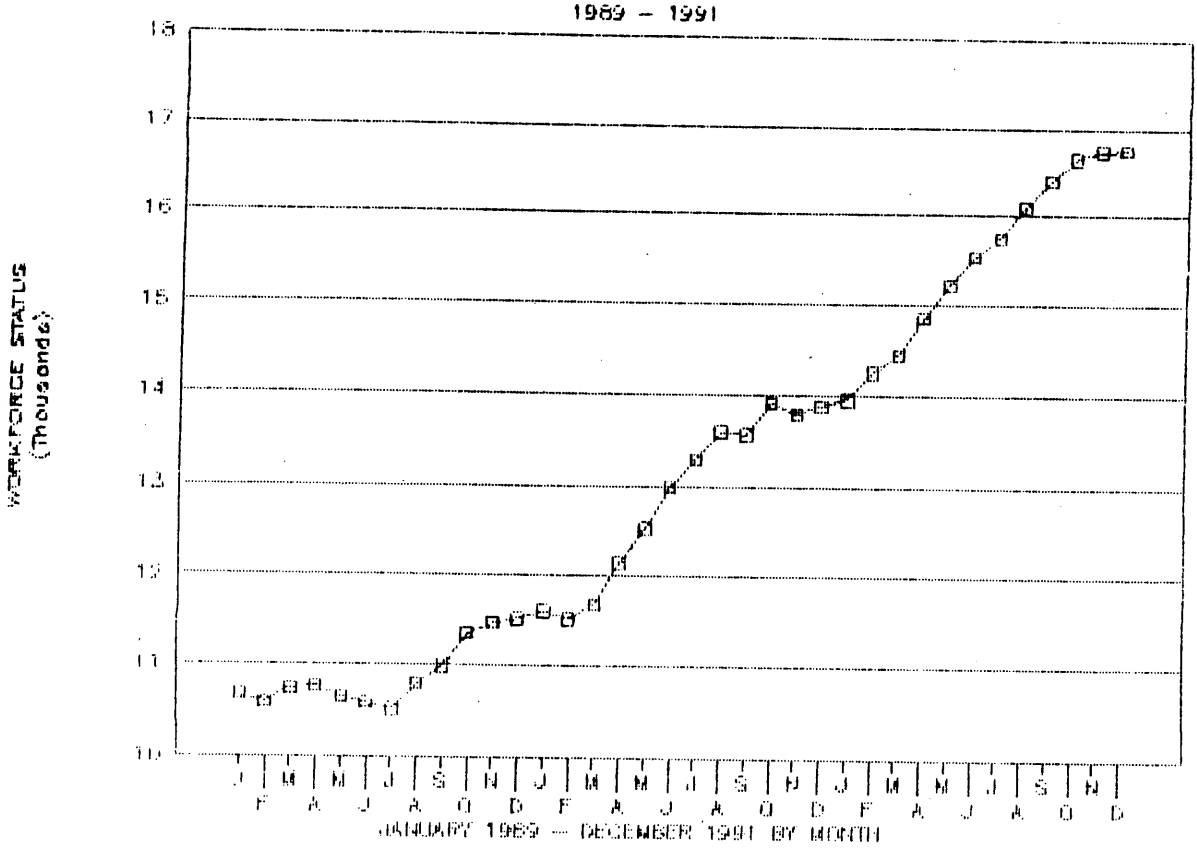
The attached (Chart 1A) shows Ingalls' manpower build-up over the last three (3) years. From January 1989 to December 1991, employment headcount increased by an average of 4,671 employees. This feat would have been virtually impossible without the ability to perform on-site drug testing.

Even in non build-up periods, attrition rates require hiring as many as 60 people per week to maintain employment levels.

Various stages of ship production require workforce mix changes. Today hundreds of painters are needed. Next week or next month painters are reduced, but hundreds of additional outfitting types such as sheetmetal workers and electricians may be needed. The shipbuilding workforce is necessarily dynamic and on-site testing allows a drug free workforce while at the same time meeting schedules and budgets, with a minimum of lost work time for employees or prospective employees.

INGALLS SHIPBUILDING, INC.

1989 – 1991



MONTH	1989	1990	1991
JANUARY	10655	11602	13951
FEBRUARY	10583	11521	14347
MARCH	10750	11814	14449
APRIL	10756	12142	14648
MAY	10650	12522	15214
JUNE	10575	12978	15581
JULY	10514	13281	15754
AUGUST	10786	13592	16149
SEPTEMBER	10987	13562	16394
OCTOBER	11350	13912	16651
NOVEMBER	11468	13797	16736
DECEMBER	11519	13881	16751
AVERAGE	10980	12870	15559

CHART 1-A

B. THE INGALLS PROCESS

Due to the importance of placing applicants and recalls on the job in a timely manner as well as returning employees tested for cause and accident who test negative back to the job in the shortest time period possible, it is necessary that the initial test be performed on-site.

Test specimens are collected, split, documented and tested by trained technicians who follow written procedures and instructions in ensuring that their tasks are performed in a technically proficient, courteous, dignified, professional manner.

The actual testing is conducted using Food and Drug Administration (FDA) approved Abbott Laboratories ADX Analyzers which employ the fluorescence polarization method of immunoassay. Ingalls' technicians have been trained at Abbott Laboratories in the operation of this equipment.

In-house medical doctors have oversight regarding the program and act as Medical Review Officers (MRO).

Specimens are processed through the Abbott analyzers immediately upon collection. The results of the tests are either positive or negative as determined by the pre-set cut-off level for the drug for which the individual is tested.

Negative results trigger an immediate continuation of processing for applicants and those returning from leaves of absence. A negative result also immediately returns to work those tested for cause or accidents.

In the event of a positive initial test, the sealed split is forwarded by courier to an independent, College of American Pathology and National Institute on Drug Abuse certified laboratory for confirmation using Gas Chromatography/Mass Spectrometry technology.

Other than calibrating, maintaining and programming the Abbott analyzers to perform the tests for which they are designed and recording the temperature, pH, and specific gravity of the sample, Ingalls' Testing Facility personnel perform no manipulation, interpretation, calculation, or forensic analysis regarding the sample. Their function is to collect, test, record, and report results.

Since medical doctors oversee the in-house testing function and perform the function of MROs, this process should require no additional level of supervision above the qualifications possessed by plant medical doctors.

The split sample is a good faith effort demonstrating to union representatives, as well as non-represented employees, that a third party may validate, question or disagree with the result if it can be properly documented.

Third party confirmation takes away the employee, applicant and union representative concern that the Company may be grading its' own homework, so to speak. With proper and careful chain-of-custody control, there is no reason to require such a program to perform both initial testing and confirmation at the same site as required by NIDA. It is both an unnecessary delay and unreasonable requirement.

C. THE INGALLS VIEW

All testing facilities should not be required to conform to imposed mandatory NIDA guidelines designed for the testing of government employees. If these guidelines are imposed for other than government related testing, the imposition should be limited to those whose primary mission is scientific analysis, including toxicological urine testing, for-profit.

Ingalls is in the business of producing quality ships for the United States Navy, on schedule and within budget. We have been very successful in doing this. There is no necessity, nor should this testing facility be required to conform to the same guidelines as those who perform drug testing for a profit.

Private employers engaged in drug testing as a necessity to provide a safe working environment and to contribute to reducing the drug problem in our society should not be saddled with the burdensome and unnecessary restrictions invoked in the NIDA Guidelines, and other well meaning proposals and legislation.

The time-sensitive nature of placing workers in jobs initially and back on the job subsequently, requires simplification in drug testing where private, labor-intensive industry is concerned.

The following is a more detailed description of the various elements of Ingalls On-Site Testing Program.

II. THE ON-SITE TESTING ASPECTS OF THE PROGRAM

A. INTRODUCTION

The following elements are those identified and stressed during Dr. Douglas Rollins's visit to our facility. Dr. Rollins is chairman of the NIDA sponsored on-site drug testing committee.

B. PERSONNEL

There are three persons whose primary function is drug testing. All have completed Emergency Medical Technician coursework at the local Community College. All have received on-the-job training by representatives of Abbott Diagnostics and completed a 32-hour formal program on-site at the Abbott Diagnostics Facility in Dallas.

One Technician is a certified Phlebotomist and was trained and certified in the collection, documentation and processing of blood and urine samples during an eight (8) year assignment at the local (Singing River) hospital laboratory department.

One Technician received training and certification on five different types of drug detection analyzers while performing collection and analysis functions during a five year period with the Mississippi Department of Corrections.

One Technician has Associate Degrees in Medical Laboratory Technology and Electronic Technology. He has been a state certified Medical Laboratory Technician since 1988 and is a member of The American Society of Clinical Pathologists. He has performed practical laboratory work at the Ocean Springs branch of Singing River Hospital, Biloxi Veterans Administration Hospital, Greene County Hospital and Roche Bio-Medical Laboratories.

Performance evaluation of these employees is conducted annually by the department manager and the Medical Review Officer (MRO). All have been with the company and have worked with the drug testing program since March of 1989.

C. SPECIMEN HANDLING

The flow of specimens is essentially as follows: The employee/applicant provides a urine specimen at the collection site which is adjacent to the drug testing facility. The collection site attendant is in the same room as the person providing the specimen, however, there is no direct observation of the initial urine collection. At the time of urine collection, the chain-of-custody with identifying information including social security number, control number, date and time of specimen collection is initiated. Upon receiving the specimen from the employee/applicant the attendant checks the temperature, pH and specific gravity. After the urine is determined to be acceptable, the attendant pours at least 5 ml of the specimen into an identical container and both containers are appropriately labeled and sealed in the presence of the employee, thus creating a split specimen; one split for an initial test and one for follow-up confirmation. The specimens are passed through a window to the testing facility and a technician inspects them for satisfactory condition and integrity of tamper proof seals. The chain-of-custody form is also inspected to make sure that all information is appropriate and entered into a substance abuse log. One of the specimens is tested using the Abbott ADX fluorescence polarization immunoassay.

Only positive results are documented on the chain-of-custody. Negatives are stamped "negative" on the chain-of-custody and the specimen is discarded. If the specimen is identified as presumptive-positive, the other split specimen is sent by overnight courier to a National Institute on Drug Abuse (NIDA) certified reference laboratory for confirmation by Gas Chromatography/Mass Spectrometry (GC/MS). Presumptive-positive specimens are stored in a locked refrigerator in the drug testing facility pending results of the split sent to the reference laboratory. Confirmed positive specimens are stored for one year at the reference laboratory, negative specimens are discarded immediately by the on-site facility. If the employee/applicant's initial test is negative, normal processing continues for an applicant and employees are returned to their jobs. However, if the initial test is positive, the employee/applicant is sent home with the information that he/she will be notified of the results of the confirmation test.

//

D. SECURITY

The test facility is in the same building with and adjacent to the urine collection site which in turn is adjacent to the Security Department and the site for processing new employees. A chart showing the laboratory area is attached as Chart 6-A. The drug testing facilities are locked or attended at all times. A large sign "Authorized Personnel Only," is prominently displayed on all doors. The three technicians and the Department Manager are the only authorized personnel allowed unescorted access to the Test Facility. Specimen integrity is closely maintained. Temperature, pH and specific gravity are obtained during the collection process. Specimens are never left unattended or unlocked and an aliquot of the specimen is removed for testing (the original specimen is split for initial testing and confirmation testing). Results of screening tests are entered into the testing facility on-site computer which has password access. All initial screen and confirmation results are initially reported only to the Manager of Medical/Security or the company physician. The Labor Relations Department is advised of those positive tests relating to Union represented personnel.

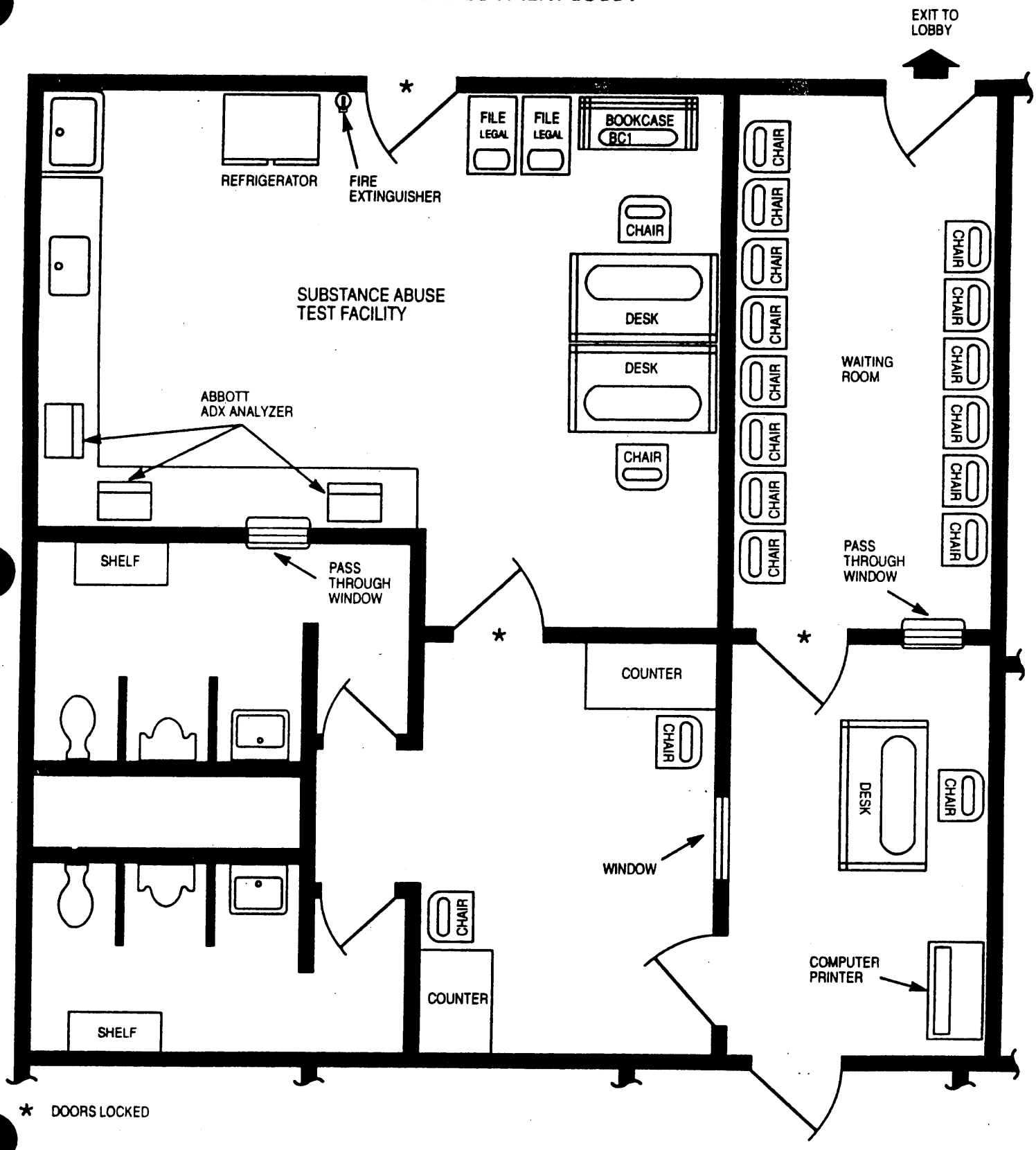
E. DRUG TESTING METHODS

Our facility uses the Food and Drug Administration (FDA) approved Abbott ADX fluorescence polarization drug testing system. The standards being used are those provided by Abbott Diagnostics. Controls are also obtained from Abbott Diagnostics. Cut-off concentrations are documented according to the Abbott ADX manual. The Company is testing for cannabinoids, opiates, phencyclidine, cocaine, amphetamines, barbiturates, and benzodiazepines. A screening-positive result is determined if the instrument printout indicates that the concentration present in the specimen is at or higher than the cut-off calibrated into the instrument. Currently we are testing only urine for drugs of abuse. All presumptive-positive specimens are confirmed by (GC/MS) at a reference laboratory that is NIDA certified.

Confirmation of an applicant's test means the person will not be hired, but may apply again in six (6) months.

Confirmation for an employee means automatic referral to an employee assistance/rehabilitation process which, if successfully completed, guarantees their return to duty subject to random testing for a one year period.

EMPLOYMENT LOBBY



SECURITY DEPARTMENT

CHART 6-A

F. QUALITY CONTROL

A Standard Operating Procedures Manual (SOP) covers specimen handling and reporting of results. Operation of the ADX equipment is covered in the Abbott Manual supplied with the equipment.

Utilizing the Abbott Laboratories Operators Guide for the Abbott ADX System and Ingalls prepared policies, procedures and departmental operating instructions, the Company is preparing an Ingalls Testing Facility Operators Manual that will describe the operational aspects of the ADX System as applied in this specific process.

Technicians run one quality control specimen supplied by Abbott Laboratory each day. The technicians are the designated persons in charge of quality control and the technician running specimens on a particular day determines whether or not the quality control specimen is acceptable. There is a log of the daily control run which is reviewed. There is a regular schedule of instrument maintenance as indicated in the Abbott manual. When the instruments were setup, the procedures were validated by Abbott.

In 1991, we initiated a blind specimen program with a NIDA certified laboratory which challenges the Company's operation on an average of two times per month. Attached as Chart 7A is a letter from the laboratory attesting to Ingalls' ability to properly identify specimens.

In November of 1991, Ingalls hired a second medical doctor, not only for increased treatment capability, but additional testing facility and testing program oversight as well.

G. PROFICIENCY

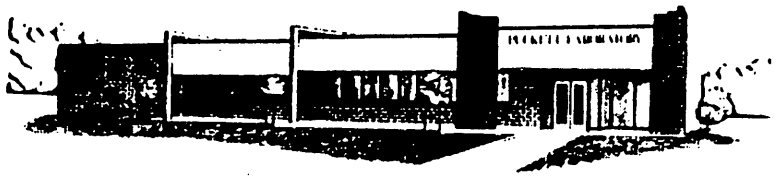
In 1991, the Testing Facility staff was challenged by Aegis Analytical Laboratories, Inc. of Nashville, Tennessee to respond to a validation exercise designed by Dr. David L. Black, Ph.D., DABFT, DABCC-T, the President and Laboratory Director of Aegis.

This challenge consisted of our personnel processing samples submitted by Aegis to assess the ability of our people, processes and machines in four (4) main areas:

ACCURACY
PRECISION
LINEARITY
SPECIFICITY

Enclosed as Appendix A, is Dr. Black's report of the results of this challenge. It lends strong support that Ingalls' on-site program is conducted by capable personnel who efficiently and effectively apply the processes, and maintain and operate quality equipment resulting in accurate and timely testing.

THOMAS P.
PUCKETT
LABORATORY



4200 MAMIE STREET/HATTIESBURG, MS 39402/(601) 264-3856

June 26, 1992

Al Downs
Ingalls Shipbuilding, Inc.
P.O. Box 149 M/S 1020-04
Pascagoula, MS 39567

Mr. Downs,

The Toxicology department here at Puckett lab has been happy to participate in your blind control program. The first sample was sent to Ingalls in October or November of 1991 for your evaluation with your regular drug screens. Since then we have sent two samples each month for your analysis. The samples have been a mix of both positive and negative specimens. Your record so far has been 100% in giving the correct screening result. I also appreciate the concern and professionalism of your staff whenever a question arises concerning a control or drug testing in general.

Please call if I can be of any further assistance.

Sincerely,

Lance C. Presley

Lance C. Presley, Ph.D.
Certifying Scientist
QA/QC Officer

CHART 7-A

51-C TACON STREET/MOBILE, AL 36607/(205) 473-3838
1040 CALHOUN STREET/NEW ORLEANS, LA 70118/(504) 899-8282
764 LAKELAND, SUITE 314/JACKSON, MS 39216/(601) 792-4276
1245 BROAD AVENUE/GULFPORT, MS 39501/(601) 863-4562
1030 RIVER OAKS DRIVE/JACKSON, MS 39208/(601) 936-2397

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15

H. DRUG TESTING POLICIES

Ingalls has a written policy stating its position regarding drug testing, a Standard Procedure describing program administration, and departmental operating instructions setting forth testing facility and MRO guidelines to ensure that testing and evaluations are consistent. We perform pre-employment, for cause and post-accident testing. The laboratory technician tells the job applicant that if the initial test is presumptively-positive, further processing of the application will not occur unless the confirmation test is negative. In the case of for cause testing, the laboratory technician passes the results to the Manager of the Medical and Security Departments, the Medical Review Officer (MRO) and the Labor Relations Department, when applicable.

The Company has chosen an on-site drug testing policy because of the time involved in processing pre-employment applications and the need to return employees who test negative back to work as soon as possible. There are times when it is necessary to hire a large number of persons on a particular day (over 7,000 were hired in 1991), and there is a need to process these individuals as expeditiously as possible. Off-site drug testing cannot provide the necessary turnaround time.

The Company Medical Review Officers (who are also the company physicians) review all confirmation-positives. The Medical Review Officers confirm prescription medication and other potential challenges to the confirmed positive results. Records are stored within the testing facility in a locked file cabinet. Descriptive statistical data are maintained and there are audits of the on-site testing lab 3 to 4 times a year by a private consulting group.

Ingalls is very pleased with its on-site program and feels it has demonstrated that this is a very acceptable method if done properly with pride in methods and concern for those being tested. In fact, in many aspects of the testing itself, it is a superior program, requiring positive results of two separate testing facilities before a positive test is fully confirmed.

The following recommendations regarding the regulation of on-site testing were derived from experience in actually conducting this method of testing and research into how it could be done effectively and efficiently.

III. RECOMMENDATIONS FOR THE REGULATION OF ON-SITE TESTING

As a member of the On-Site Drug Testing Committee chaired by Dr. Douglas Rollins, I too, am concerned that there may be those who are conducting tests in less than a responsible manner and who by doing so, cause those of us who are providing accurate, fair and quality programs to be included in with them when on-site testing is criticized. The diversity of on-site testing methods very simply tells us that controls are necessary.

I am equally concerned however, by the suggestion that only certain highly over-qualified individuals can conduct on-site initial screens and that they must be conducted in accordance with the government-imposed NIDA guidelines, thus placing small, of necessity, on-site screening facilities on the same plane as complex, for-profit, high volume, high tech laboratories.

The fair and reasonable answer is somewhere between these two extremes. I offer the following recommendations as a start toward establishing reasonable guidelines for on-site facilities, while avoiding the extreme qualifications imposed on for-profit laboratories.

GENERAL RECOMMENDATIONS AS A BASIS FOR ON-SITE TESTING REGULATIONS

1. The testing method (EMIT, FPIA, RIA, etc.) must be Food and Drug Administration (FDA) approved.

2. The program must be monitored by a person with at least medical doctor qualifications and who will certify the operational proficiency and results of the on-site facility. This may be an employee of the testing entity or a person under contract to it. This person may also act as the Medical Review Officer.

3. The program should be characterized by a split sample collection procedure to allow confirmation of the unopened split by Gas Chromatography/Mass Spectrometry at a NIDA certified lab.

4. Final disciplinary action should be stayed pending confirmation of the presumptive test results.

5. Chain of custody procedures should be such as to satisfy the requirements of the confirming laboratory.

6. Specimen collection procedures should generally be in accordance with NIDA Guidelines. It is suggested that universal specific gravity and pH ranges be established (as is temperature) to ensure consistency in determining whether or not a sample is valid.

7. Specimens may be collected by a company representative who has been provided training and instruction in collection and chain of custody procedures.

8. Operators of the testing equipment shall have been trained by the manufacturer of the equipment and shall demonstrate proficiency in equipment operation prior to being allowed to perform any function of the actual testing operation.

9. On-site facilities should purchase blind performance (blank and spiked) testing services from a NIDA approved laboratory. The volume of such testing should be reasonable as it relates to the numbers of tests performed in a given period.

10. Each facility shall have a procedure manual which includes the principles of each test, preparation of reagents, standards and controls, calibration procedures, derivation of results, linearity of methods, sensitivity of methods, cut-off values, mechanisms for reporting results, etc.

11. Periodic third party inspections of the on-site facilities should be conducted with a reasonable frequency utilizing predetermined criteria against which the facility would be reviewed. A favorable review would allow the facility to operate for a given period. An unfavorable review would invoke probation after which a reinspection would determine the facility's fate.

12. Facilities should be challenged at least once each year by an independent laboratory which administers a proficiency test assessing the ability of the facility's personnel, equipment and procedures for accuracy, precision, linearity and specificity.

13. The real key elements of my recommendations are that no specimen may be considered positive until a NIDA certified lab says it is positive, and no discipline is final until the specimen is confirmed positive by the NIDA certified lab.

14. Our program at Ingalls, also allows a re-hab period after the user's initial positive. If the employee completes the re-hab and the subsequent test is negative, the employee is returned to work.

IV. SUMMARY

1. On-site testing does work and can continue to work if a sensible approach to regulation is adopted. To include industrial on-site screening facilities with for-profit labs and NIDA regulations is both costly to industry and the worker, and counter-productive to the goal of stamping out drug use in our society.

2. Industry is expected to assist in defeating the drug scourge in our society and we willingly accept the challenge. We are however, bound by Public Law 100-690, The Drug Free Workplace Act, Federal Acquisition Regulation 252.223-7004, Drug Free Work Force Requirements, NIDA Guidelines, CLIA Requirements, and D.O.T. Requirements.

3. We can make a significant contribution toward discouraging people from using drugs. Give us some help in doing so. Simplify the process. For example, if an employer can certify to minimum requirements and has all presumptive positives confirmed by GC/MS at a NIDA certified laboratory, allow that employer to on-site test. We are not asking for total exemption from regulation, but simplification so that we can reasonably perform the tasks assigned us. We should not be included in with sophisticated, for-profit laboratories.

4. The layer upon layer of restrictions and regulations is smothering the ability of industry to contribute to dramatically reducing the drug problem in our country.

Any questions or requests for additional information may be directed to:

D. B. MASSENGALE, JR.
Director, Industrial Relations Services
Ingalls Shipbuilding, Inc.
Post Office Box 149 - Mail Station 2050-03
Pascagoula, MS 39568-0149

(601) 935-5847
(601) 935-5804 (FAX)

APPENDIX A

AEGIS
ANALYTICAL
LABORATORIES, INC.

624 Grassmere Park Rd. Suite 21 • Nashville, Tennessee 37211
(615) 331-5300 1-800-533-7052

AUGUST 27, 1991

D. B. MASSENGALE, JR.
DIRECTOR
INDUSTRIAL RELATIONS SERVICES
INGALLS SHIPBUILDING, INC.
P.O. BOX 149
PASCAGOULA, MISSISSIPPI 39568-1122

DEAR MR. MASSENGALE,

THANK YOU VERY MUCH FOR YOUR PROMPT RESPONSE AND REPORT OF RESULTS FOR THE VALIDATION SPECIMENS SUBMITTED TO INGALLS SHIPBUILDING. I DO APPRECIATE YOUR STAFF WOULD BE ANXIOUS TO RECEIVE THE ENCLOSED REPORT OF THEIR PERFORMANCE AND I APPRECIATE YOUR PATIENCE AS I HAVE "RECOVERED" FROM RETURNING FROM VACATION. I AM SURE YOU AND YOUR STAFF WILL BE PLEASED BY THE ENCLOSED REPORT. PLEASE ADVISE ME IF THERE ARE ANY AREAS OF THE REPORT WHICH MIGHT REQUIRE FURTHER CLARIFICATION. ALSO PLEASE NOTE THAT I AM FORWARDING A COPY OF THIS REPORT TO MR. PAUL LANDAUER OF ABBOTT LABORATORIES.

THANK YOU FOR YOUR INVITATION TO VISIT THE INGALLS SHIPYARD AND I HOPE AN OPPORTUNITY WILL ARISE WHERE I MIGHT TAKE ADVANTAGE OF YOUR OFFER. CONSIDERING THE CRITICISMS BEING LEVIED AT ON-SITE DRUG TESTING SITES IT MIGHT BE HELPFUL TO REVIEW THE MAINTENANCE, REPAIR, CALIBRATION AND QUALITY CONTROL RECORDS; HOWEVER YOUR LABORATORIES EXCELLENT PERFORMANCE DOCUMENTS THAT THESE ISSUES MUST BE WELL ADDRESSED.

I HAVE ENJOYED THIS EXERCISE AND HOPE IT HAS PROVEN HELPFUL TO YOU AND YOUR STAFF.

SINCERELY,

DAVID L. BLACK, PH.D., DABFT, DABCC-T
PRESIDENT AND LABORATORY DIRECTOR

CC: MR. PAUL LANDAUER
ABBOTT LABORATORIES

URINE DRUG TESTING METHODS VALIDATION EVALUATION

August 25, 1991

KIT LOT #: 31-101391

DATE: July 31, 1991

CONTENT

I; INTRODUCTION

THE DATA REPORTED WAS ASSESSED FOR THE FOLLOWING TESTING CHARACTERISTICS:

ACCURACY: THE ABILITY OF A TESTING METHOD TO IDENTIFY AND/OR QUANTITATE SUBSTANCES CORRECTLY

PRECISION: THE ABILITY OF A TESTING METHOD TO PERFORM CONSISTENTLY AND TO BE FREE FROM EXTERNAL AND INTERNAL SOURCES OF VARIATION

LINEARITY: THE RANGE OF DRUG CONCENTRATIONS THE METHOD IS ABLE TO ACCURATELY QUANTITATE

SPECIFICITY: THE DEGREE OR ABILITY OF A TESTING METHOD TO REACT ONLY WITH THE DRUGS OR METABOLITES BEING TESTED AND TO EXCLUDE ALL OTHER DRUGS

THE DOCUMENTATION WAS RETURNED FOR REVIEW APPROPRIATELY AND ALL INFORMATION WAS IN ORDER. THE TECHNOLOGISTS FOLLOWED INSTRUCTIONS AND COMPLETED THE TABULATED DATA CORRECTLY.

II: ACCURACY

ACCURACY: THE ABILITY OF A TESTING METHOD TO IDENTIFY AND/OR QUANTITATE SUBSTANCES CORRECTLY

ACCURATELY IDENTIFYING WHICH DRUG MAY BE PRESENT IN A URINE SAMPLE IS PERHAPS THE SINGLE MOST IMPORTANT ANALYTICAL CRITERIA OF CONCERN TO A DRUG TESTING PROGRAM. THE ISSUE ALSO INCLUDES THE CONCERN OF CORRECTLY DETERMINING THE AMOUNT OF DRUG PRESENT SINCE A POSITIVE RESULT IS ALSO DEFINED AS HAVING THE DRUG PRESENT AT A LEVEL GREATER THAN THE THRESHOLD (CUTOFF) ESTABLISHED FOR THE PROGRAM. THE SUBMITTED VIALS A-I CONTAINED DRUGS "BLIND" TO YOUR LABORATORY AS TO WHICH DRUG AND HOW MUCH. VIALS A-I WERE ANALYZED AS PER NORMAL PROCEDURE AND THE RESULTS RECORDED ON FORM II. THE "EXPECTED" AND "REPORTED" RESULTS ARE INDICATED IN TABLE II.

TABLE II: ACCURACY DATA

THIS TABLE PRESENTS THE CORRECT ("EXPECTED") RESULTS AND THE RESULTS REPORTED FROM INGALLS SHIPBUILDING ("REPORTED"). PLEASE NOTE THE EVALUATION IS ALL IN "NG/ML" AND THEREFORE THE ANSWERS THAT WERE SUBMITTED AS "MCG/ML" HAVE BEEN CHANGED (FOR EXAMPLE THE SAMPLE C AMPHETAMINE ANSWER OF 1.72 MCG/ML HAS BEEN CHANGED TO 1720 NG/ML).

SAMPLE	EXPECTED (NG/ML)	REPORTED (NG/ML)
A	PCP (70)	PCP (73.6)
B	MORPHINE (600)	OPIATES (637)
C	AMPHETAMINE (2000)	AMPHETAMINES (1720)
D	CANNABINOIDS (50)	CANNABINOIDS (57.2)
E	SECOBARBITAL (600)	BARBITURATES (650)
F	NORDIAZEPAM (600)	BENZODIAZEPINES (546)

G	CODEINE (700)	OPIATES (778)
H	COCAINE METABOLITES (1000)	COCAINE (1060)
I	METHAMPHETAMINE (2000)	AMPHETAMINES (2170)

III. PRECISION

PRECISION: THE ABILITY OF A TESTING METHOD TO PERFORM CONSISTENTLY AND TO BE FREE FROM EXTERNAL AND INTERNAL SOURCES OF VARIATION

THE PRECISION OF A DRUG TESTING METHOD WILL IN LARGE PART HELP DETERMINE HOW EFFECTIVE DRUG USING INDIVIDUALS WILL BE IDENTIFIED. THE OBJECTIVE IS TO HAVE A DRUG TESTING METHOD WHICH WILL PERFORM DAY AFTER DAY WITH VERY LITTLE VARIATION DUE TO THE SKILL OF THE OPERATOR. METHODS MUST BE VERY PRECISE WHEN TESTING OCCURS AT DRUG CONCENTRATIONS NEAR THE THRESHOLD (CUTOFF) OF THE TEST TO PREVENT THE POSSIBILITY OF FALSE NEGATIVE RESULTS. A FALSE NEGATIVE RESULT IS DEFINED AS REPORTING DRUG OR METABOLITE WAS NOT DETECTED WHEN IN FACT THE AMOUNT OF DRUG OR METABOLITE IS PRESENT IN THE SAMPLE ABOVE THE TEST THRESHOLD (CUTOFF). A TEST METHOD WHICH IS PRECISE NEAR THE TEST THRESHOLD WILL PROTECT AGAINST REPORTING FALSE NEGATIVE ANSWERS. THE SUBMITTED VIALS CONTAINED THE FOLLOWING DRUGS:

VIAL #1: AMPHETAMINE
VIAL #2: METHAMPHETAMINE
VIAL #3: COCAINE METABOLITE (BENZOYLECGONINE)
VIAL #4: CANNABINOID METABOLITE (MARIJUANA)
VIAL #5: OPIATES - CODEINE
VIAL #6: OPIATES - MORPHINE
VIAL #7: PHENCYCLIDINE (PCP)
VIAL #8: BARBITURATES (SECOBARBITAL)
VIAL #9: BENZODIAZEPINE METABOLITES (NORDIAZEPAM)

THE WITHIN RUN AND BETWEEN RUN DATA IS COMPILED AND REPORTED IN TABLE III. THE DATA PRESENTED IN TABLE III IS A COMPILATION OF THE DATA SUBMITTED AND DEMONSTRATES THE MEAN VALUE, STANDARD DEVIATION AND COEFFICIENT OF VARIATION (%CV) FOR EACH ASSAY. THE IMPORTANT CRITERIA IN THIS EVALUATION IS THE %CV WHICH IS A MEASURE OF THE PRECISION (OR IMPRECISION) OF THE STAFF AND METHOD. ACCEPTABLE PRECISION IS 10% CV OR LESS; VERY GOOD PRECISION IS 6% CV OR LESS.

TABLE III: PRECISION DATA

VIAL	DRUG	WITHIN RUN (N=6)			BETWEEN RUN (N=12)		
		X	SD	%CV	X	SD	%CV
1	AMPHETAMINE	1588	110	7.0	1633	156	9.5
2	METHAMPHETAMINE	2037	173	8.5	2100	211	10.0
3	COCAINE METAB	843	32	4.0	857	30	3.5
4	CANNABINOID	46.9	2.8	6.0	50	3.0	6.2
5	CODEINE	577	32.9	5.7	583	28	4.8
6	MORPHINE	590	17.2	2.9	595	15.5	2.6
7	PHENCYCLIDINE	63.2	2.6	4.2	61.6	3.6	5.8
8	SECOBARBITAL	527	16.3	3.1	535	27.8	5.2
9	NORDIAZEPAM	439	13.8	3.1	436	10.7	2.5

LEGEND: N STANDS FOR NUMBER OF TIMES TEST PERFORMED
X STANDS FOR MEAN VALUE FOR ALL REPORTED TESTS
SD STANDS FOR STANDARD DEVIATION
%CV STANDS FOR PERCENT COEFFICIENT OF VARIATION

IV. LINEARITY

LINEARITY: THE RANGE OF DRUG CONCENTRATIONS THE METHOD IS ABLE TO ACCURATELY DETECT AND/OR QUANTITATE

VIALS I AND II CONTAINED THE DRUGS TO BE ANALYZED AT HIGH AND LOW CONCENTRATIONS; THE HIGH CONCENTRATION WAS AT THE UPPER LIMIT OF THE METHOD QUANTITATION CAPABILITY AND THE LOW CONCENTRATION IS AT THE LOWER LIMIT OF THE METHODS PERFORMANCE. THE RESULTS IN TABLE IV ARE ENTERED IN UNITS OF "NG/ML" ALTHOUGH SOME RESULTS WERE REPORTED ON THE TAPES AND DATA SHEET IN "MCG/ML".

TABLE IV: LINEARITY

THE RESULTS IN THIS TABLE ARE IDENTIFIED AS "EXPECTED" (EXP) AND "REPORTED" (REP).

	RESULTS (NG/ML)			
	VIAL I		VIAL II	
DRUG/DRUG CLASS	EXP	REP	EXP	REP
AMPHETAMINES	8000	HIGH	1600	1670
BARBITURATES	4000	HIGH	800	790
BENZODIAZEPINE MET.	4000	HIGH	800	765
CANNABINOIDS	50	46.7	13	LOW
COCAINE METABOLITE	800	840	180	180
OPIATES	1500	HIGH	300	332
PHENCYCLIDINE (PCP)	75	73.7	15	14.7

V. SPECIFICITY

SPECIFICITY: THE DEGREE OR ABILITY OF A TESTING METHOD TO REACT ONLY WITH THE DRUGS OR METABOLITES BEING TESTED AND TO EXCLUDE ALL OTHER DRUGS

SPECIFICITY OF IMMUNOASSAY SCREENING TESTS IS BASED ON THE WAY IN WHICH THE ANTIBODIES DEVELOPED "RECOGNIZE" OR REACT WITH THE DRUG BEING TESTED FOR. DIFFERENT MANUFACTURERS OF IMMUNOASSAY DRUG TESTING PRODUCTS HAVE "GROWN" ANTIBODIES USING DIFFERENT TECHNIQUES; THESE DIFFERENT TECHNIQUES MAY GREATLY EFFECT HOW WELL THE TESTING METHOD MAY REACT WITH ONLY THE DRUG/DRUG CLASS OF INTEREST AND NOT REACT WITH OTHER UNDESIRED DRUGS. THE BEST ILLUSTRATION OF THIS POINT IS THE AMPHETAMINE IMMUNOASSAY TEST WHICH MAY VARY GREATLY FROM ONE MANUFACTURER TO THE NEXT WITH REGARD TO HOW SPECIFICALLY THE TEST WILL ONLY DETECT AMPHETAMINES. SOME IMMUNOASSAY AMPHETAMINE ASSAYS WILL DETECT THE PRESENCE OF COLD MEDICATIONS AS IF THEY ARE AMPHETAMINES; THEREFOR IT IS EXTREMELY IMPORTANT TO EVALUATE THE TEST METHOD REGARDING THE POSSIBILITY OF A CROSS REACTION TO THESE NON-TARGETED COMPOUNDS.

TABLE V: SPECIFICITY

THE DATA IN THE FOLLOWING TABLE ARE THE EXPECTED AND REPORTED FOR VIALS XX-1 THROUGH XX-15. THE CONCENTRATION OF EACH TARGETED ANALYTE IS INDICATED IN PARENTHESES OR A UNDESIRED DRUG WHICH WAS IN THE SPECIMEN.

SAMPLE	EXPECTED (NG/ML)	REPORTED (NG/ML)
XX-1	NEGATIVE (EPHEDRINE)	NEGATIVE
XX-2	COCAINE MET (330)	COCAINE MET (360)
XX-3	NEGATIVE (PHENTERMINE)	AMPHETAMINE (690)
XX-4	NEGATIVE	NEGATIVE
XX-5	MORPHINE (400)	OPIATES (460)
XX-6	CANNABINOIDS (33)	NEGATIVE
XX-7	METHAMPHETAMINE (500)	NEGATIVE
XX-8	HYDROMORPHONE (600)	OPIATES (323)
XX-9	NORDIAZEPAM (400)	BENZODIAZEPINE (384)
XX-10	PHENOBARBITAL (500)	BARBITURATES (350)
XX-11	NEGATIVE (TYRAMINE)	NEGATIVE
XX-12	AMPHETAMINE (400)	NEGATIVE
XX-13	COCAINE MET (330)	COCAINE MET (360)
XX-14	CODEINE (400)	OPIATES (475)
XX-15	NEGATIVE (PHEYLPROP.)	NEGATIVE

VI. DISCUSSION

OVERALL THE TECHNOLOGY AND LABORATORY STAFF PERFORMED EXCELLENT. EACH OF THE VARIOUS AREAS STUDIES ARE DISCUSSED SEPARATELY.

ACCURACY

THE DATA PRESENTED IN TABLE II DEMONSTRATE THAT THE LABORATORY WAS ABLE TO CORRECTLY IDENTIFY 100% OF THE DRUGS CONTAINED IN VIALS A-I AND WITHOUT ANY "FALSE" POSITIVES. IN ADDITION THE EXPECTED AND REPORTED RESULTS COMPARE VERY WELL. THREE DIFFERENT TECHNICIANS WERE INVOLVED IN THE ANALYSIS OF THESE SPECIMENS (KREBS, GRUICH AND JONES) WHICH HELPS DOCUMENT THE ACCURACY OF THE ENTIRE STAFF AND LABORATORY SYSTEM.

VIAL A: PHENCYCLIDINE RESULTS COMPARED VERY WELL WITH A TARGET CONCENTRATION OF 70 NG/ML AND MEASURED OF 73.6 NG/ML.

VIAL B: MORPHINE AT TARGETED CONCENTRATION OF 600 NG/ML COMPARES WELL WITH REPORTED 637 NG/ML CONCENTRATION. MORPHINE IS THE PRINCIPAL OPIATE OF ABUSE OF CONCERN IN DRUG TESTING PROGRAMS.

VIAL C: AMPHETAMINE AT TARGETED CONCENTRATION OF 2000 NG/ML COMPARES WELL WITH REPORTED 1720 NG/ML (1.72 MCG/ML) CONCENTRATION.

VIAL D: CARBOXY-THC METABOLITE FROM MARIJUANA USE AT TARGETED CONCENTRATION OF 50 NG/ML COMPARES WELL WITH 57.2 NG/ML REPORTED CONCENTRATION.

VIAL E: SECOBARBITAL AT TARGETED CONCENTRATION OF 600 NG/ML COMPARES VERY WELL WITH 650 NG/ML (0.65 MCG/ML) REPORTED CONCENTRATION FOR BARBITURATES. SECOBARBITAL IS AN ABUSED SHORT ACTING BARBITURATES WHICH IS THE TARGETED ANALYTE FOR BARBITURATE IMMUNOASSAY SCREENING METHODS.

VIAL F: NORDIAZEPAM AT TARGETED CONCENTRATION OF 600 NG/ML COMPARES VERY WELL WITH 546 NG/ML REPORTED CONCENTRATION FOR BENZODIAZEPINE METABOLITES. NORDIAZEPAM IS A PRINCIPAL METABOLITE OF SEVERAL BENZODIAZEPINES AND IS THE TARGETED ANALYTE FOR BENZODIAZEPINE METABOLITE IMMUNOASSAY SCREENING METHODS.

VIAL G: CODEINE AT TARGETED CONCENTRATION OF 700 NG/ML COMPARES WELL WITH 778 NG/ML REPORTED CONCENTRATION FOR OPIATES. CODEINE IS ANOTHER OPIATE OF CONCERN FOR ABUSE BUT MAY ALSO BE PRESENT IN URINE FROM PRESCRIPTION TYLENOL #3 USE.

VIAL H: COCAINE METABOLITE (BENZOYLECGONINE) AT TARGETED CONCENTRATION OF 1000 NG/ML COMPARES WELL WITH 1060 NG/ML (1.06 MCG/ML) REPORTED CONCENTRATION. BENZOYLECGONINE IS THE PRINCIPLE URINE METABOLITE DOCUMENTING COCAINE/CRACK USE.

VIAL I: METHAMPHETAMINE AT TARGETED CONCENTRATION OF 2500 NG/ML COMPARES WELL WITH 2170 NG/ML (2.17 MCG/ML) REPORTED CONCENTRATION. NON-MEDICAL METHAMPHETAMINE USE IS INCREASING IN THE FORM OF SMOKABLE ICE.

PRECISION

ALL RESULTS FOR VIALS 1-9 DOCUMENTING WITHIN RUN AND BETWEEN RUN PRECISION ARE EXCELLENT. THE RESULTS ARE EVEN MORE IMPRESSIVE BECAUSE THEY WERE COMPILED OVER SEVERAL DAYS ON THREE DIFFERENT INSTRUMENTS BY THREE DIFFERENT TECHNICIANS. THE %CV INDICATED FOR EACH ASSAY IN THESE TABLES IS A "TRUE" INDICATION OF THE PRECISION OF INGALLS SHIPBUILDING LABORATORY. ONLY THE AMPHETAMINES ASSAY FOR AMPHETAMINE AND METHAMPHETAMINE DEMONSTRATED A BETWEEN RUN PRECISION THAT IS AT THE UPPER LIMIT OF ACCEPTABLE PERFORMANCE; ALL OTHER ASSAYS WERE AT %CV 6.2 OR LESS, WHICH IS EXCELLENT. WHAT IS PARTICULARLY IMPORTANT ABOUT THIS PARAMETER IS THAT THE DRUG SCREENING METHOD WILL PERFORM RELIABLY EACH DAY AT THE DECISION POINT (CUTOFF/THRESHOLD) OF THE ASSAY. THESE RESULTS ALSO DOCUMENT THE EXCELLENT PERFORMANCE OF STAFF IN MAINTENANCE, CALIBRATION AND OPERATION OF THE ADx INSTRUMENT SYSTEMS.

LINEARITY

ALL RESULTS FOR VIAL I AND VIAL II PERFORMED AS TO BE EXPECTED. THE DRUG CONCENTRATIONS INDICATED IN TABLE IV FOR VIAL I CHALLENGED THE UPPER END OF THE CALIBRATION CONCENTRATION RANGE. THE HIGHER CONCENTRATIONS FOR AMPHETAMINES, BARBITURATES (SECOBARBITAL), BENZODIAZEPINE METABOLITES (NORDIAZEPAM AND OPIATES ALL READ "HIGH" RATHER THAN A NUMERICAL VALUE; THESE RESULTS ARE NOT UNCOMMON FOR THESE DRUG CONCENTRATIONS. SPECIMENS WHICH READ "HIGH" MAY BE DILUTED TO OBTAIN A NUMERICAL VALUE; IN FACT THE DRUG CONCENTRATIONS IN VIAL II WERE A 1 TO 5 DILUTION OF VIAL I EXCEPT FOR CANNABINOIDS WHICH WERE A 1 TO 4 DILUTION. THE REPORTED RESULTS FOR VIAL II ARE ALL VERY CLOSE TO THE EXPECTED DRUG CONCENTRATIONS; THE ONLY RESULT WHICH DID NOT CORRELATE WAS CANNABINOIDS CHALLENGED AT 13 NG/ML AND WHICH WAS REPORTED AS "LOW". THE "LOW" CANNABINOIDS RESULT REPORTED IS NOT NECESSARILY A FAILURE ON THE PART OF THE LABORATORY BUT RATHER A VERY AGGRESSIVE EVALUATION OF THE DRUG TESTING PROGRAM.

SPECIFICITY

THE RESULTS OF EACH VIAL WITH REGARD TO DRUG PRESENT AND CONCENTRATION ARE DISCUSSED INDIVIDUALLY AS FOLLOWS.

VIAL XX- 1: THIS VIAL CONTAINED EPHEDRINE, A NONTARGETED DRUG, AT A CONCENTRATION OF 2000 NG/ML. EPHEDRINE IS AN OVER THE COUNTER DRUG WHICH REACTS WITH MOST AMPHETAMINE IMMUNOASSAY SCREENING METHODS TO YIELD AN UNDESIRED POSITIVE RESPONSE. THE NEGATIVE TEST RESULT DOCUMENTS THE ABBOTT FPIA FAILS TO DETECT THE EPHEDRINE AS A CROSS-REACTING COMPOUND. A PRACTICAL BENEFIT IS THAT SAMPLES CONTAINING EPHEDRINE WILL NOT GIVE A POSITIVE FPIA AMPHETAMINE RESULT AND THEREFOR WILL NOT HAVE TO BE ANALYZED BY GC/MS TO PROVE THE ABSENCE OF AMPHETAMINES.

VIAL XX- 2: THIS VIAL CONTAINED BENZOYLECGONINE (COCAINE METABOLITE) AT A CONCENTRATION OF 330 NG/ML, WHICH COMPARES VERY WELL WITH THE 360 NG/ML COCAINE METABOLITE REPORTED BY THE LABORATORY. THIS SPECIMEN WAS SUBMITTED A SECOND TIME AS XX-13 TO FURTHER ASSESS THE LABORATORIES ACCURACY AND PRECISION AND THE RESULTS DUPLICATED EXACTLY.

VIAL XX- 3: THIS VIAL CONTAINED PHENTERMINE AT A CONCENTRATION OF 2000 NG/ML AND THE LABORATORY REPORTED A 690 NG/ML AMPHETAMINE CONCENTRATION. PHENTERMINE IS ANOTHER OVER THE COUNTER DRUG WHICH HAS BEEN DETERMINED TO CROSS REACT WITH AMPHETAMINE IMMUNOASSAY SCREENING METHODS TO GIVE A "FALSE" POSITIVE RESPONSE. THIS SPECIMEN DEMONSTRATES THE POSSIBILITY OF THE ABBOTT FPIA GIVING A POSITIVE RESPONSE FOR AMPHETAMINES WHEN THIS DRUG IS PRESENT IN A SAMPLE. AS A PRACTICAL ISSUE THIS RESULT EMPHASIZES THE IMPORTANCE OF CONFIRMING IMMUNOASSAY AMPHETAMINE RESULTS BY GC/MS.

VIAL XX- 4: THIS SPECIMEN WAS A QUALITY CONTROL - URINE NEGATIVE AND WAS PROPERLY REPORTED AS A NEGATIVE.

VIAL XX- 5: THIS SPECIMEN CONTAINED MORPHINE AT A CONCENTRATION OF 400 NG/ML, WHICH COMPARES VERY WELL WITH THE 460 NG/ML OPIATES REPORTED.

VIAL XX- 6: THIS SPECIMEN CONTAINED CARBOXY-THC (MARIJUANA METABOLITE) AT A CONCENTRATION OF 33 NG/ML. THE LABORATORY REPORTED THE RESULT AS "NEGATIVE" SINCE THE CONCENTRATION RECORDED ON THE ADX TAPE IS 34.8 NG/ML AND THEREFOR BELOW THEIR APPARENT CUTOFF OF 50 NG/ML. THE EXPECTED AND MEASURED CONCENTRATIONS COMPARE VERY WELL. THESE RESULTS ILLUSTRATE THE IMPLICATIONS OF ESTABLISHING AN ARBITRARY THRESHOLD WHICH WILL "MISS" TRUE POSITIVE SPECIMENS WHEN THE TECHNOLOGY CAN ACCURATELY IDENTIFY LOWER CONCENTRATIONS.

VIAL XX- 7: THIS SPECIMEN CONTAINED METHAMPHETAMINE AT A CONCENTRATION OF 500 NG/ML. THE LABORATORY REPORTED THE RESULT AS "NEGATIVE" SINCE THE CONCENTRATION RECORDED ON THE ADX TAPE IS 490 NG/ML AND THEREFOR BELOW THEIR APPARENT CUTOFF OF 500 NG/ML. THE EXPECTED AND MEASURED CONCENTRATIONS COMPARE VERY WELL.

VIAL XX- 8: THIS SPECIMEN CONTAINED HYDROMORPHONE, AN OPIATE THAT IS USED FOR NON-MEDICAL PURPOSES, AT A CONCENTRATION OF 600 NG/ML. SINCE HYDROMORPHONE IS AN ABUSED OPIATE IS DESIRED TO TEST FOR THIS DRUG; HOWEVER OTHER IMMUNOASSAY OPIATE METHODS WILL NOT DETECT THE PRESENCE OF THIS DRUG AND WOULD HAVE REPORTED THIS RESULT AS NEGATIVE. AN IMPORTANT ISSUE IS INSURING THE LABORATORY PROVIDING GC/MS CONFIRMATION SERVICES TO SUPPORT THE SCREENING LABORATORY RESULTS INCLUDE ANALYSIS FOR HYDROMORPHONE, IN ADDITION TO MORPHINE AND CODEINE. THE RESULT REPORTED OF 323 NG/ML OPIATES IS CORRECT DUE TO THE WAY IN WHICH THIS DRUG IS DETECTED BY THE FPIA METHOD.

VIAL XX- 9: THIS SPECIMEN CONTAINED NORDIAZEPAM (BENZODIAZEPINE METABOLITE) AT A CONCENTRATION OF 400 NG/ML, WHICH COMPARES VERY WELL WITH THE REPORTED 384 NG/ML BENZODIAZEPINE METABOLITES. NORDIAZEPAM IS A METABOLITE FORMED IN THE BODY FROM SEVERAL DIFFERENT BENZODIAZEPINE DRUGS.

VIAL XX-10: THIS SPECIMEN CONTAINED PHENOBARBITAL (BARBITURATES) AT A CONCENTRATION OF 500 NG/ML, WHICH COMPARES WELL WITH THE REPORTED 350 NG/ML (0.35 MCG/ML) BARBITURATES. THE BARBITURATES ASSAY IS KEYED ON SECOBARBITAL WHICH IS AN ABUSED SHORT ACTING BARBITURATE; ALTHOUGH PHENOBARBITAL IS DETECTED IT IS DETECTED AS A LOWER CONCENTRATION DUE TO ITS CROSS REACTIVITY CHARACTERISTICS. OTHER IMMUNOASSAY METHODS ARE ALSO TARGETED ON SECOBARBITAL AND HAVE

A POOR RESPONSE AND DETECTION TO OTHER BARBITURATES. THIS SPECIMEN HIGHLIGHTS THE ADVANTAGE OF ABBOTT FPIA BARBITURATE ASSAY TO DETECT OTHER BARBITURATES.

VIAL XX-11: THIS SPECIMEN CONTAINED TYRAMINE AT A CONCENTRATION OF 1000 NG/ML. TYRAMINE IS A COMPOUND OFTEN FOUND IN URINE AND IN MOST AMPHETAMINE IMMUNOASSAY METHODS WILL RESULT IN A POSITIVE TEST. THIS SPECIMEN WAS CORRECTLY REPORTED AS NEGATIVE AND DOCUMENTS THE FPIA METHOD CAPABILITY OF NOT DETECTING THIS UNDESIRED COMPOUND.

VIAL XX-12: THIS SPECIMEN CONTAINED AMPHETAMINE AT A CONCENTRATION OF 400 NG/ML. ALTHOUGH THE LABORATORY REPORTED THE RESULT AS NEGATIVE THE ADX TAPE INDICATES AN AMPHETAMINE RESPONSE OF 410 NG/ML AND WAS APPARENTLY REPORTED NEGATIVE SINCE THE CONCENTRATION IS BELOW THE CUTOFF OF 500 NG/ML.

VIAL XX-13: REPEAT OF VIAL XX-2.

VIAL XX-14: THIS SPECIMEN CONTAINED CODEINE AT A CONCENTRATION OF 400 NG/ML, WHICH COMPARES WELL WITH THE 475 NG/ML OPIATES RESULT REPORTED.

VIAL XX-15: THIS SPECIMEN CONTAINED PHENYLPROPANOLAMINE AT A CONCENTRATION OF 1000 NG/ML. THIS DRUG IS AVAILABLE OVER THE COUNTER AND HAS BEEN DEMONSTRATED TO REACT WITH MOST AMPHETAMINE IMMUNOASSAY METHODS TO GIVE A FALSE POSITIVE RESPONSE. THE NEGATIVE RESULT REPORTED IS CORRECT.

perform his or her position; and

(b) the following, or appropriate alternatives:

(i) employee assistance programs, including contractor run, contractor sponsored, or contractor approved community based programs; and (ii) provisions for self-referrals and supervisory referrals.

(2) The contractor's program shall also include

(a) employee testing--

(i) upon reasonable suspicion that an employee uses a controlled substance;

(ii) when an employee has been involved in an on-the-job accident or unsafe practice;

(iii) as part of or as a follow-up to counselling or rehabilitation for illegal drug use.

(b) as part of a procedure of testing applicants for employment.

(3) Any drug testing program instituted under this clause shall conform to the "Mandatory Guidelines for Federal Workplace Drug Testing Programs" published by the Department of Health and Human Service (53 FR 11970), April 11, 1988.

(D) The Contractor shall not permit an employee to work in a sensitive position if

(1) the employee tests positive for the use of a controlled substance during a test pursuant to paragraphs (c)(1)(a) or (c)(2) of this clause;

(2) the use of a controlled substance is determined to be unlawful; or
(3) the employee is convicted of violating a criminal drug statute.

(E) The Contractor may permit an employee covered by paragraph (D) of this clause to work in a sensitive position in accordance with the contractor's established procedures only when--
(1) the contractor determines that the employee can adequately perform in his or her position;
(2) the employee is complying with any conditions or requirements of a rehabilitation program that the contractor requires; and
(3) the contractor notifies the contracting officer (or in the case of a contractor with a cognizant administrative contracting officer, such cognizant administrative contracting officer) of such determination.

(F)(1) This clause shall take precedence over any state or local law, rule or regulation or existing collective bargaining agreement to the contrary.
(2) "All costs incurred by the contractor in implementing this clause shall be fully allowable if otherwise reasonable, notwithstanding any rule to the contrary. The government agrees to indemnify the contractor for all other costs, including the costs of legal proceedings, fines, penalties,

judgments, and third party settlements concurred in by the government, if any, incurred by the contractor in carrying out this clause or defending any action brought against the contractor for complying with this clause."

(3) This clause shall not apply to commercial, or commercial-type products (See FAR 11.001).

(4) This clause shall not apply to a contract, or to that part of a contract, that is performed outside of the United States and its territories and possessions.

(5) This clause shall apply to the prime contract only.

(6) This clause shall not apply to any contract below the small purchase threshold (See FAR 13).

(end of clause)

DCS CORPORATION 1330 Braddock Place * Alexandria, Virginia 22314 * (703) 683-8430

August 5, 1992

Defense Acquisition Regulations Council
Attn: Mrs. Linda W. Neilson
OUSD A1. 3062 Defense Pentagon
Washington, D.C. 20301-3062

Re: DAR Case 88-083

Dear Mrs. Neilson:

In response to your request for comments regarding the Drug-Free Workforce Act, I would like to inform you of some of the difficulties we are encountering in establishing our random testing program:

1. Because the rule requires random testing for all "employees in a sensitive position", it is necessary for us to include employees who are located in our small offices, at least one of which is located in a rather remote location. We have several of these small offices scattered throughout the U.S. and it is difficult to find and make arrangements for collection sites which conform to the requirements you specify we must meet as stated in the "Mandatory Guidelines." I have not yet finished my research, but wonder what may happen if I am unable to find such sites? Could offices with less than (?) employees be exempted from the ruling, or could companies be allowed to deviate from the mandatory guidelines in selecting a collection site if unable to find one which meets all the guideline criteria?

2. Part of the mandatory guidelines [2.5 (d) (2)] stipulates that each agency must submit blind performance test specimens to its contract laboratories. The percentage of samples that must be submitted seems inordinately high given:

    a) The number of agencies using each approved laboratory;

    b) The quality assurance and quality control measures placed upon the laboratories and;

c) The expense to companies for the purchase of the specimens and payment for the testing to comply with this directive.

Since these costs are "allowable", contractors will be including them during the proposal process as part of their O/H expense, further adding to the government's cost of doing business. I do not believe the cost is justified and could be minimized by lowering the percentage of samples which must be submitted.

3. Despite the prominence of the MRO's function in the drug testing/verification process, the mandatory guidelines which we are required to follow place no "quality controls" on the MRO other than he/she be a "licensed physician with knowledge of substance abuse disorders." Since doctors, themselves, have a high percentage of substance abuse problems, this apparent lack of "quality control" over these physicians is somewhat troubling.

4. Finally, by whose authority does the DoD final ruling "take precedence over any state and local laws"?

Sincerely,

DCS CORPORATION

Barbara J. Napier
Human Resources Manager

BJN/mjw

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EAP ASSOCIATION

EMPLOYEE ASSISTANCE PROFESSIONALS ASSOCIATION, INC.

September 22, 1992

Defense Acquisition Regulations Council
ATTN: Mrs. Linda W. Neilson
OUSD(A)
3062 Defense Pentagon
Washington, DC 20301-3062

Re: **DAR Case 88-083**

Dear Mrs. Neilson:

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The Association's active membership represents most of the cumulative industry efforts to address workplace misuse and abuse of alcohol and other drugs. Additionally, we have a very active Department of Defense Special Interest Group which represents membership from all sizes of DoD contractor companies. As the spokesperson for these respective members, I would like to comment on the Department of Defense's request for comments notice printed in the July 23, 1992, *Federal Register*, **Defense Federal Acquisition; Regulation Supplement, Drug-Free Work Force.**

EAPA agrees illicit substance use and abuse has an adverse effect on the workplace. We do, however, maintain that the execution of a comprehensive drug-testing program alone is not the most effective way to deter substance abuse in the workplace. EAPA believes the implementation of a comprehensive Drug Free Workplace Program, utilizing employee assistance programs, as well as prevention programs and drug testing where appropriate, will more effectively respond to job performance and safety concerns at the workplace.

EAPA is concerned about the lack of a role for Employee Assistance Programs in the proposed rule. The notice proposes to incorporate by reference the "Mandatory Guidelines for Federal Workplace Drug Testing Programs; Final Guidelines," which require referral of a positive test result to an EAP. We believe that there should be an explicit reference to Employee Assistance Programs. Employees who test positive for illicit substances should immediately be referred to the employee assistance professional. This referral should be done regardless of disciplinary action taken by the employer, up to and including termination of the employee. Contractors, therefore, should be put on notice through an explicit reference in the rule to the requirement of an Employee Assistance Program.

The EAPA Board of Directors approved the following definition of an employee assistance program in 1988. This definition has been included in H.Rep. 102-522, which accompanied PL 102-321. To assist you in your efforts to appropriately include EAPs in the regulations, we recommend the following EAPA definition.

> ***An Employee Assistance Program (EAP) shall be a worksite-based program designed to assist in the identification and resolution of productivity problems associated with employees impaired by personal concerns, including, but not limited to: health, marital, family, financial, alcohol, drug, legal, emotional, stress, or other personal concerns that may adversely affect employee job performance.***
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> ***The specific core activities of EAPs shall include both of the following: (1) Expert consultation and training to appropriate persons in the identification and resolution of job-performance issues related to the employee personal concerns listed above and (2) Programming characterized by confidential, appropriate, and timely problem assessment services; referrals for appropriate diagnosis, treatment, and assistance; establishment of linkages between workplace and community resources that provide such services; and follow-up activities for employees who use those services.***

We would also like to take this opportunity to comment on confidentiality. Employee Assistance Programs maintain a strict sense of confidentiality, including compliance with the U.S. Department of Health and Human Services, Title 42 CFR Part II: Confidentiality of Alcohol and Drug Abuse Patient Records; Final Rule, where applicable. From our perspective, confidentiality is the keystone of any successful employee assistance program, and if violated, would have negative repercussions throughout the industry. EAPA has developed *Standards for Employee Assistance Programs*. Included in the Standards is the following provision on confidentiality.

> ***The EAP Professional shall prepare and implement a written confidentiality policy consistent with all professional standards and ethics, and adhere to all other regulations that may apply to information in the possession of the EAP. Disclosures specified by government guidelines and EAP policy will be communicated to users of the EAP services. The limits of the confidentiality policy shall be disclosed in writing to those who use the EAP.***

EAPA is also concerned about the lack of supervisory training requirements in the proposed rule. As noted in the definition, an EAP provides appropriate ongoing training and education. The rule should include a provision for supervisory training to assist in identifying and addressing deteriorating job performance or judgement, or observation which may result from illegal drug use by an employee. In addition to supervisory training, we would suggest education on substance abuse.

On behalf of all of EAPA members, I would like to thank the U.S. Department of Defense for this opportunity to comment on this proposed regulation and contribute to a drug-free work environment.

Sincerely,

Michael L. Benjamin, MPH
Chief Operating Officer

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EAPA agrees illicit substance use and abuse has an adverse effect on the workplace. We do, however, maintain that the execution of a comprehensive drug-testing program alone is not the most effective way to deter substance abuse in the workplace. EAPA believes the implementation of a comprehensive Drug Free Workplace Program, utilizing employee assistance programs, as well as prevention programs and drug testing where appropriate, will more effectively respond to job performance and safety concerns at the workplace.

EAPA is concerned about the lack of a role for Employee Assistance Programs in the proposed rule. The notice proposes to incorporate by reference the "Mandatory Guidelines for Federal Workplace Drug Testing Programs; Final Guidelines," which require referral of a positive test result to an EAP. We believe that there should be an explicit reference to Employee Assistance Programs. Employees who test positive for illicit substances should immediately be referred to the employee assistance professional. This referral should be done regardless of disciplinary action taken by the employer, up to and including termination of the employee. Contractors, therefore, should be put on notice through an explicit reference in the rule to the requirement of an Employee Assistance Program.

The EAPA Board of Directors approved the following definition of an employee assistance program in 1988. This definition has been included in H.Rep. 102-522, which accompanied PL 102-321. To assist you in your efforts to appropriately include EAPs in the regulations, we recommend the following EAPA definition.

> ***An Employee Assistance Program (EAP) shall be a worksite-based program designed to assist in the identification and resolution of productivity problems associated with employees impaired by personal concerns, including, but not limited to: health, marital, family, financial, alcohol, drug, legal, emotional, stress, or other personal concerns that may adversely affect employee job performance.***
>
> ***The specific core activities of EAPs shall include both of the following: (1) Expert consultation and training to appropriate persons in the identification and resolution of job-performance issues related to the employee personal concerns listed above and (2) Programming characterized by confidential, appropriate, and timely problem assessment services; referrals for appropriate diagnosis, treatment, and assistance; establishment of linkages between workplace and community resources that provide such services; and follow-up activities for employees who use those services.***

We would also like to take this opportunity to comment on confidentiality. Employee Assistance Programs maintain a strict sense of confidentiality, including compliance with the U.S. Department of Health and Human Services, Title 42 CFR Part II: Confidentiality of Alcohol and Drug Abuse Patient Records; Final Rule, where applicable. From our perspective, confidentiality is the keystone of any successful employee assistance program, and if violated, would have negative repercussions throughout the industry. EAPA has developed *Standards for Employee Assistance Programs*. Included in the Standards is the following provision on confidentiality.

> ***The EAP Professional shall prepare and implement a written confidentiality policy consistent with all professional standards and ethics, and adhere to all other regulations that may apply to information in the possession of the EAP. Disclosures specified by government guidelines and EAP policy will be communicated to users of the EAP services. The limits of the confidentiality policy shall be disclosed in writing to those who use the EAP.***

EAPA is also concerned about the lack of supervisory training requirements in the proposed rule. As noted in the definition, an EAP provides appropriate ongoing training and education. The rule should include a provision for supervisory training to assist in identifying and addressing deteriorating job performance or judgement, or observation which may result from illegal drug use by an employee. In addition to supervisory training, we would suggest education on substance abuse.

On behalf of all of EAPA members, I would like to thank the U.S. Department of Defense for this opportunity to comment on this proposed regulation and contribute to a drug-free work environment.

Sincerely,

Michael L. Benjamin, MPH
Chief Operating Officer

4601 North Fairfax Drive
Suite 1001
Arlington, VA 22203

Telephone (703) 522-6272
Fax (703) 522-4585

EAP · ASSOCIATION ·

EMPLOYEE ASSISTANCE PROFESSIONALS ASSOCIATION, INC.

September 22, 1992

Defense Acquisition Regulations Council
ATTN: Mrs. Linda W. Neilson
OUSD(A)
3062 Defense Pentagon
Washington, DC 20301-3062

Re: **DAR Case 88-083**

Dear Mrs. Neilson:

The Employee Assistance Professionals Association (EAPA) is the non-profit, international professional membership association representing individuals and organizations in the Employee Assistance Program (EAP) field. EAPA was founded in 1971 and presently has approximately 7,000 members and 85 chapters. It is governed by a voluntary Board of Directors and headquartered in Arlington, Virginia.

The Association's active membership represents most of the cumulative industry efforts to address workplace misuse and abuse of alcohol and other drugs. Additionally, we have a very active Department of Defense Special Interest Group which represents membership from all sizes of DoD contractor companies. As the spokesperson for these respective members, I would like to comment on the Department of Defense's request for comments notice printed in the July 23, 1992, *Federal Register*, **Defense Federal Acquisition; Regulation Supplement, Drug-Free Work Force.**

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>
> ***The specific core activities of EAPs shall include both of the following: (1) Expert consultation and training to appropriate persons in the identification and resolution of job-performance issues related to the employee personal concerns listed above and (2) Programming characterized by confidential, appropriate, and timely problem assessment services; referrals for appropriate diagnosis, treatment, and assistance; establishment of linkages between workplace and community resources that provide such services; and follow-up activities for employees who use those services.***

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> ***The EAP Professional shall prepare and implement a written confidentiality policy consistent with all professional standards and ethics, and adhere to all other regulations that may apply to information in the possession of the EAP. Disclosures specified by government guidelines and EAP policy will be communicated to users of the EAP services. The limits of the confidentiality policy shall be disclosed in writing to those who use the EAP.***

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On behalf of all of EAPA members, I would like to thank the U.S. Department of Defense for this opportunity to comment on this proposed regulation and contribute to a drug-free work environment.

Sincerely,

Michael L. Benjamin, MPH
Chief Operating Officer

Enzymatics, Inc.

500 Enterprise Road
Horsham, PA 19044
215-674-3288
Fax 215-674-3273
800-245-6845

September 14, 1992

Defense Acquisition Regulations Council
Attn: Mrs. Linda W. Neilson
OUSD(A), 3062 Defense Pentagon
Washington, D.C. 20301-3062

SUBJECT: DAR Case 88-083, Proposed Rule and Request for Comment

Dear Mrs. Neilson:

The purpose of this letter is to respond to the request for public comment concerning the Proposed Rule for implementing the Drug Free Workplace Regulation Supplement. It is our hope that the following information may be of assistance to the Department of Defense in promoting security and safety within the defense contractor-based workplace.

The preservation of National Security is obviously enhanced by a Drug-Free workplace. The Department of Defense, particularly the uniformed military services, have always been at the forefront of resolving troubling social issues in the United States. In the contractor/civilian-oriented drug-free workplace, however, the Departments of Energy and Transportation are setting the standard for excellence and rational thought by including alcohol in the concept for drug testing.

Promoting National Security and safety in the workplace are hollow concepts without including testing for the single most damaging drug in use in the United States: alcohol.

Since alcohol is the most abused drug in the United States, we recommend that the Department of Defense follow the leadership of the Departments of Energy and Transportation and amend Paragraph 223.570-1 Policy to read:

"...eliminating the unlawful use of any drug (to include alcohol) by employees whose duties affect health, safety, national security, or accomplishment of the DoD mission."

Further recommend that the Omnibus Transportation Employee Testing Act of 1991, established under Public Law 102-143, dated October 28, 1991 be viewed as a potential model for implementing alcohol testing DoD-wide within the contractor base. After all, the Transportation Industry is probably the single greatest asset in the United States promoting our collective National Security.

If the concept works for transportation, it should work for the defense contractors. From a practical point-of-view, it is less expensive to test for alcohol abuse, and the resultant savings in lives, injuries and so forth, is instantaneous because testing is real-time. Drug testing results, on the other hand, take days to receive while any damage done is to the National psyche and is usually a matter of historical record.

DoD must concentrate on solving real-time problems (alcohol abuse) with real-time impact on National Security on a real-time basis. Advanced technology now exists to address this problem of workplace drug abuse (alcohol abuse) in an economical and cost-effective manner. The same technology is being used widely in the military, and soon will be a part of the Transportation and Energy cultures.

Sincerely,

David E. Sanderson
Director of Government
Business Development

G
C A
N

Government Contractor's Assistance Network

Post Office Box 28944
Santa Ana, CA 92799-8944
(714) 542-2710
FAX: (714) 542-6814

September 14, 1992

Defense Acquisition Regulation Council
Attention: Mrs. Linda W. Neilson, OUSD (A)
3062 Defense Pentagon
Washington, DC 20301-3062

Subject: Drug-Free Work Force Policy

Reference: DAR Case 88-083, 57 FR 32769

Dear Mrs. Neilson:

In response to your solicitation for comments on the subject and referenced DAR Case, we are pleased to submit the following:

1. No issue is taken with the proposed clause as written.

2. It is our contention that the area that requires revision is the application. It is generally understood that some seventy percent (70%) of the dollars expended today on Department of Defense (DoD) contracts flow through the prime contractor to subcontractors and suppliers. Although our review of the legislative history leading to the Drug-Free Work Place Act reveals no proscription as to the flow down, neither the Federal Acquisition Regulation (FAR) or Department of Defense Federal Acquisition Regulation Supplement (DFARS) implementation of the Act provides for its flow down to subsequent tiers. Almost every other socio-economic clause requires flow down and places the burden on the prime contractor to monitor and ensure compliance and reporting.

3. The final clause should also establish and implement a program of compliance review to ensure ; (1) contractor implements a Drug-Free Program ; (2) contractor identifies employee's in sensitive positions which , and (3) establish the required re-habilitation programs for employee's who test positive.

Finally, in April of this year we addressed our concerns and recommendations to the Office of National Drug Control Policy and the DoD; reference the FAR clause.

Thank you for your cooperation in this matter; it is greatly appreciated.

Sincerely,

GOVERNMENT CONTRACTOR'S ASSISTANCE NETWORK

Herbert W. McCoy, CPPM, CF
Principal

Grumman Corporation
Bethpage, New York 11714-3582

CB&FP/CD-0992-17
18 September 1992

Defense Acquisition Regulations Council
Attn: Mrs. Linda W. Neilson, OUSD(A)
3062 Defense Pentagon
Washington, DC 20301-3062

Subject: DAR Case 88-083
Defense Federal Acquisition Regulation
Drug Free Work Force

Dear Mrs. Neilson:

The proposed final rule set forth at 57 Federal Register 32769-32770 makes three changes that together make this proposed rule burdensome and create serious legal issues. We suggest that the proposed rule be withdrawn.

The interim rule covers only employees granted access to classified information or other employees who the Contractor determines involve functions requiring a high degree of trust and confidence. The proposed final rule as defined would expand the coverage to almost every employee. Our analysis is that over eighty percent of our work force would fall into this category.

The interim rule gives the contractor considerable flexibility, both in establishing the criteria for a drug testing program and in dealing with those who are using drugs illegally. The proposed final rule would require that contractors start a random drug testing program for covered employees. The rule would further mandate that contractors "not permit" a covered employee to work on a DOD contract if he or she tests positive for illegal drug use.

Finally, the clause set forth in the interim rule specifically provides that the drug testing program "shall not apply" to the extent "inconsistent with State or local law." The clause set forth in the proposed final rule would provide that "the requirements of this clause take precedence over any State and local laws to the contrary."

Concerning the latter point, the kind of broadly-based compulsory random drug testing program contemplated by the proposed final rule is probably not valid under New York State law. See Fiorenza f. Grumman, 140 A.D. 2d 295, 527 NYS.2d 806 (1988). The final rule pre-empting of State and local legislation and possible individual rights of privacy considerations leaves the contractor vulnerable to Government and Personal Litigation.

The stipulation which requests the approval of the Contracting Officer before an employee can return to work after successfully completing a rehabilitation program conflicts with current employment practices. The responsibility for rehabilitation clearly rests with the employee and the employer. The final rule should not increase the administrative burden by interjecting the government into this process.

On the Federal level, there is considerable support for the proposition that this kind of broadly-based compulsory random drug testing program imposed by the Federal Government is unconstitutional. This is a violation of the right to protection against unreasonable searches and seizures provided by the Fourth Amendment to the U.S. Constitution. In the past, random drug testing programs have passed judicial muster when limited to such obviously critical employees as nuclear power plant employees or prison guards. A random sampling program aimed, according to the proposed final rule, at almost every employee involved in the manufacturing process, would very likely be held by the courts as constitutionally invalid. See Harmon v. Thornburgh, 878 F.2d 484 (D.C. Cir. 1989), cert. den. 110 S.Ct. 865 (1990).

Thank you for this opportunity to respond to the referenced proposed rule.

Very truly yours,

GRUMMAN CORPORATION
Corporate Operations

Ronald L. Smith
Director of Corporate Contracts
and Business Policy

RLS/es

cc: R. Fitzgerald
R. Foster
J. Groen
M. Polansky

ES-768

Grumman Corporate Operations
Bethpage New York 11714-3586

CB&FP/CD-0992-20
22 September 1992

Defense Acquisition Regulations Council
Attn: Mrs. Linda W. Neilson, OUSD(A)
3062 Defense Pentagon
Washington, DC 20301-3062

Subject: DAR Case 88-083
Defense Federal Acquisition Regulation
Drug Free Work Force

Reference: Grumman Corporation Letter
CB&FP/CD-0992-17 dated 18 September 1992

Dear Mrs. Neilson:

Per our above-referenced letter, the citation on page two, first paragraph, "Fiorenza f. Grumman," should be "Fiorenza v. Gunn."

I am sorry for this inconvenience.

Very truly yours,

GRUMMAN CORPORATION
Corporate Operations

for Ronald L. Smith
Director of Corporate Contracts
and Business Policy

RLS/es

ES-774

INSPECTOR GENERAL
DEPARTMENT OF DEFENSE
400 ARMY NAVY DRIVE
ARLINGTON, VIRGINIA 22202-2884

Audit Policy
and Oversight

AUG 18 1992

MEMORANDUM FOR DIRECTOR, DEFENSE ACQUISITION REGULATIONS COUNCIL

SUBJECT: Defense Acquisition Regulatory Case 88-083

The Office of the Inspector General, Department of Defense, does not wish to comment on Defense Acquisition Regulatory Case 88-083 (Drug-Free Work Force). We appreciate the opportunity to review the case.

Donald E. Davis
Deputy Assistant Inspector General
for Audit Policy and Oversight

International
Association of
Machinists and
Aerospace Workers

9000 Machinists Place
Upper Marlboro, Maryland 20772-2687

Area Code 301
967-4500

OFFICE OF THE GENERAL VICE PRESIDENT

GL 2 Legal Department

September 21, 1992

Defense Acquisitions Regulations Council
3062 Defense
Pentagon, Washington, DC 20301-3062

ATTENTION: Mrs. Linda W. Neilson, OUSD(A)

Subj: DAR CASE 88-083 - Comments of the International Association of Machinists and Aerospace Workers, AFL-CIO, and International Union of Electronic, Electrical, Salaried, Machine and Furniture Workers, AFL-CIO, in Response to the DOD's Proposed Rulemaking Concerning the Defense Federal Acquisition Regulation Supplemental Interim Rule for a Drug-Free Workplace

Dear Mrs. Neilson:

The International Association of Machinists and Aerospace Workers, AFL-CIO, and the International Union of Electronic, Electrical, Salaried, Machine and Furniture Workers, AFL-CIO, submit the enclosed Comments in response to the above-referenced proposed rule.

Sincerely yours,

Owen E. Herrnstadt
ASSOCIATE GENERAL COUNSEL
International Association of
Machinists and Aerospace Workers

OEH/bk

Enclosures

DAR CASE 88-083

COMMENTS OF THE INTERNATIONAL ASSOCIATION OF MACHINISTS AND AEROSPACE WORKERS, AFL-CIO, AND INTERNATIONAL UNION OF ELECTRONIC, ELECTRICAL, SALARIED, MACHINE AND FURNITURE WORKERS, AFL-CIO, IN RESPONSE TO THE DOD'S PROPOSED RULE-MAKING CONCERNING THE DEFENSE FEDERAL ACQUISITION REGULATION SUPPLEMENTAL INTERIM RULE FOR A DRUG-FREE WORKFORCE

The International Association of Machinists and Aerospace Workers, AFL-CIO, and International Union of Electronic, Electrical, Salaried, Machine and Furniture Workers, AFL-CIO, are labor unions representing employees in a variety of industries, including defense. Among other positions, IAM and IUE members employed in the defense industry include mechanics and related employees, machinists, tool and die makers, machine operators, helpers, production workers engaged in the manufacture of aircraft and other equipment and its component parts, and office and technical workers.

The proposed regulations depart from the DOD's interim rule issued in 1988 in several significant respects and could potentially result in random drug testing for tens of thousands of IAM and IUE represented workers. Perhaps the most significant departure is the vague and expansive definition of an employee in a "sensitive position." As proposed, the class of employees who will be required to undergo random testing would include virtually all employees engaged in the manufacture of defense equipment and its major component parts, regardless of whether the actual job functions of the employees are in any way "sensitive." In addition, the Notice does not address the potential costs of testing so many employees, nor the fact that defense contractors

will undoubtedly attempt to pass such costs on to the DOD and ultimately the American people.

The interim rule had stated that the clause's drug testing provisions were inapplicable to the extent they were inconsistent with an existing collective bargaining agreement. They also required the contractor to raise the inconsistencies in contract negotiations. The final regulations do not refer to collective bargaining at all. While we, of course, share the DOD's interest in safety, it is our view that the proposed rule is unsupported and concerns matters that should be resolved through labor-management negotiations rather than government-imposed regulations.

Thus, the Notice fails to document any need for the regulations it contains. This should not be surprising since no significant support for these regulations exist. Given this lack of basic information, there should be no effort to implement any type of drug testing program industry-wide until such time as there is hard evidence documenting industry-wide substance abuse problems that, in fact, are jeopardizing safety. In the event that there is such evidence, which at this time we doubt, then the problem should be addressed in the same manner that other problems of this nature have been dealt with in other industries -- through rehabilitation and drug awareness programs negotiated by employers and their unions.

If the DOD, nevertheless, insists on proceeding with industry-wide regulations concerning drug testing, then we strongly recommend that the regulations be in the form of guidelines for

those contractors who have documented substance abuse problems that are affecting safety. Such guidelines should encourage programs that have as their fundamental premise education and prevention of drug addiction. In addition DOD guidelines should require that any program fully protect employee privacy and provide nonpunitive, rehabilitation-oriented responses for those individuals whose drug addiction has, in fact, impaired their job performance.

With these basic principles in mind, any DOD guidelines regarding substance abuse programs also should include the following specific provisions:

1. Substance abuse is a treatable illness that will be viewed as any other long-term serious illness. In all cases, rehabilitation and education of affected employees will be the primary goal.

2. It will be recognized that while both contractors and employees have a proper interest in workplace safety and job performance, every employee has a right to his or her private life and no action shall be taken against an employee based on off-duty conduct unless it can be conclusively demonstrated that the employee's off-duty conduct is <u>specifically</u> and <u>directly</u> impairing his or her on-the-job performance.

3. It will follow then that the use of drug tests will be strictly limited to those situations where there is a

specific, objective reason to believe that the person who is to be tested is jeopardizing workplace safety or is not performing his or her job because of on-the-job intoxication and impairment. Random testing will not be permitted, nor may a contractor perform any test until the "reason to believe" the employee is impaired is documented in writing. This documentation will be by more than one management official and include someone who is not the employee's immediate supervisor. The employee's union representative shall be advised any time there is a request to submit to a drug test.

4. If and when drug tests are to be performed, there will be the maximum technological and procedural safeguards in place. Thus, only federally certified laboratory procedures will be utilized, and any laboratory selected must demonstrate that it observes the most rigorous quality control procedures, requires its technicians to be fully trained and experienced in the procedures being utilized, and has systems in place to assure a proper "chain of custody" of the samples taken. Furthermore, any employee who is required to take a drug test may, upon request, obtain a "split sample" to be tested by his or her own laboratory. The employee shall then have the right to challenge the accuracy of the employer's test results <u>prior</u> to any employer action.

a. DOD guidelines must further provide for retesting of any sample testing positive on an initial drug screen. This confirmation test shall be done using state-of-the-art gas chromatography and mass spectrometry. If a contractor fails to so confirm a positive test result, that test may not provide the basis for any adverse employment action, nor may any record of such an unconfirmed test be left in an employee's personnel file.

b. Any employee who tests negative or successfully challenges the accuracy of a positive result shall be compensated for the embarrassment, invasion of privacy, and mental duress involved in being required to submit to the process.

5. The DOD guidelines shall require that any employee who has a confirmed positive test will be referred to an agreed-upon rehabilitation program or Employer Assistance Plan established, where applicable, through the collective bargaining process. Rehabilitation shall be covered under established benefit plans and health insurance coverage. If it ever becomes necessary to impose discipline for on-the-job infractions that stem from substance induced impairment, discipline will be progressive and subject to challenge under the "just cause" provisions of any collective bargaining agreement.

* * * * * * * * * * *

We trust the foregoing responds to your request for comments. Where we have not commented, it is because the information is unavailable to us. Once again, we urge the DOD to move with great caution in this area so as to avoid unwarranted and unnecessary disruptions in the lives of our respective employees.

Thank you for considering our views.

Respectfully submitted,

George J. Kourpias

George J. Kourpias
INTERNATIONAL PRESIDENT
International Association of
Machinists and Aerospace Workers

William H. Bywater

William H. Bywater
INTERNATIONAL PRESIDENT
International Union of
Electronic, Electrical,
Salaried, Machine and
Furniture Workers

International Association of Machinists
and Aerospace Workers

LODGE NO. 389

AFFILIATED WITH DISTRICT NO. 50 AND CALIFORNIA STATE CONFERENCE OF MACHINISTS A. F. OF L.-C. I. O.

September 16, 1992

MACHINISTS UNION HALL
5150 KEARNY MESA ROAD
SAN DIEGO, CALIFORNIA 92111

PHONE 292-5150

Mrs. Linda W. Nelson, OUSED (A)
Defense Acquisition Regulations Council
3062 Defense Pentagon
Washington, D.C. 20301-3062

Subject: Proposed Random Drug Testing for US Navy Contract Procurement Language. (DAR Case 88-083)

Dear Mrs. Nelson:

In San Diego we represent over six hundred shipyard workers at National Steel and Shipbuilding Company (NASSCO), over one hundred shipyard workers at Campbell's Shipyard and a small number at several of the subcontractors on our waterfront.

Last May we received from NASSCO management a copy of the DOD's proposed new "Clause A, DRUG-FREE WORK FORCE (DEC 1991)" from its Federal Acquisition Regulations which states "as a minimum the program shall provide for the random drug testing of contractor employees working in sensitive positions."

Given the proposal's wide-ranging definition of "employee in a sensitive position" all of our production and maintenance workers in the shipyards plus many others working there would be subject to random drug testing. We think the proposal is very wrong and should not be adopted for the following reasons:

1. Random drug testing is an unreasonable invasion of our members' privacy absent any evidence of a particular problem of drug abuse in our shipyards. All of our employers on the waterfront have drug testing programs that include pre-hire screening, for cause testing and employee assistance programs to deal with what drug abuse problems we do have. No one has shown that these programs are inadequate.

2. Random drug testing in the eyes of many of our members means that they are suspected of drug abuse just because they happen to pull a wrench for a defense prime contractor. As veterans and loyal defense workers many of these people are insulted by such testing without cause. There is no real justification for singling them out from the rest of our population and subjecting them to random drug testing procedures. In fact they are less potentially dangerous to society than the car driver on the road.

3. The cost of the proposed random drug testing program on our shipbuilding and ship repair industry only adds to the current financial strains we are facing, especially in this period of

declining defense budgets. At a time when we must become competitive in the world market in order to survive, this proposal is but another cost disadvantage against foreign competitors who subsidize rather than punish their shipyards. It makes us less competitive not more competitive!

4. We are a partner in joint health and safety programs with most of our employers and believe that employee/employer cooperation and good OSHA laws and standards are the best tools to deal with health and safety issues in our shipyards. Random drug testing has never been an item on our or OSHA's agenda. We are the ones that work in these yards, who live and die with the health and safety problems we create. For an administration that preaches reducing government restrictions on business and reducing regulations, this proposal is going in the wrong direction.

5. Not only is this proposal unnecessary and unfair it is inconsistent because it does not require the same program for subcontractors. As a result in each shipyard subject to clause A there would be employees of the prime contractor who would be tested working along side employees of subcontractors who would not be subject to random drug testing. Is this fair or safe for the employees of the prime contractor? Is this fair to those shipyards who must bear the cost of the proposal while subcontractors do not? Is this bureaucratic nonsense or what?

Given these shortcomings the proposal we saw from DOD shows that the people who put it together are out of touch with the needs of the real world they are trying to make the rules for. Enough is enough. Please leave us alone. We have enough problems trying to survive without more hassles.

Sincerely,

Peter Zschiesche
Business Representative
PZ:lcb
opeiu-30

cc: Kourpias, Int'l Pres.
Poulin, GVP, NE Terr.
Ostro, GVP, West Terr.
Burnsky, MTD, AFL-CIO
Beck, Gen. Counsel
Batson, DBR
Hardin, Sec-Treas., PCMTDC
Maudlin, DBR
LL 389

TAMPA BAY AREA LODGE NO. 570

INTERNATIONAL ASSOCIATION of MACHINISTS and AEROSPACE WORKERS

August 24, 1992

From:
Bob Betterton
President
4020 80th Avenue
Pinellas Park, Fl. 34665

To:
The Defense Acquisition Regulations Council
Attn.: Mrs. Linda W. Nelson, OUSED (A)
3062 Defense Pentagon
Washington, D.C. 20301-3062

Dear Council,

It is our opinion and belief that the drug-free work force clause of September, 1988 should NOT be changed to accommodate random drug testing for the following reasons:

1.) It is an unreasonable and unacceptable invasion of privacy. (i.e.; body fluids)

2.) It is unfair to force the added financial burden on employers particularly at this time when most if not all shipyards in the United States are struggling to survive a dormant market in repairs and new ship construction.

3.) It has never been determined that a problem of drug abuse is at a level at our shipyards (i.e. The American Ship Building Co., Tampa Shipyards, Inc.) that warrants random vs. probable cause.

4.) It is our intention to see money spent that we as the work force, in partnership with our management, have determined to be real problems and a threat to our health and safety.

In conclusion, we feel that it would be a perfidious act for any agency or department of the United States Government to mandate random drug testing to private shipbuilding and repair yards.

Sincerely,

Bob Betterton

BB/kw
cc:file
E. House
G. Kourpias
R. Cox

TAMPA BAY AREA LODGE NO. 570

INTERNATIONAL ASSOCIATION of MACHINISTS and AEROSPACE WORKERS

August 24, 1992

From:
Bob Betterton
President
4020 80th Avenue
Pinellas Park, Fl. 34665

Subj: Random Drug Testing
DAR Case 88-083
United States Navy Contract
Procurement Language

To:
The Defense Acquisition Regulations Council
Attn.: Mrs. Linda W. Nelson, OUSED (A)
3062 Defense Pentagon
Washington, D.C. 20301-3062

Dear Council,

It is our opinion and belief that the drug-free work force clause of September, 1988 should NOT be changed to accommodate random drug testing for the following reasons:

1.) It is an unreasonable and unacceptable invasion of privacy. (i.e.; body fluids)

2.) It is unfair to force the added financial burden on employers particularly at this time when most if not all shipyards in the United States are struggling to survive a dormant market in repairs and new ship construction.

3.) It has never been determined that a problem of drug abuse is at a level at our shipyards (i.e. The American Ship Building Co., Tampa Shipyards, Inc.) that warrants random vs. probable cause.

4.) It is our intention to see money spent that we as the work force, in partnership with our management, have determined to be real problems and a threat to our health and safety.

In conclusion, we feel that it would be a perfidious act for any agency or department of the United States Government to mandate random drug testing to private shipbuilding and repair yards.

Sincerely,

Bob Betterton

BB/kw
cc:file
E. House
G. Kourpias
R. Cox

TAMPA BAY AREA LODGE NO. 570

INTERNATIONAL ASSOCIATION of MACHINISTS and AEROSPACE WORKERS

August 24, 1992

From:
Bob Betterton
President
4020 80th Avenue
Pinellas Park, Fl. 34665

Subj: Random Drug Testing
DAR Case 88-083
United States Navy Contract
Procurement Language

To:
The Defense Acquisition Regulations Council
Attn.: Mrs. Linda W. Nelson, OUSED (A)
3062 Defense Pentagon
Washington, D.C. 20301-3062

Dear Council,

It is our opinion and belief that the drug-free work force clause of September, 1988 should NOT be changed to accommodate random drug testing for the following reasons:

1.) It is an unreasonable and unacceptable invasion of privacy. (i.e.; body fluids)

2.) It is unfair to force the added financial burden on employers particularly at this time when most if not all shipyards in the United States are struggling to survive a dormant market in repairs and new ship construction.

3.) It has never been determined that a problem of drug abuse is at a level at our shipyards (i.e. The American Ship Building Co., Tampa Shipyards, Inc.) that warrants random vs. probable cause.

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Bob Betterton

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R. Cox

IRONWORKERS

SHOPMEN'S LOCAL UNION NO. 627

International Association
of Bridge, Structural and
Ornamental Iron Workers
AFL-CIO

2957 54th Street
San Diego, California 92105
Telephone: 262-2431

September 18, 1992

Re: DAR Case 88-083

Mrs. Linda W. Neilson, OUSD(A)
Defense Acquisition Regulations Council
3062 Defense Pentagon
Washington, D.C. 20301-3062

Dear Mrs. Neilson:

I was very disturbed to find that DOD has published for comment a proposed clause putting onerous new requirements on defense contractors and their employees. This new clause specifies that drug-free workplace policies in the shipbuilding and ship repair industries shall "as a minimum . . . provide for the random drug testing of Contractor employees working in sensitive positions."

This labor organization represents some 1,500 skilled shipyard workers on the San Diego waterfront. The vast majority are involved is some phase of ship construction or repair under contract to the US Navy. Let me assure you, Mrs. Neilson, our members are not criminals or drug addicts. They are hard-working men and women with families and homes. They are good citizens and many are honorably-discharged veterans of the armed forces. Our members served to protect this country's precious heritage of individual liberties. Why shouldn't they now be allowed to enjoy the rights they fought to protect?

This proposed new rule is a completely unjustified invasion of the privacy rights of US citizens and taxpayers. No one has shown or even asserted that a generalized problem of drug abuse exists in our industry.

But our industry does have its problems. It is in precarious financial condition. It operates on the slimmest of profit margins in a world market in which it competes against foreign enterprises that are heavily subsidized by their governments. What sense does it make to burden our industry with yet another layer of expensive and unnecessary regulation?

Mrs. Neilson, this proposed rule is bad policy at its worst. It was proposed to remedy a problem that doesn't exist. It imposes a burdensome disadvantage upon a threatened strategic industry. And in doing so it offends and outrages the sensibilities of law-abiding citizens. Please don't carry out this plan.

Very truly yours,

Thomas J. McCammon

Thomas J. McCammon
President

Litton
Corporate

Litton Industries, Inc.
360 North Crescent Drive
Beverly Hills, California
90210-4867

Tel: 213 859-5960
Fax: 213 859-5940

John E. Preston
Vice President
Associate General Counsel

Via Federal Express

22 September 1992

Defense Acquisition Regulations Council (DARS)
Attn: Mrs. Linda W. Neilson
C-103 CAFRITZ Bldg.
1211 South Fern Street
Arlington, VA 22202

Re: Public Comment, DAR Case 83-083, "Drug Free Work Force Policy"

Dear Mrs. Neilson,

This responds to the Department of Defense Drug Free Work Force Policy proposed regulation announced in 57 Federal Register 32769 on 23 July 1992. That announcement invited public comment to assist in the formulation of the final rule. Per telephone call with Newton Lesh of my staff on 18 September 1992 you granted us a four day extension (to 25 September 1992) for submission of comments and provided us the above address to be used for Federal Express deliveries. This submission is within the extension period. Our comments below relate to the requirement for mandatory random drug testing.

We perceive substantial societal and economic benefit flowing to the nation by the adoption of a workable drug free policy. Litton Industries is committed to a drug free society and has established policies and guidelines to achieve that end among its employees. However, in designing and implementing our policies we have become aware of legal and administrative constraints which force us to tailor our policies to meet the requirements of state constitutional and statutory law as well as the federal constitution, and certain federal statutes concerning collective bargaining.

Indeed, all of our divisions that sell to the U. S. government comply with the Drug Free Workplace Act and its implementing regulation found in the Federal Acquisition Regulations. We also comply with the 1988 version of the DoD Drug Free Work Force Clause. Our divisions whose operations are regulated by a Department of Transportation (DOT) agency, (FAA, Coast Guard, Federal Highway Administration) conduct random drug testing as required under those Department of Transportation rules.

We recite this because we wish to contrast these rules, with which we have had experience, with the proposed DoD rule. We believe that the proposed DoD rule is fraught with compliance difficulties particularly in four respects.

1. No Preemption of State Law

The proposed rule purports to preempt contrary state constitutional and statutory law in those states which, like California, have and enforce constitutional and statutory protections against random drug testing of employees except in extremely limited circumstances.

In California, violation of privacy rights is against public policy and subjects the employer to punitive damages. For example, Article 1, Section 1, of the California Constitution guarantees each California resident the right of privacy from unwarranted intrusion into his or her private life, whether by government entities or California private businesses. This constitutional right has been the subject of appellate court decisions and opinion that prohibit a government contractor located in California from instituting random drug testing across a broad scope of job positions, such as required in the proposed DoD clause.

Unless the DoD drug testing requirement preempts existing California constitutional and common law, as well as similar laws of other states, DoD contractors will certainly be exposed to immense liability to employees who seek to enforce their state constitutional rights, by either refusing to submit a specimen when directed, or, by suing when discharged or removed from a sensitive position for such refusal or for failing to qualify for reinstatement after testing positive.

We are not aware of any ground upon which it can be argued that the DoD clause preempts state constitutional or statutory law to the contrary without express Federal statutory authority. Indeed, we have attempted to elicit rationale and statutory grounds from the DoD General Counsel's office without success. In addition, Mr. Mike Wermouth, Deputy Assistant Secretary of Defense for Drug Enforcement Policy, and other DoD officials, during public meetings with contractors, were unable to recite grounds for preemption.

It is well settled that an agency's authority must derive from a specific statute enacted by Congress that authorizes that agency to regulate in a particular manner. *Lyng v. Payne,* 90 L.Ed.2d 921, 933; *Burlington Truck Lines v. United States,* 9 L.Ed.2d 207, 215; *Civil Aeronautics Bd. v. Delta Airlines,* 6

L.Ed.2d 869, 874. We do not believe that the DoD can point to any statute as a basis for preemption. It should be noted that in 1988, when Congress considered the Drug Free Workplace Act, it expressly rejected language which would impose random drug testing upon employees of government contractors. Now, four years later, DoD seeks to implement by regulation the very same random drug testing that Congress had rejected.

This is in contrast to the clear statutory authority of the FAA to require random drug testing, not of those who sell to the FAA, but rather of those who conduct operations which are pervasively safety regulated by the FAA. The FAA's statutory basis for this pervasive regulation is contained in the Federal Aviation Act.

And, as stated above, our divisions that operate in that regulated industry, even those located in California, conduct random drug testing, but only for those employees who are clearly covered by the narrowly drawn scope of the FAA drug testing program. That program has been in effect for two years without challenge by employees because the FAA has the clear statutory authority to preempt state constitutional and statutory law. The FAA took great pains to design a requirement narrow in scope and clearly bottomed on its mandate to insure safety.

Although employee litigation based on state law will initially involve only the contractor, it can be expected that any contractor sued will quickly join the Department of Defense as a party to the law suit. In a similar vein, we perceive an ethical question regarding knowingly engaging in an unlawful act that may be raised by the proposed rule, both in the context of the absence of preemption of contrary state law and in the absence of preemption of the National Labor Relations Act and collective bargaining agreements thereunder (3 below). Therefore we recommend that the Department of Defense seek a formal opinion from the Department of Justice on the issue of preemption.

Consequently, until and unless Congress grants the DoD statutory authorization to invade the private workplace by instituting random drug testing, we believe that the random drug testing requirement must be deleted from the proposed rule.

2. Overbroad Scope of "Sensitive Position" (Fourth Amendment)

Only those in "sensitive positions" need be tested under either the 1988 or the current proposed version of the rule. However, the scope of the DoD

definition of "sensitive position" has been greatly expanded in the proposed rule from the narrow scope defined in the 1988 version. The proposed rule's broader scope raises serious U. S. Constitutional, Fourth Amendment questions concerning the need for random drug testing where health, safety or national security will not be immediately and directly impacted. The two leading Supreme Court cases in this area and their Appellate Court progeny (*International Brotherhood of Teamsters v. Dept. of Transportation*, 932 F.2d 1292 (9th Cir. 1991): *International Brotherhood of Electrical Workers v Skinner*, 913 F.2d 1454 (9th Cir. 1990); *Bluestein v Skinner*, 908 F.2d 451 (9th Cir. 1990); and *Taylor v. O'Grady*, 888 F.2d 1189 (7th Cir. 1989)) make it clear that unless there is a direct and immediate connection between the job function and its impact on the safety of others, any random drug testing requirement would violate the Fourth Amendment.

Thus in the 1988 version of the Drug Free Work Force Clause, the DoD correctly defined "sensitive position" as simply one occupied by an employee having access to classified information or other employee as determined by the contractor. The proposed rule greatly expands the scope of sensitive position to include those employees who, among others, design, manufacture, test and evaluate...aircraft, ships, vehicles and heavy equipment, munitions, toxic materials, weapons, weapon systems and potentially dangerous equipment...or major components. Under Supreme Court decisions interpreting the Fourth Amendment, an employee involved in the design, manufacture, test or evaluation of a product may not be required to submit to random testing unless the employee's function is directly and immediately related to the safety of operation by the end user, or others affected by its use.

Further in contrast with the proposed DoD rule, the FAA rule expressly excludes design, manufacture, test and evaluation functions from its random testing program. The FAA limited its scope of random drug testing to operators of aircraft (pilots, flight crew, flight attendants), airport security personnel, air traffic controllers and those who maintain the aircraft or its components (i.e., those functions having a direct and immediate effect on safety). Although it had preemptive authority, the FAA nevertheless was concerned that it not abuse the authority and be taken to court for overstepping its bounds established under the Fourth Amendment. We believe that the proposed rule's large scope of functions described in the Sensitive Position definition is overbroad and will subject DoD and its contractors to a flood of litigation on U.S. Constitutional grounds.

3. Violation of Existing Collective Bargaining Agreements

The proposed rule ignores the implications of existing collective bargaining agreements which may not allow the contractor to implement random drug testing. Contrast this with the 1988 version of the rule which allowed contractors to phase in drug testing by reaching agreement with the labor union in the next union contract renewal negotiation. No such recognition is apparent in the proposed rule.

Drug testing is a mandatory subject of bargaining under the National Labor Relations Act (NLRA). The Supreme Court in *Ford Motor Co. v. NLRB*, 441 U.S. 488 (1979) described mandatory subjects of bargaining as matters that are "plainly germane to the 'working environment'" and "... not among those 'managerial decisions which lie at the core of entrepreneurial control.'" Based upon that rationale the NLRB, in *Johnson-Bateman Co.*, 131 LRRM 1393, 1397 (1989), held that drug testing was a mandatory condition of bargaining. The Board noted that drug and alcohol testing:

> ...does not involve the commitment of investment capital and cannot otherwise be characterized as a decision taken with a view toward changing the scope of nature of the Respondent's enterprise. It is rather a more limited decision directed toward reducing workplace accidents and attendant insurance risks...

Accordingly, the Board held that Johnson-Bateman had violated Section 8(a)(5) of the NLRA by unilaterally implementing a drug-testing program.

Thus, any employer with an existing collective bargaining agreement that does not specifically allow drug testing would have three options if the proposed DoD regulation becomes effective:

1. Attempt to secure agreement from the union to allow the testing required by the regulations.

2. Failing to obtain such agreement, the contractor would be required to intentionally violate the NLRA or the collective bargaining agreement, or both if it elected to participate in a DoD contract.

3. Remove itself from consideration as a contractor.

4. Inclusion of Contracts for Commercial Items

The proposed rule does not exempt contracts for the procurement of commercial items or items from commercial vendors (as opposed to established defense contractors). Again, this is a departure from the 1988 version of the rule. The 1988 version exempted contracts for commercial or commercial type products that did not involve access to classified information. It would appear that imposing random drug testing on commercial companies who have been in business for years would discourage their participation in the DoD initiative toward more commercial acquisitions. As DoD already knows, there are many responsible commercial vendors who choose not to do business with the government because of the added cost of regulations and compliance. The proposed rule is another addition to that cost and burden.

In summary we believe the proposed clause must, at a minimum, be rewritten to satisfy the four points raised above. We believe that the 1988 version of the DoD Drug Free Work Force Clause accomplishes that result.

I am available to amplify the above comments, provide more detailed statutory and case citations or otherwise further discuss these issues. Please call me at (310) 859-5983 or Newton D. Lesh, II of my staff at (805) 378-2410.

Sincerely,

John E. Preston
Vice President and
Associate General Counsel

cc.: Defense Acquisition Regulations Council (DARS)
Attn.: **Ms. Linda W. Neilson**
OUSD (A)
3062 Defense
The Pentagon
Washington, D. C. 20301-3062 (by Federal Express)

Litton
Ingalls Shipbuilding

P.O. Box 149
Pascagoula, Mississippi
39568-0149
601-935-1122

DBM-92-115

17 September 1992

Defense Acquisition Regulations Council
Attn: Mrs. Linda W. Neilson
OUSD(A)
3062 Defense Pentagon
Washington, DC 20301-3062

RE: DAR Case 88-083
Comments on 252.223-7500 Drug Free Workforce

Dear Mrs. Neilson:

Enclosed are comments concerning the views of Ingalls Shipbuilding as they relate to Section 252.223-7500 of the Federal Acquisition Regulations Final Rule invoking Random Drug Testing.

Ingalls is extensively involved in drug testing and appreciates this opportunity to comment on this vital issue.

In support of our comments, we have taken the liberty of including a detailed description of our testing program.

Sincerely yours,

INGALLS SHIPBUILDING, INC.

D. F. Knecht
Vice President
Public/Industrial Relations

DFK/DBMJr/skm

Enclosures (as stated)

(b) The Contractor shall institute and maintain a program for achieving a drug-free workforce. As a minimum, the program shall provide for the random drug testing of Contractor employees working in sensitive positions. The Contractor's drug testing program shall conform to the "Mandatory Guidelines for Federal Workplace Drug Testing Programs" published by the Department of Health and Human Services (53 FR 11970), April 11, 1988.

COMMENT

Ingalls Shipbuilding does not agree that random drug testing is necessary to achieve a Drug-Free Work Force. This Company has had in place an extremely effective program of pre-employment testing as well as a program wherein all employees are subject to testing "for cause" or when involved in accidents causing injury or property damage. This program has proven to be effective, while at the same time withstanding a number of procedural challenges, including process through Federal District Court and U.S. Court of Appeals.

We also believe it's a matter of importance that in the process of bringing industry to the forefront of combating the drug problem by requiring contractors to conduct various forms of education and testing, that the Government not lose sight of other important elements of efficiently and effectively performing the requirements of a contract. Shipbuilding and many other industries, have a dynamic, constantly-changing workforce. The mix of skills required to perform the steel-preparation function differs from that required to assemble the components installed in a ship. The mix required to erect steel differs from that required to outfit the hull after it is assembled and erected. In order to assure that the right people are in the right place at the right time, our industry must, of necessity, hire in large numbers and in some cases temporarily lay-off and recall workers as the work flow dictates.

All of this personnel activity requires that our employment function react quickly in order to provide the workforce in the number and skills required.

To ensure that we can do this and at the same time comply with the Drug Free Workplace, Drug Free Workforce requirements imposed in 1988, we instituted an on-site testing program. The basic premise is that we perform an on-site initial screen using a Food and Drug Administration approved procedure. A split sample of any screen presumptive positive is sent to a National Institute on Drug Abuse (NIDA) approved laboratory for confirmation by Gas Chromotography/Mass Spectrometry (GC/MS).

There are two major pluses to a program which is operated in this fashion. (1) No final discipline is invoked on an employee or applicant until the presumptive test has (a) been GC/MS confirmed, (b) reviewed by our Medical Review Officer (MRO), and (c) the procedure has been reviewed by our Substance Abuse Review Committee. (2) Those testing negative at the time of the on-site processed screen can go directly to work with a minimum of delay. This on-site determination allows us to react to our manning requirements in a timely manner while at the same time providing our employees with well-paying jobs with a minimum of delay.

The invoking of the NIDA Guidelines in each and every testing program devised by the Government is placing a stranglehold on industries' ability to comply with the regulations while at the same time meeting the other obligations of its contract.

On-site initial screens backed by NIDA lab GC/MS confirmation of presumptive positives is a reasonable, timely and effective method of accomplishing a drug free environment.

We have attached a complete outline of our program in expectation that the Department of Defense might consider adopting these procedures throughout the defense industry. This program accomplishes effective drug detection and deterrence while simultaneously maintaining individual rights, and considering the need of business and industry to continue to conduct its business on behalf of the Department of Defense efficiently and effectively.

DRUG TESTING

AT

INGALLS SHIPBUILDING, INC.

This paper describes how on-site drug testing is performed in a large, defense oriented manufacturing facility.

Prepared by:

Donald B. Massengale, Jr.
Director, Industrial Relations Services
Ingalls Shipbuilding, Inc.
Post Office Box 149 - Mail Station 2050-03
Pascagoula, Mississippi 39568-0149

Telephone: (601) 935-5847
FAX: (601) 935-5804

SUBSTANCE ABUSE TESTING
AT
INGALLS SHIPBUILDING, INC.

INTRODUCTION

Ingalls Shipbuilding, located on the Gulf Coast in Pascagoula, Mississippi, builds, repairs and overhauls surface combatant ships for the United States Navy and others.

Current activity includes new construction of Ticonderoga Class Cruisers (CG 47), Arleigh Burke Class Destroyers (DDG 51), and General Purpose Amphibious Assault Ships (LHD 1) for the United States Navy. Ingalls is also building SA'AR 5 Class Corvettes for the Israeli Navy and overhauls a variety of ships. Ingalls also overhauled and returned to service the battleships Iowa and Wisconsin, and the Frigate Stark after it was damaged by an Iraqi missile.

Ingalls currently employs over 15,000 people and has a work backlog exceeding $4 billion. The production work force is unionized, and enjoys excellent labor management relations.

Ingalls' Drug Testing Program, which includes a rehabilitation phase prior to invoking discipline and confirmation of presumptive positives by a National Institute on Drug Abuse (NIDA) certified laboratory, is operating smoothly with a minimum of protests or grievances. The key to the program is conducting initial drug testing on-site. Ingalls' program is existing proof that these initial tests can be conducted by industry, on-site, in a technically proficient, courteous, dignified, and professional manner.

The following pages depict three (3) categories of presentation:

I. The Ingalls Method - A General Overview

- A. The Ingalls Program
- B. The Ingalls Process
- C. The Ingalls View

II. The On-Site Testing Aspects of the Ingalls Program

- A. Introduction
- B. Personnel
- C. Specimen Handling
- D. Security
- E. Drug Testing Methods
- F. Quality Control
- G. Proficiency
- H. Drug Testing Policies

III. Recommendations for the Regulation of On-Site Testing

I. THE INGALLS METHOD - A GENERAL OVERVIEW

A. THE INGALLS PROGRAM

In order to assure a safe, alcohol and drug-free environment and to comply with Public Law 100-690, The Drug-Free Work Place Act of 1988, and Federal Acquisition Regulation 252.223-7500, The Drug-Free Work Force Clause of Part 252 of the regulation regarding solicitation provisions and contract clauses, Ingalls instituted a Drug Testing Program on 03 April 1989, for Pre-employment and Recall reasons and extended it on 01 May 1989, to include For Cause and Accident events.

Final discipline is invoked only after an on-site determined presumptive positive is Gas Chromatography/Mass Spectrometry (GC/MS) confirmed by a NIDA certified laboratory and the employee has failed to meet the rehabilitative criteria of the program.

Ingalls' Employee Assistance Program Coordinator counsels, refers and tracks all employees who are positive in a directed test or who voluntarily seek help for a substance abuse problem.

During the nine month period from 03 April 1989, when the testing program went into effect, until 31 December 1989, the facility conducted 2,748 tests. Of this number, 278 (10%) were presumptive positive and required additional processing, while the 2,470 or 90%, who tested negative could be hired or returned to work immediately with a minimum of employment processing or work activity interruption. Likewise, for the period of January 1990 through December 1990, 5,452 tests were conducted, with 351 (7%) being presumptive positive, meaning that the 5,101 or 93%, who tested negative could be hired or restored to work immediately with a minimum of interruption. In this situation, on-site testing is an absolute necessity.

The calendar year 1991 experience shows that Ingalls conducted 7,017 tests, 317 or 5% of which were positive. On-site testing allowed the other 6,700 or 95% to go straight to their jobs without delay. This could not be done in the absence of on-site testing and in this case the delay would be costly for thousands of employees as well as the Company.

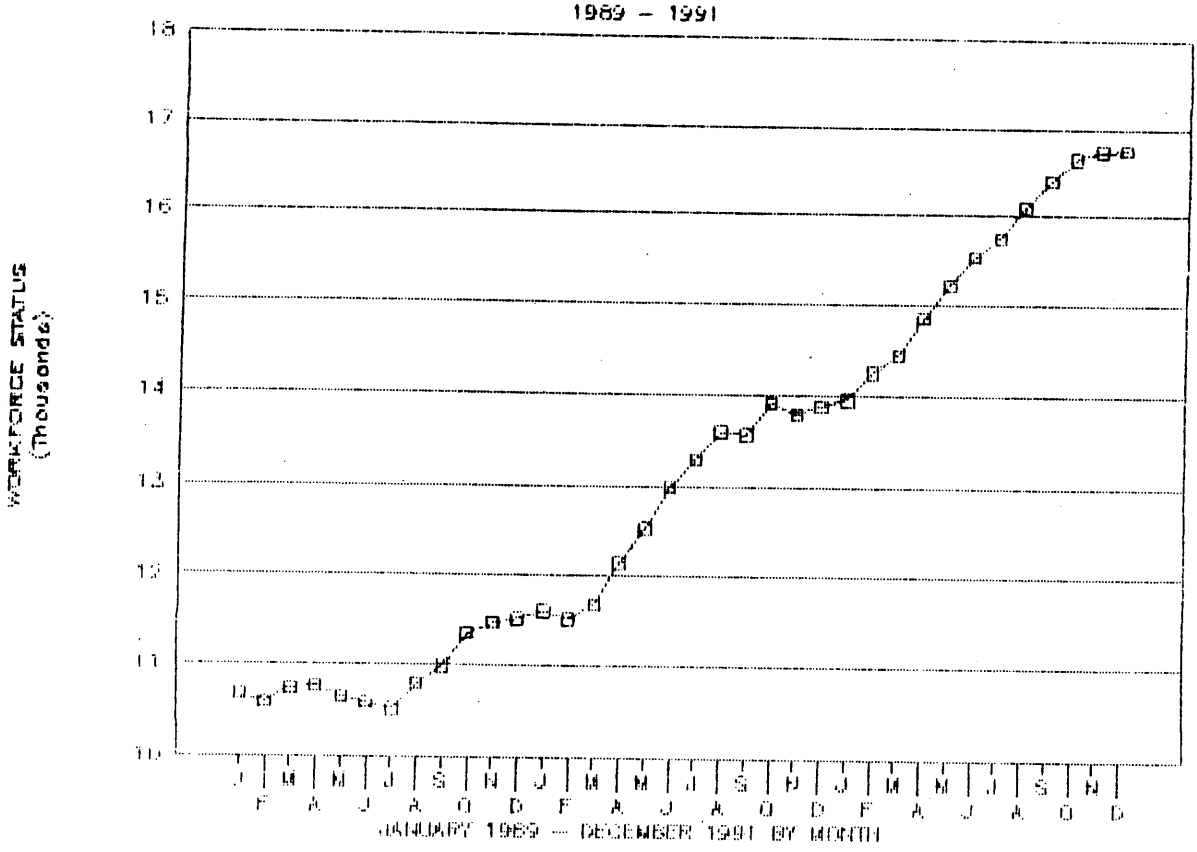
The attached (Chart 1A) shows Ingalls' manpower build-up over the last three (3) years. From January 1989 to December 1991, employment headcount increased by an average of 4,671 employees. This feat would have been virtually impossible without the ability to perform on-site drug testing.

Even in non build-up periods, attrition rates require hiring as many as 60 people per week to maintain employment levels.

Various stages of ship production require workforce mix changes. Today hundreds of painters are needed. Next week or next month painters are reduced, but hundreds of additional outfitting types such as sheetmetal workers and electricians may be needed. The shipbuilding workforce is necessarily dynamic and on-site testing allows a drug free workforce while at the same time meeting schedules and budgets, with a minimum of lost work time for employees or prospective employees.

INGALLS SHIPBUILDING, INC.

1989 – 1991



MONTH	1989	1990	1991
JANUARY	10655	11602	13951
FEBRUARY	10583	11521	14347
MARCH	10750	11814	14449
APRIL	10756	12142	14648
MAY	10650	12522	15214
JUNE	10575	12978	15581
JULY	10514	13281	15754
AUGUST	10786	13592	16149
SEPTEMBER	10987	13562	16394
OCTOBER	11350	13912	16651
NOVEMBER	11468	13797	16736
DECEMBER	11519	13881	16751
AVERAGE	10980	12870	15559

CHART 1-A

B. THE INGALLS PROCESS

Due to the importance of placing applicants and recalls on the job in a timely manner as well as returning employees tested for cause and accident who test negative back to the job in the shortest time period possible, it is necessary that the initial test be performed on-site.

Test specimens are collected, split, documented and tested by trained technicians who follow written procedures and instructions in ensuring that their tasks are performed in a technically proficient, courteous, dignified, professional manner.

The actual testing is conducted using Food and Drug Administration (FDA) approved Abbott Laboratories ADX Analyzers which employ the fluorescence polarization method of immunoassay. Ingalls' technicians have been trained at Abbott Laboratories in the operation of this equipment.

In-house medical doctors have oversight regarding the program and act as Medical Review Officers (MRO).

Specimens are processed through the Abbott analyzers immediately upon collection. The results of the tests are either positive or negative as determined by the pre-set cut-off level for the drug for which the individual is tested.

Negative results trigger an immediate continuation of processing for applicants and those returning from leaves of absence. A negative result also immediately returns to work those tested for cause or accidents.

In the event of a positive initial test, the sealed split is forwarded by courier to an independent, College of American Pathology and National Institute on Drug Abuse certified laboratory for confirmation using Gas Chromatography/Mass Spectrometry technology.

Other than calibrating, maintaining and programming the Abbott analyzers to perform the tests for which they are designed and recording the temperature, pH, and specific gravity of the sample, Ingalls' Testing Facility personnel perform no manipulation, interpretation, calculation, or forensic analysis regarding the sample. Their function is to collect, test, record, and report results.

Since medical doctors oversee the in-house testing function and perform the function of MROs, this process should require no additional level of supervision above the qualifications possessed by plant medical doctors.

The split sample is a good faith effort demonstrating to union representatives, as well as non-represented employees, that a third party may validate, question or disagree with the result if it can be properly documented.

Third party confirmation takes away the employee, applicant and union representative concern that the Company may be grading its' own homework, so to speak. With proper and careful chain-of-custody control, there is no reason to require such a program to perform both initial testing and confirmation at the same site as required by NIDA. It is both an unnecessary delay and unreasonable requirement.

C. THE INGALLS VIEW

All testing facilities should not be required to conform to imposed mandatory NIDA guidelines designed for the testing of government employees. If these guidelines are imposed for other than government related testing, the imposition should be limited to those whose primary mission is scientific analysis, including toxicological urine testing, for-profit.

Ingalls is in the business of producing quality ships for the United States Navy, on schedule and within budget. We have been very successful in doing this. There is no necessity, nor should this testing facility be required to conform to the same guidelines as those who perform drug testing for a profit.

Private employers engaged in drug testing as a necessity to provide a safe working environment and to contribute to reducing the drug problem in our society should not be saddled with the burdensome and unnecessary restrictions invoked in the NIDA Guidelines, and other well meaning proposals and legislation.

The time-sensitive nature of placing workers in jobs initially and back on the job subsequently, requires simplification in drug testing where private, labor-intensive industry is concerned.

The following is a more detailed description of the various elements of Ingalls On-Site Testing Program.

II. THE ON-SITE TESTING ASPECTS OF THE PROGRAM

A. INTRODUCTION

The following elements are those identified and stressed during Dr. Douglas Rollins's visit to our facility. Dr. Rollins is chairman of the NIDA sponsored on-site drug testing committee.

B. PERSONNEL

There are three persons whose primary function is drug testing. All have completed Emergency Medical Technician coursework at the local Community College. All have received on-the-job training by representatives of Abbott Diagnostics and completed a 32-hour formal program on-site at the Abbott Diagnostics Facility in Dallas.

One Technician is a certified Phlebotomist and was trained and certified in the collection, documentation and processing of blood and urine samples during an eight (8) year assignment at the local (Singing River) hospital laboratory department.

One Technician received training and certification on five different types of drug detection analyzers while performing collection and analysis functions during a five year period with the Mississippi Department of Corrections.

One Technician has Associate Degrees in Medical Laboratory Technology and Electronic Technology. He has been a state certified Medical Laboratory Technician since 1988 and is a member of The American Society of Clinical Pathologists. He has performed practical laboratory work at the Ocean Springs branch of Singing River Hospital, Biloxi Veterans Administration Hospital, Greene County Hospital and Roche Bio-Medical Laboratories.

Performance evaluation of these employees is conducted annually by the department manager and the Medical Review Officer (MRO). All have been with the company and have worked with the drug testing program since March of 1989.

C. SPECIMEN HANDLING

The flow of specimens is essentially as follows: The employee/applicant provides a urine specimen at the collection site which is adjacent to the drug testing facility. The collection site attendant is in the same room as the person providing the specimen, however, there is no direct observation of the initial urine collection. At the time of urine collection, the chain-of-custody with identifying information including social security number, control number, date and time of specimen collection is initiated. Upon receiving the specimen from the employee/applicant the attendant checks the temperature, pH and specific gravity. After the urine is determined to be acceptable, the attendant pours at least 5 ml of the specimen into an identical container and both containers are appropriately labeled and sealed in the presence of the employee, thus creating a split specimen; one split for an initial test and one for follow-up confirmation. The specimens are passed through a window to the testing facility and a technician inspects them for satisfactory condition and integrity of tamper proof seals. The chain-of-custody form is also inspected to make sure that all information is appropriate and entered into a substance abuse log. One of the specimens is tested using the Abbott ADX fluorescence polarization immunoassay.

Only positive results are documented on the chain-of-custody. Negatives are stamped "negative" on the chain-of-custody and the specimen is discarded. If the specimen is identified as presumptive-positive, the other split specimen is sent by overnight courier to a National Institute on Drug Abuse (NIDA) certified reference laboratory for confirmation by Gas Chromatography/Mass Spectrometry (GC/MS). Presumptive-positive specimens are stored in a locked refrigerator in the drug testing facility pending results of the split sent to the reference laboratory. Confirmed positive specimens are stored for one year at the reference laboratory, negative specimens are discarded immediately by the on-site facility. If the employee/applicant's initial test is negative, normal processing continues for an applicant and employees are returned to their jobs. However, if the initial test is positive, the employee/applicant is sent home with the information that he/she will be notified of the results of the confirmation test.

//

D. SECURITY

The test facility is in the same building with and adjacent to the urine collection site which in turn is adjacent to the Security Department and the site for processing new employees. A chart showing the laboratory area is attached as Chart 6-A. The drug testing facilities are locked or attended at all times. A large sign "Authorized Personnel Only," is prominently displayed on all doors. The three technicians and the Department Manager are the only authorized personnel allowed unescorted access to the Test Facility. Specimen integrity is closely maintained. Temperature, pH and specific gravity are obtained during the collection process. Specimens are never left unattended or unlocked and an aliquot of the specimen is removed for testing (the original specimen is split for initial testing and confirmation testing). Results of screening tests are entered into the testing facility on-site computer which has password access. All initial screen and confirmation results are initially reported only to the Manager of Medical/Security or the company physician. The Labor Relations Department is advised of those positive tests relating to Union represented personnel.

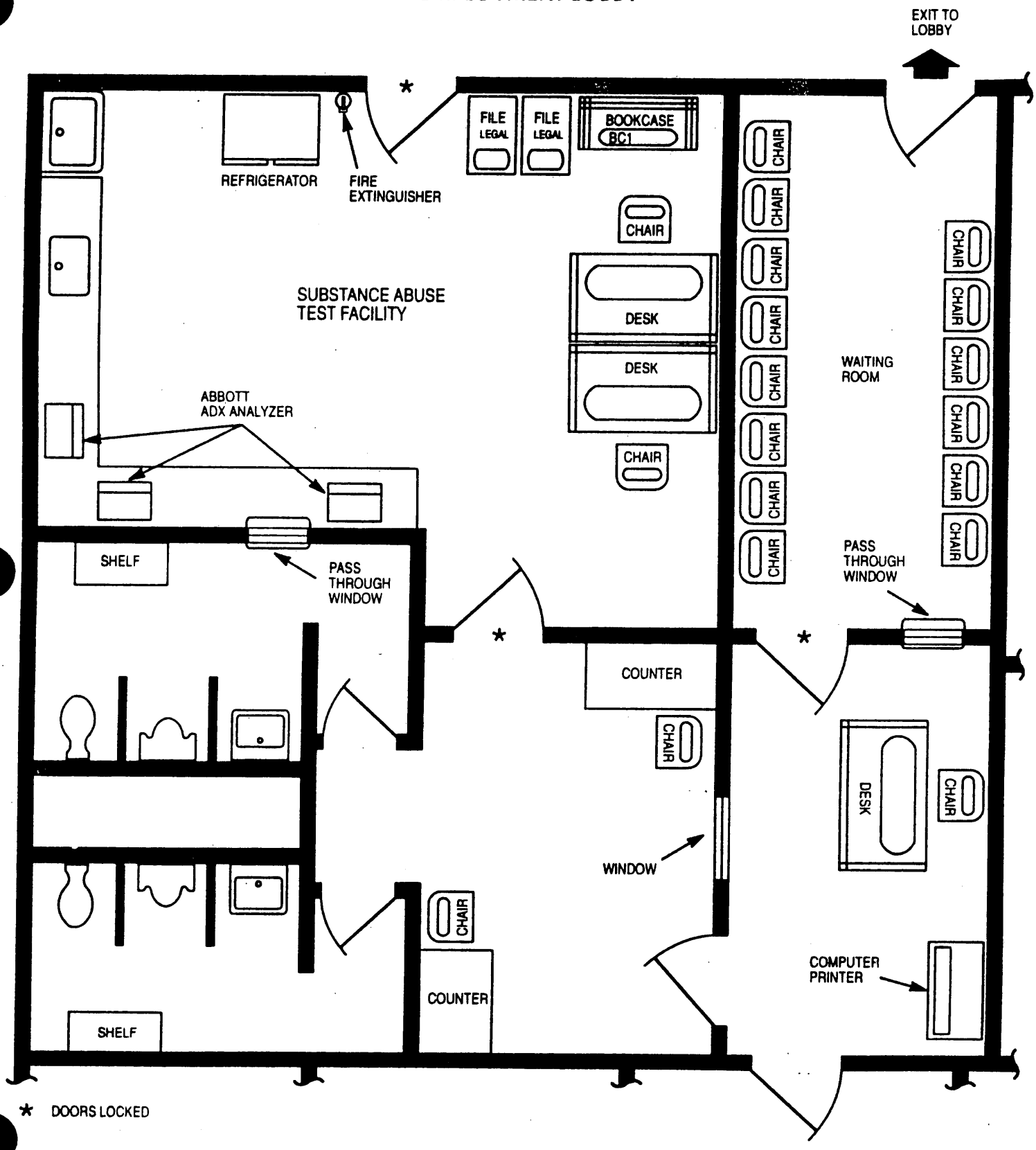
E. DRUG TESTING METHODS

Our facility uses the Food and Drug Administration (FDA) approved Abbott ADX fluorescence polarization drug testing system. The standards being used are those provided by Abbott Diagnostics. Controls are also obtained from Abbott Diagnostics. Cut-off concentrations are documented according to the Abbott ADX manual. The Company is testing for cannabinoids, opiates, phencyclidine, cocaine, amphetamines, barbiturates, and benzodiazepines. A screening-positive result is determined if the instrument printout indicates that the concentration present in the specimen is at or higher than the cut-off calibrated into the instrument. Currently we are testing only urine for drugs of abuse. All presumptive-positive specimens are confirmed by (GC/MS) at a reference laboratory that is NIDA certified.

Confirmation of an applicant's test means the person will not be hired, but may apply again in six (6) months.

Confirmation for an employee means automatic referral to an employee assistance/rehabilitation process which, if successfully completed, guarantees their return to duty subject to random testing for a one year period.

EMPLOYMENT LOBBY



SECURITY DEPARTMENT

CHART 6-A

F. QUALITY CONTROL

A Standard Operating Procedures Manual (SOP) covers specimen handling and reporting of results. Operation of the ADX equipment is covered in the Abbott Manual supplied with the equipment.

Utilizing the Abbott Laboratories Operators Guide for the Abbott ADX System and Ingalls prepared policies, procedures and departmental operating instructions, the Company is preparing an Ingalls Testing Facility Operators Manual that will describe the operational aspects of the ADX System as applied in this specific process.

Technicians run one quality control specimen supplied by Abbott Laboratory each day. The technicians are the designated persons in charge of quality control and the technician running specimens on a particular day determines whether or not the quality control specimen is acceptable. There is a log of the daily control run which is reviewed. There is a regular schedule of instrument maintenance as indicated in the Abbott manual. When the instruments were setup, the procedures were validated by Abbott.

In 1991, we initiated a blind specimen program with a NIDA certified laboratory which challenges the Company's operation on an average of two times per month. Attached as Chart 7A is a letter from the laboratory attesting to Ingalls' ability to properly identify specimens.

In November of 1991, Ingalls hired a second medical doctor, not only for increased treatment capability, but additional testing facility and testing program oversight as well.

G. PROFICIENCY

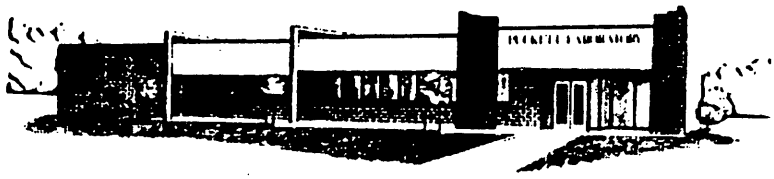
In 1991, the Testing Facility staff was challenged by Aegis Analytical Laboratories, Inc. of Nashville, Tennessee to respond to a validation exercise designed by Dr. David L. Black, Ph.D., DABFT, DABCC-T, the President and Laboratory Director of Aegis.

This challenge consisted of our personnel processing samples submitted by Aegis to assess the ability of our people, processes and machines in four (4) main areas:

ACCURACY
PRECISION
LINEARITY
SPECIFICITY

Enclosed as Appendix A, is Dr. Black's report of the results of this challenge. It lends strong support that Ingalls' on-site program is conducted by capable personnel who efficiently and effectively apply the processes, and maintain and operate quality equipment resulting in accurate and timely testing.

THOMAS P.
PUCKETT
LABORATORY



4200 MAMIE STREET/HATTIESBURG, MS 39402/(601) 264-3856

June 26, 1992

Al Downs
Ingalls Shipbuilding, Inc.
P.O. Box 149 M/S 1020-04
Pascagoula, MS 39567

Mr. Downs,

The Toxicology department here at Puckett lab has been happy to participate in your blind control program. The first sample was sent to Ingalls in October or November of 1991 for your evaluation with your regular drug screens. Since then we have sent two samples each month for your analysis. The samples have been a mix of both positive and negative specimens. Your record so far has been 100% in giving the correct screening result. I also appreciate the concern and professionalism of your staff whenever a question arises concerning a control or drug testing in general.

Please call if I can be of any further assistance.

Sincerely,

Lance C. Presley

Lance C. Presley, Ph.D.
Certifying Scientist
QA/QC Officer

CHART 7-A

51-C TACON STREET/MOBILE, AL 36607/(205) 473-3838
1040 CALHOUN STREET/NEW ORLEANS, LA 70118/(504) 899-8282
764 LAKELAND, SUITE 314/JACKSON, MS 39216/(601) 792-4276
1245 BROAD AVENUE/GULFPORT, MS 39501/(601) 863-4562
1030 RIVER OAKS DRIVE/JACKSON, MS 39208/(601) 936-2397

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15

H. DRUG TESTING POLICIES

Ingalls has a written policy stating its position regarding drug testing, a Standard Procedure describing program administration, and departmental operating instructions setting forth testing facility and MRO guidelines to ensure that testing and evaluations are consistent. We perform pre-employment, for cause and post-accident testing. The laboratory technician tells the job applicant that if the initial test is presumptively-positive, further processing of the application will not occur unless the confirmation test is negative. In the case of for cause testing, the laboratory technician passes the results to the Manager of the Medical and Security Departments, the Medical Review Officer (MRO) and the Labor Relations Department, when applicable.

The Company has chosen an on-site drug testing policy because of the time involved in processing pre-employment applications and the need to return employees who test negative back to work as soon as possible. There are times when it is necessary to hire a large number of persons on a particular day (over 7,000 were hired in 1991), and there is a need to process these individuals as expeditiously as possible. Off-site drug testing cannot provide the necessary turnaround time.

The Company Medical Review Officers (who are also the company physicians) review all confirmation-positives. The Medical Review Officers confirm prescription medication and other potential challenges to the confirmed positive results. Records are stored within the testing facility in a locked file cabinet. Descriptive statistical data are maintained and there are audits of the on-site testing lab 3 to 4 times a year by a private consulting group.

Ingalls is very pleased with its on-site program and feels it has demonstrated that this is a very acceptable method if done properly with pride in methods and concern for those being tested. In fact, in many aspects of the testing itself, it is a superior program, requiring positive results of two separate testing facilities before a positive test is fully confirmed.

The following recommendations regarding the regulation of on-site testing were derived from experience in actually conducting this method of testing and research into how it could be done effectively and efficiently.

III. RECOMMENDATIONS FOR THE REGULATION OF ON-SITE TESTING

As a member of the On-Site Drug Testing Committee chaired by Dr. Douglas Rollins, I too, am concerned that there may be those who are conducting tests in less than a responsible manner and who by doing so, cause those of us who are providing accurate, fair and quality programs to be included in with them when on-site testing is criticized. The diversity of on-site testing methods very simply tells us that controls are necessary.

I am equally concerned however, by the suggestion that only certain highly over-qualified individuals can conduct on-site initial screens and that they must be conducted in accordance with the government-imposed NIDA guidelines, thus placing small, of necessity, on-site screening facilities on the same plane as complex, for-profit, high volume, high tech laboratories.

The fair and reasonable answer is somewhere between these two extremes. I offer the following recommendations as a start toward establishing reasonable guidelines for on-site facilities, while avoiding the extreme qualifications imposed on for-profit laboratories.

GENERAL RECOMMENDATIONS AS A BASIS FOR ON-SITE TESTING REGULATIONS

1. The testing method (EMIT, FPIA, RIA, etc.) must be Food and Drug Administration (FDA) approved.

2. The program must be monitored by a person with at least medical doctor qualifications and who will certify the operational proficiency and results of the on-site facility. This may be an employee of the testing entity or a person under contract to it. This person may also act as the Medical Review Officer.

3. The program should be characterized by a split sample collection procedure to allow confirmation of the unopened split by Gas Chromatography/Mass Spectrometry at a NIDA certified lab.

4. Final disciplinary action should be stayed pending confirmation of the presumptive test results.

5. Chain of custody procedures should be such as to satisfy the requirements of the confirming laboratory.

6. Specimen collection procedures should generally be in accordance with NIDA Guidelines. It is suggested that universal specific gravity and pH ranges be established (as is temperature) to ensure consistency in determining whether or not a sample is valid.

7. Specimens may be collected by a company representative who has been provided training and instruction in collection and chain of custody procedures.

8. Operators of the testing equipment shall have been trained by the manufacturer of the equipment and shall demonstrate proficiency in equipment operation prior to being allowed to perform any function of the actual testing operation.

9. On-site facilities should purchase blind performance (blank and spiked) testing services from a NIDA approved laboratory. The volume of such testing should be reasonable as it relates to the numbers of tests performed in a given period.

10. Each facility shall have a procedure manual which includes the principles of each test, preparation of reagents, standards and controls, calibration procedures, derivation of results, linearity of methods, sensitivity of methods, cut-off values, mechanisms for reporting results, etc.

11. Periodic third party inspections of the on-site facilities should be conducted with a reasonable frequency utilizing predetermined criteria against which the facility would be reviewed. A favorable review would allow the facility to operate for a given period. An unfavorable review would invoke probation after which a reinspection would determine the facility's fate.

12. Facilities should be challenged at least once each year by an independent laboratory which administers a proficiency test assessing the ability of the facility's personnel, equipment and procedures for accuracy, precision, linearity and specificity.

13. The real key elements of my recommendations are that no specimen may be considered positive until a NIDA certified lab says it is positive, and no discipline is final until the specimen is confirmed positive by the NIDA certified lab.

14. Our program at Ingalls, also allows a re-hab period after the user's initial positive. If the employee completes the re-hab and the subsequent test is negative, the employee is returned to work.

IV. SUMMARY

1. On-site testing does work and can continue to work if a sensible approach to regulation is adopted. To include industrial on-site screening facilities with for-profit labs and NIDA regulations is both costly to industry and the worker, and counter-productive to the goal of stamping out drug use in our society.

2. Industry is expected to assist in defeating the drug scourge in our society and we willingly accept the challenge. We are however, bound by Public Law 100-690, The Drug Free Workplace Act, Federal Acquisition Regulation 252.223-7004, Drug Free Work Force Requirements, NIDA Guidelines, CLIA Requirements, and D.O.T. Requirements.

3. We can make a significant contribution toward discouraging people from using drugs. Give us some help in doing so. Simplify the process. For example, if an employer can certify to minimum requirements and has all presumptive positives confirmed by GC/MS at a NIDA certified laboratory, allow that employer to on-site test. We are not asking for total exemption from regulation, but simplification so that we can reasonably perform the tasks assigned us. We should not be included in with sophisticated, for-profit laboratories.

4. The layer upon layer of restrictions and regulations is smothering the ability of industry to contribute to dramatically reducing the drug problem in our country.

Any questions or requests for additional information may be directed to:

D. B. MASSENGALE, JR.
Director, Industrial Relations Services
Ingalls Shipbuilding, Inc.
Post Office Box 149 - Mail Station 2050-03
Pascagoula, MS 39568-0149

(601) 935-5847
(601) 935-5804 (FAX)

APPENDIX A

AEGIS
ANALYTICAL
LABORATORIES, INC.

624 Grassmere Park Rd. Suite 21 • Nashville, Tennessee 37211
(615) 331-5300 1-800-533-7052

AUGUST 27, 1991

D. B. MASSENGALE, JR.
DIRECTOR
INDUSTRIAL RELATIONS SERVICES
INGALLS SHIPBUILDING, INC.
P.O. BOX 149
PASCAGOULA, MISSISSIPPI 39568-1122

DEAR MR. MASSENGALE,

THANK YOU VERY MUCH FOR YOUR PROMPT RESPONSE AND REPORT OF RESULTS FOR THE VALIDATION SPECIMENS SUBMITTED TO INGALLS SHIPBUILDING. I DO APPRECIATE YOUR STAFF WOULD BE ANXIOUS TO RECEIVE THE ENCLOSED REPORT OF THEIR PERFORMANCE AND I APPRECIATE YOUR PATIENCE AS I HAVE "RECOVERED" FROM RETURNING FROM VACATION. I AM SURE YOU AND YOUR STAFF WILL BE PLEASED BY THE ENCLOSED REPORT. PLEASE ADVISE ME IF THERE ARE ANY AREAS OF THE REPORT WHICH MIGHT REQUIRE FURTHER CLARIFICATION. ALSO PLEASE NOTE THAT I AM FORWARDING A COPY OF THIS REPORT TO MR. PAUL LANDAUER OF ABBOTT LABORATORIES.

THANK YOU FOR YOUR INVITATION TO VISIT THE INGALLS SHIPYARD AND I HOPE AN OPPORTUNITY WILL ARISE WHERE I MIGHT TAKE ADVANTAGE OF YOUR OFFER. CONSIDERING THE CRITICISMS BEING LEVIED AT ON-SITE DRUG TESTING SITES IT MIGHT BE HELPFUL TO REVIEW THE MAINTENANCE, REPAIR, CALIBRATION AND QUALITY CONTROL RECORDS; HOWEVER YOUR LABORATORIES EXCELLENT PERFORMANCE DOCUMENTS THAT THESE ISSUES MUST BE WELL ADDRESSED.

I HAVE ENJOYED THIS EXERCISE AND HOPE IT HAS PROVEN HELPFUL TO YOU AND YOUR STAFF.

SINCERELY,

DAVID L. BLACK, PH.D., DABFT, DABCC-T
PRESIDENT AND LABORATORY DIRECTOR

CC: MR. PAUL LANDAUER
ABBOTT LABORATORIES

URINE DRUG TESTING METHODS VALIDATION EVALUATION

August 25, 1991

KIT LOT #: 31-101391

DATE: July 31, 1991

CONTENT

I; INTRODUCTION

THE DATA REPORTED WAS ASSESSED FOR THE FOLLOWING TESTING CHARACTERISTICS:

ACCURACY: THE ABILITY OF A TESTING METHOD TO IDENTIFY AND/OR QUANTITATE SUBSTANCES CORRECTLY

PRECISION: THE ABILITY OF A TESTING METHOD TO PERFORM CONSISTENTLY AND TO BE FREE FROM EXTERNAL AND INTERNAL SOURCES OF VARIATION

LINEARITY: THE RANGE OF DRUG CONCENTRATIONS THE METHOD IS ABLE TO ACCURATELY QUANTITATE

SPECIFICITY: THE DEGREE OR ABILITY OF A TESTING METHOD TO REACT ONLY WITH THE DRUGS OR METABOLITES BEING TESTED AND TO EXCLUDE ALL OTHER DRUGS

THE DOCUMENTATION WAS RETURNED FOR REVIEW APPROPRIATELY AND ALL INFORMATION WAS IN ORDER. THE TECHNOLOGISTS FOLLOWED INSTRUCTIONS AND COMPLETED THE TABULATED DATA CORRECTLY.

II: ACCURACY

ACCURACY: THE ABILITY OF A TESTING METHOD TO IDENTIFY AND/OR QUANTITATE SUBSTANCES CORRECTLY

ACCURATELY IDENTIFYING WHICH DRUG MAY BE PRESENT IN A URINE SAMPLE IS PERHAPS THE SINGLE MOST IMPORTANT ANALYTICAL CRITERIA OF CONCERN TO A DRUG TESTING PROGRAM. THE ISSUE ALSO INCLUDES THE CONCERN OF CORRECTLY DETERMINING THE AMOUNT OF DRUG PRESENT SINCE A POSITIVE RESULT IS ALSO DEFINED AS HAVING THE DRUG PRESENT AT A LEVEL GREATER THAN THE THRESHOLD (CUTOFF) ESTABLISHED FOR THE PROGRAM. THE SUBMITTED VIALS A-I CONTAINED DRUGS "BLIND" TO YOUR LABORATORY AS TO WHICH DRUG AND HOW MUCH. VIALS A-I WERE ANALYZED AS PER NORMAL PROCEDURE AND THE RESULTS RECORDED ON FORM II. THE "EXPECTED" AND "REPORTED" RESULTS ARE INDICATED IN TABLE II.

TABLE II: ACCURACY DATA

THIS TABLE PRESENTS THE CORRECT ("EXPECTED") RESULTS AND THE RESULTS REPORTED FROM INGALLS SHIPBUILDING ("REPORTED"). PLEASE NOTE THE EVALUATION IS ALL IN "NG/ML" AND THEREFORE THE ANSWERS THAT WERE SUBMITTED AS "MCG/ML" HAVE BEEN CHANGED (FOR EXAMPLE THE SAMPLE C AMPHETAMINE ANSWER OF 1.72 MCG/ML HAS BEEN CHANGED TO 1720 NG/ML).

SAMPLE	EXPECTED (NG/ML)	REPORTED (NG/ML)
A	PCP (70)	PCP (73.6)
B	MORPHINE (600)	OPIATES (637)
C	AMPHETAMINE (2000)	AMPHETAMINES (1720)
D	CANNABINOIDS (50)	CANNABINOIDS (57.2)
E	SECOBARBITAL (600)	BARBITURATES (650)
F	NORDIAZEPAM (600)	BENZODIAZEPINES (546)

G	CODEINE (700)	OPIATES (778)
H	COCAINE METABOLITES (1000)	COCAINE (1060)
I	METHAMPHETAMINE (2000)	AMPHETAMINES (2170)

III. PRECISION

PRECISION: THE ABILITY OF A TESTING METHOD TO PERFORM CONSISTENTLY AND TO BE FREE FROM EXTERNAL AND INTERNAL SOURCES OF VARIATION

THE PRECISION OF A DRUG TESTING METHOD WILL IN LARGE PART HELP DETERMINE HOW EFFECTIVE DRUG USING INDIVIDUALS WILL BE IDENTIFIED. THE OBJECTIVE IS TO HAVE A DRUG TESTING METHOD WHICH WILL PERFORM DAY AFTER DAY WITH VERY LITTLE VARIATION DUE TO THE SKILL OF THE OPERATOR. METHODS MUST BE VERY PRECISE WHEN TESTING OCCURS AT DRUG CONCENTRATIONS NEAR THE THRESHOLD (CUTOFF) OF THE TEST TO PREVENT THE POSSIBILITY OF FALSE NEGATIVE RESULTS. A FALSE NEGATIVE RESULT IS DEFINED AS REPORTING DRUG OR METABOLITE WAS NOT DETECTED WHEN IN FACT THE AMOUNT OF DRUG OR METABOLITE IS PRESENT IN THE SAMPLE ABOVE THE TEST THRESHOLD (CUTOFF). A TEST METHOD WHICH IS PRECISE NEAR THE TEST THRESHOLD WILL PROTECT AGAINST REPORTING FALSE NEGATIVE ANSWERS. THE SUBMITTED VIALS CONTAINED THE FOLLOWING DRUGS:

VIAL #1: AMPHETAMINE
VIAL #2: METHAMPHETAMINE
VIAL #3: COCAINE METABOLITE (BENZOYLECGONINE)
VIAL #4: CANNABINOID METABOLITE (MARIJUANA)
VIAL #5: OPIATES - CODEINE
VIAL #6: OPIATES - MORPHINE
VIAL #7: PHENCYCLIDINE (PCP)
VIAL #8: BARBITURATES (SECOBARBITAL)
VIAL #9: BENZODIAZEPINE METABOLITES (NORDIAZEPAM)

THE WITHIN RUN AND BETWEEN RUN DATA IS COMPILED AND REPORTED IN TABLE III. THE DATA PRESENTED IN TABLE III IS A COMPILATION OF THE DATA SUBMITTED AND DEMONSTRATES THE MEAN VALUE, STANDARD DEVIATION AND COEFFICIENT OF VARIATION (%CV) FOR EACH ASSAY. THE IMPORTANT CRITERIA IN THIS EVALUATION IS THE %CV WHICH IS A MEASURE OF THE PRECISION (OR IMPRECISION) OF THE STAFF AND METHOD. ACCEPTABLE PRECISION IS 10% CV OR LESS; VERY GOOD PRECISION IS 6% CV OR LESS.

TABLE III: PRECISION DATA

VIAL	DRUG	WITHIN RUN (N=6)			BETWEEN RUN (N=12)		
		X	SD	%CV	X	SD	%CV
1	AMPHETAMINE	1588	110	7.0	1633	156	9.5
2	METHAMPHETAMINE	2037	173	8.5	2100	211	10.0
3	COCAINE METAB	843	32	4.0	857	30	3.5
4	CANNABINOID	46.9	2.8	6.0	50	3.0	6.2
5	CODEINE	577	32.9	5.7	583	28	4.8
6	MORPHINE	590	17.2	2.9	595	15.5	2.6
7	PHENCYCLIDINE	63.2	2.6	4.2	61.6	3.6	5.8
8	SECOBARBITAL	527	16.3	3.1	535	27.8	5.2
9	NORDIAZEPAM	439	13.8	3.1	436	10.7	2.5

LEGEND: N STANDS FOR NUMBER OF TIMES TEST PERFORMED
X STANDS FOR MEAN VALUE FOR ALL REPORTED TESTS
SD STANDS FOR STANDARD DEVIATION
%CV STANDS FOR PERCENT COEFFICIENT OF VARIATION

IV. LINEARITY

LINEARITY: THE RANGE OF DRUG CONCENTRATIONS THE METHOD IS ABLE TO ACCURATELY DETECT AND/OR QUANTITATE

VIALS I AND II CONTAINED THE DRUGS TO BE ANALYZED AT HIGH AND LOW CONCENTRATIONS; THE HIGH CONCENTRATION WAS AT THE UPPER LIMIT OF THE METHOD QUANTITATION CAPABILITY AND THE LOW CONCENTRATION IS AT THE LOWER LIMIT OF THE METHODS PERFORMANCE. THE RESULTS IN TABLE IV ARE ENTERED IN UNITS OF "NG/ML" ALTHOUGH SOME RESULTS WERE REPORTED ON THE TAPES AND DATA SHEET IN "MCG/ML".

TABLE IV: LINEARITY

THE RESULTS IN THIS TABLE ARE IDENTIFIED AS "EXPECTED" (EXP) AND "REPORTED" (REP).

	RESULTS (NG/ML)			
	VIAL I		VIAL II	
DRUG/DRUG CLASS	EXP	REP	EXP	REP
AMPHETAMINES	8000	HIGH	1600	1670
BARBITURATES	4000	HIGH	800	790
BENZODIAZEPINE MET.	4000	HIGH	800	765
CANNABINOIDS	50	46.7	13	LOW
COCAINE METABOLITE	800	840	180	180
OPIATES	1500	HIGH	300	332
PHENCYCLIDINE (PCP)	75	73.7	15	14.7

V. SPECIFICITY

SPECIFICITY: THE DEGREE OR ABILITY OF A TESTING METHOD TO REACT ONLY WITH THE DRUGS OR METABOLITES BEING TESTED AND TO EXCLUDE ALL OTHER DRUGS

SPECIFICITY OF IMMUNOASSAY SCREENING TESTS IS BASED ON THE WAY IN WHICH THE ANTIBODIES DEVELOPED "RECOGNIZE" OR REACT WITH THE DRUG BEING TESTED FOR. DIFFERENT MANUFACTURERS OF IMMUNOASSAY DRUG TESTING PRODUCTS HAVE "GROWN" ANTIBODIES USING DIFFERENT TECHNIQUES; THESE DIFFERENT TECHNIQUES MAY GREATLY EFFECT HOW WELL THE TESTING METHOD MAY REACT WITH ONLY THE DRUG/DRUG CLASS OF INTEREST AND NOT REACT WITH OTHER UNDESIRED DRUGS. THE BEST ILLUSTRATION OF THIS POINT IS THE AMPHETAMINE IMMUNOASSAY TEST WHICH MAY VARY GREATLY FROM ONE MANUFACTURER TO THE NEXT WITH REGARD TO HOW SPECIFICALLY THE TEST WILL ONLY DETECT AMPHETAMINES. SOME IMMUNOASSAY AMPHETAMINE ASSAYS WILL DETECT THE PRESENCE OF COLD MEDICATIONS AS IF THEY ARE AMPHETAMINES; THEREFOR IT IS EXTREMELY IMPORTANT TO EVALUATE THE TEST METHOD REGARDING THE POSSIBILITY OF A CROSS REACTION TO THESE NON-TARGETED COMPOUNDS.

TABLE V: SPECIFICITY

THE DATA IN THE FOLLOWING TABLE ARE THE EXPECTED AND REPORTED FOR VIALS XX-1 THROUGH XX-15. THE CONCENTRATION OF EACH TARGETED ANALYTE IS INDICATED IN PARENTHESES OR A UNDESIRED DRUG WHICH WAS IN THE SPECIMEN.

SAMPLE	EXPECTED (NG/ML)	REPORTED (NG/ML)
XX-1	NEGATIVE (EPHEDRINE)	NEGATIVE
XX-2	COCAINE MET (330)	COCAINE MET (360)
XX-3	NEGATIVE (PHENTERMINE)	AMPHETAMINE (690)
XX-4	NEGATIVE	NEGATIVE
XX-5	MORPHINE (400)	OPIATES (460)
XX-6	CANNABINOIDS (33)	NEGATIVE
XX-7	METHAMPHETAMINE (500)	NEGATIVE
XX-8	HYDROMORPHONE (600)	OPIATES (323)
XX-9	NORDIAZEPAM (400)	BENZODIAZEPINE (384)
XX-10	PHENOBARBITAL (500)	BARBITURATES (350)
XX-11	NEGATIVE (TYRAMINE)	NEGATIVE
XX-12	AMPHETAMINE (400)	NEGATIVE
XX-13	COCAINE MET (330)	COCAINE MET (360)
XX-14	CODEINE (400)	OPIATES (475)
XX-15	NEGATIVE (PHEYLPROP.)	NEGATIVE

VI. DISCUSSION

OVERALL THE TECHNOLOGY AND LABORATORY STAFF PERFORMED EXCELLENT. EACH OF THE VARIOUS AREAS STUDIES ARE DISCUSSED SEPARATELY.

ACCURACY

THE DATA PRESENTED IN TABLE II DEMONSTRATE THAT THE LABORATORY WAS ABLE TO CORRECTLY IDENTIFY 100% OF THE DRUGS CONTAINED IN VIALS A-I AND WITHOUT ANY "FALSE" POSITIVES. IN ADDITION THE EXPECTED AND REPORTED RESULTS COMPARE VERY WELL. THREE DIFFERENT TECHNICIANS WERE INVOLVED IN THE ANALYSIS OF THESE SPECIMENS (KREBS, GRUICH AND JONES) WHICH HELPS DOCUMENT THE ACCURACY OF THE ENTIRE STAFF AND LABORATORY SYSTEM.

VIAL A: PHENCYCLIDINE RESULTS COMPARED VERY WELL WITH A TARGET CONCENTRATION OF 70 NG/ML AND MEASURED OF 73.6 NG/ML.

VIAL B: MORPHINE AT TARGETED CONCENTRATION OF 600 NG/ML COMPARES WELL WITH REPORTED 637 NG/ML CONCENTRATION. MORPHINE IS THE PRINCIPAL OPIATE OF ABUSE OF CONCERN IN DRUG TESTING PROGRAMS.

VIAL C: AMPHETAMINE AT TARGETED CONCENTRATION OF 2000 NG/ML COMPARES WELL WITH REPORTED 1720 NG/ML (1.72 MCG/ML) CONCENTRATION.

VIAL D: CARBOXY-THC METABOLITE FROM MARIJUANA USE AT TARGETED CONCENTRATION OF 50 NG/ML COMPARES WELL WITH 57.2 NG/ML REPORTED CONCENTRATION.

VIAL E: SECOBARBITAL AT TARGETED CONCENTRATION OF 600 NG/ML COMPARES VERY WELL WITH 650 NG/ML (0.65 MCG/ML) REPORTED CONCENTRATION FOR BARBITURATES. SECOBARBITAL IS AN ABUSED SHORT ACTING BARBITURATES WHICH IS THE TARGETED ANALYTE FOR BARBITURATE IMMUNOASSAY SCREENING METHODS.

VIAL F: NORDIAZEPAM AT TARGETED CONCENTRATION OF 600 NG/ML COMPARES VERY WELL WITH 546 NG/ML REPORTED CONCENTRATION FOR BENZODIAZEPINE METABOLITES. NORDIAZEPAM IS A PRINCIPAL METABOLITE OF SEVERAL BENZODIAZEPINES AND IS THE TARGETED ANALYTE FOR BENZODIAZEPINE METABOLITE IMMUNOASSAY SCREENING METHODS.

VIAL G: CODEINE AT TARGETED CONCENTRATION OF 700 NG/ML COMPARES WELL WITH 778 NG/ML REPORTED CONCENTRATION FOR OPIATES. CODEINE IS ANOTHER OPIATE OF CONCERN FOR ABUSE BUT MAY ALSO BE PRESENT IN URINE FROM PRESCRIPTION TYLENOL #3 USE.

VIAL H: COCAINE METABOLITE (BENZOYLECGONINE) AT TARGETED CONCENTRATION OF 1000 NG/ML COMPARES WELL WITH 1060 NG/ML (1.06 MCG/ML) REPORTED CONCENTRATION. BENZOYLECGONINE IS THE PRINCIPLE URINE METABOLITE DOCUMENTING COCAINE/CRACK USE.

VIAL I: METHAMPHETAMINE AT TARGETED CONCENTRATION OF 2500 NG/ML COMPARES WELL WITH 2170 NG/ML (2.17 MCG/ML) REPORTED CONCENTRATION. NON-MEDICAL METHAMPHETAMINE USE IS INCREASING IN THE FORM OF SMOKABLE ICE.

PRECISION

ALL RESULTS FOR VIALS 1-9 DOCUMENTING WITHIN RUN AND BETWEEN RUN PRECISION ARE EXCELLENT. THE RESULTS ARE EVEN MORE IMPRESSIVE BECAUSE THEY WERE COMPILED OVER SEVERAL DAYS ON THREE DIFFERENT INSTRUMENTS BY THREE DIFFERENT TECHNICIANS. THE %CV INDICATED FOR EACH ASSAY IN THESE TABLES IS A "TRUE" INDICATION OF THE PRECISION OF INGALLS SHIPBUILDING LABORATORY. ONLY THE AMPHETAMINES ASSAY FOR AMPHETAMINE AND METHAMPHETAMINE DEMONSTRATED A BETWEEN RUN PRECISION THAT IS AT THE UPPER LIMIT OF ACCEPTABLE PERFORMANCE; ALL OTHER ASSAYS WERE AT %CV 6.2 OR LESS, WHICH IS EXCELLENT. WHAT IS PARTICULARLY IMPORTANT ABOUT THIS PARAMETER IS THAT THE DRUG SCREENING METHOD WILL PERFORM RELIABLY EACH DAY AT THE DECISION POINT (CUTOFF/THRESHOLD) OF THE ASSAY. THESE RESULTS ALSO DOCUMENT THE EXCELLENT PERFORMANCE OF STAFF IN MAINTENANCE, CALIBRATION AND OPERATION OF THE ADx INSTRUMENT SYSTEMS.

LINEARITY

ALL RESULTS FOR VIAL I AND VIAL II PERFORMED AS TO BE EXPECTED. THE DRUG CONCENTRATIONS INDICATED IN TABLE IV FOR VIAL I CHALLENGED THE UPPER END OF THE CALIBRATION CONCENTRATION RANGE. THE HIGHER CONCENTRATIONS FOR AMPHETAMINES, BARBITURATES (SECOBARBITAL), BENZODIAZEPINE METABOLITES (NORDIAZEPAM AND OPIATES ALL READ "HIGH" RATHER THAN A NUMERICAL VALUE; THESE RESULTS ARE NOT UNCOMMON FOR THESE DRUG CONCENTRATIONS. SPECIMENS WHICH READ "HIGH" MAY BE DILUTED TO OBTAIN A NUMERICAL VALUE; IN FACT THE DRUG CONCENTRATIONS IN VIAL II WERE A 1 TO 5 DILUTION OF VIAL I EXCEPT FOR CANNABINOIDS WHICH WERE A 1 TO 4 DILUTION. THE REPORTED RESULTS FOR VIAL II ARE ALL VERY CLOSE TO THE EXPECTED DRUG CONCENTRATIONS; THE ONLY RESULT WHICH DID NOT CORRELATE WAS CANNABINOIDS CHALLENGED AT 13 NG/ML AND WHICH WAS REPORTED AS "LOW". THE "LOW" CANNABINOIDS RESULT REPORTED IS NOT NECESSARILY A FAILURE ON THE PART OF THE LABORATORY BUT RATHER A VERY AGGRESSIVE EVALUATION OF THE DRUG TESTING PROGRAM.

SPECIFICITY

THE RESULTS OF EACH VIAL WITH REGARD TO DRUG PRESENT AND CONCENTRATION ARE DISCUSSED INDIVIDUALLY AS FOLLOWS.

VIAL XX- 1: THIS VIAL CONTAINED EPHEDRINE, A NONTARGETED DRUG, AT A CONCENTRATION OF 2000 NG/ML. EPHEDRINE IS AN OVER THE COUNTER DRUG WHICH REACTS WITH MOST AMPHETAMINE IMMUNOASSAY SCREENING METHODS TO YIELD AN UNDESIRED POSITIVE RESPONSE. THE NEGATIVE TEST RESULT DOCUMENTS THE ABBOTT FPIA FAILS TO DETECT THE EPHEDRINE AS A CROSS-REACTING COMPOUND. A PRACTICAL BENEFIT IS THAT SAMPLES CONTAINING EPHEDRINE WILL NOT GIVE A POSITIVE FPIA AMPHETAMINE RESULT AND THEREFOR WILL NOT HAVE TO BE ANALYZED BY GC/MS TO PROVE THE ABSENCE OF AMPHETAMINES.

VIAL XX- 2: THIS VIAL CONTAINED BENZOYLECGONINE (COCAINE METABOLITE) AT A CONCENTRATION OF 330 NG/ML, WHICH COMPARES VERY WELL WITH THE 360 NG/ML COCAINE METABOLITE REPORTED BY THE LABORATORY. THIS SPECIMEN WAS SUBMITTED A SECOND TIME AS XX-13 TO FURTHER ASSESS THE LABORATORIES ACCURACY AND PRECISION AND THE RESULTS DUPLICATED EXACTLY.

VIAL XX- 3: THIS VIAL CONTAINED PHENTERMINE AT A CONCENTRATION OF 2000 NG/ML AND THE LABORATORY REPORTED A 690 NG/ML AMPHETAMINE CONCENTRATION. PHENTERMINE IS ANOTHER OVER THE COUNTER DRUG WHICH HAS BEEN DETERMINED TO CROSS REACT WITH AMPHETAMINE IMMUNOASSAY SCREENING METHODS TO GIVE A "FALSE" POSITIVE RESPONSE. THIS SPECIMEN DEMONSTRATES THE POSSIBILITY OF THE ABBOTT FPIA GIVING A POSITIVE RESPONSE FOR AMPHETAMINES WHEN THIS DRUG IS PRESENT IN A SAMPLE. AS A PRACTICAL ISSUE THIS RESULT EMPHASIZES THE IMPORTANCE OF CONFIRMING IMMUNOASSAY AMPHETAMINE RESULTS BY GC/MS.

VIAL XX- 4: THIS SPECIMEN WAS A QUALITY CONTROL - URINE NEGATIVE AND WAS PROPERLY REPORTED AS A NEGATIVE.

VIAL XX- 5: THIS SPECIMEN CONTAINED MORPHINE AT A CONCENTRATION OF 400 NG/ML, WHICH COMPARES VERY WELL WITH THE 460 NG/ML OPIATES REPORTED.

VIAL XX- 6: THIS SPECIMEN CONTAINED CARBOXY-THC (MARIJUANA METABOLITE) AT A CONCENTRATION OF 33 NG/ML. THE LABORATORY REPORTED THE RESULT AS "NEGATIVE" SINCE THE CONCENTRATION RECORDED ON THE ADX TAPE IS 34.8 NG/ML AND THEREFOR BELOW THEIR APPARENT CUTOFF OF 50 NG/ML. THE EXPECTED AND MEASURED CONCENTRATIONS COMPARE VERY WELL. THESE RESULTS ILLUSTRATE THE IMPLICATIONS OF ESTABLISHING AN ARBITRARY THRESHOLD WHICH WILL "MISS" TRUE POSITIVE SPECIMENS WHEN THE TECHNOLOGY CAN ACCURATELY IDENTIFY LOWER CONCENTRATIONS.

VIAL XX- 7: THIS SPECIMEN CONTAINED METHAMPHETAMINE AT A CONCENTRATION OF 500 NG/ML. THE LABORATORY REPORTED THE RESULT AS "NEGATIVE" SINCE THE CONCENTRATION RECORDED ON THE ADX TAPE IS 490 NG/ML AND THEREFOR BELOW THEIR APPARENT CUTOFF OF 500 NG/ML. THE EXPECTED AND MEASURED CONCENTRATIONS COMPARE VERY WELL.

VIAL XX- 8: THIS SPECIMEN CONTAINED HYDROMORPHONE, AN OPIATE THAT IS USED FOR NON-MEDICAL PURPOSES, AT A CONCENTRATION OF 600 NG/ML. SINCE HYDROMORPHONE IS AN ABUSED OPIATE IS DESIRED TO TEST FOR THIS DRUG; HOWEVER OTHER IMMUNOASSAY OPIATE METHODS WILL NOT DETECT THE PRESENCE OF THIS DRUG AND WOULD HAVE REPORTED THIS RESULT AS NEGATIVE. AN IMPORTANT ISSUE IS INSURING THE LABORATORY PROVIDING GC/MS CONFIRMATION SERVICES TO SUPPORT THE SCREENING LABORATORY RESULTS INCLUDE ANALYSIS FOR HYDROMORPHONE, IN ADDITION TO MORPHINE AND CODEINE. THE RESULT REPORTED OF 323 NG/ML OPIATES IS CORRECT DUE TO THE WAY IN WHICH THIS DRUG IS DETECTED BY THE FPIA METHOD.

VIAL XX- 9: THIS SPECIMEN CONTAINED NORDIAZEPAM (BENZODIAZEPINE METABOLITE) AT A CONCENTRATION OF 400 NG/ML, WHICH COMPARES VERY WELL WITH THE REPORTED 384 NG/ML BENZODIAZEPINE METABOLITES. NORDIAZEPAM IS A METABOLITE FORMED IN THE BODY FROM SEVERAL DIFFERENT BENZODIAZEPINE DRUGS.

VIAL XX-10: THIS SPECIMEN CONTAINED PHENOBARBITAL (BARBITURATES) AT A CONCENTRATION OF 500 NG/ML, WHICH COMPARES WELL WITH THE REPORTED 350 NG/ML (0.35 MCG/ML) BARBITURATES. THE BARBITURATES ASSAY IS KEYED ON SECOBARBITAL WHICH IS AN ABUSED SHORT ACTING BARBITURATE; ALTHOUGH PHENOBARBITAL IS DETECTED IT IS DETECTED AS A LOWER CONCENTRATION DUE TO ITS CROSS REACTIVITY CHARACTERISTICS. OTHER IMMUNOASSAY METHODS ARE ALSO TARGETED ON SECOBARBITAL AND HAVE

A POOR RESPONSE AND DETECTION TO OTHER BARBITURATES. THIS SPECIMEN HIGHLIGHTS THE ADVANTAGE OF ABBOTT FPIA BARBITURATE ASSAY TO DETECT OTHER BARBITURATES.

VIAL XX-11: THIS SPECIMEN CONTAINED TYRAMINE AT A CONCENTRATION OF 1000 NG/ML. TYRAMINE IS A COMPOUND OFTEN FOUND IN URINE AND IN MOST AMPHETAMINE IMMUNOASSAY METHODS WILL RESULT IN A POSITIVE TEST. THIS SPECIMEN WAS CORRECTLY REPORTED AS NEGATIVE AND DOCUMENTS THE FPIA METHOD CAPABILITY OF NOT DETECTING THIS UNDESIRED COMPOUND.

VIAL XX-12: THIS SPECIMEN CONTAINED AMPHETAMINE AT A CONCENTRATION OF 400 NG/ML. ALTHOUGH THE LABORATORY REPORTED THE RESULT AS NEGATIVE THE ADX TAPE INDICATES AN AMPHETAMINE RESPONSE OF 410 NG/ML AND WAS APPARENTLY REPORTED NEGATIVE SINCE THE CONCENTRATION IS BELOW THE CUTOFF OF 500 NG/ML.

VIAL XX-13: REPEAT OF VIAL XX-2.

VIAL XX-14: THIS SPECIMEN CONTAINED CODEINE AT A CONCENTRATION OF 400 NG/ML, WHICH COMPARES WELL WITH THE 475 NG/ML OPIATES RESULT REPORTED.

VIAL XX-15: THIS SPECIMEN CONTAINED PHENYLPROPANOLAMINE AT A CONCENTRATION OF 1000 NG/ML. THIS DRUG IS AVAILABLE OVER THE COUNTER AND HAS BEEN DEMONSTRATED TO REACT WITH MOST AMPHETAMINE IMMUNOASSAY METHODS TO GIVE A FALSE POSITIVE RESPONSE. THE NEGATIVE RESULT REPORTED IS CORRECT.

MCDONNELL DOUGLAS

LAW DEPARTMENT

September 18, 1992

VIA FACSIMILE (703) 697-9845

Defense Acquisition Regulations Council
Attention: Mrs. Linda W. Neilson OUSD(A)
3062 Defense Pentagon
Washington, D.C. 20301-3062

Subject: **MDC Comments On DoD Proposed Rule For Drug-Free Work Force**

Dear Mrs. Neilson:

This correspondence reflects the views of McDonnell Douglas Corporation (MDC) regarding the DoD proposed rule for a Drug-Free Work Force (the Rule). For the sake of brevity, our comments are generally more practical than philosophical:

(a) While MDC believes that some subparts of the Rule should be clarified, we support the Rule in *principle*, particularly its approach to random urinalysis testing of employees in narrowly and carefully tailored subgroups based on sensitive workplace activities. Through the collective bargaining process, our union consistencies responded generally favorably to the Rule. We believe the failure to ultimately readopt the Rule (in an improved form) would send confounding and ill-timed signals regarding the seriousness with which DoD views drug use/abuse issues in the workplace.

(b) Assuming DoD decides to modify the Rule, we propose the following changes:

(i) 252.223-7004(a)(2) Illegal drugs should be expanded to include the abuse of valid prescription drugs. We have found circumstances when employee testing results far exceed pharmacological dosages.

(ii) 252.223-7004(a)(2)(i) Access to classified information should be better defined. We suggest that the definition include only those in possession of Secret and Top Secret clearances granted by the DoD.

(iii) 252.223-7004(b) The DoD should specifically reference the requirements of the contractor's program to include reasonably suspicion, post-accident or unsafe practice testing and voluntary and post-counselling testing.

(iv) 252.223-7004(c)(1) If comment (iii) is acceptable, then this sentence should amended to include other tests.

(v) 252.223-7004(d)(1) This subpart should be modified to make clear that the intended DoD representative is the Administrative Contracting Officer responsible for the contractor's overall operations.

(vi) 252.223-7004(d)(2) The term "supervised rehabilitation program" should be defined as that approved by either the MRO or the contractor's EAP office.

(vii) 252.223-7004(e) As a corporation with component companies in several states, MDC supports the inclusion of this paragraph to insure consistency of its drug and alcohol testing program. It is strongly recommended that DoD provide explanatory materials relating to the legal sufficiency and enforceability of this preemption clause.

(c) As a contractor who has instituted wide-spread testing and compliance programs based on the November 27, 1991 Final Rule, we feel that implementation should not be a convoluted and protracted process. Whatever the outcome, the DoD should move to implement a Final Rule as soon as practicable.

Respectfully submitted,

MCDONNELL DOUGLAS CORPORATION

By: _____
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September 21, 1992

Defense Acquisition Regulations Council
ATTN: Mrs. Linda W. Neilson
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Washington, DC 20301-3062

Re: DAR Case 88-083: Comments on DOD's Proposed Final Rule Amending the DFARS Drug-Free Work Force Clause

Dear Mrs. Neilson:

We are writing to oppose the Department of Defense's ("DOD") proposed final rule amending the Defense Federal Acquisition Regulation Supplement ("DFARS") Drug-Free Work Force clause (DFARS § 252.223-7004). 57 Fed. Reg. 32,769 (July 23, 1992). Although DOD's continuing efforts to eradicate drug use within the defense industry work force are commendable, we believe the proposed rule, if adopted, would create significant legal and financial difficulties for defense contractors. In light of these difficulties, which are discussed more fully below, and the fact that DOD has not identified any shortcomings in the interim rule which it seeks to correct by implementation of the final rule, we recommend that DOD withdraw the proposed final rule and continue using the existing Drug-Free Work Force clause for new acquisitions.

I. THE HISTORY OF THIS RULEMAKING

To implement its new policy that "defense contractors shall maintain a program for achieving a drug-free work force," DOD promulgated an interim rule on September 28, 1988, prescribing the use of a new DFARS Drug-Free Work Force clause (DFARS § 252.223-7500) in procurements involving access to classified information or where the contracting officer determined it necessary in the interest of national security, health, or safety. DFARS § 223.7504, 53 Fed. Reg. 37,763, 37,764 (September 28, 1988). The September 1988 clause, which was recently reinstated pending comments on the proposed final rule and which has been renumbered as DFARS § 252.223-7004, requires a contractor to "institute and maintain a program for achieving the objective of

a drug-free work force," through implementation of "alternative approaches comparable to the criteria" outlined in paragraph (c) of the clause. DFARS § 252.223-7004(b). Most notably, paragraph (c) requires a contractor to "establish a program that provides for testing for the use of illegal drugs by employees in sensitive positions." Id. § 252.223-7004(c)(4)(i).

A contractor has considerable flexibility, however, in selecting and implementing the appropriate drug testing program. Moreover, "Employee in a sensitive position" has the limited meaning of "an employee who has been granted access to classified information; or employees in other positions that the contractor determines involve national security, health or safety, or functions other than the foregoing requiring a high degree of trust and confidence." Id. § 252.223-7004(a). The clause further provides in paragraph (e) that the drug testing provisions of the clause "shall not apply to the extent they are inconsistent with state or local law, or with an existing collective bargaining agreement."

In prepared comments accompanying the release of questions and answers providing guidance on the new clause, DOD explained that

> a measured approach to the drug-free workforce issue within the defense contractor community should include a requirement for the initiation and maintenance of flexible, contractor-developed programs for preventing, detecting and treating drug abuse by employees whose duties entail access to classified information or production of critical items of military equipment.

Id. at 2, 3.

DOD further stated that "[t]he rule does not dictate the criteria, details, or other elements of the testing program," and that DOD did not desire to place its contractors in the position of adopting drug testing programs that are inconsistent with state or local law, or an existing collective bargaining agreement. DOD Comments at 1.

On November 27, 1991, more than three years after the interim rule had taken effect, DOD published the final rule to effect significant changes to the clause. 56 Fed. Reg. 60,066, 60,068 (Nov. 27, 1991). However, in response to defense industry

concerns over the extent to which the final rule departed from the interim rule, DOD decided on July 23, 1992, to remove the final rule, reinstate the interim rule, and request comments on the now proposed final rule. 57 Fed. Reg. 32,736 (July 23, 1992).

II. IF ADOPTED, DOD'S PROPOSED FINAL RULE WOULD INVITE LEGAL CHALLENGES ON SEVERAL FRONTS

DOD proposes to make several significant changes to the DFARS Drug-Free Work Force clause by the adoption of this final rule. First, the definition of "employee in a sensitive position" would be greatly expanded to encompass broad categories of contractor employees "whose duties could reasonably be expected to affect health, safety, or national security, including, but not limited to," work involving "[a]ccess to classified information;" the "[d]esign, manufacture, test and evaluation, or maintenance [or control] of aircraft, vessels, vehicles, heavy equipment, munitions, toxic materials, weapons, weapons systems . . . or major components of the foregoing;" and transportation, storage, or protection of toxic, nuclear, or potentially dangerous materials. 57 Fed. Reg. at 32,770 (proposing revision of 48 C.F.R. § 252.223-7004(a)(2)). Significantly, the contractor would no longer have discretion in deciding which employees are working in "sensitive positions"; rather, the determination would be governed by the regulatory standard.

Second, the proposed final rule would eliminate the contractor's flexibility under the existing clause in fashioning an appropriate program for achieving a drug-free work force, and in establishing an employee drug testing program. Random drug testing would be required for all contractor employees working in broad categories of "sensitive positions."

Finally, DOD proposes to reverse its position on the applicability of the clause in the instance of conflicting state and local laws or collective bargaining agreements. Subsection (e) would be amended to provide that "[t]he requirements of this clause take precedence over any State and local laws to the contrary." The provision regarding the applicability of the drug testing requirements in the instance of a conflicting collective bargaining agreement would be deleted.

If adopted, these changes would result in protracted and uncertain lawsuits against defense contractors by contractor employees and/or their unions challenging the constitutional

validity of the federal preemption and random drug testing provisions, and DOD's statutory authority to promulgate the Drug-Free Work Force clause in its proposed form. We further believe the dilemma that defense contractors would confront over whether to comply with the provisions of the clause in the face of a conflicting collective bargaining agreement would inevitably lead to litigation based either on contract default, if the contractor chooses to honor the existing collective bargaining agreement, or violation of the collective bargaining agreement if the contractor elects to comply with the clause.

The various grounds upon which these challenges could be based are highlighted below.

A. The Proposed Final Rule Is of Questionable Constitutional Validity

1. DOD Lacks Sufficient Preemptive Authority

We believe DOD lacks sufficient statutory authority for the DFARS Drug-Free Work Force clause to preempt inconsistent state or local laws. The Supreme Court has established clear standards for determining whether federal law preempts state or local law. With respect to both express and implied preemption in the areas of health and safety, the Court recently reiterated that "'historic police powers of the States were not to be superseded by the Federal Act unless that was the clear and manifest purpose of Congress'" in promulgating the act. Wisconsin Public Intervenor v. Mortier, 111 S. Ct. 2476, 2482 (1991) (quoting Rice v. Santa Fe Elevator Corp., 331 U.S. 218, 230 (1947)).

DOD has not promulgated the Drug-Free Work Force clause pursuant to an act of Congress envisioning mandatory random drug testing of DOD contractor employees working in broadly defined categories of sensitive positions. Rather, DOD cites its "housekeeping" authority under 5 U.S.C. § 301 (1988) as the legal basis for the clause. 53 Fed. Reg. at 37,764; 57 Fed. Reg. at 32,769. This is hardly a statute expressing a clear and manifest congressional purpose to preempt state and local laws.[1/] The new

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1/ The only congressional pronouncement in the area of drug-free workplace initiatives is section 705 of the Drug-Free Workplace Act of 1988, 41 U.S.C. §§ 701-707 (1988), which DOD has not cited for its authority and which

(Footnote continued on next page)

preemption provision is therefore sure to be challenged in states or localities which prohibit random drug testing, on grounds that the statutory authority underlying the clause does not overcome "the presumption against the pre-emption of state police power regulations." Cipollone v. Liggett Group, Inc., 112 S. Ct. 2608, 2618 (1992).

2. The Final Rule Would Be Subject to Challenge Under the Fourth Amendment

If the proposed final rule, which greatly expands the definition of "employee in a sensitive position," is adopted, contractor employees and/or their unions are likely to challenge the clause based on whether the mandatory random drug testing provision violates the Fourth Amendment ban against unreasonable searches and seizures. Although the Supreme Court recently has affirmed the constitutional validity of federally-mandated random drug testing of railroad engineers involved in train accidents and customs agents carrying firearms or working in the interdiction of narcotics, Skinner v. Railway Labor Executives' Ass'n, 489 U.S. 602 (1989); National Treasury Employees Union v. Von Raab, 489 U.S. 656 (1989), the outcome of a challenge to DOD's Drug-Free Work Force clause, covering broad categories of contractor employees, is far from certain.

The Skinner/Von Raab analysis of the constitutionality of random drug testing turns on overcoming the Fourth Amendment warrant/probable cause requirement and the need for individualized suspicion. In assessing generally the need to conduct random drug tests, the governmental interest in testing defense industry employees is substantial. The design, manufacture, and testing of defense and weapon systems is critical to our nation's security. Moreover, extraordinary safety and national security hazards would arise if employees in "sensitive positions" are using illegal drugs. An error by such an employee could result in a disastrous loss of life and the public should not bear such

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(Footnote continued from previous page)

requires contractors to maintain a drug-free workplace. That Act does not mandate drug testing, and Congress did not preempt state laws that limit the ability of employers to implement drug testing programs. Indeed, the legislative history of that Act suggests an intent not to repeal long-standing state labor laws. See 134 Cong. Rec. H11,249 (daily ed. Oct. 21, 1988) (statement of Rep. Brooks).

a risk created by employees who suffer from impaired perception and judgment. Von Raab, 489 U.S. at 670-71.

The privacy interests of the employees then must be balanced against such compelling government interests. It can be argued that employees working in the defense industry have a diminished expectation of privacy, and that the Department of Health and Human Services' "Mandatory Guidelines for Federal Workplace Drug Testing Programs," to which the contractor's program must conform, limits the intrusiveness of the program by permitting unobserved urination, by demanding standardized collection of specimens and chain of custody procedures, and by ensuring confidential test results.

Nevertheless, despite the overall appearance of constitutionality, the DOD rule is vulnerable to attack based on the Court's decision in Von Raab to remand with instructions to determine whether the agency had defined the category of employees required "to handle classified material" more broadly than necessary. 489 U.S. at 677.

Under the DFARS clause, "employee in a sensitive position" similarly includes employees whose duties involve access to classified information. This category encompasses virtually all contractor employees, and could therefore be challenged on grounds that it is broader than necessary to achieve DOD's policy. Moreover, DOD has not recited evidence of a real problem involving unauthorized disclosures of classified information due to drug use within the defense industry, or that the flexibility afforded to contractors under the existing clause in selecting an appropriate drug testing program is not sufficient to prevent such disclosures.

B. DOD's Proposed Final Rule May Exceed DOD's Statutory Authority

Another ground upon which the proposed clause is subject to challenge is that DOD has exceeded its statutory housekeeping authority under 5 U.S.C. § 301 in issuing its Drug-Free Work Force clause to mandate random drug testing of contractor employees. In this regard, the Supreme Court has stated that 5 U.S.C. § 301 is a housekeeping statute authorizing only the issuance of internal DOD guidelines and procedures, not substantive regulations. Chrysler Corp. v. Brown, 441 U.S. 281, 310 (1979); see also Greene v. McElroy, 360 U.S. 474, 507 (1959) (the scope of regulatory authority delegated to an agency by Congress is subject to greater scrutiny where constitutional issues are

implicated by the agency's action). Certainly, DOD's DFARS Drug-Free Work Force clause goes beyond the issuance of internal guidelines and procedures.

C. The Proposed Final Rule Creates Conflict with Existing Collective Bargaining Agreements

The proposed final rule would also place defense contractors in the dilemma of having to choose whether to comply with the clause or honor an existing collective bargaining agreement to the extent it is inconsistent with the random drug testing requirements of the clause. The reinstated interim rule provides that the drug testing provisions of this clause do not apply to the extent they are inconsistent with an existing collective bargaining agreement, provided the contractor agrees that the drug testing provisions will be a subject of negotiations during the next collective bargaining session. 57 Fed. Reg. at 32,738, DFARS § 252.223-7004(e). If the proposed final rule is adopted, the provision regarding the impact on existing collective bargaining agreements would be deleted from paragraph (e), and a contractor would be required to implement the clause, notwithstanding any existing collective bargaining agreement, to avoid being terminated for default. The precedential effect of the clause in the face of a conflicting collective bargaining agreement would surely be challenged by one or more unions.

Supreme Court precedent instructs that, in order to take precedence over an existing collective bargaining agreement, the new clause must be based on a "well defined and dominant" public policy. W.R. Grace & Co. v. Local Union 759, 461 U.S. 757, 766 (1983). The Court stated that whether such a public policy exists "is to be ascertained 'by reference to laws and legal precedents and not from general considerations of supposed public interests.'" Id. (quoting Muschany v. United States, 324 U.S. 49, 66 (1945)). As an example of general considerations which do not rise to the level of a well-defined public policy, the Court has more recently identified a company policy which prohibited the operation of machinery by an employee under the influence of controlled substances. The Court held that such a policy, although admittedly in accordance with common sense, did not owe its duty to statutes or legal precedents. United Paperworkers International Union v. Misco, Inc., 484 U.S. 29, 44-45 (1987).

By contrast, however, a lower court identified the drug testing programs of federal agencies and departments, including DOD, as evidence of programs that advanced a well-defined public policy. Georgia Power Co. v. IBEW, Local 84, 707 F. Supp. 531,

537 (N.D. Ga. 1989), aff'd, 896 F.2d 507 (11th Cir. 1990). In Georgia Power, an arbitrator had held that the company's anti-drug policy failed to establish reasonable and sufficient cause within the meaning of the collective bargaining agreement to terminate an employee. 707 F. Supp. at 534. The district court, citing federal agency drug-testing programs established pursuant to an Executive Order and the Drug-Free Workplace Act of 1988, overturned the arbitrator's decision and held that reinstating the employee pursuant to the collective bargaining agreement was contrary to public policy. Id. at 539.

DOD claims the new Drug-Free Work Force clause similarly represents a well-defined and dominant public policy:

> The unlawful use by contractor employees of controlled substances threatens national security and the safety of personnel and equipment. Therefore, DOD policy is to ensure that DOD contractors have a program for eliminating the unlawful use of controlled substances by employees whose duties affect health, safety, national security, or accomplishment of the DOD mission.

56 Fed. Reg. 67,208, at 67,215 (Dec. 30, 1991) (codified at DFARS § 223.7500).

Although a contractor faced with this dilemma likely would choose to risk being sued for violating an existing collective bargaining agreement rather than to default on the contract, the outcome of this costly and contentious litigation is also uncertain. Depending on the legal precedent in the relevant jurisdiction (and a national union would attempt to select the most favorable forum), a court may hold that the DFARS Drug-Free Work Force clause was not implemented pursuant to a sufficiently well-defined and dominant public policy to justify taking precedence over an existing collective bargaining agreement. This outcome is particularly plausible given DOD's reliance upon its general housekeeping authority under 5 U.S.C. § 301, not Executive Order 12564 or the Drug-Free Workplace Act of 1988, as the legal basis for the clause.

Regardless of the litigation's outcome, however, the new clause could create severe problems for a contractor in relations with its employees and/or their union. Notably, DOD has not indicated that allowing contractors flexibility in

establishing appropriate drug testing programs under the interim rule is unworkable, or that collective bargaining agreements frustrate implementation of DOD's policy of achieving a drug-free work force. In the absence of any such evidence, and in light of the dilemma the proposed final rule would thrust upon contractors, we recommend that the proposed final rule be withdrawn.

III. CONTRACTORS WILL INCUR SIGNIFICANT ADDITIONAL COSTS UNDER NEW AND EXISTING CONTRACTS

For the reasons noted above, defense contractors will undoubtedly incur significant litigation expenses if the proposed final rule is adopted. In addition, industry representatives have estimated that the cost of implementing the new clause would be between $2.5 and $5 billion. 58 Fed. Cont. Rep. (BNA) 75 (July 20, 1992). Although DOD previously indicated in conjunction with promulgation of the September 1988 clause that these costs are allowable, and are to be charged to contracts in accordance with FAR cost principles, DOD has provided no guidance in either the text or preamble to the proposed final rule regarding the allocability and recoverability of these additional costs under existing fixed-price contracts. The question of cost recoverability is particularly troubling to contractors in light of the statement by DOD Director of Defense Procurement, Eleanor Spector, that contractors should not expect relief under their fixed price contracts for increased costs resulting from a reduced defense business base.

The financial difficulties confronting contractors under the proposed version of the clause is best illustrated by way of example. Assume that a new fixed-price contract contains the new Drug-Free Work Force clause, and that, as a result, virtually every employee in the contractor's plant is subject to random drug testing. Assume further that the new contract represents only a small percentage of the contractor's business with DOD, and the rest of the business consists of existing fixed-price contracts presumably not covered by the clause. Under the FAR and generally accepted accounting principles, these costs properly should be recovered through the contractor's indirect cost pools and allocated to all existing contracts. The proposed final rule provides no assurances, however, that either existing fixed-price contracts will be reopened to absorb these additional costs, or that DOD will declare these costs allocable only to new contract(s).

The proposed final rule also fails to provide guidance regarding its effect on existing fixed-price contracts that contain the September 1988 version of the DFARS Drug-Free Work Force clause. If the new requirements proposed by the final rule are super-imposed on existing fixed-price contracts, contractors may be unable to recover the additional costs without an adjustment to the contract price.

IV. CONCLUSION

Due to the costly and protracted litigation that would confront defense contractors in the event the final rule is adopted, and the fact that DOD has not indicated any difficulties in achieving its policy of a drug-free work force under the interim rule, we recommend that DOD withdraw the proposed final rule and continue using the September 1988 version of the DFARS Drug-Free Work Force clause in new acquisitions.

Sincerely,

McKENNA & CUNEO

By: _____
Raymond S.E. Pushkar

Mission Research Corporation
SANTA BARBARA

735 STATE STREET
P.O. DRAWER 719
SANTA BARBARA
CALIFORNIA 93102-0719
(805) 963-8761
(805) 962-8530 FAX

September 10, 1992

Defense Acquisition Regulations Council
3062 Defense Pentagon
Washington, DC 20301-3062

Attn: Mrs. Linda W. Nelson, OUSD(A)

re: DAR Case 88-083

Dear Mrs. Nelson:

I am writing in opposition to the adoption of a rule that would require our company to implement drug testing. A defense contractor, Mission Research Corporation has downsized from 450 to 320 employees in the past three years. Overhead cost reductions have included the layoff of many staff members. We simply do not have the staff required to handle the additional burden of implementing and maintaining a drug testing program and we do not want to add staff, cost allowability notwithstanding.

In our current and future efforts to penetrate non-defense business areas, we greatly fear the handicap of excessive costs and a cumbersome bureaucracy. Also, given the post cold war environment, it is our opinion that additional security measures, such as mandated random drug testing, are highly questionable.

Steven L. Gutsche

Steven L. Gutsche
President

cc: Congressman Robert J. Lagomarsino

MOTOROLA INC.

September 22, 1992

Defense Acquisition Regulations Council
ATTN: Mrs. Linda W. Neilson, OUSD(A)
3062 Defense Pentagon, Washington, DC

RE: Comments of Motorola Inc.
DAR Case 88-083 - "Drug-Free Work Force"

Dear Mrs. Neilson:

Pursuant to a telephone conversation on September 17, 1992 between Vivian Hsu of the Motorola Law Department and Steve Slavsky of DoD, it is our understanding that Motorola's comments on DAR Case 88-083 - "Drug-Free Work Force" will be accepted for review beyond the established deadline of September 21, 1992.

Thank you for your accommodation in this matter.

Sincerely yours,

Maryann Clifford

Maryann Clifford
Associate General Attorney

MC-16.19/pjl
Attachment

MOTOROLA INC.

September 23, 1992

Defense Acquisition Regulations Council
ATTN: Mrs. Linda W. Neilson, OUSD (A)
3062 Defense Pentagon
Washington, DC 20301-3062

RE: Comments of Motorola
DAR Case 88-083, "Drug-Free Work Force"

Dear Mrs. Neilson:

Motorola submits the following comments on the proposed DoD rule issued for public comment on July 23, 1992.

Motorola's Drug Testing Program

Motorola successfully implemented a universal non-biased testing program for its employees effective January 1, 1991. This testing program is one component of Motorola's drug-free work force policy, which also includes education and rehabilitation efforts. Motorola's initial efforts to eradicate drugs from its work place began with the establishment of its Employee Assistance Program (EAP) in 1979 and in its implementation of applicant and for-cause drug testing policies in 1987. Motorola's applicant drug testing program is designed to screen out applicants currently using certain drugs and prevent drug users from becoming part of Motorola's work force. The universal random testing of current employees is designed to promote a drug-free work environment and to eliminate illegal drug use by its employees by identifying and rehabilitating those Motorola employees who test positive under the program. The Motorola testing program is recognized as the leading program of its type by corporate America. The program was also recognized by the Department of Defense as a model program by letter from Secretary Cheney. A copy of this letter is attached to this comment.

Motorola's goal is to treat its employees with constant respect. Adherence to this goal is evident in our drug testing policy. Although not subject by law to the HHS guidelines, Motorola's testing procedures adhere to or afford employees more privacy than the HHS guidelines mandate, e.g. split sample testing and unobserved sample collection. Pursuant to Motorola's policy, employees who test positive are not removed from their position, unless an employee holds a security clearance, is working in a health or safety sensitive position or, in the professional opinion of the EAP professional or external provider assigned to the case, is unable to continue to work during rehabilitation.

Corporate Offices
1303 E. Algonquin Road, Schaumburg, IL 60196-1065 • (708) 576-5000

DoD Proposed Rule

Motorola's concerns about the DoD proposed rule focus on two primary areas: 1) the proposed definition of "employees in sensitive positions", and 2) the proposed requirement that employees who test positive for drug use be removed from their positions, pending rehabilitation and approval for return to the position by the contracting officer.

1. Under the proposed rule, if an employees holds a "sensitive position," he or she must be removed from that position, pending rehabilitation and approval of the contracting officer. The proposed DFARs clause broadly defines employees in "sensitive positions" and provides examples in a number of defined areas. Motorola submits that the proposed rule's definition of employees in sensitive positions is over-broad and does not consider the difficulties many companies will have in identifying which employees are within this definition. As a result, many contractors can be expected to consider a substantial percentage of its work force to be "employees in sensitive positions" and, to the extent any of these employees test positive for drug use, employers will be forced to remove employees from their positions, rather than risk violating the rule. In addition, as a contractor makes personnel, customer, and product line changes, the contractor must face the logistical nightmare of identifying and re-identifying employees in sensitive positions.

Many companies, like Motorola, that sell commercial products to the DoD "off the shelf" have no reasonable means of clearly identifying which employees are working or might work on products that could ultimately be purchased or used by the DoD. Motorola does not segregate all of its defense contract work from its other work because many of its products have both civilian and defense applications. Thus, even if DoD sales account for a very minor portion of the total sales of a product, any employee working in the design, manufacture, test, etc., of the entire product line could be considered an employee in a sensitive position under the proposed rule.

This proposed definition poses similar difficulties for large companies that transfer components or other materials within the company for other product manufacture. For example, a microchip produced in the thousands daily may be transferred to another group or division within the same company, for use in a product ultimately sold to a DoD customer. The division producing these chips has no realistic way of monitoring the ultimate end-user for its microchips, and therefore all engineers, designers, and production workers at the entire production site could be subjected to the proposed rule's "sensitive position" definition.

2. In addition to the over-broad definition of "employees in sensitive positions," Motorola objects to the requirement in the proposed rule that all employees in sensitive positions who test positive for drug use must be removed

from their position pending rehabilitation and approval from the contracting officer. Motorola's universal drug testing policy for current employees permits the majority of its employees who test positive and agree to rehabilitation to remain in his or her position. Motorola's policy is not to terminate an employee from employment solely because of a first-time positive test result. In many cases, a treatment plan through EAP results in continued and improved job performance. To require that these employees be removed from their position would, in most cases, result in termination of employment, since for many companies, alternative positions in non-sensitive positions are not available. This result is inconsistent with several of Motorola's goals in implementing its drug-free work force policy and promoting EAP to retain skilled and valued employees, to help employee drug users become rehabilitated and to reduce the cost of employee turnover.

Motorola's EAP experience with rehabilitation, which is typical of the professional EAP and medical community, is that an individual with no work, and no future prospects of work has diminished chances of successful rehabilitation. Forcing individuals into a possible desperate personal situation by stripping them of their livelihood is incompatible with the DoD's professed intention of promoting a drug-free America. In fact, employment provides the catalyst to motivate employees to participate in rehabilitation thereby increasing the likelihood of recovery. We believe that the goal of a drug-free America can best be achieved in part by rehabilitation--not punitive measures. For this reason, we submit that this requirement be removed from the final rule.

In addition, Motorola takes issue with the requirement in the proposed rule that provides for approval by the contracting officer before an employee is returned to his or her position after rehabilitation is completed. The final decision on whether an individual has successfully completed rehabilitation should rest with the trained professionals managing the rehabilitation and not a lay person unfamiliar with drug use and the rehabilitation process.

Motorola also believes that this requirement may raise privacy concerns with its employees and could unnecessarily delay the return to work for an employee.

Motorola's Recommendation

For the reasons outlined above, Motorola suggests that the proposed rule be modified so that 1) the definition of "employees in sensitive positions" be more clearly narrowed and defined; 2) the requirement to remove employees from their positions be deleted as long as an employee agrees to participate in an approved EAP treatment plan or rehabilitation program; and 3) the requirement that the contracting officer approve the employee's return to work be removed. Motorola also suggests a limitation on the requirement to provide names of employees with positive drug test results--that contractors be required to report only positive results for employees with access to classified information.

Motorola requests that consideration be given to including a provision in the proposed rule which would permit the DoD, at the contractor's request, to certify the contractor's policy as compliant with DoD requirements to the extent that a contractor, such as Motorola, has its own policies and procedures in place which, among many things, provides for the removal of employees from their positions under certain circumstances. With the implementation of a voluntary certification process the contractor and the DoD need not be unnecessarily burdened with day-to-day administrative and reporting requirements which require a broader dissemination of positive drug test results.

Sincerely,

Joseph F. Miraglia
Senior Vice President and
Assistant Director of Personnel

JFM:okg

Attachment

THE SECRETARY OF DEFENSE
WASHINGTON, DC 20301

Dr. George Fisher
Chairman of the Board and
Chief Executive Officer
Motorola, Incorporated
1303 E. Algonquin Road
Schaumburg, Illinois 60196

The Great American Investme

Dear Dr. Fisher:

I would like to take this opportunity to commend Motorola for its ambitious anti-drug policy and drug-free work force plan. Together, they are an excellent example of your corporation's recognition of its responsibilities to its employees, their families, and the community at large. It also demonstrates Motorola's commitment to the Defense Department's requirement that defense contractors in the areas of national security, public health or safety, have drug-free work force plans.

The elimination of drug abuse in America will require the dedicated efforts of every segment of our society. Motorola and other corporations with similar anti-drug programs are among the leaders in this important undertaking. Your efforts to educate your employees about the dangers of illegal drug use and to provide them with a safe work place, are in keeping with the highest ideals of American industry.

Sincerely,

Dick Cheney

NATIONAL STEEL AND SHIPBUILDING COMPANY

September 15, 1992

Defense Acquisition Regulations Council
Attn: Mrs. Linda W. Neilson, OUSD(A)
3062 Defense Pentagon
Washington, DC 20301-3062

Re: DAR Case 88-083

Dear Mrs. Neilson:

Following are our comments on the referenced subject matter. These comments apply only to the random testing requirement.

1. Among other things, the proposed rule would require a clause in government contracts which would require random drug testing of all Contractor's employees who work on that contract. The proposed clause states that it takes precedence over any state and local laws to the contrary. The proposed clause does not have a "pass down" provision requiring subcontractors to comply.

2. The California Constitution guarantees the right of privacy. Californian courts have interpreted this to extend to the random drug testing by a private employer. It held such testing to be an unwarranted invasion of privacy, actionable at law for damages. Refusal by an employee to submit to random testing which results in disciplinary termination would also be actionable at law for damages for wrongful termination.

3. We operate a major shipyard in San Diego, California with approximately 4,000 employees. We perform work (new construction and repair) for both the Navy and private ship owners at the same time, in the same facility, and with the same workforce. Many of our employees will work on both government and commercial contracts in the same week, or even on the same day.

4. Subject to the comment in paragraph 8. below, the provision in the clause which states that the clause takes precedence over state laws <u>may</u> shield us from liability when the random testing provisions of the clause are applied to workers who are working on a government contract. However, it clearly cannot shield us from liability if the random drug testing is applied to workers who are working on commercial contracts (and thereby protected under state constitutional guarantees).

HARBOR DRIVE AND 28TH STREET • P.O. BOX 85278 • SAN DIEGO CA 92186-5278
TELEPHONE 619 544-3400 TWX 910 335 1250 TELEX 695034

5. It will be extremely difficult, if not impossible, to accurately administer the random drug testing requirement on a workforce which works on a mix of government and commercial work, without being exposed to costly litigation. For random testing purposes, how do we treat the individual who works only one day a week on a government contract, or one day a month, or one day a year?

6. The costs of administering the random testing is a burden that should not be placed on industry, i.e., the direct costs of the tests, the indirect costs of administering the random testing program in a mixed-work facility, and the costs of labor grievances and litigation that will arise from random testing.

7. The lack of a pass-down provision is another major problem. In preparing to implement the proposed clause (while it was in effect), our company drafted a drug testing program and negotiated with our labor unions on the matter. The aspects of the proposed clause which are most disturbing to the unions are (i) the random testing and (ii) the lack of a pass-down clause. Our shipyard, as is typical of all shipyards, has at all times a substantial number of subcontractor personnel working inside our facility, side-by-side with our own employees. We, and our unions, feel it is grossly unfair to require our people to submit to a drug testing program and not apply it to subcontractor personnel. Our company dares not require subcontractors to comply without a pass-down clause for two reasons:

   (a) If our competitors don't require subcontractors to comply, our competitors will get lower prices from subcontractors which may make us non-competitive.

   (b) Without a pass-down clause, we would be exposed to litigation by subcontractor personnel.

8. We are gravely concerned with the legal authority of DoD to impose the random drug testing requirement. The proposed rule is not based on statutory authority, but, rather, on the so-called inherent authority of DoD to protect government property and the safety of government personnel. This is a questionable basis for violating the rights of people under state constitutions, and their rights against unreasonable search and seizure under the 4th Amendment to the U. S. Constitution. We have no reason to believe that drug use in our shipyard has placed in jeopardy the safety of government personnel or property. When this issue is tested in court, as it inevitably will be, we hope that the government has available convincing evidence of a reasonable relationship

between drug use in the workplace and jeopardy to the safety of government personnel and property.

9. Recommendations:

The comments in this letter are directed solely to the random testing requirement. We have for some time had a program for pre-employment testing, for-cause testing, and safety-sensitive position testing. We see no particular difficulty in implementing post-accident testing. Our labor unions have generally gone along with these programs. It is the random testing that creates the problem. Accordingly, we recommend that, with respect to random testing:

(a) The random testing requirement be eliminated; or

(b) Facilities with a mix of government and non-government work be exempted; or

(c) The government obtain statutory authority to require random testing of each workforce engaged in the manufacture of any product in interstate commerce; and

(d) If random testing is to be required, include a pass-down clause.

Very truly yours,

S. D. Timmons

S. D. Timmons
Vice President,
Business Affairs
and General Counsel

SDT:mh

Olin

September 18, 1992

LYNN HAAS BROOKSHIER
Government Business Compliance Officer

Defense Acquisition Regulations Council
ATTN: Mrs. Linda W. Neilson, OUSD(A)
3062 Defense Pentagon
Washington, DC 20301-3062

Dear Mrs. Neilson:

With reference to the proposed drug free work force rule FAR Case 91-12 published July 23, 1992 in the Federal Register, it is the position of Olin Corporation and its subsidiaries, Rocket Research Company, Pacific Electro Dynamics and Physics International, that the rule should be withdrawn.

While the goal of maintaining a work force free from the influence of unlawful drugs is an admiral one, and one that is supported by Olin and its subsidiaries, the proposed rule as drafted is overly broad, costly and interferes unnecessarily with the ability of management to make decisions related to its own work force.

Provisions in the proposed rule that define "safety sensitive" to include a variety of work activities is overly inclusive in nature. There has not been a demonstrated need to include such a large number of manufacturing tasks in the definition. Additionally, the rule is unclear in its application to the numerous workers who may perform a myriad of tasks related to the "safety sensitive" activity but whose jobs are remote from those associated with actual performance of the product.

The rule ignores the circumstances of each contractor with regard to the prevalence of drug use in both the work and local communities. Contractor management best knows the extent to which the illegal drug use is an issue in its facility. Rather than allowing those contractors to define their pool of workers eligible for random drug testing in response to these conditions, the proposed rule usurps such decision making authority and arbitrarily forces all contractors engaged in these activities to randomly drug test an enormous base of individuals.

To require random drug testing of such a large pool of people will significantly raise contractors' -- and the government's -- costs. The requirement that NIDA guidelines be followed will also increase costs for many contractors.

OLIN CORPORATION • EAST ALTON, ILLINOIS 62024-1174
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The proposed rule also puts contractors in the untenable and unrealistic position of having to reopen labor agreements long since negotiated with bargaining unit employees. It further places Department of Defense contractors in the position of having to violate state law in order to comply with the the conditions of a U.S. Government contract. Any rule which forces contractors to make such a choice is inherently unfair and certainly ill advised.

For the above stated reasons Olin and its subsidiaries urge the withdrawal of this rule and recommend that the existing (1988) rule remain in place.

Sincerely,

Lynn Haas Brookshier

Lynn Haas Brookshier

md

Seattle Professional Engineering Employees Association

15205 52nd Avenue South • Seattle, Washington • 98188
Telephone 206/433-0991 • FAX # 206/248-3990

D³P
DDP 9-?|15
CPA —

September 10, 1992

92-357

Mrs. Eleanor R. Spector
Director of Defense Procurement
The Pentagon
Room 3E 144
Washington, D.C. 20301-3000

Dear Eleanor:

Please refer to a letter dated July 23, 1992 to Mr. Donald J. Atwood from Mr. Daniel M. Mahoney entitled "Drug-Free Work Force." Also please refer to your letter to Mr. Daniel M. Mahoney, dated August 27, 1992. Your letter was a response to my letter to Mr. Atwood.

When I received your August 27, 1992 letter I was surprised that our paths have crossed again. When I wrote to Mr. Atwood about my union's concerns over the Drug Free Work Force Rule that the Department of Defense is currently reconsidering, I had forgotten all about my participation on the D.O.D. Advisory Committee on uncompensated overtime -- a committee which you chaired in 1989.

The issues of overtime compensation for employees of defense contractors and a country wide drug testing policy for all defense contractor employees seemed to me to be so disparate that I think it is remarkable that my objections to both policies would end up on your desk, given the vastness of the Department of Defense bureaucracy.

The above comments, Eleanor, are obviously completely irrelevant to the subject at hand. I simply could not restrain from making them.

In your August 27, 1992 letter you suggest that I submit written comments to you even if we are successful in arranging a meeting with Mr. Wermuth. I understand the value of such written comments, but at this particular point in time, since I have had no dialogue as yet with anyone from the D.O.D., the only comments I can make are very generalized.

Although I have not talked with it's authors, I do find myself in harmony with the views expressed by Mr. Don Fuqua and Mr. James R. Hogg in a letter they sent to Mr. Atwood, dated April 27, 1992 under the letterhead, "Aerospace Industries Association, National Security Industrial Association."

What the members of our union and other unions whose employees work at defense contractor companies find most objectional is the concept of total random testing. Our pulse of the people reflects the proposition that the union represented people can accept random testing for truly safety sensitive jobs. They cannot understand why everyone who works for a defense contractor in any kind of capacity should be forced to submit to drug testing on a random basis.

Surprisingly, virtually no one we know of, either in management or among the ranks of non management employees, suggests that substance abuse is a significant problem at the companies where they work.

As I noted in my letter to Mr. Atwood, The Seattle Professional Engineering Employees Association (SPEEA) spent many months negotiating a **Drug and Alcohol-Free Work Place Program.** These negotiations involved people, both from the management and union side, with outstanding expertise in all of the disciplines related to substance abuse and it's impact on the work place. They culminated in the preparation and signing of a letter of understanding.

The program negotiated between SPEEA and The Boeing Company uses the "reasonable suspicion standard" to identify Boeing employees who must submit to a drug test. It has become the company-wide plan for all Boeing Company employees, including those represented by unions other than SPEEA.

It provides a detailed plan of action for the rehabilitation of employees who test positive on their initial test. It is a very humane program, and it has the definite advantage of being accepted by the employees without resentment since they had great input into it and since it clearly protects both the individual employees interests as well as the Boeing Company's interests.

I attach with this letter the copy of the plan SPEEA has negotiated with Boeing. We at SPEEA are really quite proud of it, and we feel that many of it's components could well serve as a model for D.O.D.'s final regulation.

In conclusion, I note that pursuant to your letter I have contacted the office of Mr. Michael A. Wermuth, and arrangements are being made for a personal visit with him.

Sincerely,

Daniel M. Mahoney
General Counsel

DMM/mjr

Enclosure: Boeing/SPEEA letter of understanding on Drug and Alcohol-Free Workplace Program.

LETTER OF UNDERSTANDING NO. ___

Subject: Joint Company - Union Drug and Alcohol Dependency Program

The Company and the Union agree to continue the Joint Alcohol and Drug Dependency Program as an integral part of the Company's drug- and alcohol-free workplace objectives. As part of that program, the parties agree to establish a Joint Advisory Committee to:

- Review the drug and alcohol segments of the Employee Assistance Program on a regular basis, and
- Make recommendations on enhancing the effectiveness of those segments.

This advisory committee will be composed of two Company representatives (including the Employee Assistance Program Administrator) and two Union officials.

The parties further agree that their activities in support of Alcoholics Anonymous have been successful and that those activities should be expanded to include other self-help groups, such as Narcotics Anonymous and Cocaine Anonymous. In addition to the current support provided, the Company and the Union will publicize the efforts of these self-help groups.

This Letter of Understanding supercedes the Letter of Understanding dated November 16, 1986, and marked "Attachment 5" to the parties' collective bargaining agreement that became effective December 2, 1989.

Dated: October 22, 1990.

SEATTLE PROFESSIONAL ENGINEERING EMPLOYEES ASSOCIATION

By _____

THE BOEING COMPANY

By _____

159:DPK2

LETTER OF UNDERSTANDING NO. _____

SUBJECT: DRUG- AND ALCOHOL-FREE WORKPLACE PROGRAM

The Company and the Union enter this Letter of Understanding to address the serious societal problem of drug and alcohol abuse. The Company and the Union affirm their joint objective to achieve a drug- and alcohol-free workplace. To that end, the parties agree to a drug- and alcohol-free workplace program with these principal components: a comprehensive employee assistance program emphasizing rehabilitation; employee awareness; training; and testing.

A. Employee Assistance Program

1. The Company has established and will continue to provide a comprehensive Employee Assistance Program (EAP). One of the major purposes of the program is to rehabilitate employees experiencing drug and alcohol problems through a professional assessment and referral service with follow-up counseling. The service will be provided by trained, professional counselors employed either by the Company or by an EAP company under contract with Boeing.

2. Voluntary participation in the EAP may occur through referral (self, union, management, others). These employees will have their treatment monitored by the EAP and be subject to follow-up counseling and testing by the treatment provider. If these employees experience a treatment failure within two years of their initial referral, they will receive a second rehabilitation opportunity.

3. Mandatory participation in the EAP will be offered as an alternative to discharge to employees who have (a) experienced a treatment failure within two years of initial referral, (b) had a termination for attendance or performance problems held in abeyance, (c) violated Company rules on unauthorized possession or use of drugs or alcohol, or (d) a verified positive drug or alcohol test administered by the Company. Mandatory participants will be subject to the terms and conditions of the "Last Chance Memorandum" (attached hereto). Violation of any of the terms of the Last Chance Memorandum normally will result in termination of employment.

B. Employee Awareness

1. The Company will establish a drug and alcohol awareness program designed to inform employees of the drug- and alcohol-free workplace program, including opportunities for rehabilitation through the EAP, the dangers of drug and alcohol abuse, and drug and alcohol testing.

2. The awareness program will disseminate the information through pamphlets, news articles, mailouts, video tapes, and other media.

C. Training

1. The Company will implement a drug- and alcohol-free workplace training program for its managers, medical professionals, and other selected employees. The training will be designed to:

a. Identify the extent and impact of drug and alcohol use.

b. Describe the principal federal legislation and regulations for a drug-free workplace.

c. Identify the Company rules pertaining to drugs and alcohol and the appropriate action to be taken upon violation.

d. Identify the principal components of the Drug- and Alcohol-Free Workplace Program (rehabilitation, awareness, training, and testing).

e. Explain the Employee Assistance Program, opportunities for rehabilitation, and the consequences of rehabilitation failure.

f. Explain the facts of drug and alcohol testing accuracy and procedures, such as chain of custody.

g. Enable participants to effectively apply observed and documented performance criteria and appropriate procedures in referring the employee to the Employee Assistance Program.

h. Enable participants to effectively apply observed and documented criteria typically indicative of drug or alcohol use and apply appropriate reasonable suspicion testing guidelines in referring employees to medical for medical observation and possible testing.

i. Enable participants to apply appropriate post-accident testing guidelines in referring employees for testing.

2. The training will not be designed to teach participants to be substance abuse experts or professional counselors.

3. Union selected individuals, including but not limited to the Union's Executive Board, council representatives, and staff members, will be invited to participate in training.

4. Whenever practicable, Union selected individuals and Company managers will be trained together.

D. Drug and Alcohol Testing

1. The Company will implement a drug and alcohol testing program designed to deter abuse and to provide a means for early identification, referral for treatment, and rehabilitation of employees with abuse problems.

2. The Company will at all times comply with its policy and procedures and with applicable government regulations designed to safeguard the accuracy and reliability of drug testing and to protect the confidentiality of those tested. Specifically, the Company will follow applicable regulations (49 C.F.R. Part 40, "Procedures for Transportation Workplace Drug Testing Programs") covering the following:

a. Collection procedures, including strict chain of custody to prevent mislabeling or alteration of urine samples and to account for the integrity of each sample from the point of collection to final disposition;

b. Use of a United States government certified laboratory with state-of-the-art testing methodologies, including confirmation testing using gas chromatography-mass spectometry instrumentation;

c. Testing only for substances required by the regulations and for which the laboratory has been certified by the United States government, using government mandated cutoff and confirmation levels;

d. Undertaking a quality assurance and quality control program designed further to ensure laboratory testing accuracy;

e. Periodic inspections of the laboratory;

f. Employment of qualified medical review officers (MRO) who are licensed physicians with knowledge of substance abuse disorders and with the medical training to interpret and evaluate a positive test result, medical history, and other relevant data for the purpose of verifying positive results and making return-to-work recommendations;

g. Giving the employee an opportunity to provide a legitimate, alternative medical explanation for the result. Should such an explanation be provided, the test result will be reported as negative;

h. Providing the employee an opportunity, within 60 days of being notified of a positive result, to retest the original specimen, at the employee's expense, at the same or another United States government certified laboratory. The Company will reimburse the employee for said expense if the retest result is negative. That portion of the original specimen not subjected to the testing process will be placed in proper storage and retained by the laboratory in case subsequent testing is requested or required.

i. Ensuring confidentiality of test results, of information provided by the employee to the MRO, and of employee participation in the EAP in accordance with existing Company policy and the federal regulations; and

j. Retaining all confirmed positive specimens at the laboratory for at least one year in accordance with the federal regulations.

3. Alcohol testing will be conducted using breath samples. The instrument shall be approved by the Department of Transportation as an evidentiary breath testing device and used only by trained operators. An employee may request, at his expense, that a blood sample also be collected and analyzed for alcohol. The Company will reimburse the employee for said expense if the blood test result is negative. For alcohol testing, levels at or above .04 percent blood alcohol content will be considered positive.

4. The Company will conduct employee testing under the following circumstances:

a. Reasonable suspicion drug and alcohol testing covering all employees. "Reasonable suspicion" means there is information that would cause a reasonable person to believe that an employee has used or is impaired by alcohol or drugs. The Company will use the following standards promulgated by the federal government (Department of Health and Human Services) to determine when testing may be appropriate: (1) direct observation of drug or alcohol use or possession on Company premises or while on Company business; (2) signs of impairment, such as difficulty

in maintaining balance, slurred speech, abnormal or erratic behavior, or apparent inability to do assigned work in a safe or satisfactory manner; (3) an employee's arrest or conviction for a drug-related offense, or identification as the focus of a criminal investigation into illegal drug possession, use, or traffic; (4) information provided by (a) a reliable and credible source or (b) independently corroborated sources; or (5) newly discovered evidence that the employee may have tampered with a previous drug test.

In addition, the Company will require that all information relied upon to initiate a reasonable suspicion test be documented prior to testing, that two designated individuals (at least one of whom has been trained as referenced in paragraph C.1) agree that testing is appropriate and sign required documentation, and that a trained medical professional concur for "observable behavior"-based testing (see para. D.4.a.(2)). In the event a Company location does not have a staffed medical facility when the employee is escorted for review, a trained manager will determine whether the employee should be escorted to an off-premises medical facility for the required evaluation.

b. Post-accident drug and alcohol testing or testing following a serious violation of a safety rule or standard, covering all employees. The Company will use the following standards to determine when testing may be appropriate: (1) death or personal injury requiring immediate hospitalization or (2) violation of a safety rule or standard that endangers the employee or others to the potential of death, serious bodily injury, or substantial property damage. The Company will also comply with post-accident testing standards set forth in applicable federal regulations that differ from the foregoing.

c. Periodic drug testing for those employees required by United States Department of Transportation regulations to receive periodic medical certification verifying fitness for duty. The specimen will be collected as part of the physical examination.

d. Random drug testing of designated employees as expressly required by the United States Department of Transportation. The Company will use neutral selection criteria to determine which of the designated employees will be tested. The Company will

comply with random testing standards set forth in applicable Department of Transportation regulations.

e. Follow-up drug and alcohol testing of all employees who (1) experience a treatment failure within two years of initial referral, (2) have a first-time verified positive drug or alcohol test, (3) have a termination for performance or attendance problems held in abeyance, or (4) violate a company rule on unauthorized possession or use of drugs or alcohol.

f. Pre-assignment drug testing of employees selected to transfer into or otherwise perform in a position designated for random drug testing by United States Department of Transportation regulations.

5. Refusal to (1) take a test following adequate explanation of the consequences of refusal, (2) accept EAP referral from the MRO, (3) when required, accept EAP treatment recommendations, or (4) accept the terms and conditions of the Last Chance Memorandum, is considered insubordination and will result in discipline, up to and including termination of employment. Failure to appear for testing without an excused absence is considered refusal to take a test.

6. The employee's written consent shall be obtained prior to collecting either a breath or urine sample.

7. For reasonable suspicion and post-accident testing only, the employee has the right to request the presence of a union representative at the collection site. The union representative shall not in any way interfere with or otherwise obstruct the collection process. The parties agree that the collection may be delayed a reasonable period, not to exceed thirty minutes, to await the arrival of the union representative. The thirty-minute period will commence when the union, to include a union representative, is notified.

8. Consequences of a Positive Test Result

a. No employee will be terminated because of a first verified positive test result. Instead, the employee will be required to submit to EAP evaluation and, if recommended, will have a one-time opportunity to enter a treatment program. Such employees remain subject to discipline, up to and including termination, for independent reasons.

b. An employee who has a second verified positive test result within three years of the first such result or on a Company-administered follow-up test conducted after that period, normally will be terminated from employment.

9. Procedure Following a Positive Test Result

a. An employee will not be removed from continuous pay status because of a drug or alcohol test result until the Medical Review Officer verifies the test result. An employee in a position designated for random testing may be administratively removed, with pay, pending the MRO review.

b. As part of the verification process, the MRO will attempt, in accordance with applicable regulations, to contact the employee to determine whether an acceptable medical explanation for the confirmed positive result exists. The MRO will review in confidence any information provided by the employee. If the MRO determines there is an acceptable medical explanation for the positive test result, the result shall be reported as negative.

c. After verification of a positive test result, the employee shall be placed on leave of absence for a maximum of five workdays so that an EAP assessment can be made. An appointment for an EAP assessment will be made. Failure to keep the appointment without an acceptable excuse will result in termination of employment. The employee may not be returned from the leave until an EAP evaluation is made and either (1) the EAP determines the employee needs no treatment and recommends return to work, or (2) treatment is recommended and the employee accepts it and begins it as scheduled.

d. The employee may not return to work until results on drug and alcohol tests administered by the Company are negative.

e. The employee is required to accept and comply with the terms of a Last Chance Memorandum.

f. The employee is subject to follow-up testing, as directed by the MRO, for no less than 12 and no more than 60 months following return to work.

10. The Union reserves the right to grieve and arbitrate the question of whether the Company's program is consistent with the terms described in this letter.

Dated October 22, 1990

SEATTLE PROFESSIONAL ENGINEERING EMPLOYEES ASSOCIATION

By _____

THE BOEING COMPANY

By _____

154:DPK2

LAST CHANCE MEMORANDUM

_____, _____, has read and understands that:
(Name) (Social Security No.)

(1) In consideration of the Company's accommodation of my substance use problem, I must adhere to the following terms and conditions:

(a) I will successfully complete the required treatment program outlined in the Rehabilitation Agreement and any amendments thereof. My participation in the treatment program is required and shall continue until the EAP determines that treatment is no longer necessary. Any and all changes in the treatment program shall be in writing and coordinated in advance with the EAP. Any violation of this paragraph or of the terms and conditions of the treatment program shall be grounds for immediate termination from the Company's employment.

(b) Any future absence from work or other work-related problem (whether related to performance, conduct, or otherwise), directly or indirectly caused by my violation of this memorandum, by drug or alcohol use since my return to work, or by any need to be absent from work for further treatment, shall be grounds for immediate termination from the Company's employment.

(c) I will be subject to unannounced follow-up drug and alcohol testing for a period to be determined by the Company's Medical Review Officer. I understand that a verified positive test result will be grounds for immediate termination from the Company's employment.

(d) Boeing Medical personnel will be obligated to report to cognizant management any evidence of a violation of the terms and conditions of this memorandum.

(e) The Union (if applicable) and I waive any right to challenge any termination pursuant to paragraphs (a), (b), or (c) through any court, arbitration, or other form of proceeding.

(f) This memorandum does not protect me from any discipline, up to and including termination, on grounds not related to the matters addressed in paragraphs (a), (b), and (c).

(g) These terms and conditions will remain in effect for a three-year period commencing on the date indicated below.

(2) I am/am not (circle and initial) a member of a bargaining unit represented by a union.

I do/do not (circle and initial) request union involvement in this matter.

(3) THESE TERMS AND CONDITIONS ARE EFFECTIVE WHETHER OR NOT THIS MEMORANDUM IS SIGNED BY THE EMPLOYEE.

EMPLOYEE

_____
(I have read the above statement and received a copy of it)

_____
(Typed name)

FOR THE UNION

_____

_____
(Typed name)

FOR THE COMPANY

_____
(Signature)

_____
(Typed name)

DATE

_____, 19___

Shipbuilders Council of America
Suite 330
4301 N. Fairfax Drive
Arlington, Virginia 22203
Tel: 703-276-1700 Fax: 703-276-1707

August 31, 1992

To: Ms. Linda W. Neilson
OUSD (A)
Defense Acquisition Regulations Council
3062 Defense
The Pentagon
Washington, DC 20301-3062

Subject: Drug Free Work Force (DAR Case 88-083)

On behalf of the Shipbuilders Council of America, the national trade association which represents American shipyards and suppliers of marine equipment and services, I wish to submit the following comments on the proposed revisions to the Defense Federal Acquisition Regulation Supplement interim rule for a Drug Free Work Place.

Redundancy:

What is seemingly overlooked is the fact that all responsible contractors recognize the importance of a Drug Free Work Place and its impact on productivity and profit. Accordingly, we believe that the need for either the proposed regulation or the interim final regulation now in effect is redundant. In this regard, the coverage of the Federal Acquisition Regulation (FAR) on the subject of Drug-Free Work Place is adequate and provides the contractor with the required flexibility for an effective program. Furthermore, adequate direction is now provided in the FAR on the responsibility of contractors; and when contractors are found deficient, a finding of non-responsibility can be made under the FAR Regulations to eliminate contractors that ignore proper management of their companies with regard to maintaining a Drug-Free Work Place.

Random Testing:

Although the many thousands of responsible DoD contractors are diverse organizations with different needs, they all support a Drug Free Work Place policy. However, it is grossly inefficient to adopt a "one rule fits all" policy, without regard to a company's organizational structure which permits each contractor to tailor its program in a manner that optimizes costs, while at the same time ensuring that the ultimate goal of a Drug Free Work Place is met. Accordingly, we recommend that the proposed regulation and contract clause be carefully worded in order to permit the contractor to determine who should be tested and how many should be tested. By analogy, DoD statistics reflect that random testing of officers reveal a

/

much smaller incidence of drug abuse than among young enlisted personnel. Likewise, a company that dedicates extra resources to refining its employment screening process will result in a higher caliber of a work force and a lower likelihood of drug abuse. Such contractor initiatives often are more effective at accomplishing the Drug Free Work Place goal than random testing, and should be factored into an overall program that balances need with cost effective safeguards.

Testing:

For initial testing, contractors should be permitted to use their own laboratories. To confirm positive tests, the contractor should be permitted to select any certified laboratory in order to control costs that invariably escalate when some certified laboratories are summarily excluded. In short, "certified" should be the only criteria.

Cost:

All costs associated with a mandated testing program should be specifically identified as an allowable cost under the Regulation. Furthermore, all litigation expenses associated with enforcing mandatory requirements should also be specifically identified as an allowable cost.

Thank you for this opportunity to provide our comments which support a Drug Free Work Place while eliminating unnecessary costs that add no substantive value or additional safeguards that would preclude drug abuse by a work force that produces products or services for the Department of Defense, as well as for all commercial customers which expect and have every right to expect services or products to be provided in a drug free environment.

Sincerely,

John J. Stocker
President

Spectra Diode Laboratories, Inc.

80 Rose Orchard Way
San Jose, CA 95134-1356
(408) 943-9411
FAX: (408) 943-1070

September 8, 1992

Defense Acquisition Regulations Systems
3062 Defense Pentagon
Washington, DC 20301-3062

Attention: Mrs. Linda W. Neilson

Subject: Regulatory Flexibility Act - DAR Case 88-083

Reference: Federal Register Notice Dated 7/23/92

Dear Mrs. Neilson:

Spectra Diode Laboratories, Inc. is a small business doing defense work with the U. S. Government. We find the proposed rule for a Drug Free Work Force to be an economic and administrative burden to our company. SDL proposes the Regulatory Flexibility Act be amended to state that small businesses with DoD contracts are excluded from compliance with this proposed rule.

If you have any questions, please contact me.

Sincerely,

SPECTRA DIODE LABORATORIES, INC.

John P. Melton
Vice President, Business Operations

STI OPTRONICS An Amoco Company

Post-it™ brand fax transmittal memo 7671	# of pages ▸ 2
To Ms. Neilson	From S. Matsen
Co.	Co.
Dept.	Phone #
Fax # 703-697-9845	Fax #

21 September 1992

Defense Acquisition Regulations Council
Attn: Mrs. Linda W. Neilson
OUSD(A)
3062 Defense Pentagon
Washington DC 20301-3062

Re: DAR Case 88-083 Drug Free Work Force

This letter is in response to the proposal to reinstate the 15 November 1991 *Drug Free Work Force* regulations at DFAR 252.223-7004.

STI Optronics, Inc. (STI) is a small contract R&D company with about 100 employees. We are classified as a large company because we are owned by Amoco Technology Company, even though their support or involvement in STI government contracts is minimal. STI performs R&D laser technology work for DoD, at a level of about $5M per year, primarily under cost-type contracts. These contracts often require the design, construction and/or test and evaluation of pre-prototype lasers. The deliverable for these programs is usually a paper report.

Additionally, STI sells "HRL" and "Mirage" lasers to government agencies, including DoD, for research purposes. These products are sold with warranty and other product terms and conditions. We sell approximately fifteen to twenty such lasers to the government and government contractors each year.

STI complies with the FAR Drug Free Workplace regulations. We have an effective EAP with a drug education program. We are concerned about the proposed implementation of the DFAR drug free work force regulations mandating random testing. We believe that the FAR provisions adequately protect DoD and ultimate laser users.

We believe that mandatory random drug testing is not a useful method for handling defective design and/or product concerns. Through our employee and supervisor training program, we put a priority on detection of <u>impaired</u> individuals. Employees suspected of impairment are referred to qualified professionals administering the EAP for assessment and treatment. In this way, workers whose work has been affected due to alcohol abuse, emotional or family problems, or drug use can be detected and helped.

A person with an alcohol problem is as dangerous as a person with a drug problem. And our actual historical experience is that alcohol-related performance problems are far more prevalent than drug related performance problems. This regulation does not address the alcohol problem because alcohol abuse is not subject to discovery through testing.

Finally, if mandatory drug testing is such an issue that cost effectiveness is not of concern and DoD does proceed with mandatory random drug test requirements, then we request that you review the required testing list for appropriateness, particularly:

> "(iii) Design, manufacture, test and evaluation, or maintenance of potentially dangerous equipment/materials/or applications (such as lasers, explosives, unstable chemicals or medical equipment with potentially life threatening consequences)..."

We have found that most serious hazards involving lasers are posed by user carelessness or neglect, not by defects in design, manufacture or testing. It is the inappropriate or unsafe use of a properly functioning research laser that causes laser injuries. These products are not like automobiles or medical equipment, for instance, in that improper functioning due to design or production-related defects will almost never result in incurred hazard to the user. A laser is most hazardous when it is functioning properly. Therefore, we believe that your listing is unnecessary, and that it should be up to DoD buyers to determine on a case by case basis whether the clause should be included. The inclusion of all lasers with explosives, unstable chemicals and medical equipment in the definition of "potentially dangerous equipment/materials/or applications" is technically unjustified.

STI, like other companies with whom we have talked about this problem, will implement a mandatory testing program if so required. However, it will not help us to provide safer products or services to DoD, but it will cost both STI and the government.

Thank you for your consideration.

Sincerely,

Suzanne Matsen

Suzanne Matsen
Director of Contracts

cc: Dr. Ewing, STI President
EAP Committee

TAMPA SHIP

TAMPA SHIPYARDS INCORPORATED

P.O. BOX 1277 • TAMPA, FLORIDA 33601 • (813) 247-1183

August 26, 1992

Defense Acquisition Regulations Council
Attn: Mrs. Linda W. Neilson, OUSD (A)
3062 Defense Pentagon
Washington, D.C. 20301 - 3062

RE: DAR Case 88-083
Navy Random Drug Testing Requirements

Dear Mrs. Neilson,

Tampa Shipyards, Inc. supports the proposed DOD requirements for random drug testing in it's acquisition regulations.

We believe that random testing would be an effective, efficient, and economical way to achieve a truly drug free workplace.

The requirement should be extended to sub-contractors at all tiers as well.

Very Truly Yours,

Fred Turner
Director of Labor Relations

International Brotherhood of Electrical Workers, Local 108

International Brotherhood of [redacted]rmakers, Iron Shipbuilders, [redacted]ksmiths, Forgers and Helpers, Local 807

International Association of Sheet Metal Workers, Local 15

United Association of Journeymen Plumbers and Steamfitters of America and Canada, Local 726

Tampa Metal Trades Council

(AFL-CIO)

United Brotherhood of Carpenters and Joiners of America, Local 140

Brotherhood of Painters and Allied Trades, District Council 66

Construction Shipyard and General Laborers, Local 1207

International Association of Machinists and Aerospace Workers, Local 570

International Union of Operating Engineers, Local 925

August 23, 1992

From:
Bob Betterton
President
c/o I.A.M.& A.W. Lodge 570
4020 80th Avenue North
Pinellas Park,Florida 34665

Subject:
Random Drug Testing DAR Case 88-083
United States Navy Contract
Procurement Language

To:
The Defense Acquisition Regulations Council
Attn: Mrs. Linda W. Nelson, OUSD (A)
3062 Defense Pentagon
Washington D.C. 20301-3062

[redacted]ar Council,

It is our opinion and belief that the drug-free work force clause of September 1988 should NOT be changed to accommodate randon drug testing for the following reasons:

1.) It is a unreasonable and unacceptable invasion of privacy.(ie; body fluids)
2.) It is unfair to force the added financial burden on employers particularly at this time,when most if not all shipyards in the United States are struggling to survive a dormant market in repairs and new ship construction.
3.) It has never been determined that a problem of drug abuse is at a level in our shipyards (ie; The American Ship Building Co., Tampa Shipyards Inc.)that warrants random vs. probable cause.
4.) It is our intention to see money spent that we as the work force, in partnership with our management,have determined to be real problems and a threat to our health and safety.

In conclusion,we feel that it would be a perfidious act for any agency or department of the United States Government to mandate randon drug testing to private shipbuilding and repair yards.

Sincerely,

Bob Betterton

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Sincerely,

Bob Betterton

Bob Betterton

[redacted]

3M Government R&D Contracts

3M Center Bldg. 224-2S-25
St. Paul. MN 55144-1000
612/733 1110

3M

August 14, 1992

Mrs. Linda W. Neilson, Procurement Analyst
Defense Acquisition Regulations System
3062 Defense Pentagon
Washington, DC 20301-3062

SUBJECT: Proposed Final Rule on Drug-Free Work Force

Dear Mrs. Neilson:

Thank you for the opportunity to comment on the proposed final rule on the requirement for a drug-free work force. It is our opinion the proposed final rule is so much more burdensome, so much more costly to implement, so much more apt to lead to law suits, and so much more likely to discourage the sale of commercial products to the Government that it should be abandoned and the interim final rule published September 28, 1988 should be adopted as the final rule.

The bases for this opinion include the following:

- The proposed rule greatly expands the types of employees subject to its requirements. While the interim rule applies only to employees granted access to classified information and employees in other positions that the contractor determines involve national security, health or safety, or functions requiring a high degree of trust and confidence, the proposed rule requires random drug testing of all employees whose duties can reasonably be expected to affect health, safety, or national security. The new language will undoubtedly lead to disputes as to which employees are covered by the proposed rule; it will greatly increase the number of employees tested; and it will, therefore, be much more expensive to implement. Such results run directly contrary to the Administration's goals to reduce regulatory burdens as documented in the President's moratorium on new regulations, to eliminate budget deficits, and to assist U.S. companies to be more competitive in the global marketplace.

- The interim rule states that its requirements pertaining to drug testing programs do not apply if they are inconsistent with an existing collective bargaining agreement. The proposed rule is silent on this matter. Such silence may result in contractors having to attempt to reopen existing collective bargaining agreements, and that action may lead to costly labor disputes. Failure to negotiate union bargaining agreements which are consistent with the proposed rule may prevent companies from receiving contracts.

- The interim rule refers to the "Mandatory Guidelines for Federal Workplace Drug Testing Programs," (53 FR 11980 (April 11, 1988)), issued by the Department of Health and Human Services, merely as a source for identifying the illegal drugs a contractor must test for. However, the proposed rule requires that a contractor's drug testing program "shall conform" to those Mandatory Guidelines. Thus the proposed rule appears to mandate compliance with all of the very specific requirements of the Guidelines, including requirements that the designated collection site be "secure," that chain of custody standardized forms executed by authorized collection site personnel be used upon receipt of specimens, that toilet bluing agents be used and no other source of water, etc., etc.

While the interim rule gives a contractor flexibility in devising a testing program, the proposed rule imposes very specific, very rigid requirements on contractors. This will make the devising and implementing of a testing program unnecessarily costly.

- The proposed rule introduces a requirement, not found in the interim rule, that a contractor must obtain a Contracting Officer's approval before permitting an employee to return to work in a sensitive position on a DoD contract following a violation of DoD's drug policy or a criminal drug statute. This requirement conflicts with established statutes, regulations, personnel practices, and labor agreements and will result in unnecessary costs in its implementation.

- In DFARS Section 223.7504 of the interim rule, it is stated explicitly that the clause at DFARS 252.223-7500 is not to be included in contracts for commercial or commercial-type products, other than contracts involving access to classified information. That provision has been deleted from the proposed rule. Instead the proposed rule provides that the proposed clause shall be used in all contracts that require contractor employees to perform in sensitive positions, and the definition of "sensitive positions" has been broadened so much in the proposed rule that many contracts for commercial or commercial-type products will be subject to the requirements of the proposed rule. This will necessitate drug testing of additional people at additional cost, which will make U.S. products less competitive.

  It may be difficult or impossible to segregate from a contractor's established line for production of commercial products those particular items of such products that are sold to the Government. A contractor faced with the possibility of becoming less competitive in commercial sales because of the costs of drug testing may decide not to make any future sales to the Government.

For all of these reasons, we recommend that the proposed rule be abandoned and the interim rule made the final rule.

If you have any questions on these matters, please do not hesitate to call on me. My telephone number is 612-733-6723.

Sincerely,

Robert C. Spreng
Operations Manager

RCS/bjf
F:20814.bjf

UNIVERSITY OF CALIFORNIA

BERKELEY • DAVIS • IRVINE • LOS ANGELES • RIVERSIDE • SAN DIEGO • SAN FRANCISCO

SANTA BARBARA • SANTA CRUZ

DAVID PIERPONT GARDNER
President

RONALD W. BRADY
Senior Vice President—
Administration

OFFICE OF THE PRESIDENT
Employee & Labor Relations
300 Lakeside Drive
Oakland, California 94612-3550

September 21, 1992

Defense Acquisition Regulations Council
ATTN: Mrs. Linda W. Neilson, OUSD(A)
3062 Defense Pentagon
Washington, DC 20301-3062

Re: DAR Case 86-083
Department of Defense Drug-Free Work Force Proposed Rule

Dear Mrs. Neilson:

The University of California welcomes the opportunity to comment on the proposed drug-free work force rule in the Federal Register of July 23, 1992. This rule requires that the University include in its contracts with DOD use of the clause at 225.223-7004, Drug-free Work Force, which directs contractors to institute and maintain a program for achieving a drug-free work force, including, at a minimum, random drug testing of employees in sensitive positions. The University has responded previously to this interim rule on September 15, 1988, a copy of which is attached.

The University of California is seriously concerned about the proliferation of regulations on substance abuse being issued by the Federal government and their impact on the faculty and staff of the University. Employees subject to these regulations are covered by either personnel policies or collective bargaining agreements that apply to other employees throughout the University system. This proposed rule would require the University to treat employees covered by the same policies differently on the basis of funding source and is inconsistent with the University's philosophy of employee relations. This is so because a limited number of staff on DOD funds would be tested, whereas staff in identical job classifications and not on DOD funds would not be tested.

The University is in full compliance with the Drug-Free Workplace Act of 1988 and believes that it is unnecessary to mandate drug testing for its employees. University employees are public employees and as such are vested with certain job rights, and although the DOD regulation states that the contract clause takes precedence over any State and local laws, the California Constitution protects the privacy of all citizens in this state and would serve as a formidable basis for legal challenge.

The University does not believe that its employees working under DOD contracts are engaging in the illegal use of controlled substances or endangering health, safety, or the

national security. However, in the event such an act would occur, the University has personnel policies, including substance abuse policies, to deal with these situations. More importantly, in order to establish a basis for drug testing, the University believes that a nexus between the position held by the employee and the necessity for testing must be established.

The University is concerned about the scope of this proposed rule and the overly broad definition of "sensitive position" and offers the following comments in addition to those enumerated in our letter of November 28, 1988:

- The definition of "sensitive position" refers to employees having duties "involving" a number of activities. The term "involving" is expansive so as to apply to an individual only peripherally engaged in any of the activities identified, including anyone who is engaged in some aspect of a shipment of chemicals. Further, it assumes that the theoretical harm that could result from the employee's mishandling of his or her duties justifies drug testing of all such employees without consideration of whether the contractor has actually had such an experience.

  Similarly, the phrase "design, manufacture, test and evaluation, or maintenance of aircraft, vessels, vehicles, heavy equipment, . . . potentially dangerous equipment/materials/or applications (such as lasers, explosives, unstable chemicals, or medical equipment with potentially lifethreatening consequences. . ." is too broad and fails to legally establish a nexus between the employee's job responsibilities and the requirement for random testing. The numbers of employees subject to testing should be limited through the development of definitions for terms such as "heavy equipment", "toxic materials", "unstable chemicals" and "medical equipment with potentially life-threatening consequences."

  The actual, past experiences of the contractor in endangering health, safety, or national security should be a factor in determining whether preventing such future occurrences through drug testing is needed. To allow such reasonable consideration, the current regulation at 252.223-7004 (September 1988) should be continued, allowing the contractor to determine, based on actual experience, which job classifications at which locations and on which projects constitute sensitive positions.

- "Access to classified information" requires clarification and definition. It is conceivable that "access" could be interpreted to reach any and all employees who handle classified information, including mail carriers and clerical staff as well as people who have clearances who have never received any classified information. The definition should be narrowed so as to apply only to those employees with <u>direct</u> access to classified information and who have the potential to significantly impact the national security.

It is my understanding from talking with Steve Slavsky on September 15, 1992 that this contract clause is applicable only to prime contracts and not to grants or subcontracts. Further, it applies only to employees who are working directly on the contract, which would exclude any other University employees whose work may impact indirectly or tangentially on the work of the contract. Therefore, I recommend that a definition of "employee" be included which states that "an employee is one who is directly engaged in the work being contracted for by the DOD in this contract and whose duties could reasonably be expected to significantly impact on the work of the contract".

Because the University environment and the work performed for the DOD is so unique and different from that of a commercial contractor, we must have flexibility in implementing this regulation if it is not possible to exclude the University entirely. In summary, the University strongly recommends that the DOD use the September 1988 version of this clause as a starting point, thereby allowing the contractor to determine the appropriate action necessary for creating a drug-free workforce based upon actual experience.

We hope that these comments, along with our November 1988 comments, will be considered in the finalization of the regulation and that the DOD will seriously weigh the costs of implementing a nationwide random testing program for all DOD contractor employees against the benefits that it hopes to derive. It should be mentioned that some University faculty may refuse to perform work for the DOD, if drug testing is a condition of the award.

Sincerely,

Judy McConnell

Judy McConnell
Assistant Director--
Employee Relations Programs

Attachment

cc: President Gardner
Senior Vice President Brady
Acting Senior Vice President Schwartz
Assistant Vice President Levin
Assistant Vice President Switkes
Director Kramp
Director Mears
Personnel Managers
University Counsel Canning

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Senior Vice President—
Administration

OFFICE OF THE PRESIDENT
BERKELEY, CALIFORNIA 94720

November 28, 1988

Defense Acquisition Regulatory Council
ATTN: Mr. Charles W. Lloyd, Executive Secretary
DAR Council
ODASD(P)/DARs
c/o OASD, P&L (MRS)
Room 3D139
The Pentagon
Washington, DC 20301-3062

Reference: DAR Case 88-83

Dear Mr. Lloyd:

The University of California welcomes the opportunity to comment on the interim drug-free workforce rule in the Department of Defense Federal Acquisition Regulation Supplement, published in the Federal Register of September 28, 1988 and referenced above.

We prefer that the DOD and all Federal Agencies move deliberately and uniformly on this sensitive topic. We support the type of regulatory approach embodied in the Omnibus Drug Bill of 1988 (HR 5210), which requires the Office of Federal Procurement Policy to coordinate government-wide regulations in support of a drug-free workplace in lieu of Agencies and Departments acting independently to issue their own regulations. Such a coordinated approach is essential in order to avoid duplication, proliferation, and conflicting implementing regulations. This approach would allow for more considered judgment in developing a regulatory consensus in this sensitive and litigious area.

We believe that implementing the interim rule at this time is premature. Many of the drug-testing requirements of the interim rule could well prove to be unconstitutional under either the U.S. Constitution or the California Constitution, or both. There are several cases currently before the U.S. Supreme Court involving drug-testing issues which may require substantial revision of the DOD rule if the rule is finalized prematurely.

If, despite these concerns, the DOD decides to proceed independently, the University urges certain minimum revisions to the rule before it is finalized. See Attachment.

The requested revisions are intended as clarifications.

1. The definition of employee in a sensitive position refers to having been granted access to classified information. We have added the notion of actually having received classified information. This addition addresses the case where persons with clearances may never receive classified information because they do not have a need to know.

2. The proposed contract clause is to be included in contracts "involving access to classified information." Not infrequently there are cases involving university faculty where they do not do classified work on their campus but may need to have access to a classified DOD facility to obtain unclassified raw data for their research. It would not be appropriate for the proposed rule or the clause to be applied in this case. We are concerned that the proposed clause not be mechanically and blindly applied . Therefore, this revision provides for the contracting officer to make determinations before the clause is applied.

3. The interim rule excludes application of the clause to work performed in whole or part outside of the United States. The vast majority of research performed at Universities is unclassified. We believe it is appropriate to add unclassified research to the nondomestic exclusion. It is also consistent with the practice of many Universities to not perform classified research.

4. The interim rule appears to require a form and scope of drug-testing which is not constitutionally certain at this time. Two revisions are in response to this status.

5. The interim rule specifies considerations which a contractor may review as part of determining an appropriate testing program. We have added the level of the security clearance as a consideration to reflect varying levels of importance.

reiterate our strong preferences that the DOD interim rule be coordinated with the OMB effort to implement the Omnibus Drug Act, and not be issued prematurely before the U.S. Supreme Court opines on several current testing cases.

Sincerely,

David F. Mears
University Contracts and Grants
Coordinator

Attachment
cc: Senior Vice President Frazer
Senior Vice President Brady
Vice President Baker

ATTACHMENT

RECOMMENDED REVISIONS IN TEXT OF PROPOSED INTERIM RULE

Subpart 223.7502 Definitions:

Amend the definition of "Employee in a sensitive position" as follows:

"Employee in a sensitive position," as used in this subpart, means an employee who has been granted access to and has actually received classified information;"

Subpart 223.7504 Contract Clause.

Revise subparagraphs (a) and (b) as follows:

(a) All contracts involving access to classified information when the contracting officer specifically determines that inclusion of the clause is necessary for reasons of national security; or

(b) Any other contract when the contracting officer specifically determines that inclusion of the clause is necessary for the purpose of protecting the health or safety ..."

Amend (c) as follows:

(c) This clause does not apply to a contract, or to that part of a contract, that is to be performed outside of the United States, its territories, and possessions, except as otherwise determined by the contracting officer, or to contracts or subcontracts the purpose of which is to perform unclassified research.

Section 252.223-7500 Drug-free work force, Contract Clause text

Amend the clause portions identified as follows:

(a) Definitions.

"Employee in a sensitive position," as used in this clause, means an employee who has been granted access to and has actually received classified information:..."

(c)(4) Provision for identifying illegal drug users, ~~including~~ which may include testing on ~~a controlled and carefully monitored~~ an individual, for cause basis. ~~Employee drug testing programs shall be established~~ taking into account the following:

(i) The Contractor ~~shall~~ may establish a program that provides for testing for the use of illegal drugs by employees in sensitive positions. The extent of and the criteria for such testing shall be determined by the contractor based on considerations that include the

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nature of the work being performed under the contract, the employee's duties, the efficient use of Contractor resources, and the risks to public health, safety, national security <u>including the level of an employee's security clearance</u> that could..."

DEPARTMENT OF DEFENSE
WASHINGTON HEADQUARTERS SERVICES
WASHINGTON, DC 20301-1155

(RE&F-AM)

SEP 18 1992

MEMORANDUM FOR DEFENSE ACQUISITION REGULATION COUNCIL,
ATTN: LINDA NEILSON, OUSD(A)

SUBJECT: DAR Case 88-083

We have reviewed the interim rule regarding the Drug-Free Work Force which was republished in the Federal Register on July 23, 1992. Please consider the following comments:

(i) Although paragraph 223.570-3 (b)(1) of the rule finalized on November 27, 1991 specifically exempted contracts below the small purchase threshold, the interim rule has no such exemption.

(ii) Paragraph 223.570-4 (a) of the interim rule states that the clause is required in "all solicitations and contracts." Exceptions are cited only in the cases of solicitations or contracts for (b)(1) commercial or commercial-type products or (b)(2) performance or partial performance outside the U.S. Since the FAR definition of contracts includes purchase orders (see FAR 2.101), the implication is that use of the clause is applicable to small purchases under the interim rule.

(iii) We believe that the security and safety circumstances identified in subparagraphs 223.570-4 (a)(1) and (2) of the interim rule, justify the use of the clause regardless of the dollar amount of the contract. If a contract involves handling of toxic chemicals, access to explosives, high voltage electrical systems, access to classified information, complex and potentially dangerous machinery or weapons, etc., we believe the Contracting Officer should be authorized to include the clause on an optional basis for contracts under the small purchase limitation.

If you have amy questions regarding this matter please contact Stephen Zvolensky at (703) 693-3768.

Lawrence J. Rizzi, Director
Acquisition Management and
Oversight Office