

REVIEW OF URINALYSIS DRUG TESTING PROGRAM

**REPORT BY A PANEL OF ARMY AND
CIVILIAN EXPERTS IN TOXICOLOGY
AND DRUG TESTING LEGAL ISSUES**

FOR

**THE SURGEON GENERAL OF
THE U.S. ARMY**

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REVIEW OF
URINALYSIS DRUG TESTING PROGRAM

1. Background. On 24 October 1983 the Deputy Surgeon General tasked the Panel to review the operations and procedures in each of the Army/Air Force drug testing laboratories to assess if their results are legally sufficient for use as evidence under the military rules of evidence in disciplinary or characterization of discharge actions (see Appendix A). Additionally the Panel was to:

a. Certify procedures which would ensure both technical and legal sufficiency of the urinalysis testing program.

b. Create and certify a quality assurance program which will guarantee the continuing integrity of the urinalysis testing program.

2. Specific Requirements for the Panel. The Panel was to:

a. Develop specific criteria for test results to assure that test results will meet scientific requirements and be considered legally sufficient to label a urine specimen as positive or negative.

b. Provide a Panel assessment as to the reliability and accuracy of current laboratory operations and procedures within each Army/Air Force drug testing laboratory, along with recommendations for improvements/changes in operations, procedures or resources.

c. Provide an assessment of at least the past four months of laboratory results currently on hand at each laboratory.

3. Panel Composition. The Panel consisted of:

MG David W. Einsel, Jr., Chairman
BG Joseph L. Ecoppi, Deputy Chairman
Mahmoud A. Elsohly, Ph.D.
Robert K. Simon, Ph.D.
Robert E. Willette, Ph.D.
Professor Edward J. Imwinkelried, for Legal Addendum
Major Jerome L. Lemberger, JAGC
(for Fort Meade and Brooks AFB visit)
Major John T. Rucker, JAGC (for Wiesbaden AB visit)
Maj John T. Burton, JAGC (for AFIP and Tripler AMC visits)
MSGT(P) Jessie Del Valle, Administrative Assistant

As a group, the Panel provided a wide-ranging background of experience. Both Drs. Elsohly and Willette have been closely associated with the National Institute on Drug Abuse (NIDA). Dr. Simon is a consultant on forensic toxicology and currently is the Director of Industrial Operations for the American Medical Laboratories. Dr. Elsohly is currently the Assistant, Director of the Research Institute of Pharmaceutical Sciences and a Research Associate Professor at the School of Pharmacy of the University of Mississippi. Dr. Willette is with Research Designs, Inc., and serves as consultant to the U.S. Navy, US Courts, and Federal Bureau of Prisons. MSGT(P) Del Valle is the Medical Laboratory Specialist for the US Army Drug and Alcohol Technical Activity (USADATA). Their full backgrounds are summarized in Appendix B.

4. Panel Procedures. The Panel held its initial organizational meeting on 24 October 1983 and the Chairman met with the Deputy Surgeon General, the Assistant Judge Advocate General and the Director of Human Resources, Deputy Chief of Staff for Personnel on the 24th and 25th. The Panel developed the following schedule of on-site visits to each operating drug laboratory:

24-25 October - Drug Urinalysis Test Center, Fort Meade, MD

4-5 November - Drug Abuse Detection Center, Aerospace Medical Command, Brooks AFB, San Antonio, TX

17-19 November - US Army Drug Testing Laboratory, Wiesbaden Airbase, GE

2-3 December - US Army Drug Urinalysis Laboratory, Tripler Army Medical Center, Schofield Barracks, Hawaii.

a. At each laboratory the Panel met with the staff, toured the facility as a group and reviewed administrative, policy and procedural matters with the staff. The Panel then reviewed each technical function in detail at the work area of each section; reviewed random chromatograms, records, chain of custody (COC) procedures, SOPs and procedures in detail. Usually a number of on-the-spot suggestions were made and frequently a number of technical questions were answered. In many cases, the Panel requested and was provided additional back-up information and in a few cases, laboratory personnel made quick checks to verify a reagent, check the variability of a factor or the reliability of a figure or procedure. Where administrative difficulties were evident, a Panel member called or visited the supporting installation element to confirm a fact. In several cases, one of the Panel members took specimen samples and had them independently checked at his personal facility. Where equipment operation, training or maintenance questions were involved, a number of quick checks were made with equipment manufacturers to provide answers. After each

visit, the entire laboratory supervisory staff was invited to the debriefing, for their education; informal exit interviews were provided to the next higher unit; and a trip report on the laboratory was provided within the week to the laboratory, their senior headquarters and the Army Deputy Surgeon General (Appendices C and E through G). Overall the laboratory visits seemed to be received in a helpful and enthusiastic manner; and, encouragingly to the Panel, a number of improvements have been implemented in the short span of about a month, inasmuch as the Panel has maintained close followup of the laboratories by phone and personal visits (especially in the case of the Fort Meade laboratory).

b. In addition to the laboratory visits, a number of personal calls and visits were made by Panel members to personnel otherwise involved in the drug program; such as the Director, DOD Task Force on Drug Enforcement, the Deputy Assistant Secretary of Defense (Health Affairs), various members of the Surgeons General and the Judge Advocates General of the Army and the Air Force; the Deputy Chief of Staff for Personnel, the Director of the US Army Drug Abuse and Technical Activity, the Director of AFIP, and the Commanding Generals of WRAMC, Health Services Command and the 7th Medical Command.

c. In the course of the laboratory visits, it became evident that visits to AFIP and Hewlett-Packard would be beneficial. The Panel visited AFIP on 30 November to review the Tri-Service QA program. (See Appendix H for visit report at AFIP.) The Panel visited the Hewlett-Packard Scientific Instrument Division in Palo Alto, California on 1 December to review their equipment, maintenance and training programs. (Most of the current GC and GC/MS equipment at US Army and Air Force laboratories is manufactured by the Hewlett-Packard Corporation.)

d. As outlined in the summary of Fort Meade activities, close coordination has been maintained with this laboratory in remedial actions, leading to a recommendation on 14 November 1983, after personal review of initial results by two technical members of the panel, that resumption of testing and reporting of drug urinalysis results should begin at an initially reduced rate (Appendix D).

e. Professor Edward J. Imwinkelried of the Washington University School of Law reviewed all of the reports, researched the relevant case law and authored the Legal Addendum to this report.

5. Radioimmunoassay (RIA) Reviews. The four USA/USAF Biservice Drug Testing Laboratories use the Roche Abuscreen Radioimmunoassay (RIA) for the initial detection of the presence of target drugs (and/or their metabolites). All

laboratories are similarly equipped to conduct the assay, utilizing automatic pipetting systems (APS) and counters manufactured by Micromedic (the laboratory at Brooks AFB had not yet received its recently ordered counters).

a. Although this RIA procedure is amenable to high volume throughput, it is labor intensive. Staffing levels varied between the laboratories, but based on the number of specimens processed, averaged about one staff member per 200 specimens processed per day. The process involves transfer of an aliquot of each specimen, "marrying" that rack of tubes to a rack of empty test tubes, pipetting the sample and the first reagents into the empty tube (by the APS), an incubation period, pipetting in a second reagent (which requires a different APS), a second mixing and incubation period, centrifugation, careful pouring off of the supernatant, counting the precipitate in the tubes, (Brooks AFB counts supernatant), and processing the data. Overall, this process takes from five to eight hours per batch, depending on batch size.

b. Although reagents and equipment are nearly identical, the batch sizes, numbers of standards, placement of standards, and data handling all vary. An effort to minimize potential differences in establishing cutoffs (which could cause identifying drug presence at different levels) was made by the implementation in all laboratories of a statistically based, one-sided tolerance limit cutoff determination. This assumes that variations in reagents, pipetting errors, counting efficiency, operators and batch size, can be controlled adequately by the statistical adjustment of the cutoff. The disadvantage, as noted by the originators (Brooks AFB) of the statistical analysis method, is that it will identify a higher number of positive specimens that require confirmation.

c. Batch sizes varied by laboratory from 384 to 1080. The ratio of standards to specimens were all about 10%, although the number of 100 ng/ml (See paragraph 6d.) standards used to establish the cut-off varied from laboratory to laboratory. Another aspect that distinguished the RIA operation at Brooks AFB from the three Army laboratories was its use of chain of custody on the first, and only, RIA analysis performed. Army laboratories conduct the initial RIA with procedures not completely under COC controls and then retest all initial RIA positives by a second RIA under COC. Also, laboratories at Brooks AFB, Wiesbaden AB, and Fort Meade (at least prior to December 1983) allowed RIA personnel to enter the specimen accession area to do the initial pouring. The Tripler AMC, and now Fort Meade laboratories limit admission to this area only to the authorized accession staff.

6. RIA - Problems and Conclusions. Based on AFIP results and the Panel review of laboratory RIA data, there is no evidence

to suggest that the RIA for cannabinoids produces any significant number of false positive results. For instance, variabilities in incubation time might cause a given sample to be above or below the statistical cutoff, but could not cause a negative sample to appear above the positive cutoff. Failure of one of the first pipetting stations would cause an outlier value for which provisions are made to exclude. Failure of the second pipetting station would lead to no precipitate and create an outlier value which is excludable by all procedures. A systematic but constant error in pipetting affects both standards and samples and would not affect the final results. Failure to clean or maintain the pipetting equipment could conceivably cross contaminate samples, giving a changed RIA value in an adjacent sample. However, since the second RIA or GC confirmation is run on a separate aliquot, this would then be reported as a negative.

a. The Panel agrees that the RIA testing as presently conducted is reliable in distinguishing negative from positive specimens. Thus, it should serve as the prime indicator of drug-use prevalence. As noted below, the inherent difficulties associated with the confirmation procedures for all drugs make confirmation rates or numbers of confirmed positives an unreliable indicator of drug use.

b. Although the RIA procedure has proven to be effective in detecting positive specimens, disposal of radioactive waste is a problem. For example, the Panel found extensive consumption of time and effort by the staff at the Tripler AMC Laboratory devoted to washing and counting tubes prior to disposal. Glass crushers have been ordered at Tripler AMC to permit containerization and storage. This should eliminate the problem. At Wiesbaden, local regulations precluded facile disposal, until a local contract was arranged.

c. The Panel was disturbed by the poor coordination of RIA data handling capabilities among DTLs. The laboratory at Wiesbaden had developed a very efficient data reduction program for the RIA process and subsequent procedures. However, the Tripler AMC DTL possessed nearly comparable equipment, but still lacked an inexpensive peripheral device (a disk drive) to implement the Wiesbaden AB program. Furthermore, the Panel subsequently learned that OTSG has contracted with Micromedic to develop a report-generating program for data stations ordered recently for the RIA counters. Meanwhile, incomplete and poorly coordinated planning has gone into acquisition of central computers, e.g., HP 1000s, one of which is already installed at the Fort Meade DTL. The Panel recommends that all such purchases or plans be delayed until a properly constituted and

broadly based review of equipment compatability, and systems requirements is completed. The Panel was given no such plan to review in its present mission.

d. The Panel did not have the opportunity to review in detail the statistical approach to establishing RIA cutoffs and cannot at this time endorse it as the best approach. The Panel recommends that a thorough review should be made of the effect that batch size and the current statistical cutoff method have on drug detection and confirmation. Such a review should include the possibility of using the simple mean of the 100 ng/ml positive standards as the cut-off level.

7. Gas Chromatography Review. Gas chromatography (GC) is used by all USA/USAF Drug Testing Laboratories (DTLs) as the main method of confirmation of the RIA results.

a. GC Methodology for THC. At the time of review, the current THC procedure used by all USA/USAF DTLs involve the use of the Prep-I System for the extraction step and oxyphenbutazone as the internal standard. All DTLs use a packed OV-17 column while Brooks AFB Laboratory uses a DB-5 capillary column. The basic principle of the methodology is that the specimen, along with an added internal standard, is subjected to a base hydrolysis step. The pH is then adjusted to 9.0. The mixture is then extracted using the Prep-I system to give an extract which contains both the Delta-9 THC metabolite and the internal standard. The residue is then derivatized prior to injection into the GC. As the sample components pass through the column, a detector measures the concentration of each volatile component and plots its retention time (RT) on an output device. Typically one expects to get two significant peaks on the curve, one at the RT of the internal standard and a second at the RT of the expected metabolite. The system is calibrated by using a known concentration of drug against the internal standard. Since the solvent is also volatile, it comes through the column first and is usually a large peak. As the column temperature increases, all samples come through faster (shorter RT). As a result, if the temperature is too high, there will be a large solvent front with the internal standard and the metabolite peaks appearing as spikes on the overall solvent front. The quantification of acid metabolite involves comparison of the peak responses for the internal standard and acid metabolite.

b. The Extraction Step for THC Samples. The extraction of THC is carried out using the Prep-I System. There have been a number of changes in the adjustment of the pH of the hydrolyzed urine prior to extraction using the Prep-I System. The recommended pH was originally 7.0-7.5 (no internal standard), which was then changed in June 1983 to 8.0-8.5 (oxyphenbutazone as internal standard), and changed again to pH 9 (per recommendation from AFIP to OTSG in late September 1983) as a result of poor

recovery of oxyphenbutazone observed by Dr. Whiting at Ft. Meade. When pH 9 was recommended, some laboratories had worse results after the change (e.g., Wiesbaden AB Laboratory); nevertheless, it made the change based upon directive from OTSG. One laboratory, Tripler AMC, studied the change before implementation. The change to pH 9, however, was not based on a comprehensive study by any laboratory or authoritative source. Although these pH changes have been made in quick succession and may have been disruptive to good laboratory procedures, they have not, regardless of which pH was used, lead to a false positive. They affect the percent recovery of the sample and thus might, in effect, permit a true user to be declared a non-user. If recovery were perfect, a 100 ng/ml specimen would be so reported. On the other hand, if recovery erratically falls to 20 percent, this same user's specimen might appear to be 20 ng/ml. Similarly, though less likely, a 100 ng/ml specimen could appear to be 200 ng/ml if only the standard were poorly recovered. It should be emphasized that a zero remains a zero specimen.

c. Internal Standard: Oxyphenbutazone was being used by all laboratories as the internal standard. The major problem system-wide with the GC procedure is the variable recovery of this internal standard. Some laboratories had less problems (e.g., Tripler) with recovery than others. The worst situation was observed at the Fort Meade Laboratory, where the recovery was extremely variable from none to poor. The other laboratories had adequate but still inconsistent recovery. In the Panel's review as to whether this variability could conceivably lead to a false positive report, it concluded that it cannot. If a zero level of THC is present, the THC peak will be zero regardless of the recovery efficiency. However, variability in recovery can, and probably has, led to some users with higher levels being reported as negative and more importantly increased the number of reextractions of borderline samples. The correct handling of such a variable is to closely document it, know the standard deviation (SD), and reject or retest the entire batch when the internal standard recovery rate exceeds the expected SD. Without such a procedure, analysis of a given result requires expert study of the entire batch to retrospectively judge the samples. Though this can be done, (and the Panel did so on occasions) it is poor procedure. This problem could be alleviated by the use of pyrene butyric acid (PBA) as an internal standard with an OV-1 column (a procedure currently being used by the US Navy). The PBA internal standard method is already being used at Fort Meade and is being tested at Tripler AMC with encouraging results.

d. Calibration Curves and Cutoff Values: The only laboratory that prepared calibration curves and carefully studied the recovery of the internal standard and the THC metabolite was the Tripler AMC Laboratory. The other DTL's used only a positive control sample within the run to calibrate the instrument for a cutoff

value. There is inconsistency among all laboratories as to the interpretation of the cutoff value. An Army standard operating procedure (SOP) is needed among all laboratories to statistically evaluate and properly identify a positive sample, whether the directed cutoff is 75 or 50 ng/ml. Only Tripler AMC Laboratory has developed analytically and statistically valid criteria, based upon actual laboratory data, to securely identify positives (75 ng/ml), reruns (50-75 ng/ml) and negatives (less than 50 ng/ml). The current Tripler method for documenting cutoffs should be considered for all DTLs.

e. GC on Other Drugs: The current GC methods used by the DTL for other drugs (cocaine, amphetamines, opiates, barbiturates, PCP) are different among laboratories and do not follow DA SOPs. There is no consistency among laboratories in this regard. Currently none of the DTLs have validated their GC procedures for drugs other than THC by GC/MS, an easy procedure which could be done on standard samples. No quality control protocol or program is being followed in any DTL to support the GC methods for other drugs.

(1) Amphetamine/methamphetamine GC procedures at the DTLs suffer from contaminant peaks possibly due to the decomposition of urine specimens caused by bacterial degradation during long shipment periods. Chromatographic criteria for amphetamines in the DTLs are adequate, but the current long shipment times require GC/MS to validate the peaks and/or GC data on known negative samples subjected to similar shipping conditions and decomposition products. Over-the-counter anorexic drugs could also cause interference in this method.

(2) Opiate methods reviewed at Wiesbaden AB, Tripler AMC and Brooks AFB appeared adequate except that some improved resolution is warranted in some cases between codeine/morphine or codeine and the previous eluting peaks.

(3) Barbiturate GCs were reviewed at only two DTLs. The data was adequate although allowance for phenobarbital elution was not followed consistently.

(4) Cocaine GC confirmation techniques were reviewed in all DTLs. The Panel found adequate methods at Brooks and Wiesbaden only. Further, standardization of cocaine GC methods is needed before 100% testing is directed. GC/MS quality control documentation is mandated in each DTL if cocaine results are to be reported using current GC procedures.

(5) In conclusion, GC procedures for other drugs need a standardized approach using a SOP approved by the Biservice Drug Testing Commands prior to implementation. While DTLs are

currently attempting to do a credible job with other drugs, considerable effort is needed to upgrade GC efforts for the other drugs.

8. Gas Chromatography/Mass Spectroscopy (GC/MS) Review.

Currently the USA/USAF drug testing laboratories (DTL) are required to confirm THC results by GC/MS only upon request of prosecution, defense, court martial authority, the individual tested or a command request. No official Army SOP exists specifying that the DTLs must use their GC/MS capability in a quality control role by using GC/MS to confirm a certain percentage of GC positive samples for THC and other drugs. This seems a major oversight to the Panel, since the Panel believes this would probably be the best data to assure the DA and the individual of the overall validity of the GC confirmation process. No official SOP exists that the DTLs can follow concerning how GC/MS should be run, maintained, implemented, standardized, how data should be interpreted or how evidence should be prepared for legal testimony. No official Army SOP exists on which specimens should be retested.

a. Currently all laboratories, except Brooks AFB, have one HP5995B GC/MS full-time for the drug program. Brooks AFB shares its GC/MS unit and operator with the Brooks Aerospace Medical Clinical Chemistry Unit. The major observation on the DTL GC/MS program is that it is currently marginal in terms of number of units and operators to provide a full assessment of the DTL's GC/MS capabilities. This is not surprising, since most of the GC/MS equipment is very new, as noted below.

b. The Panel found that the following programs are in place:

(1) Fort Meade: packed column HP5995B in place with two operators plus Maj J. Jewell, currently TDY on staff.

(2) Brooks AFB: one operator plus some outside expertise, HP5995B packed column unit being incorrectly operated with a capillary column.

(3) Wiesbaden AB: HP5995B received January 1983, installed August 1983, packed column operations; no trained operators and a marginal environmental/maintenance/training effort.

(4) Tripler AMC: HP5995B packed column received May 1983, installed June 1983; operated by the OIC only with minimal support and training. No full time operators are trained and no GC/MS is done when the OIC is unavailable due to other duties.

c. The major observations on the DTL GC/MS program are:

(1) There is no consistent program for the use of GC/MS in the QC of GC confirmations between laboratories.

(2) Most of the GC/MS effort has been on THC with no effort on other drugs.

(3) No laboratory properly understands the correct THC ratio algorithm, and no laboratory has the personnel trained to provide forensic testimony on the THC or other drug GC/MS data.

d. The GC/MS program is poorly supported in all laboratories except Brooks AFB in regard to facilities support, air conditioning, adequate maintenance contracts and other areas. Fort Meade had a better program (and came closer to a 10% QC check on GC) than Wiesbaden AB and Tripler AMC. While Brooks AFB had good environmental and facility support, the part-time nature of the Brooks GC/MS program mitigates against its advantages.

e. No DTL has adequate expertise to support GC/MS internally and forensically document (for courts-martial) GC/MS. The USAF Homestead AFB case is a glaring example of an adequate program which was clearly misrepresented in courts-martial due to inadequate presentation of GC/MS data by in-house GC/MS expertise to the JAG.

f. No laboratory had a proper GC/MS training program and no records existed to document operator certification. The laboratories appeared to depend upon Hewlett-Packard to somehow train the personnel or correct problems without a clear program designed to educate, train and support quality GC/MS. Of interest, the Panel would have expected that the Health Service Command's Academy would have made an effort sometime in the past year to arrange for such training.

g. All DTLs clearly misunderstand the implications of GC/MS for their GC confirmation programs. Rather than use GC/MS to document the level of excellence of their GC confirmations and to support, improve, resolve problems and identify new testing areas, the DTLs consider GC/MS only as a mandated forensic (court) device to be used only when required. Although Fort Meade has recently generated more GC/MS on THC and Brooks AFB, by number of requests, has done similarly, no adequate direction towards increasing GC/MS use has been given by anyone in the DTL system. Moreover, a valuable documentation of GC confirmation probably already exists, even from the limited use of GC/MS thus far, but has not been collected or tabulated. Of interest, Fort Meade confirmed some 800-plus of their positive samples in October by commercial GC/MS and has several thousand more GC positive specimens on hand.

h. Where available, the GC/MS data appeared adequate to document GC-THC confirmations. Brooks AFB had valid scientific data on THC to support a consistent ratio algorithm review. Unfortunately, Brooks AFB did not routinely use GC/MS for THC QC. Fort Meade and Tripler AMC data appeared scientifically acceptable although inadequate in quantity to be considered necessary quality control to GC. Wiesbaden AB is far behind the other laboratories in GC/MS and does not have sufficient data for proper review.

i. Each DTL has an inadequate number of operators to correctly support their GC/MS programs. Furthermore, reliance on a single GC/MS unit, even when properly operated, is not prudent. Considering the expanded screening requests (5 drugs at Wiesbaden AB, 100% cocaine at all other laboratories) one GC/MS cannot adequately provide enough support even if triple shifts were run. (Maintenance and downtime considerations would likely preclude a third shift under the best of conditions.)

j. Implications and Conclusions on GC/MS.

(1) A major effort is needed immediately in all DTLs to expand the instrumentation (at least 2 GC/MS units/laboratory as soon as proper facilities are provided as noted below) and number of certified operators, and to train forensically acceptable GC/MS witnesses for legal purposes.

(2) The Commands which have DTLs assigned must develop a plan to implement required requests for facilities support to GC/MS (e.g., space, air conditioning, electrical support, maintenance contracts by Hewlett-Packard, and mass spectroscopic grades of supplies). A system-wide GC/MS program must be designed and implemented that will maintain program integrity, instrument warranty and forensic acceptability. The Panel recommends that the Army GC/MS program that is designed and implemented should be consistent with the proposed standardized DoD drug laboratory testing procedures.

(3) The current GC/MS status in all DTLs supports the conclusion that the 1984 purchase of the MSD and additional GC units is premature and potentially dangerous to the current program unless a major effort is initiated to train personnel and provide the facility support prior to receiving these units. It is the Panel's conclusions that the purchase order for the MSDs and additional GC units should be delayed for six months, or until the proper support is provided. The proposed HP training program in GC-capillary GC-MS should be directed to begin in early 1984. Until the DTLs have the capability and expertise to properly implement the 5970 MSD program, there is no reason to ship and receive these units. The present unplanned

and poorly coordinated effort to purchase multiple MSDs without proper laboratory cooperation and a program implementation plan and an Army SOP could compromise the entire DTL program.

9. Security and Chain of Custody Review. The current internal chain of custody procedures at each laboratory, except Fort Meade, were good. Minor deficiencies were corrected on-the-spot and principally involved reducing the number of persons handling a given specimen. Follow-on visits to the Fort Meade Laboratory in November 1983 by the OTJAG Panel members indicate that the significant internal chain of custody deficiencies at that laboratory have been satisfactorily corrected. The chain of custody requirements of Interim Change 2, AR 600-85, dated 11 Feb 83, were not implemented by submitting units until mid-March 1983, apparently due to a delay in receiving the regulation. From mid-March through June 1983, compliance with the directive was gradually improved; however, the laboratories did process and issue reports on specimens which were not accompanied by a properly documented chain of custody during this period. Following HQ DA guidance in late June 1983, all laboratories have been uniformly rejecting all specimens received without a properly documented chain of custody.

Building security was not adequate at the Fort Meade and Wiesbaden laboratories. Follow-on visits to Fort Meade by Panel members indicate that security of the overall building has not improved significantly. Security deficiencies stem from both a lack of understanding of the security requirements for forensic evidence and a lack of adequate physical facilities. Both problems can be corrected by frequent physical security inspections coordinated with the local staff judge advocate, periodic security training for all laboratory personnel, strictly enforced limited access not only to the laboratory itself, but also to each work area within the laboratory; and, adequate funding to upgrade building security features (which is lacking at each Army laboratory visited and is aggravated by the fact that each of three Army laboratories are tenants on a separate installation from their chain of command).

10. Management Environment, Support and Administration. Although most of the comments in this section do not directly influence the technical scientific validity of the DTL's reporting of urine positive results, they are occasionally cited by aggressive defense witnesses seeking to discredit a DTL's forensic abilities and thus do influence the overall Army's drug testing program. Many of the factors and situations are characteristic of any high priority program for which major changes are desired quickly. As a minimum, a number of these factors need to be considered closely in that they diffuse the OIC and DTL staff from their technical responsibilities, and establishment of needed in-house DTL management. Except in a general manner this section does not address the Brooks AFB laboratory which

operates under USAF direction and is on the same base as its immediate command.

a. Management Environment. The Panel notes the following:

(1) The DTLs went from testing 10% of samples for THC to 100% testing in early 1983 and received major inputs of new centrally-procured GC equipment, automatic pipetters, centrifuges, and Micromedic counters all at very nearly the same time. The procurement of all this identical equipment was a helpful move toward uniformity. Without this action, the Army would have been in a very difficult and impossible situation.

(2) Army Laboratory OICs, at time of the Panel visits, were junior (1 Major and 2 Captains). They have done a superb job in getting the program underway, however, their "clout" in recognizing and solving problems, knowing administrative procedures, and in dealing with higher headquarters on support/administrative matters is truly lacking. Each needs help from their chain of command, which usually lack a knowledgeable (and several yet do not have) staff element, and frequently is not directly involved in many of the DTL changes in specimen quotas, new equipment, program planning, personnel authorizations and funding.

(3) Health Services Command is not frequently mentioned as having any staff element which spends any significant amount of effort in supporting the DTLs. HSC has not made any significant changes in its training programs to train or arrange for training of GC/MS, GC, or RIA operators even though it is clear that a significant requirement exists considering the numbers of machines in use, shifts operated (two to three at each DTL), and the likely rotation of personnel. The Panel was told that drug program activities were not even a subject at the most recent HSC Commander's Conference.

(4) AFIP never augmented its personnel when the increased testing program at the DTLs began. AFIP personnel have not visited the laboratories (except Fort Meade) since the enhanced program began.

(5) The OTSG does not have a staff element or officer who spends 100 percent of his time on DTLs, nor anyone experienced in the operating problems of the DTLs. (Both the USN and USAF keep at least one senior experienced person "in charge.")

(6) The only Army agency of a DA-level staff element working essentially full time on the drug program is the USADATA, a DCSPER FOA. USADATA frequently has been called upon to fund equipment and chemicals directly, outside the normal TSG chain of command when funds were not available. Apparently, there is

no resource management plan or system designated for the DTLs. (e.g., On occasion, Fort Meade has run out of reagents because someone at WRAMC failed to place an order on time.)

(7) The laboratory OIC's stated that this Panel's visit was the first technical inspection by anyone familiar with drug testing equipment and its use in other drug testing laboratories.

(8) Meetings among the operating DTLs are very rare. (The last was in June 1983 and was hosted by USADATA).

(9) Changes in procedures, specimen quotas, and equipment have apparently been made by single individuals from varying agencies, they are frequently made directly to one or more or all three laboratories by phone, electrical message, letter, or visit without prior testing, peer review, or DTL input. They are done without fully considering the support requirements for training, chemical reagents, facilities, maintenance, and many other items often requiring variances from the DTL's host-tenant agreement. There is no single management/supervisory agent for the DTLs.

b. Support and Administration. The following general observations were made by the panel:

(1) Appearances at Courts-Martial. The limited supervisory assets and the critical presence of laboratory technicians are hindered by telephone queries, personal visits to the laboratory, and requests for appearances as a witness at courts martial. Personnel should be specifically identified, designated and made available to support requests for information, laboratory tours, and demands for expert witness testimony on laboratory procedures. DA policy is required to establish guidance to prevent excessive demands for witness appearances. The extreme cases the Panel were told about ranged from a laboratory OIC and 25 of his staff for two days to an OIC and seven to nine of his staff on two occasions for a week at a time. In at least two instances, several Tripler AMC Laboratory personnel went to courts martial at Fort Lewis, Washington, which were resolved on procedural grounds not requiring their presence. The crippling effects of this turbulence and loss of supervision and worker absence significantly hamper specimen processing and throughput.

(2) Training of JAG Officers and Need for Physical Security Assistance. There is an immediate need for training of Judge Advocate General officers in the technical aspects of specimen control, processing and reporting. Local Staff Judge Advocates and physical security personnel should be designated to visit the laboratory monthly to provide assistance on chain of custody, physical security and appropriate SOPs. Considerably

more attention is required in training of legal personnel on the technical aspects of forensic toxicology and to prepare them for examination of expert witnesses.

(3) Physical plant and space requirements. The DTLs generally lack proper space to establish and organize efficient and highly productive operations. (This is probably not surprising considering the recentness of their expanded activities.) Planned initiatives are needed for additions of new equipment for ADP Data Reduction Systems, GC, and GC/MS otherwise, crowded conditions, inadequate physical plants and support facilities will be impacted. Of the latter, air conditioning, ventilation, environmental control, power supply, lighting, contaminated waste disposal, and physical security deficiencies are most critical. Factors contributing to the criticality of these deficiencies are inadequate command emphasis and attention to program requirements, inadequate knowledge of forensic toxicology laboratory standards, and existing conditions of operational DTLs. General observations revealed crowded work areas and other physical constraints not conducive to efficient internal organization, and also make-shift efforts to maintain highly sensitive equipment in environments not fully complying with those recommended by the manufacturers. The Brooks AFB laboratory was an example of good lighting, work atmosphere, environmental control, space and internal organization. One of the most disturbing points of contention from the DTLs has been their inability to convince the chain-of-command that work orders are needed for installation of equipment, equipment support devices and utilities. These work orders must be given high priority by host installations. Command emphasis at all echelons is required to alleviate adverse operational conditions. The DTL's may well be facing saturation points in program implementation. Planned equipment acquisition in the next six to eight months will be difficult to adequately accommodate because of laboratory constraints in physical plant deficiencies, operator knowledge and training, environmental controls, first echelon supervision, personnel authorizations and funding. Planning personnel must plan and coordinate with the various commands which provide facility support to assure that electrical capacity maintenance and facility changes are available when major changes are suggested. (Such was not the case in the GC/MS, and GC procurements.) Failure to plan for this support has led frequently to many months of delay before new equipment became operational.

(4) Tables of Distribution and Allowances. Considering the number of specimens processed per month, the number and type of drugs tested, the requirements for training, new equipment upgrade and introduction, consistent increases in specimen allocations, and turbulence from testimony on procedures and laboratory operations, the Panel questions the adequacy of authorizations of personnel both in number and skill speciality. Critical elements of personnel shortages are first-line super-

visors, quality control, training, specimen processing and control, and reporting. OTSG must determine resource needs and properly interface with Army budget/manpower systems.

(5) Automatic Data Processing--Data Reduction Systems. Automatic reading and rapid accurate data scanning transcription of specimen testing, where it has been implemented, increases productivity, accuracy and reliability of forensic statistical compilation. Through the use of automation and appropriate equipment, mass-production procedures can be developed, in-process statistical review of results can be analyzed and corrective measures implemented almost automatically and uninterrupted. A good example of a successful program is that in the Wiesbaden AB laboratory. The panel recommends that immediate action should be initiated to integrate the strengths of Wiesbaden AB sample receipt and processing and RIA analysis into all three DTLs. Past efforts in computerization have been successful but have been dependent upon the personal initiative and skill of selected individuals. However, these ADP achievements have not been passed throughout the DTLs. This is evidenced by the success of the Wiesbaden AB software for specimen processing and RIA throughput. Command emphasis is needed to develop a standard integrated system of data reduction to include uniformity of hardware and software within the DTL program. Planning, programming and scheduled implementation of ADP equipment is confusing to laboratory managers, is not understood, and lacks field input as to purpose and results desired. For example, it is not clear that recent plans to add Micromedic data reduction units to existing RIA equipment is compatible for longer range needs for total ADP integration.

11. Procedures to Ensure Continued Credibility. The Panel recommends that laboratories be inspected periodically by internal and external sources to ensure adherence to professional standards and the DA SOP so that scientific and legal support and approval is obtained from forensic toxicology experts in the civilian community. The inspection system must be frequent and rigid enough to ensure standards are maintained during the growth and expansion of the program. As the demands of the program create unsettled operational situations, specimen testing and reporting cannot be interrupted or quality degraded. Overall, certification of a laboratory's technical proficiency can be best conducted at the DA level of staff responsibility charged with the overall technical responsibility for all Army DTLs. A mutual interservice support agreement is required with the Air Force. The College of American Pathology, or a qualified panel of civilians, must conduct a yearly Army-wide inspection of the drug testing program. Depending on the programs of standardization and the attainment of laboratory stability, these expert bodies consisting of board certified toxicologists could conduct inspections on an alternating yearly basis. Army laboratories must be certified, preferably on a yearly basis. Any significant

change of procedures or equipment should be certified on a case-by-case basis, based on some type of peer review by another of the labs, or an equally competent review group. Command internal recommendations for certification of changes proposed by DTLs would probably be conducted better at a level two echelons above that of the activity responsible for the operational control of each Army drug testing laboratory to assure a refereed, but quicker, response to needed changes. Certification of laboratories must include more than specimen quality assurance or control procedures. Planning, programming, funding, personnel, equipment, certified standing operating procedures, training, personnel certification, facilities, logistical support and maintenance must all be included within the minimum essential requirements for certification. To be certified, all DTLs must meet and use the same SOP. Additionally, the policy development level at DA (ODCSPER) must have a knowledgeable consultant in forensic toxicology and drug testing, (probably in the near-term) who is external to the Army. The DA policymaking activity must have an element which understands the technical implications of proposed policy decisions, but is independent of the staff activity responsible for technical laboratory operations.

12. The Quality Assurance Program Required to Assure Continuing Integrity. A Quality Assurance Program must insure that each Army DTL complies with the DA SOP so that its technical data will be scientifically and legally supportable. A complete QA program does not currently exist in the DTLs, although their records indicate that considerable QA data does exist or could be obtained. The QA program must address questions such as:

- Did you have and follow the proper certified procedure?
- What data do you have to establish that false positives are not being reported?
- What overall daily management controls of the results do you have to demonstrate that a specific batch of samples was actually done in full accord with your procedures?
- How do you document your precision, accuracy, and method of recovery?
- How much variation do you have? Accept?
- What data do you have that all reagents/solvents are under QC Control?
- What documentation do you have that all your people know how to operate the equipment?

- What documentation exists to demonstrate that the equipment is properly operated, calibrated, and maintained?

a. The criteria recommended below emphasize the need for adequately documenting quality control throughout the process. In addition to the criteria listed, which are for the use of individual laboratories, these criteria assume an overall structure is available to assure that inter-laboratory problems, recommendations for change, and higher headquarters directions are indeed, themselves, consistent, validated, certified and responsively provided. Without such a management environment, it would be difficult, if not impossible, to maintain a credible program. With proper supervision and management, the Army can maintain a high state of professional excellence, very similar to that maintained among various hospitals in professional areas such as surgery and patient care standards.

CRITERIA FOR URINALYSIS TEST RESULTS

1. The limits of detection, by quantifying background noise on negative specimens, must be documented by each DTL.
2. At each step in a procedure, sufficient information must be developed within each laboratory to document the variability observed. This documentation must be formally preserved and compared over a period of time, with cross analyses as to its expected value versus changing conditions.
3. In confirming a positive, documentation must establish that the standard deviations of the cut-off level for positive confirmations are such that there is a well-known probability that a data point reported as positive will not, and could not, credibly be the same data point of a true negative specimen based on the standard deviations maximally credible for the negative limit of detection analysis.

b. Since the Panel observed that many personnel in a policy-making, technical inspecting and management role did not recognize "good" from "bad" or "less desirable" chromatograms a short summary on interpretations of chromatograms is offered at Appendix I.

13. Scientific and legal sufficiency of results reported by the DTLs.

a. The Panel recognizes that the techniques of immunoassays and GC are widely and generally accepted, and used in

forensic toxicology laboratories for drug testing. The identification of THC metabolites by the combination of immunoassays and GC testing has only come into general use within the past three years and is in the process of gaining acceptance through publications and peer review at national scientific meetings. The Panel finds that the confirmation of the presence of THC by the current Army procedures involving an RIA and confirmation by GC can be scientifically and legally defensible providing adequate quality control criteria exist and are available for review. As evidence for the finding:

- In an independent test of 814 Fort Meade reported positive samples, Mead CompuChem confirmed positive by GC/MS all but two of the Fort Meade samples--an apparent rate of better than 99.8 percent. The Panel recommends retesting of these two specimens.

- In reviewing all US Air Force and Army data reported by AFIP to OASD(HA) and in discussions with Col. Manders and Dr. Whiting at AFIP, covering CY 1983 to date (Jan-Sep 1983), none of the 1,260 negative controls (samples with no THC) were reported as positive.

- In reviewing a representative sample of in-house performed GC/MS data, we found no case where proper GC/MS failed to confirm a previously confirmed GC positive sample.

b. The Panel's conclusion is that, when proper internal laboratory controls are present, a positive test for THC is both scientifically and legally supportable when it is detected by the RIA procedure and confirmed independently by either GC or GC/MS. This has been true whether procedures are identical or not among laboratories, as long as internal consistency has been demonstrated by the laboratory performing the analysis. In fact, based on differing chemicals, equipment, state of maintenance of the equipment and state of training, there have been quantitative differences among laboratories, but none of the differences would cause the false reporting of a negative as a positive.

c. Current GC procedures for THC can be used, when proper quality controls are present, down to a cut-off level of 50 ng/ml. If one desires to detect concentrations at a lower level, then one must expect to make the higher investment in dollars, equipment, and manpower that GC/MS procedures will give. GC/MS can operate at levels down to 5 ng/ml. Obviously, either system can provide scientifically acceptable data at higher cutoff levels such as 75 ng/ml. Selecting a higher level will reduce the confirmed positive rate.

d. With respect to the the Panel's review of the THC technical data at the DTLs, the Panel finds no evidence to

suggest that there have been any false positive THC results reported by the laboratories. However, the quality of the official records, and the poor quality control records will make it difficult, and, in many cases, impossible to provide scientifically and legally supportable documentation. The Panel concluded that if a review of the data for any specific case indicates it would be scientifically and legally supportable as it stands (since many credible GC's do exist) it should be defended. Detailed evaluations of the credibility of results are provided in Appendices C thru G.

e. The scientifically and legally supportable documentation for the results reported by the DTLs for their drugs must be reviewed on a case-by-case and or laboratory-by-laboratory basis for the reasons discussed in section 7e.

e. The percentage figures noted for each laboratory of THC chromatograms that are not scientifically and legally supportable are estimates based upon the review of representative samples and do not reflect an actual count. If the actual number of these chromatograms is deemed to be necessary, a more detailed audit would be required.

In summary:

- At Fort Meade, RIA results confirmed by GC should be acceptable from 15 November 1983 on. Prior to that time, RIA results, confirmed by GC only, would be scientifically and legally supportable in less than 10 percent of the cases.

- At the Brooks AFB Laboratory; since October 1983, about 94 percent; for the period June to October 1983, about 90 percent; for January to June 1983, about 75 percent; and during the period when a packed column was being used, possibly as low as 40 percent of the RIA results confirmed by GC can be scientifically and legally supported.

- At Wiesbaden AB Laboratory, prior to April 1983 (before Prep I procedures were used), only about 25 percent; from April to June 1983, about 80-90 percent; and since June 1983, about 95 percent could be scientifically and legally supportable.

- At the Tripler AMC Laboratory, for May-June 1983, about 90 percent; for July 1983 (when procedures were being changed), about 80 percent; and since August 1983, about 98 percent could be scientifically and legally supportable.

- When proper GC/MS data are available or could be provided, additional cases for THC and other drugs could be scientifically and legally supportable.

14. Panel Assessment as to Reliability and Accuracy of Current Laboratory Operations and Procedures for each DTL with Recommendations for Improvements and Changes:

a. Fort Meade Laboratory.

(1) Inspection and Review. The Panel visited the Fort Meade Laboratory on October 24-25, 1983. Subsequently, Panel members have revisited the Fort Meade Laboratory on four occasions between 25 October and 9 December 1983. The Panel visit occurred during a period of suspension of testing (since 1 October 1983) due to serious questions about the quality of the laboratory. THC test positive urines (814) from Fort Meade have been analyzed by the USN contractor, Mead CompuChem, by GC/MS. This data was also reviewed by the Panel. Also, a committee of experts was established and implemented to review all GC data for Fort Meade THC testing. Conclusions below about the Fort Meade Laboratory are therefore based on all of these factors.

(2) Security and Chain of Custody.

The Fort Meade Lab is housed in the Medical Testing Laboratory along with normal clinical chemistry operations. The Lab has processed up to 18,000 specimens per month (100% for THC) with pulses for one other drug. The three story building has very poor security both from outside egress and internal movement between the urine drug testing and other medical operations. The current specimen receipt and pouring room was too small, crowded and lacks ventilation and proper storage space. Access to the COC room was allowed without need-to-access or proper documentation. There was a severe deficiency in the ability to forensically document COC for Fort Meade specimens. No attempt was made to monitor urine-volumes-upon-receipt for legal purposes (as specified in the Army SOP). In general, the staff attitude towards security and COC was inadequate and the facilities utilization was poor throughout. As noted, the laboratory is making changes since the Panel's original visit.

(3) RIA Program.

The RIA procedure was basically correct although the re-RIA (for COC urines) did not provide adequate standards compared to the initial RIA screen to properly establish scientific cutoffs. All data was initially hand calculated although some initial desk top computerization had been started. Record keeping was inadequate, sloppy and poorly documented. The approach to RIA was clinical rather than forensic. In

comparison to other USA/USAF DTLs, Fort Meade did not have a clear concept of cut-offs, statistical quality control and overall program validity. The Panel extracted information rather than reviewed it.

(4) GC Program.

(a) The GC confirmation for THC program (prior to the Panel-directed pyrene butyric acid (PBA) internal standard method) was ineffective. This laboratory's concept of GC was inadequate with no sound program for operator training, quality control, bench supervision, instruction to operators, monitoring of analytical parameters (THC cutoff levels, THC recovery, control charts), and recordkeeping. Panel discussions with laboratory technicians confirmed that they did not know how to properly use GCs and the Panel was surprised that the civilian supervisor had been routinely signing reports which had no or inadequate standards evident, obvious coeluting peaks and very poor solvent fronts. He had not established controls on the process nor required appropriate calibration. Quality control was sporadic and unplanned. The evening shift was actually supervised by a technician. These observations on the GC confirmation program are supported by Panel and Expert Committee reviews. The initial Panel review showed that at least 50% of all chromatograms reviewed would not be scientifically and legally supportable. The Panel found, and the Mead CompuChem GC/MS data confirmed, that false positive THC results (based on RIA and confirmation) were not being reported. However, the GC program did not provide valid scientifically and legally supportable data. The GC program review by the committee of three (chaired by Colonel Sanders Hawkins) supported the Panel's observations. For support of the Panel's observations see the Hawkin's Report at Appendix J. The recovery of oxyphenbutazone in the reviewed GC data ranged from zero to poor yet Fort Meade continued to call GC results positive in many cases if any peak at the corresponding retention time appeared in the sample. The current practice of using OIC personnel to supervise the two GC shifts must be changed.

(b) Subsequent to the Panel visit, the GC program has been changed to PBA internal standard on an SE-30 versus the previous oxyphenbutazone/OV-17 method of Whiting and Manders. Although significant improvement has been shown by all but one of the operators using PBA.

(5) GC/MS Program.

GC/MS was in better shape than GC. Captain Shingleton and one operator ran the Hewlett-Packard 5995B (packed column). Maintenance and operator logs were marginally satisfactory. No understanding of THC ratios was evident, (this has been corrected). GC/MS training and increased personnel are needed to provide a

minimally acceptable QC program for GC/MS. The Fort Meade lab is not currently prepared for capillary GC/MS (or capillary GC) or the anticipated GC/MSD (mass selective detectors) scheduled for 1984.

(6) Personnel, Training and Overall Review.

(a) In general, Fort Meade still does not have either the command support or the understanding by the command to solve its problems. The recent addition of a chemist as the quality control officer (who has not had experience and training in drug testing) means another period of poor intralaboratory/interlaboratory program development. The new QC officer, who is learning QC, cannot be expected to resolve easily all of the immediate deficiencies (blind QC, operator training, program instruction, GC certification, capillary training, etc.). To attempt to resolve all problems in a short time may be falacious and shows a lack of command understanding of the Fort Meade situation. Additional trained staff is essential. The Fort Meade report generation to the field commands shows some good points with the HP1000 computer program, but again inadequate staffing and software prevent full use of this computer support to field commands and legal communities. The current state of computer support for lab operations (RIA, GC, COC) is highly unplanned and inadequate.

(b) In summary, the Fort Meade Laboratory, even with the new PBA/GC method for THC, is currently operating on a probationary, provisional basis. Attention still is needs to the establishment of proper RIA cutoffs. A significant force of trained personnel is needed immediately at Fort Meade to provide the capability to meet certification standards and prepare Fort Meade for the future. The short-sighted approach of crisis management must be replaced by sound, long range planning.

b. Brooks AFB Laboratory.

(1) Inspection and Review. The Panel visited the USAF School of Aerospace Medicine's Drug Detection Laboratory on 4 and 5 November 1983, the laboratory currently processes 22,200 specimens per month for THC and one other drug.

(2) Security and Chain of Custody. The security of the laboratory and of the specimens room was very adequate, and the chain of custody SOP was complete and similar to that outlined by OTSG, HQ DA. No attempt was made to document urine volumes upon receipt for legal purposes (as was questioned in the Homestead AFB case).

(3) RIA Program. Due to equipment limitations, counting of the supernatant (as opposed to pellet counting) is being carried out at Brooks AFB laboratory. Although the

supernatant counting usually results in greater fluctuation of results, the laboratory uses a statistically based determination of the cutoff levels. The RIA procedure in the Panel's opinion is scientifically and legally supportable.

(4) GC Confirmation and GC/MS.

(a) GC: The THC procedure currently used by Brooks AFB laboratory utilizes the Prep I extraction and a capillary (DB-5) column with oxyphenbutazone as internal standard. Although this is the only laboratory using capillary columns, the Panel feels that the data generated is scientifically and legally supportable. This is in view of the fact that negative standards and positive controls are always included in each batch run and that the laboratory has an adequate internal quality assurance program. In addition, GC/MS confirmation of the samples has been carried out with no conflicting results. It is the Panel's opinion that the GC/MS confirmations carried out as a quality control measure are adequate to support the GC analysis. The major problems found by the Panel in reference to the GC methodology were: (1) the appearance of extraneous peaks in the chromatograms of most samples, and (2) the procedure used to establish the 75 ng/ml cutoff was not reliable the difficulty in establishing the 75 ng/ml cutoff assumed reproducible recovery and GC response of the oxyphenbutazone internal standard. The laboratory did not have the needed evidence to support its cutoff. The extraneous peaks appeared to be coming from the reagents or solvents used in the analysis. Although these peaks were not at the exact retention time of the THC metabolite, they were close enough that in some samples the THC metabolite peak was distorted or incompletely resolved from the contaminant peak. This often resulted in re-testing of the sample under question, a procedure that adds to the work load of the laboratory. The Panel strongly recommended that the laboratory take the time to trace the origin of such peaks and solve the problem.

(b) GC/MS: The GC/MS data was handicapped by the fact that a capillary column was used on an instrument which was designed for a packed column interface. This resulted in a large dead space volume which seriously affected the peak shape (broad) and sensitivity. It was recommended by the Panel that the laboratory should use a packed column with this particular GC/MS system or obtain its own instrument with a capillary interface. The GC/MS program is scientifically and legally supportable; however, the Panel recommends that it should be expanded (by acquisition of its own instrument) and improved to increase the sensitivity for detection of lower concentrations and used to confirm other drugs as well.

(5) Personnel and Training and Overall Review. The laboratory is staffed with qualified individuals in the different

areas of drug detection and has the best physical facilities of the four laboratories visited. The Panel also observed that a routine training and certification program that each operator has to fulfill before being assigned to a particular job was in place. It is the Panel's opinion that the laboratory is operating at a maximum level and any staff reduction would adversely affect the turn around time and might create a backlog of samples.

The laboratory seems to have strong command support and understands the importance of maintaining the needed backup documentation for operating a forensic laboratory rather than a clinical laboratory.

c. Wiesbaden AB Laboratory.

(1) Inspection and Review. The Panel visited the Wiesbaden AB Drug Testing Laboratory (WDTL) on 17-19 November 1983. This laboratory currently processes about 31,000 urine specimens per month for five drugs (THC, amphetamines, cocaine, opiates and barbiturates) with a present staff of 97 personnel.

(2) Security and Chain of Custody. The WDTL is housed in a command building on the secured Wiesbaden AB Army Community. Base security appeared excellent although the lab itself was somewhat less than secure (no front entrance log-in, and the back door was not secured). The handling of specimens under COC met forensic and judicial guidelines. A staff developed computer program to provide a complete intralaboratory COC System for all operations was in use, working well, documented and very practical. The staff was well trained in the use of the COC program. The only problem in specimen handling was a lack of command support in providing adequate frozen storage for positive, processed specimens. No effort was made to document urine volumes upon receipt for legal purposes (as specified in Army SOP).

(3) RIA Program. The RIA procedures and laboratory operations were well-planned, monitored/supervised properly and provided scientifically valid data for all five drugs. The RIA supervisor displayed good overall laboratory knowledge and served also to QC final reports on specimens. Good use of data reduction was evident in RIA with floppy disc storage of data used for processing of large batches (1080 specimens and standards) on the Hewlett-Packard 9835 computer. Standards, controls, statistical QC and overall analytical criteria judgments were sound and in evidence.

(4) GC Program. The GC program for THC used the oxyphenbutazone, packed OV-17 column procedure with Prep I extraction for THC. Overall operator knowledge and use as well as supervision of the GC program was good. Proper HP 5880

documentation, data handling and maintenance/use was evident. Standardization calibration and data interpretation (although somewhat variable during the 82/83 period) were analytically acceptable. THC chromatograms showed virtually no background contamination peaks. The Panel found that approximately 75 percent (pre-Prep I, Jan-April 1983), 10-20 percent (pre-June 1983) and 5 percent (since June 1983) of the chromatograms would not be scientifically and legally supportable. A program for operator certification of training on GC was needed although the operators appeared well-trained. The overall conclusion on GC was that the program was satisfactory for forensic purposes and well run by the current supervisor, CPT Prescott.

(5) GC On Other Drugs. The GC for other drugs showed that amphetamines/methamphetamines should not be reported without a GC/MS confirmation (due mostly to the possible decomposition of urine specimens during long shipment times). The opiate/codeine procedure showed that some specimens required GC/MS to resolve some contaminant peaks or closely eluting peaks just before the codeine retention time. The Wiesbaden AB data emphasized that the Army-wide system for opiate reporting needs review to clarify reporting of individual opiates so as to indicate more clearly which opiate had been taken originally. The Panel suggests for drugs other than THC, that consideration should be given to the use of the nitrogen detectors (rather than FID since at least Wiesbaden AB and Tripler AMC Laboratories have them on hand) and suggests that better integration of the existing Varian GC units can be made into the daily, routine program.

(6) GC/MS Program. The GC/MS program (HP 5995B) was a disappointment. The instrument was received in Jan 1983, but was not installed until August 1983. The laboratory is, therefore, not currently conducting an adequate QC confirmation program of GC positive results on the GC/MS. No personnel are properly trained. The current maintenance/operation, record-keeping system, lack of MS expertise, and program response to amphetamine/codeine and other problems is highly inadequate. It is hard for the Panel to understand the poor support to the laboratory in the GC/MS area. Repeated requests for logistical and facility support have not been answered. This has led to possible violation of the Hewlett-Packard GC/MS warranty. The current reliance of the laboratory on an outside consultant is inadequate. Immediate response is needed to establish a well-maintained, well-documented GC/MS program with qualified operators.

(7) Training, Personnel, and Overall Review. Overall the laboratory is well-maintained and shows a staff knowledgeable in clear and adequate analytical principles. Despite the presence of mosquitos in November (another glaring command problem that defies explanation), the laboratory is well-run. A strong QC effort is evident and programming towards a full QA

unit should be continued. More attention to SOP details, training documents and analytical assessment of laboratory data under statistical quality control would provide additional improvement. Failure to improve training, GC/MS deficiencies, and physical plant inadequacies will prevent implementing the planned 1984 capillary GC/MS programs.

d. Tripler AMC Laboratory.

(1) Inspection and Review. The Panel visited the Tripler AMC Drug Testing Laboratory on 2 December 1983. Currently the laboratory is processing about 11,000 specimens per month, a reduction from 15,000 specimens per month.

(2) Security and Chain of Custody. Security and chain of custody within the laboratory are adequate. Limited access to the laboratory secure specimen room and the adherence of laboratory personnel to the SOP outlined by OTSG, HQ DA makes it noteworthy. However, the proposed installation of freezers for specimen storage at a different location (about 300 yards from the laboratory) should be abandoned, since it will compromise the COC integrity and specimen security. The laboratory currently documents urine volumes upon receipt (as specified in the Army SOP).

(3) RIA Program. The RIA procedure used by the laboratory is scientifically and legally supportable. The proper standards are used and a statistical method is evaluated to establish cut-off values. In addition, calibration curves are routinely plotted and criteria is established for the acceptance or rejection of a batch. The only disadvantage the laboratory has is the lack of data processing capability in the laboratory. The data are currently hand-calculated, hand-transferred, and manually processed, which could make it subject to errors.

(4) GC Confirmation and GC/MS

(a) GC. The THC procedure currently in use by the Tripler AMC Laboratory is the Prep I extraction and OV-17 column using oxyphenbutazone as the internal standard. Appropriate calibration curves and recovery data are used to monitor the analytical procedure. The laboratory used the GC instrumentation to its full capability and a data processing program was internally developed to monitor the set-up parameters and the quantitation aspects of the procedure. The laboratory has a good understanding of the quantitative cutoff value of 75 ng/ml, which is closely monitored. This laboratory has the highest percentage of scientifically and legally supportable chromatograms.

(b) GC/MS. The GC/MS program is used in support of the GC analysis only for requested retesting or for courts martial. The Panel recommends that the GC/MS program should be expanded to daily analysis of at least 10 percent of all positive samples analyzed by GC as part of an internal quality control program on the GC analysis. The laboratory was using the library search capability of the GC/MS system (Hewlett-Packard 5995B) for THC metabolite identification. It was pointed out by the Panel to the OIC (who is also the MS operator) that the daily use of positive and negative standards as well as peak ratio calculations (357/313 and 372/313) is the acceptable method for identification. The P

Although the amphetamine GC procedure was good, the Panel has the same reservations at Tripler AMC that it has expressed at other laboratories where long transportation times could lead to possible decomposition products. (See Section 7e.)

(5) Personnel Training and Overall Review. The laboratory is staffed with qualified individuals who are familiar and competent in the RIA and GC aspects of the laboratory operation. The expertise the laboratory has in GC/MS is centered around the OIC, which is an overload on him. The laboratory desperately needs additional GC/MS operators trained to initiate and implement a GC/MS quality control program.

The Panel noted that the laboratory is operating at a higher capacity than its current number of personnel should permit. Additional personnel support and added automation is needed. Otherwise, the specimen load needs to be reduced to keep a valid and defensible program. The Tripler AMC Laboratory demonstrates the best appreciation and understanding of the importance of a training program. The laboratory initiated and implemented an outstanding internal training program including video tapes prepared in the laboratory.

e. Armed Forces Institute of Pathology (AFIP).

(1) Visit Purpose. The Panel visited AFIP on 30 November 1983, to review the DOD Tri-service Quality Assurance Program it conducts and to clarify its role in methods development and implementation.

(2) The AFIP Proficiency Testing Program. AFIP has conducted an acceptable proficiency testing program wherein approximately 36 QC samples per week are submitted blind to the military units to be submitted to the DOD drug testing laboratories. The program has succeeded in demonstrating that the laboratories can reliably distinguish positive from negative specimens. Recent reports revealed no false positive results.

The laboratories report positive results at better than 90% accuracy at the relatively high AFIP concentrations. This same system is used in certifying laboratories for new testing procedures, or in recertifying laboratories which have failed the QC program.

(3) Other Assistance. AFIP has been designated to advise The Surgeon General and the OASD(HA) on technical issues involving the drug program. In the past, this had been through the forum of the Biochemical Testing Committee managed by OASD(HA). On recent occasions, this advice has been directed to the Surgeon General's office directly and, occasionally, directly to the laboratories.

(4) Panel Observations. The Panel found the current blind proficiency testing program to provide a valuable measure of the laboratories' abilities not to report false positive results. This should be continued and intensified. On the other hand, the Panel questioned the continuation of the current efforts to submit positive samples for drugs other than THC. Firstly, the concentrations used are 33 to 150 percent above present DOD cutoffs and, thus, do not test the laboratories' ability to maintain minimal sensitivity levels. See the table below.

	RIA Minimum Machine Sensitivity Levels ng/mL	AFIP Quality Control Minimum Concentration Levels ng/mL
Opiates	300	500
Barbiturates	200	500
Amphetamines	1,100	1,500
Methaqualone	750	1,000
Cocaine	750	1,000
Phencyclidine	25	50
Cannabinoid	100	150

Secondly, in order to attempt to preserve spiked specimens, sodium azide is added. This produces a characteristic odor which can be detected by the laboratories, although the Panel found no evidence that the laboratories do make use of this. Thirdly, the present policy of doing pulse testing for selected drugs makes the present system unnecessarily inefficient and ineffective, since some AFIP positives get "thrown-out" because they are not being pulsed. The Panel noted, however, that the positive samples do assure against "penciling" AFIP results since they otherwise would not be expecting any QC positives and serve as a partial check, especially for those laboratories doing all drugs.

The Panel found several instances where poorly substantiated instructions or even casual advice from AFIP was adopted by The Surgeon General's office or by the laboratories themselves. A clear example was the recommendation in October 1983 to change the extraction pH in the cannabinoid confirmation assay to pH 9. The Panel also concluded that AFIP's limited exposure to the laboratories and limited experience in high volume operations have hampered their ability to provide fully needed expert advice on all DTL matters.

(5) Panel Recommendations on AFIP.

Advice on new methods or changes in existing methods should not be provided directly by AFIP to the laboratories, but must be provided by an appropriately constituted body that can thoroughly review and conduct a proper evaluation before field implementation.

Serious and immediate consideration must be given to determining what the best system for handling AFIP positive samples will be--perhaps shipping positive samples directly to laboratories, tailoring the positive samples to match the laboratory testing regime, or developing a graded series of positive samples which would really challenge laboratory sensitivity capabilities.

OVERALL PANEL RECOMMENDATIONS

The major recommendations of the Panel are listed below. Other recommendations have already been cited above and are summarized in Appendix K.

- a. At DA level a full-time staff element, headed by a senior officer with expertise in drug testing must be available to the OTSG. This will provide long range, coordinated, knowledgeable planning; detect early indicators of potential difficulty; and coordinate effectively with the US Navy and Air Force programs. Additionally, the DCSPER must control and direct the drug testing program among the OTSG, OTJAG, and ODCSPER elements.
- b. The current ambiguities as to who does, can and must direct the DTLs must be clarified by OTSG and, once clarified, each level of command must develop the requisite qualified staffs to support, direct and review the DTLs. Supervision, approval of changes, and direction must flow up and down the designated chain of command rather than on the present ad hoc basis.
- c. A system of proficiency testing, laboratory certification, and routine laboratory inspections must be established similar to other professional accreditation programs within OTSG.
- d. The Health Services Command must plan now for the training of laboratory officers, NCO's and specialists who will begin major turnovers in 1984-85. In addition, a short orientation course(s) must be mandatory for personnel being newly assigned to DTLs.
- e. The DA should recommend to OSD that the DoD Biochemical Testing Advisory Committee must become more active in resolving many of the technical difficulties cited in this report.
- f. If the DA wishes to maintain or increase the current amount/level of drug use detection, additional resources (in staff, facilities, and equipment) must be provided in a well coordinated manner. Key priorities are in staff training, facility upgrading, and automation. Current plans to add mass spectral detectors to the existing GC equipment must be delayed until proper personnel training and facility support is completed. Short-term improvements in automation could be accomplished quickly by providing requisite travel authorities and minimum equipment procurement to the DTLs.
- g. Commands with DTLs assigned must review their support agreements with the tenant commands so that facilities, logistics and maintenance support are given the same coordinated priorities

as are used in setting workloads and in procuring new and added equipment. Similarly commands must arrange for continuing legal advice and physical security support.

h. An Army SOP that includes all the drug testing issues, must be adopted after peer review and validation. (The 27 September 1983 revised DA SOP has been reviewed and found not properly validated). Each laboratory must be tasked to validate its ability to perform each method with vigorous quality control. A knowledgeable element (within the OTSG) must be tasked to review and achieve validation by at least one laboratory. The system should be relatively fast acting, such as is used in making other critically sensitive changes in aviation SOPs when an accident indicates they should be changed.

i. Each DTL must have a fully operational quality assurance organization.

j. Where training cannot be provided, strong consideration should be given to using TDY (as was done at Brooks AFB to make a quick workload change), or using excess authorizations of qualified officers, NCO's, and operator specialists until proper training can be provided.

k. DTLs must hold frequent technical meetings to exchange mutual problems, mutual successes, and develop standardized procedures.

l. The direct role of AFIP with the DTLs should be limited to its present QC program; with its technical advisory role being to advise the Surgeon General and OASD(HA). The DTLs should be informed as to AFIP's role.

m. The use of PBA as an internal standard with an OV-1 or SE30 column must be adopted. The Panel has concluded that a 50 ng/ml GC cutoff can be instituted upon the proper documentation of PBA internal standards by each DTL.

n. From a management viewpoint, the DA should choose a cutoff level for reporting which does two things--assures no false positives with the system and procedures chosen, and assures confirmation of those persons who are actually using the drug. For instance a much lower level cutoff can be selected, when GC/MS is mandated than can be chosen if GC is used. However, it would be extremely unwise to select a lower-level cutoff for reporting without the laboratory being able to prove that its overall accuracy/precision is such that it can with high confidence assure that the lowest confirmed positive reading is well above the statistical level expected for a zero level.

o. Command emphasis is needed to develop a standard integrated system of data reduction to include uniformity of

hardware and software within the DTL program. Planning, programming and scheduled implementation of ADP equipment is confusing to laboratory managers, is not understood, and lacks field input as to purpose and results desired. This is the number one priority overall, except for validation of technical procedures.

p. High priority should be given to implementing an adequate GC/MS capability in each DTL. Primarily this will involve providing needed facility support, maintenance, and operator training.

q. The panel found no evidence of false THC positives in specimens which had positive RIA screens and positive GC confirmations. Based on the apparent high correlation of confirmation rates by GC/MS of RIA plus GC positive rate, the panel believes that a positive RIA plus a positive GC confirmation is a scientifically credible confirmation for the presence of THC, which should be legally credible unless the most stringent interpretations of legal sufficiency are applied. The OTSG should take firm action to document the degree of correlation between GC/MS confirmations and RIA plus GC confirmation. With such corroboration, there should be increased acceptance of the scientific and legal sufficiency of RIA plus GC confirmation.

LEGAL ADDENDUM

LEGAL ADDENDUM

In the past few months, some questions have arisen about the accuracy of the urinalysis testing procedures currently employed by the Department of the Army. To resolve these questions, the Deputy Surgeon General of the Army appointed a blue ribbon panel to review those testing procedures. The panel's mission has been to study the scientific and technical aspects of the procedures. My complementary mission has been to review the panel's reports and prepare a legal addendum to the reports.

This addendum discusses the evidentiary problems posed by the introduction of urinalysis test results in characterization of discharge actions and courts-martial. With respect to both types of proceedings, this memorandum addresses three basic questions: (1) Are the test results of RIA and GC procedures admissible evidence in the proceeding? (2) Is the cumulative probative value of RIA and GC procedures sufficient to sustain a discharge or conviction? and (3) If the discharge or conviction satisfies the military admissibility and sufficiency standards, will the discharge or conviction withstand collateral attack in civilian courts?

I. ADMINISTRATIVE BOARD PROCEEDINGS

A. Admissibility

Paragraph 2-11 of Army Regulation 635-200 (1 Oct. 1982) governs the admissibility of evidence in board proceedings. That paragraph reads:

Presentation of evidence. The rules of evidence for court-martial and other judicial proceedings are not applicable before an administrative board. Reasonable restrictions will be observed, however, concerning relevancy and competency of evidence.

Paragraph 3-7 of Army Regulation 15-6 (15 June 1981) is to the same effect. Thus, the only absolute requirement for admissibility in a board proceeding is relevance.

Even if we construe "relevancy" in Paragraph 2-11 as it is technically interpreted in the law of evidence, RIA and GC tests should be admitted in board proceedings. The law of evidence demands that an item of evidence be relevant in two senses. First, the item of evidence must be relevant to the material facts in dispute. Military Rule of Evidence 401 describes the materiality requirement in this fashion:

"Relevant evidence" means evidence having any tendency to make the existence of any fact that is of consequence to the determination of the action more probable or less probable than it would be without the evidence.

RIA and GC test results satisfy this requirement. In a board proceeding, the government would offer the test results to strengthen the inference that the respondent had ingested contraband drugs, and the test results have a tendency in reason to show precisely that.

The law of evidence requires relevancy in a second sense: authentication or underlying probative value. Military Rule of Evidence 104(b) states:

When the relevancy of evidence depends upon the fulfillment of a condition of fact, the military judge shall admit it upon, or subject to, the introduction of evidence sufficient to support a finding of the fulfillment of the condition.

Military Rule 901(b) illustrates the types of facts governed by Rule 104(b). Military Rule 901(b) (9) specifically provides that:

(T)he following are examples of authentication . . . conforming with the requirements of this rule . . . : Process or system. Evidence describing a process or system used to produce a result and showing that the process or system produces an accurate result.

The commentators uniformly interpret "process or system" as including scientific techniques. 5 D. LOUISELL & C. MUELLER, FEDERAL EVIDENCE §522 (1981); 5 J. WEINSTEIN & M. BERGER, WEINSTEIN'S EVIDENCE ¶901(b) (9) (01)-(Q3) (1983).

There is no logical necessity for requiring relevance in this second sense. C. MCCORMICK, HANDBOOK OF THE LAW OF EVIDENCE § 218 (2d ed. 1972). "In the everyday affairs of business and social life, it is the custom" to accept physical objects such as writings at face value; if we receive a letter purportedly authored by someone, we usually assume that the letter is genuine even absent evidence of authenticity. *Id.* For that reason, it would be possible in board proceedings to dispense with proof of authentication without violating Paragraph 3-7.

However, the skepticism of the common law of evidence is so ingrained that even in board proceedings, authentication is often required. If authentication of RIA and GC results were required, RIA and GC tests would pass muster. As we shall see later in this memorandum, the RIA and GC techniques are methods of helping to identify chemical compounds. If a qualified expert vouched for the

usefulness of RIA and GC tests in helping to make that determination, the expert's voucher would satisfy Military Rules of Evidence 104(b) and 901(b) (9). The testimony would unquestionably satisfy the laxer standards applied in board proceedings under Army Regulations 15-6 and 635-200.

B. Sufficiency

Army Regulations 15-6 and 635-200 also specify the standards for evaluating the cumulative sufficiency of the evidence in board proceedings. Paragraph 3-10b of Army Regulation 15-6 is in point:

Unless another directive or an instruction of the appointing authority establishes a different standard, the findings of investigations and boards governed by this regulation must be supported by substantial evidence and by a greater weight of evidence than supports any different conclusion.

Paragraph 2-12a(1) clarifies the standard applicable to proceedings to separate enlisted personnel: The board will determine whether each allegation in the notice of proposed separation is supported by a preponderance of the evidence.

The cumulative probative value of a combination of RIA and GC tests is sufficient to establish by a preponderance of the evidence that the substance detected in a urine sample is a contraband drug. On the one hand, as we shall see later in this memorandum, even the combination of positive RIA and GC tests may not be specific for a particular drug. There is a good theoretical possibility that there are other drugs that will yield the same set of test results. On the other hand, again as we shall indicate later, there is hard evidence that the combination of tests is relatively specific. Major General Einsel's October 27, 1983 memorandum to the Deputy Surgeon General points out that "the Meade Compuchem GC/MS retest of 816 samples" at the Fort Meade Drug Urinalysis Test Center "showed (the) presence of THC metabolite" in 812 samples. After agreeing to serve as consultant to this committee, I contacted one of my former students, Marine Captain Terrence Brown who had served as JAG Liason Officer for the Naval Drug Screening Laboratory in San Diego. That laboratory uses RIA and GLC, and Captain Brown informs me that in one test, 99.7% of the positive RIA-GLC results were confirmed by GC/MS. In view of the state of the scientific record, a trier of fact could rationally conclude that positive RIA-GC results establish the identity of a contraband drug by a preponderance of the evidence.

C. Collateral Attack

Even at this late date, the civilian courts have not settled the question of the appropriate scope of their review of military administrative actions such as discharges. All the courts concur that the civilian courts must generally defer to military authorities' administrative decisions. Rucker v. Secretary of the Army, 702 F.2d 966, 969 (11th Cir. 1983). The civilian courts realize that if they routinely intruded into internal military affairs, their interference "might stultify the military in the performance of its vital mission." Mindes v. Seaman, 453 F.2d 197, 199 (5th Cir. 1971).

Although the courts agree on the general need for deference to military administrative decisions, the courts have used different tests to identify the rare circumstances in which they will overturn a military decision. One line of authority opts for the view that the civilian courts can invalidate military administrative action only when the action is arbitrary or capricious. Cherry v. United States, 697 F.2d 1043 (Fed. Cir. 1983); Love v. Hidalgo, 508 F.Supp. 177, 180 (D.Md. 1981). Another line of authority adopts a broader scope of review; the courts subscribing to this view assert the power to invalidate military administrative action if the action is not supported by substantial evidence. Sidoran v. Commissioner of Internal Revenue, 640 F.2d 231, 233 (9th Cir. 1981); Jackson v. Allen, 553 F.Supp. 528, 530 (D.Mass. 1982).

Under either standard, the civilian courts would ordinarily sustain an administrative discharge based on positive RIA-GC test results. Such a discharge could not be characterized as an arbitrary or capricious decision. As a matter of policy, it is eminently rational for the military to discharge persons who ingest contraband drugs; and given the state of the scientific record, it is rational to treat positive RIA-GC test results as evidence of the use of contraband drugs. Even if the civilian court applied the more rigorous, substantial evidence standard, the discharge could withstand scrutiny. Some courts declare that the substantial evidence test demands more than a scintilla of evidence to sustain the challenged action. Community Hospital of Indianapolis, Inc. v. Schweiker, 717 F.2d 372 (7th Cir. 1983). Yet, even these courts concede that substantial evidence is not even necessarily a preponderance of the evidence. Id. The substantial evidence test is satisfied if, considering the administrative record as a whole, a reasonable mind might accept the evidence as sufficient to support a given

conclusion. Id. A reasonable person might accept positive RIA-GC test results as adequate to support an administrative discharge based on use of contraband drugs. Thus, the discharge would be sustainable under both lines of legal authority.

II. COURT-MARTIAL PROCEEDINGS

The admissibility and sufficiency of RIA and GC tests in courts-martial are closer, more troublesome questions than their admissibility and sufficiency in administrative board proceedings.

A. Admissibility

The legal standards governing admissibility

As noted in our discussion of the admissibility of test results in board proceedings, the law of evidence demands relevance in two senses. The first sense is materiality, codified in Military Rule of Evidence 401. To be admissible in a court-martial, an item of evidence must tend "to make the existence of a fact . . . of consequence more probable or less probable than it would be without the evidence." Rule 401 requires that the proponent of an item of evidence in a court-martial demonstrate the item's materiality.

It is the second sense of logical relevance that can pose serious obstacles to the admission of scientific evidence: underlying logical relevance or authentication. The point of agreement is that Military Rule of Evidence 901(b) (9) will require some proof of the validity of any proffered scientific technique. The point of dispute is whether the proponent must present more than the individual expert's voucher that the scientific technique is valid. The focal point of controversy is the wisdom of the test announced in Frye v. United States, 293 F. 1013 (D.C.Cir. 1923). In Frye, the defense offered evidence based on a forerunner of polygraph, the systolic blood pressure test. The trial judge excluded the evidence, and the appellate court affirmed the trial judge's ruling. In affirming, the appellate court declared:

Just when a scientific principle or discovery crosses the line between the experimental and demonstrable stages is difficult to define. Somewhere in this twilight zone the evidential force of the principle must be recognized, and while courts will go a long way in admitting expert testimony deduced from a well-recognized scientific principle or discovery, the thing from

which the deduction is made must be sufficiently established to have gained general acceptance in the particular field in which it belongs. Id. at 1014.

In Frye, the appellate court found that there was insufficient proof of the general acceptance of the systolic blood pressure test. Hence, the trial judge properly ruled the evidence to be inadmissible.

Until recently, Frye was virtually the universal view among American courts. The overwhelming number of state courts and federal courts of appeal followed Frye. Giannelli, "The Admissibility of Novel Scientific Evidence: Frye v. United States, a Half-Century Later," 80 Columbia Law Review 1197 (1980). Frye seemed to be the controlling test in at least forty-five states. Note, 40 Ohio State Law Journal 757, 769 (1979).

However, Frye has been subjected to severe criticism. Giannelli, "The Admissibility of Novel Scientific Evidence: Frye v. United States, a Half-Century Later," 80 Columbia Law Review 1197 (1980). The criticisms include the charges that: It is sometimes difficult to identify the relevant scientific circle; the standard, "general acceptance," is ambiguous; and Frye leads to the exclusion of too much relevant, reliable scientific proof that could contribute to the search for truth. Id. In light of these criticisms, there has been substantial movement away from the Frye standard within the past few years. Some courts have abandoned Frye by case law. Coppolino v. State, 223 So.2d 68 (Fla. Dist. Ct. App. 1968), appeal dismissed, 234 So.2d 120 (Fla. 1969), cert. denied, 399 U.S. 927 (1970); Harper v. State, 249 Ga. 519, 292 S.E.2d 389 (1982); State v. Hall, 297 N.W.2d 80 (Iowa 1980), cert. denied, 450 U.S. 927 (1981); Brown v. Commonwealth, 639 S.W.2d 758 (Ky. 1982); State v. Catanese, 368 So.2d 975, 978-81 (La. 1979); People v. Young, 106 Mich. App. 323, 308 N.W.2d 194 (Ct. App. 1981); People v. Daniels, 102 Misc.2d 540, 422 N.Y.S.2d 832 (Sup. Ct. 1979); State v. Kersting, 50 Or. App. 461, 623 P.2d 1095 (1981), aff'd, 292 Or. 350, 638 P.2d 1145 (1982); Phillips v. Jackson, 615 P.2d 1228 (Utah 1980); Cullin v. State, 565 P.2d 445, 458 (Wyo. 1977). In other jurisdictions, the courts have invalidated Frye on constitutional grounds to admit relevant defense scientific evidence. State v. Dorsey, 87 N.M. 323, 532 P.2d 912 (Ct. App. 1975), aff'd, 88 N.M. 184, 539 P.2d 204 (1975); State v. Sims, 52 Ohio Misc. 31, 369 N.E.2d 24 (C.P. Cuyahoga County 1977).

While some courts have invoked their common-law powers or constitutional theories to overrule Frye, the most important theory for our purposes is the statutory abolition of Frye. Statutes purporting to liberally admit all relevant evidence may impliedly abolish Frye. Uelmen, "Proposition 8 Casts Uncertainty over Vast Areas of Criminal Law," California Lawyer, July/Aug. 1982, at 45. In particular, some courts have already concluded that the Federal Rules of Evidence and the state modes modeled after the Rules impliedly overturn Frye. United States v. Williams, 583 F.2d 1194 (2d Cir. 1978), cert. denied, 439 U.S. 1117 (1979); United States v. Dorfman, 532 F.Supp. 1118, 1134 n. 14 (N.D.Ill. 1981); Barmeyer v. Montana Power Co., 657 P.2d 594 (Mont. 1983); State v. Williams, 4 Ohio St.3d 53, 446 N.E.2d 444 (1983); State v. Williams, 388 A.2d 500 (Me. 1978); Romero, "The Admissibility of Scientific Evidence Under the New Mexico and Federal Rules of Evidence," 6 New Mexico Law Review 187 (1976).

This statutory theory is pertinent to our inquiry because the military has largely adopted the Federal Rules of Evidence, renamed the Military Rules of Evidence. In construing the Military Rules of Evidence, the United States Court of Military Appeals should probably conclude that Frye is no longer good law in courts-martial. The Court of Military Appeals should reach that conclusion for several reasons.

In adopting the Military Rules of Evidence, the military accepted the liberal standards for expert opinion testimony set out in Article VII. "Nothing in (Article VII) requires that expert testimony be based on scientific principles that are generally accepted in the scientific community." S. SALTZBURG, L. SCHINASI & D. SCHLUETER, MILITARY RULES OF EVIDENCE MANUAL 324 (1981).

It might be contended that the absence of any mention of the general acceptance standard in Article VII merely creates an ambiguity in the Military Rules. However, there is a built-in bias in favor of admissibility in the Rules, and the Rules make it clear how ambiguity is to be resolved; like the corresponding Federal Rules of Evidence, Military Rule of Evidence 402 states:

All relevant evidence is admissible, except as otherwise provided by the Constitution of the United States as applied to members of the armed forces, the Uniform Code of Military Justice, these rules, this Manual, or any Act of Congress applicable to members of the armed forces.

The Drafters' Analysis of Rule 702 shows that the Drafters of Military Rule 702 realized that there was a controversy over the continued vitality of the Frye rule when the Military Rules were adopted. S. SALTZBURG, L. SCHINASI, & D. SCHLUETER, MILITARY RULES OF EVIDENCE MANUAL 325 (1981). Although the legislative history of the Federal Rules is silent on this question, the history of the Military Rules conclusively demonstrates that the Drafters were cognizant of the controversy and could have chosen to write Frye into Article VII. In light of Rule 402, the Drafters' omission points to the conclusion that Frye has been impliedly overruled in military courts-martial.

One counterargument is that the judges can continue to apply Frye as a gloss on Military Rule 403:

Although relevant, evidence may be excluded if its probative value is substantially outweighed by the danger of unfair prejudice, confusion of the issues, or misleading the members, or by considerations of undue delay, waste of time, or needless presentation of cumulative evidence.

This counterargument is flawed. In the reported civilian decisions, the trial judge typically uses Rule 403 as authority to balance the probative value of an item of evidence against attendant probative dangers on an ad hoc, case-by-case basis. C. McCORMICK, HANDBOOK OF THE LAW OF EVIDENCE §185, at 440 (2d ed. 1972). Reading Rule 403 more broadly, that is, treating it as a basis for formulating a general rule applicable to a whole category of cases, would put Rule 403 at odds with Rule 402. Rule 402 provides that relevant evidence is admissible except as provided by certain sources, including "these rules." Rule 402's list of sources omits case or decisional law. The legislative history of the rule indicates that the omission was purposeful. United States v. Grajeda, 570 F.2d 872, 874 (9th Cir. 1978); 21 C. WRIGHT & K. GRAHAM, FEDERAL PRACTICE AND PROCEDURE: EVIDENCE 219, 222-23 (1978); 21 C. WRIGHT & K. GRAHAM, FEDERAL PRACTICE AND PROCEDURE: EVIDENCE 88 (Supp. 1982). By omitting case law from the list, Congress expressed its desire to deprive the trial judge of the power to create new, general rules of evidence. Id. Since Rules 402 and 403 are part of the same statutory scheme, they must be reconciled. 2A C. SUTHERLAND, STATUTORY CONSTRUCTION ch. 51 (1973). If trial judges could rely upon Rule 403 as a source of authority to create new general evidentiary rules, Rule 403 would swallow up and frustrate Rule 402. The best harmonization of the two statutes is the interpretation that Rule 403 was never intended to serve as the origin of evidentiary rules of general applicability; sensibly construed, Rule 403 contemplates case-by-case decisions by the judge.

Therefore, we cannot look to Rule 403 as a justification for continuing to enforce Frye. In a particular case the judge may exercise his or her power under Rule 403 to exclude scientific evidence for one of the stated probative dangers; but the regime of Frye has apparently ended in military practice.

The application of the legal admissibility standards to RIA, GC, and GC/MS tests

RIA, GC, and GC/MS tests patently satisfy the requirement of logical relevance in the sense of materiality. The test is: "(D)oes the evidence offered render the desired inference more probable than it would be without the evidence?" C. McCORMICK, HANDBOOK OF THE LAW OF EVIDENCE §185, at 437 (2d ed. 1972). Forensic experts regard a positive GC/MS test as a positive identification. A positive GC/MS test is relevant in the extreme. Although neither an RIA test nor a GC test is specific for a particular drug, RIA and GC test results are material. All experts agree that while false positives are possible, neither an RIA test nor a GC test would yield a positive result with all substances in urine samples; some substances found in urine samples would definitely not yield an apparently positive result. Thus, even if the individual tests are nonspecific, a positive RIA or GC test at least raises the probability that the subject ingested a contraband drug. Any increase in that probability renders the test result material. Id.

The application of the underlying relevance or authentication requirement to RIA, GC, and GC/MS tests requires more extended analysis. We shall examine the admissibility of RIA, GC, and GC/MS tests on three different assumptions: (1) The military courts conclude that Frye is no longer good law; (2) the military courts continue to enforce Frye and interpret Frye as demanding proof that RIA, GC, and GC/MS tests are generally accepted in scientific circles as fact-finding techniques; and (3) the courts not only continue to adhere to Frye but also construe Frye as necessitating proof that RIA, GC, and GC/MS tests are generally accepted as identification techniques rather than merely as helpful fact-finding tools.

As previously stated, I believe that the first assumption is the conclusion that the military courts should reach under the new Military Rules of Evidence. On that assumption, RIA, GC, and GC/MS test results would be readily admissible. Numerous experts have already written and would testify that in their opinion, RIA, GC, and GC/MS tests are helpful in determining whether a substance in a

urine sample is a contraband drug. If Frye is no longer good law, that testimony should be a sufficient foundation to satisfy Military Rule of Evidence 901.

Although I believe that the first assumption represents the soundest interpretation of the Military Rules of Evidence, it is possible that the military courts will embrace the second assumption, namely, Frye survived the adoption of the Rules and requires that the proponent of scientific evidence demonstrate the general acceptance of the scientific technique. My conversations and correspondence with Army and Navy judge advocates during the past year lead me to believe that a fair number of military judges are proceeding on this assumption. Chief Judge Everett apparently shares the assumption that Frye is still good law in military practice. United States v. Moore, 15 M.J. 354, 372-73 (CMA 1983) (C.J. Everett, dissenting). Moreover, absent clear guidance from the Court of Military Appeals that Frye has been invalidated, the Courts of Military Review feel compelled to insist on proof of general acceptance. United States v. Bothwell, CM # 443219 (ACMR 1983); United States v. Dodson, 16 M.J. 921, 930 (NMCMR 1983).

On this assumption, at the very least the trial counsel offering RIA, GC, or GC/MS test results would have to show that those tests are generally accepted as fact-finding tools. The courts distinguish between the general acceptance of scientific techniques for clinical and investigative purposes. For example, in a leading case applying Frye, the California Supreme Court drew that distinction. In People v. Shirley, 31 Cal.3d 18, 641 P.2d 775, 181 Cal. Rptr. 243 (1982), the California court analyzed the admissibility of testimony by witnesses with hypnotically enhanced memories. The court acknowledged that hypnosis is widely accepted in medical circles as a therapeutic tool. However, the court stressed that to satisfy Frye and qualify for admission in a court of law, a scientific technique must be accepted as a fact-finding tool. The same distinction has been made in People v. Gonzales, 415 Mich. 615, 329 N.W.2d 743 (1982), State v. Saldana, 324 N.W.2d 227 (Minn. 1982), and State v. McGee, 324 N.W.2d 232 (Minn. 1982).

RIA, GC, and GC/MS tests can satisfy this interpretation of Frye. Numerous scientific texts list RIA as a fact-finding tool for identifying illicit drugs. A. DELAAT, PRIMER OF SEROLOGY 108 (1976); H. EISEN, IMMUNOLOGY: AN INTRODUCTION TO MOLECULAR AND CELLULAR PRINCIPLES OF THE IMMUNE RESPONSES 395 (1974); Lorenzo, "Radioimmunoassay (RIA)," in METHODOLOGY FOR ANALYTICAL TOXICOLOGY 404

(I. Sunshine, ed. 1975). Some texts assert that GC can provide "prima facie evidence of the identity of a compound." G. EWING, INSTRUMENTAL METHODS OF CHEMICAL ANALYSIS 364 (4th ed. 1975). Virtually the entire scientific community attests to the great utility of GC/MS as a tool for identifying drugs. Stein, Laessig & Indriksons, "An Evaluation of Drug Testing Procedures Used by Forensic Laboratories and the Qualifications of Their Analysts," 1973 Wisconsin Law Review 727.

In light of the widespread acceptance of RIA, GC, and GC/MS tests as fact-finding tools, it is not surprising that there is a wealth of case law admitting or at least considering such evidence. See, e.g., In re Farrenkopf, 713 F.2d 714 (Fed. Cir. 1983) (RIA); Robinson v. United States, 533 F.Supp. 320 (E.D.Mich. 1982) (RIA); Migliorini v. United States, 521 F.Supp. 1210 (M.D.Fla. 1981) (RIA); State v. McDougall, 308 N.C. 1 (1983) (RIA); United States v. Distler, 671 F.2d 954 (6th Cir. 1981) (GC); State v. Smith, 656 S.W.2d 297 (Mo.App. 1983) (GC/MS). In short, even on the assumption that the courts continue to enforce this version of Frye, RIA, GC, and GC/MS test results should be admissible.

However, on the third and last assumption, it is doubtful whether RIA and GC test results would be admissible. The assumption is that the courts will not only apply Frye but enforce an extreme version of Frye, namely, a requirement that the scientific technique be accepted as an identification test rather than a screening procedure. My conversations and correspondence with Army and Navy judge advocates lead me to believe that a few trial judges have embraced this view and excluded either RIA or GC evidence on that ground.

If this interpretation of Frye were sound, it would indeed be difficult to justify introducing RIA or GC test results. One commentator asserts that RIA is so nonspecific that "there is great need to confirm all positive (RIA) results by some other procedure" to adequately identify a drug. Lorenzo, "Radioimmunoassay (RIA)," in METHODOLOGY FOR ANALYTICAL TOXICOLOGY 404 (I. Sunshine, ed. 1975). Stein, Laessig, and Indriksons state "without qualification that retention times (in GC tests) are not proof of identification unless they are supported by other evidence." Stein, Laessig & Indriksons, "An Evaluation of Drug Testing Procedures by Forensic Laboratories and the Qualifications of Their Analysts," 1973 Wisconsin Law Review 727, 752. They assert that GLC should "not be relied on for identification." Id. at 753. It is frequently observed that "chromatography is a means

of separation, not of identification." Kurzman & Fullerton, "Winning Strategies for Defense of Marijuana Cases: Chemical and Botanical Issues," 1 National Journal of Criminal Defense 487, 529 (1975). If as a condition precedent to admission the proponent must demonstrate the general acceptance of the technique as an identification test, probably only GC/MS evidence would be admissible.

However, this interpretation of Frye is unsound. The Shirley, Gonzales, Saldana, and McGee cases go as far as any appellate courts have gone in extending Frye, and they require only that the proponent show that the scientific technique is generally accepted as a fact-finding tool; they do not demand that the proponent establish that the result of the individual technique be generally accepted as sufficient to prove the fact in issue. This spurious version of Frye confuses the tests for admissibility and sufficiency. To sustain a conviction, the trial counsel must show that the cumulative probative value of the prosecution evidence - the combined weight of the RIA, GC, and GC/MS evidence - is sufficient to meet the government's burden of going forward. However, our focus now is the admissibility of an individual item of scientific evidence -- not the question whether the defense is entitled to a finding of not guilty at the close of the prosecution's case-in-chief. Requiring proof of the general acceptance of RIA or GC as a drug identification test as a condition precedent to the admission of those tests would be excessive and unwarranted.

In short, unless the military courts ultimately adopt the most extreme version of Frye, RIA, GC, and GC/MS test results should be admissible in courts-martial. Experts can be found to vouch for all three techniques, and those experts can truthfully testify that all three techniques are helpful fact-finding tools in attempting to identify illicit substances in urine samples. Whether the Military Rules abolish Frye or the military courts apply a moderate version of Frye, RIA, GC, and GC/MS tests all can surmount the admissibility hurdle.

B. Sufficiency

The legal standards governing sufficiency

We turn now from the question of the admissibility of the individual test results to the issue of the cumulative sufficiency of the prosecution evidence to defeat a defense motion for a finding of not guilty. Before we reach the merits of that issue, it is important to stress the nature of the issue: legal sufficiency. The standard for

assessing the sufficiency of the evidence is a legal one rather than a scientific one. When mental health professionals testify about a person's competency or sanity, the courts force them to employ legal concepts such as the M'Naghton test. This context is analogous. The issue is not whether the scientific tests establish an exact, 100% mathematical certitude of the identity of the substances in the defendant's urine sample; rather the issue is whether the scientific evidence satisfies the test that the law has formulated.

Paragraph 71a of the MANUAL FOR COURTS-MARTIAL, UNITED STATES, 1969 (Rev.Ed.) states one legal test for the sufficiency of the prosecution's evidence. That paragraph discusses defense motions for findings of not guilty. In pertinent part, the paragraph reads:

If there is any evidence which, together with all inferences which can properly be drawn therefrom and all applicable presumptions, could reasonably tend to establish every essential element of an offense charged or included in any specification to which the motion is directed, the motion will be granted.

Paragraph 71a announces a relatively lax test for assessing the sufficiency of the prosecution evidence. Applying a similar test, many civilian courts have rejected defense attacks on the sufficiency of the prosecution's evidence of an alleged contraband drug's identity in criminal cases. People v. Brisco, 78 Ill.App.3d 282, 33 Ill. Dec. 827, 397 N.E.2d 160 (1979), is a case in point. In Brisco, the question was the legal sufficiency of the prosecution's evidence identifying the contraband substance as cannabis. The prosecution's criminalist conducted only Duquesnois-Levine and microscopic tests. The criminalist testified that "he knows of no substance other than cannabis sativa which gives a positive reaction to both the Duquesnois with the Levine modification and the microscopic examination." Professor Marc Kurzman testified for the defense in Brisco. Kurzman characterized both the Duquesnois-Levine and microscopic techniques as mere screening tests. According to Kurzman, "One could not say with any degree of scientific certainty that a substance showing positive on both the Duquesnois-Levine and the carbon dioxide test is cannabis. If a substance passed both the Duquesnois-Levine and microscopic tests one could say with only a 5% certainty that it was cannabis." On this state of the record, the appellate court held the prosecution evidence to be sufficient and affirmed the conviction. The court stressed the criminalist's testimony that "he knew of no substance other than cannabis which would evoke positive reactions to both tests."

With Brisco as a benchmark, it seems likely that the cumulative probative value of RIA and GC tests would satisfy the standard stated in paragraph 71 of the Manual. Like the criminalist in Brisco, there are experts prepared to testify that to date, they have identified no other substances that yield positive results on both RIA and GC. Indeed, in Brisco, one of the defense arguments was that the criminalist had failed to resort to GC testing.

If it were clear that paragraph 71a still stated the governing standard in military practice, we could conclude our analysis of the legal sufficiency standards at this point. However, paragraph 71a may have been superseded by Jackson v. Virginia, 443 U.S. 307 (1979). Jackson was a federal habeas corpus petition challenging a state court conviction. One of the petitioner's attacks was on the sufficiency of the evidence to support the conviction. In response to that attack, the state invoked the "no evidence" rule of Thompson v. Louisville, 362 U.S. 199 (1960); the state argued that the federal court could grant habeas corpus relief only if there was no evidence tending to support the conviction. In Jackson, the Court overruled Thompson. Relying heavily on In re Winship, 397 U.S. 358 (1970), the Court pronounced a new, more rigorous test:

(T)he relevant question is whether, after viewing the evidence in the light most favorable to the prosecution, any rational trier of fact could have found the essential elements of the crime beyond a reasonable doubt. Once a defendant has been found guilty of the crime charged, the factfinder's role as weigher of the evidence is preserved through a legal conclusion that upon judicial review, all of the evidence is to be considered in the light most favorable to the prosecution.

Jackson holds that in criminal cases, due process mandates that the trial judge inquire whether, given all the evidence in the record, a rational juror would necessarily have a lingering, reasonable doubt about any element of the charged crime. C. McCORMICK, HANDBOOK OF THE LAW OF EVIDENCE §338, at 790 (2d ed. 1972).

Although paragraph 71a of the MANUAL FOR COURTS-MARTIAL, UNITED STATES, 1969 (Rev.Ed.) has not been amended, there are numerous indications that the military courts have embraced Jackson as the standard for evaluating the legal sufficiency of the evidence in courts-martial. The Coast Guard Court of Military Review cited Jackson in United States v. Kennedy, 11 M.J. 669 (CGCMR 1981). Both Chief Judge Everett and Judge Perry have relied on Jackson in dissenting opinions: United States v. Moore, 15 M.J.

354, 372 (CMA 1983) (C.J. Everett, dissenting); Powers, 12 M.J. 398 (CMA 1982) (C.J. Everett, dissenting); Perry, 12 M.J. 96 (CMA 1981) (C.J. Everett, dissenting); United States v. McConnico, 7 M.J. 302, 310 (CMA 1979) (J. Perry, dissenting). The Court of Military Appeals as a whole has invoked Jackson in summary dispositions: United States v. Woodrum, 10 M.J. 329 (CMA 1981); United States v. Moss, 10 M.J. 329 (CMA 1981). Finally, in its recent decision in United States v. Matthews, 13 M.J. 501, 528 (ACMR 1982), the Army Court of Military Review advanced a justification for applying Jackson to courts-martial:

Unlike most civilian appellate courts, the Courts of Military Review have independent fact-finding authority. They may not affirm a finding of guilty based upon a conclusion merely that the findings of the trial court are reasonably supported by the evidence of record, but rather they must be convinced of the appellant's guilty beyond a reasonable doubt. See Jackson v. Virginia, 443 U.S. 307 . . . (1979)

The military courts may ultimately conclude that due process compels them to follow Jackson. Alternatively, as in Matthews, the military courts may reason that the unique fact-finding powers of the Courts of Military Review warrant the extension of Jackson to courts-martial. In any event, there is a definite trend toward the use of the Jackson standard in military law. For the balance of this memorandum, we shall assume that Jackson is the governing standard: Is the prosecution's evidence legally insufficient in the sense that, considering all the evidence in the record, a rational court member or juror would necessarily have a lingering, reasonable doubt about the identity of the substance detected in the accused's urine sample?

The application of the legal sufficiency standards to the individual tests: RIC, GC, and GC/MS

We shall initially apply the Jackson standard to each individual scientific test: RIA, then GC, and finally GC/MS.

If the trial counsel relies solely on an RIA test, it seems doubtful that the prosecution evidence could satisfy Jackson. One commentator has written:

The greatest defect (of RIA) is specificity or lack thereof Very few antisera exist that are specific for one compound, although some have been prepared with very high specificity when cost was no object. Hence, there is great need to confirm all positive results by some other procedure if

specificity is important. Lorenzo, "Radioimmunoassay (RIA)," in METHODOLOGY FOR ANALYTICAL TOXICOLOGY 404 (I. Sunshine, ed. 1975).

In two articles, a member of this committee, Doctor Mahmoud ElSohly, has stressed the "non-specificity" of RIA and the need "for confirmation of the results obtained by the immunoassay methods." "Analysis of the Major Metabolite of Δ^9 -Tetrahydrocannabinol in Urine. III. A GC/ECD Procedure;" "Analysis of the Major Metabolite of Δ^9 -Tetrahydrocannabinol in Urine. II. A HPLC Procedure." Hence, it is highly debatable whether standing alone, an RIA test could satisfy Jackson and defeat a motion for a finding of not guilty. A recent Massachusetts case held that even in a prison disciplinary hearing where the government has a lower burden of proof, a similar, EMIT test would have to be "confirmed by an alternative method of analysis." Kane v. Fair, 33 Crim. L. Rep. (BNA) 2492 (Mass.Super.Ct. Aug. 5, 1983).

Similarly, it is questionable whether standing alone, a GC or GLC analysis could meet the Jackson test. The number of chemical compounds is so large that it is possible that many compounds will have the same retention time. Shapiro, "Chemical Defenses in Drug Cases," 2 National Journal of Criminal Defense 117, 136 (1976); A. MOENSSENS & F. INBAU, SCIENTIFIC EVIDENCE IN CRIMINAL CASES §6.05, at 289 (2d ed. 1978). One textwriter remarks that GC is "one of the quickest ways of getting the wrong answer -- in qualitative analysis." D. AMBROSE, GAS CHROMATOGRAPHY 235 (1971). GC "will seldom go further than to identify the class to which a compound belongs." G. EWING, INSTRUMENTAL METHODS OF CHEMICAL ANALYSIS 381 (4th ed. 1975). Some commentators assert that GC "is a means of separation, not of identification." Kurzman & Fullerton, "Winning Strategies for Defense of Marijuana Cases: Chemical and Botanical Issues," 1 National Journal of Criminal Defense 487, 529 (1975). In the same vein, respected authorities have stated that a positive GLC test is "not proof of identification unless . . . supported by other evidence." Stein, Laessig & Indriksons, "Evaluation of Drug Testing Procedures Used by Forensic Laboratories and the Qualifications of Their Analysts," 1973 Wisconsin Law Review 727, 752.

In contrast, GC/MS is widely accepted as an identification test. I discussed this issue during telephone conversations with Doctor ElSohly, Doctor Simon, and Professor Shapiro. All three experts agreed that standing alone, a positive result of a properly conducted GC/MS test would be a sufficient identification of a contraband drug. In Doctor ElSohly's words, such an

identification would be "unequivocal." Doctor Simon described GC/MS as "an absolute method." For his part, Professor Shapiro stated that he considers himself one of the harshest critics of drug identification testing in the United States. Yet he opined that a properly conducted and evaluated GC/MS test would be an adequate identification. There appears to be a widespread consensus that GC/MS is "the ideal confirmation method." 1 M. HOUTS, R. BASELT & R. CRAVEY, COURTROOM TOXICOLOGY Tetr-33 (1983).

In short, if the military courts applied the Jackson standard, only the GC/MS test might pass muster. If the record reflected expert testimony about the nonspecificity of the RIA and GC techniques, the court well might conclude that a rational court member would necessarily have a lingering, reasonable doubt about the identity of the substance detected in the accused's urine sample.

The application of the legal sufficiency standards to combinations of tests: (RIA + GC + GC/MS) or (RIA + GC)

Even if standing alone an RIA test or a GC test is too nonspecific to support a finding of guilty, positive results on both tests might be a sufficiently specific identification. In other settings, forensic experts have argued that a combination of nonspecific tests is an adequate identification of a suspected contraband drug, and the courts have accepted the argument. For example, any responsible forensic chemist would acknowledge that the Duquenois-Levine and microscopic tests for marijuana are nonspecific. However, several experts have tested other drugs and found that only marijuana yields positive results on both tests. Bailey, "The Value of the Duquesnois Test for Cannabis - A Survey," 24 Journal of Forensic Science 817 (1979); Nakamura & Thornton, "The Forensic Identification of Marijuana: Some Questions and Answers," 1 Journal of Police Science and Administration 102 (1973). In People v. Brisco, 78 Ill.App.3d 282, 33 Ill.Dec. 827, 397 N.E.2d 160 (1969), the court accepted the prosecution's argument that positive results on both tests constitute a sufficient identification of cannabis. State v. Wind, 60 Wis.2d 267, 208 N.W.2d 357 (1973), employed analogous reasoning and held that positive results on Duquesnois-Levine and thin layer chromatography tests are an adequate identification of marijuana.

The question then arises whether the combination of tests utilized in the urinalysis program is sufficient. It is obvious that any combination including GC/MS would suffice. We have already concluded that standing alone,

a positive GC/MS result would be adequate. If a positive GC/MS result were combined with other positive findings, the identification would be even stronger.

The pivotal question is whether positive results on both RIA and GC would be legally sufficient to sustain a court-martial conviction. The answer appears to be Yes. My telephone conversations with committee members and review of the literature convince me that a rational trier of fact could find that positive results on both tests establish a contraband substance's identity beyond a reasonable doubt.

One of the most current texts on toxicology is 1 M. HOUTS, R. BASELT & R. CRAVEY, COURTROOM TOXICOLOGY (1983). The text contains an extended discussion of the identification of THC. The authors initially list the various scientific techniques helpful in making the identification, including GC and RIA. Id. at Tetr-32. The authors then assert that the use of those two methods "in conjunction" is sufficient to "confirm the presence of THC in biological specimens." Id. at Tetr-33. Whiting & Manders, "Confirmation of a Tetrahydrocannabinol Metabolite in Urine by Gas Chromatography," 6 Journal of Analytical Toxicology 49 (1982) points to the same conclusion. In their article, Whiting and Manders discuss a particular GLC method for identifying cannabinoids. They argue that the combination of an RIA screening test and a chromatography confirmatory test is adequate to identify THC in urine. In their experiment, Whiting and Manders compared confirmation by chromatography with confirmation by GC/MS. In every instance in which the chromatography finding was positive, the GC/MS finding was also positive; there were no false positives on chromatography. Id. at 51.

In my conversations with Doctors ElSohly and Simon, they took the position that positive results on RIA and GC constitute a sufficient identification. Doctor ElSohly has such faith in the technique that he told me during a conversation on November 11, 1983 that with positive findings on both tests, an analyst could be "99.9%" certain of the identification. Doctor ElSohly considers false negative to be much more of a problem than false positives. In my discussion with Doctor Simon on November 16, he generally concurred with Doctor ElSohly although Doctor Simon expressed his view in less positive terms. Doctor Simon conceded that even with positive results on both procedures, there might be some - a "very few" - false positives. Moreover, he stressed that he would accept an identification based on RIA-GC "only if" the laboratory administering the tests has a rigorous quality control

regimen. Doctor Simon specifically stated that he believes that the laboratory should validate the procedures daily by subjecting at least 10% of the samples to GC/MS confirmation.

Our limited experience to date with RIA-GC testing tends to support the position taken by Doctors ElSohly and Simon. As previously stated, at Fort Meade, the GC/MS retest of 816 samples confirmed the presence of THC in 812 of the samples identified by RIA-GC. At the Naval Drug Screening Laboratory in San Diego, the figure was equally impressive: 99.7%. These figures lend hard, empirical support to the contention that used together, RIA and GC procedures are sufficiently specific.

The available data leads me to the conclusion that at least when the techniques are validated by a rigorous quality control procedure including GC/MS, positive findings on RIA and GC techniques are legally sufficient to support a court-martial conviction. This appears to be the conclusion of the AFIP staff, described on page three of Major General Einsel's memorandum on the panel's visit to AFIP. However, I must emphasize that my conclusion rests on the current state of the scientific record. To date, relatively little research has been done into the question of the specificity of the combination of the two tests. For instance, the Whiting-Manders study involved only 62 urine samples. Whiting & Manders, "Confirmation of a Tetrahydrocannabinol Metabolite in Urine by Gas Chromatography," 6 Journal of Analytical Toxicology 49, 51 (1982). Although the possibility seems remote, further research could show that there are other drugs that would yield positive results on both tests and that those other drugs are readily available to members of the armed forces. If later research established those propositions, my assessment might well change; I might then conclude that a rational court member or juror would necessarily have a lingering, reasonable doubt about the identity of the substance detected in the accused's urine sample. My conclusion rests squarely on the currently available research.

C. Collateral Attack

A strong case can be made that the civilian courts should refuse to review the question of the sufficiency of the evidence to support a court-martial conviction. In Burns v. Wilson, 346 U.S. 137 (1953), the Supreme Court grappled with the proper scope of review of court-martial convictions. The Court stated that "(i)t is the limited function of the civil courts to determine whether the

military have given fair consideration to" the legal claims urged by the military accused. In Bowling v. United States, 552 F.Supp. 54 (Ct.Cl. 1982), the court held that Burns precludes civilian courts from considering the issue of the sufficiency of the evidence in courts-martial so long as the military courts have fairly considered the issue. Id. at 62-63. This result is defensible. Reviewing the question of the evidence's legal sufficiency necessitates reconsideration of the factual information in the record of trial; that issue cannot be resolved as a pure question of constitutional law or statutory construction. It is a gross intrusion upon the military's province for a civilian court to reevaluate all the evidence presented in a court-martial. Courts-martial accord an accused many more procedural safeguards to ensure reliable fact-finding than administrative board proceedings. Hence, it would be sensible to deny review after fair consideration of the issue by the military courts.

Yet, it would be an overstatement to predict confidently that a civilian court would not reach the merits of the issue of the legal sufficiency of the evidence in a court-martial. Most federal civilian courts have not even passed on the question of whether Burns' fair consideration test applies to the issue of the legal sufficiency of the evidence in a court-martial. However, even if a civilian court rejected the reasoning in Bowling, the court-martial conviction would ordinarily withstand attack. A court rejecting Bowling might insist upon substantial evidence to sustain the conviction. As we noted in our discussion of collateral attacks on administrative discharges, a reasonable person might accept positive RIA and GC test results as adequate evidence. That is all that the substantial evidence test requires. Community Hospital of Indianapolis, Inc. v. Schweiker, 717 F.2d 372 (7th Cir. 1983).

III. CONCLUSION

In summary, at least when the techniques are regularly validated by a quality control procedure including GC/MS, positive results on RIA and GC techniques should be legally sufficient to sustain either an administrative discharge or a court-martial conviction. In cases such as People v. Brisco, 78 Ill.App.3d 292, 33 Ill.Dec. 827, 397 N.E.2d 160 (1979) and State v. Wind, 60 Wis.2d 267, 208 N.W.2d 357 (1973), the courts have shown that in evaluating the legal sufficiency of the evidence, they do not demand absolute, scientific certitude. The current state of the scientific record - the research completed to date and the confirmatory

GC/MS tests at Fort Meade and the San Diego Naval Drug Screening Laboratory - indicates that positive results on RIA and GC techniques represent a solid identification.

There are several caveats that must be added immediately. One is that the scientific record is subject to change. Further research could generate strong evidence that even a combined RIA-GC test procedure is subject to numerous false positives. If the other compounds yielding those false positives were readily accessible to service personnel, there would be a lingering, reasonable doubt about the specificity of the identification. Moreover, the bare legal sufficiency of the evidence of the compound's identity does not guarantee convictions. On the current state of the scientific record, the defense counsel may present expert testimony by chemists such as Professor Shapiro that theoretically many compounds could yield positive results on both RIA and GC. The research into the specificity of the combined RIA-GC procedure is still in its early stages, and defense experts can attack the size of the data base that prosecution experts rely on. Finally, the defense may be able to create a reasonable doubt in the court members' minds by pointing out that the prosecution neglected to submit the sample to the best scientific test, namely, GC/MS. The legal sufficiency of the RIA-GC procedure means only that the military judge will deny a defense motion for a finding of not guilty. By skillfully marshalling expert testimony, defense counsel may still be able to win acquittals in cases in which the government relies solely on the RIA-GC procedure.

There are indications of growing judicial skepticism about drug identification tests. Perhaps the two most dramatic examples are Curtis v. State, 548 S.W.2d 57 (Tex.Cr.App. 1977) and State v. Vail, 274 N.W.2d 127 (Minn. 1978). Curtis was a challenge to a probation revocation. In the jurisdiction of Texas, the burden of proof in probation revocation proceedings is a mere preponderance of the evidence. The state attempted to revoke Curtis' probation on the ground that he had used heroin. At the hearing, the state presented evidence of a Marquis reagent test to identify heroin. The record reflected that at least 25 other organic substances would yield a positive result on a Marquis test. The court held that as a matter of law, the evidence was insufficient to support a probation revocation. Vail is an even more extreme case. Vail was a bench trial without a jury. To identify marijuana, the prosecution presented evidence of a field test, microscopic analysis, Duquesnois-Levine, and thin layer chromatography. Nevertheless, the trial judge found the evidence insufficient to establish the substance's

identity beyond a reasonable doubt; and the Minnesota Supreme Court held that the finding was within the trial judge's discretion. In my conversation with Professor Shapiro, he informed me that in all of the recent federal civilian drug prosecutions in which he has participated, the prosecution has presented GC/MS evidence. The civilian prosecutors' increased use of GC/MS may be a response to their realization of the courts' growing skepticism.

As part of my research to prepare this addendum, I had occasion to review several messages and memoranda prepared at Headquarters, Department of the Army. For example, I have seen the USADATA/PEDA/DASG-PSL-L messaged, dated 280830Z Sep 83 message, subject: Change in Drug Testing Protocol (sic). That message instructed the affected laboratories to "retest urine specimens using GC-MS when requested by field command." I have also reviewed the DAJA-CL 1983-6097 memorandum, Subject: Changing the Army's Marijuana Testing Procedure of Urine from GLC to GC/MS. That memorandum recommends GC/MS retest at the request of any service member facing an administrative board or court-martial. The tenor of the memorandum suggests that ultimately, it would be prudent to move toward the objective of 100% GC/MS. I fully support all those recommendations. Implementing those recommendations would be a legally prudent course of action; the implementation of those recommendations would be important insurance of convicting the guilty and preventing miscarriages of justice. Pages three and four of the panel's report on the Weisbaden facility acknowledge the great value of GC/MS as a confirmatory test. At this time, the legal sufficiency standards do not appear to mandate the use of GC/MS in all cases. However, as we have seen, there are definite legal risks in relying on an RIA-GC procedure; the state of the scientific record may change, and the prosecution's failure to employ GC/MS may enable a skillful defense attorney to persuade the court members that reasonable doubt exists. In light of those legal risks, the wisest course may be to move steadily toward the goal of 100% GC/MS. I applaud the panel's recommendations for strengthening the GC/MS capability at all DTLs.

Our principal focus in this memorandum has been on standards of proof: How much evidence does the law require that the government present in order to prove the existence of a fact such as the identity of a substance found in the accused's urine sample? It is important to remember that the choice of a standard of proof reflects an implicit value judgment. Saltzburg, "Standards of Proof and Preliminary Questions of Fact," 27 Stanford Law Review 271 (1975). In part, our society has decreed the use of the

standard of proof beyond a reasonable doubt in criminal cases because of our society's judgment of the importance of protecting innocent persons' reputations and liberty. In re Winship, 397 U.S. 358 (1970). In Jackson v. Virginia, 443 U.S. 307 (1979), the Supreme Court announced that those social values require not only that the jury use an enhanced burden of proof but also that the judge employ an extraordinarily demanding test in assessing the legal sufficiency of the evidence. Doctor Richard Hawks of the Division of Research of the National Institute on Drug Abuse presented a perceptive paper at a recent national symposium on Urine Testing for Marijuana Use. During his presentation, Doctor Hawks counseled the audience:

The inherent possibility of error in any assay is a matter of concern which escalates in proportion to the consequences of the positive result. A false positive result occurring once in 100 true positives is insignificant in an incidence survey for research purposes. That one false positive is of grave concern, however, if it is a forensic sample from an individual whose freedom, career or civil rights hang in the balance. In forensic science, such occurrences are minimized to levels of little concern by the use of confirmatory methods of analysis. High confidence can be placed on a urine sample which is drug positive by an immunoassay method, such as EMIT (or RIA), if it is also positive by a method based on completely different principles, such as GC/MS.

Doctor Hawk's counsel is sage advice.

APPENDIX A

MEMO OF INSTRUCTIONS



DEPARTMENT OF THE ARMY
OFFICE OF THE SURGEON GENERAL
WASHINGTON, DC 20310

24 OCT 1983

REPLY TO
ATTENTION OF

DASG-PSC-L

MEMORANDUM FOR MAJOR GENERAL EINSEL

SUBJECT: Requirements for Blue Ribbon Panel Review of Urinalysis Drug Testing Program.

1. The Army has attempted to ensure that the Drug Testing Program has maintained a high degree of credibility as being both accurate and legally sufficient in the identification of drug abusers. Since the formulation of the Joint Army/Air Force Drug Laboratory System in September 1982, the Surgeon General of the Army has been working closely with other staff agencies to provide a scientifically sound and forensically oriented urinalysis system to support the Secretary of the Army and Chief of Staff of the Army's standard of non-abuse. Within the past several weeks criticism among the scientific and legal communities have been expressed regarding the legal sufficiency of a number of specimens identified as positive by the Fort Meade Laboratory. Consequently, the decision was made to form a panel of experts as quickly as possible for the purpose of reviewing Army laboratory procedures to determine if they are reporting results that can be considered legally sufficient.

2. You have been assigned as the Chairman of a panel of civilian experts in the fields of toxicology and drug testing legal issues. The Panel's charter includes a review of past and present operations and procedures within the existing Army/Air Force Drug Testing Laboratories. This review will consist of an assessment of testing procedures, standards of laboratory practice, laboratory operations, and existing laboratory resources and to conduct a review of past urine specimen results to assess if they are legally sufficient for use as evidence under the Military Rules of evidence in disciplinary or characterization of discharge actions. Additionally, the panel is to:

a. Certify procedures which will ensure both technical and legal sufficiency of the urinalysis testing program.

b. Create and certify a Quality Assurance Program which will guarantee the continuing integrity of the urinalysis testing program.

3. The members of the panel are all experts in their field (Tab A). As the Chairman of the panel you will have the responsibility to ensure that specific requirements are met, any conflicts in opinion are either resolved or documented, and that subsequent to review of each laboratory, a final report is rendered to The Surgeon General stating discrepancies, findings, and recommendations for corrections. Additionally, the reports should provide an assessment of the Panel as to the legal sufficiency of current operations, as well as a representative sampling of past specimens from which a decision will be made by the Office of The Surgeon General to recertify specific laboratories for drug testing.

DASG-PSC-L

SUBJECT: Requirements for Blue Ribbon Panel Review of Urinalysis Drug Testing Program.

4. Prior to conducting a review of laboratory operations and testing procedures, the panel should develop specific criteria of what constitutes a legally sufficient urine positive chromatogram. These criteria should be sufficiently documented to allow dissemination to all laboratories as a refinement to existing procedures. Additionally, these criteria should be sufficient to be considered professionally sound within the scientific community (attached Tab B is a strawman).

5. Specific requirements for the Panel are outlined below. Those documents, persons, and/or other resources required by the Panel in the completion of these requirements will be provided as identified.

a. Establishment of template (criteria) for test results that meet the scientific requirements to be considered legally sufficient in labeling a urine specimen as positive or negative.

b. Provide a Panel assessment as to the reliability and accuracy of current laboratory operations and procedures within each Army/Air Force Drug Testing Laboratory. This should include recommendations for improvements and/or changes in operations, procedures, and resources.

c. Provide a Panel assessment as to the legal sufficiency of a representative sampling of previous results from each laboratory. This sampling should consist of approximately 400 specimen results randomly selected from the past four months work of results currently on hand at the laboratory.

6. Because of the sensitivity and importance of this critical program, the requirement to assess past results and current operations and procedures for each laboratory must be accomplished as soon as possible but no later than 15 December. A tentative schedule (Tab C) has been developed based on known availability of Panel members. In addition to the review and assessments outlined in Paragraph 5 being completed, by 15 Dec 83, the Panel should provide a copy of certified testing procedures and Quality Control Program to The Surgeon General.

7. Administrative support will be provided by the respective laboratory or installation that the Panel is visiting. An administrative assistant has been assigned as a member of the Panel who will be responsible for coordination and overseeing of any administrative support. Funding of contracts and TDY requirements will be handled by The Surgeon General's Office and the Office of Deputy Chief of Staff, Personnel.

EDWARD J. HUYCKE
Major General, MC
Deputy Surgeon General

APPENDIX B

BACKGROUND OF PANEL MEMBERS

PANEL MEMBERS
REVIEW OF URINALYSIS DRUG TESTING PROGRAM

Major General David W. Einsel, Jr.	Deputy Assistant to the Secretary of Defense (Atomic Energy) and Executive Secretary of the Military Liaison Committee, CHAIRMAN
Brigadier General Joseph L. Ecoppi	Dep Dir, Concepts & Analysis Agency DEPUTY CHAIRMAN
Robert E. Willette, Ph.D	Former Chief, Research Technical Branch, National Institute on Drug Abuse, Consultant for Research Designs, Inc., to Naval Military Personnel Command, US Courts, and Federal Bureau of Prisons,
Robert K. Simon, Ph.D	Director, Industrial Operations, American Medical Laboratories and Consultant to Forensic Toxicology
Mahmoud A. Elsohly, Ph.D	Assistant Director, Research Institute of Pharmaceutical Sciences and Research Associate Professor, University of Mississippi and Director, NIDA Marijuana Project
Professor Edward J. Imwinkelried	Professor of Law Washington Univ School of Law, St Louis, MO
Major Jerome L. Lemberger Major John T. Rucker* Major John A. Burton**	Office of The Judge Advocate General
Master Sergeant Jessie Del Valle	Medical Laboratory Specialist, US Army Drug and Alcohol Technical Activity, ADMINISTRATIVE ASSISTANT

* For Wiesbaden AB visit

** For visit to Tripler AMC and AFIP

Chairman

Major General David W. Einsel, Jr.

- M.A. in Chemistry, The Ohio State University, 1950
- M.S. in Physics, The University of Virginia, 1956
- Formerly assigned to Toxicology Division, U.S. Army Medical Laboratories
- Formerly Deputy Commanding General, U.S. Army Armament R&D Command, responsible for chemical, biomedical and toxicological R&D activities at Aberdeen Proving Ground.
- Holder of patent on automatic electrolytic acid titration equipment for cholinesterase determinations.
- Currently Deputy Assistant to the Secretary of Defense for Atomic Energy

Deputy Chairman

Brigadier General Joseph L. Ecoppi

- B.S. in Physical Education and Biological Sciences, University of Illinois, 1954
- Formerly assigned to Office of the Deputy Chief of Staff for Personnel
- Formerly assigned to Office of the Inspector General Agency, United States Army
- Formerly commanded two artillery battalions, a division artillery and served as an Assistant Division Commander for Support
- Currently Deputy Director, United States Army Concepts Analysis Agency

Panel Member

Mahmoud A. Elsohly, Ph.D.

- Ph.D., Pharmacy, University of Pittsburgh, Pennsylvania (1975)
- Assistant Director, Research Institute of Pharmaceutical Sciences and Research Associate Professor, School of Pharmacy, University of Mississippi, University, Mississippi
- Director, NIDA Marijuana Project

Panel Member

Robert K. Simon, Ph.D.

- Ph.D., Analytical Chemistry and Toxicology, University of Maryland (1967)
- Director, Industrial Operations, American Medical Laboratories, Fairfax, Virginia
- Consultant, Forensic Toxicology

Panel Member

Robert E. Willette, Ph.D.

- Ph.D., Medicinal Chemistry, University of Minnesota (1960)
- Consultant, Research Designs, Inc., Annapolis, Maryland
- Consultant, Naval Military Personnel Command, Washington, D.C.
- Consultant, U.S. Courts and Federal Bureau of Prisons
- Former Chief, Research Technical Branch, National Institute on Drug Abuse

Panel Member

Edward J. Imwinkelried

- Professor, Washington University School of Law, St. Louis, Missouri
- Professor, School of Law, University of San Diego (1974-1979)
- Visiting Professor of Law, University of Illinois, January-May 1981
- Professor of Law, University of San Diego Program in Guadalajara, Mexico, summer 1981.
- B.A., University of San Francisco, California (1967)
- J.D., University of San Francisco School of Law, California (1969)

Panel Member

Major John T. Burton

- B.A., Duke University, J.D., University of North Carolina
- Bar Membership: North Carolina, Court of Military Appeals, Supreme Court of the United States
- Currently Litigation Attorney, Office of The Judge Advocate General, Headquarters, Department of the Army

Panel Member

Major Jerome L. Lemberger

- B.S., California State Polytechnic College (1966)
- J.D., Hastings College of the Law, University of California (1972)
- Bar Membership: California; Federal Courts (Northern District of California and 9th Circuit Court of Appeals); U.S. Court of Military Appeals; U.S. Supreme Court
- Currently Criminal Law Attorney, Office of The Judge Advocate General, Headquarters, Department of the Army

Panel Member

Major John T. Rucker

- B.A., University of North Carolina
- J.D., Louisiana State University Law School
- Bar Membership: Louisiana, Court of Military Appeals,
Supreme Court of the United States
- Currently Administrative Law Attorney, Office of The Judge
Advocate General, Headquarters, Department of the Army

Administrative Assistant

MSG(P) Jessie Del Valle

- B.S., Biochemistry, St. Martin's College, 1974
- M.S., Cell Biology, University of Texas, 1976
- M.B.A., Emphasis on Health Care Management, University of Northern Colorado, 1982
- Medical Technologist/Cytotechnologist, Certified by the American Society of Clinical Pathology (ASCP)
- Graduate of the Basic, Advanced, and Cytotechnology Courses, Academy of Health Services
- Currently serving as the Biochemical Testing Coordinator for the United States Army Drug and Alcohol Technical Activity (USADATA)

APPENDIX C

REPORT OF VISIT TO FT. MEADE LABORATORY

27 OCT 1983

MEMORANDUM FOR THE DEPUTY SURGEON GENERAL

SUBJECT: Blue Ribbon Panel Review of Urinalysis Drug Testing Program

1. This letter constitutes the initial report of the panel of experts (Tab A) in the fields of toxicology and drug testing legal issues. This report covers the review you requested of past and present operations of the Fort Meade Drug Urinalysis Test Center and reflects our initial assessments based on two days of intensive review conducted 24-25 October 1983 at the Test Center. The review covered assessment of testing procedures, standards of laboratory practice, laboratory operations and existing laboratory resources. In addition, we reviewed the legal sufficiency of past urine specimen results to assess their usefulness of evidence under Military Rules of Evidence in disciplinary or characterization of discharge actions.

2. The panel did develop chromatograph criteria (Tab B) which should be legally and technically sufficient to be considered proper evidenciary chromatograms. The strawman methodology provided was reviewed and is approved with the changes noted in Tab C.

3. The radioimmunoassay (RIA) procedures were reviewed and seem adequate and proper with the following observations:

- More care should be taken in record keeping to label data, logs and record books, and standards so that the summary RIA data stands alone. This improvement could considerably assist in future legal testimony and would establish the background and validity of standards, averages, cut-offs, etc.

- The present system of standardization and control of the RIA system should be duplicated within the Chain of Custody (COC) runs for RIA. Each RIA run should be statistically evaluated for standards and controls. It would seem that a minimum of at least four standards in quadruplicate, with at least ten standards at the cut-off must be required with each COC batch. To maintain overall efficiency, samples could be grouped together where only a small number of positive screens exist in the initial RIA screen. The percent coefficient of variance (CV) at the cut-off should be less than 7.5% for a batch to be considered acceptable.

4. With respect to current operations in the accessions area, the following observations are made:

- Controls on the accession area are being, and should be, tightened considerably to keep operators out of the accession area.

- It would seem that the SSAN should not be completed on the 5180 series forms until intralab testing is completed. Once intralab testing is completed, the SSAN could then be filled in by the accessions personnel. The lab accession numbers are more than adequate for intralab sample control.

5. In reviewing current GLC procedures, the panel observed:

- More care should be taken in record keeping. Each chromatogram should clearly list the parameters on the record, to include: machine number, operator name, column type, column temperature, mode of integration, base line mode, Pk rejects, and any other needed information to repeat the experiment. Currently some records show such information; but, most do not.

- A sensitivity sample should be run at the end of a series (as well as at the beginning) and should be within 10-15% of the level of the beginning sensitivity sample. When it is outside this level, the series should be re-run, or supervisor assistance should be gained prior to continuing further series.

- For the standards, Delta-9 THC acid must be used instead of Delta-8 THC acid for spiking GLC and GC/MS samples.

- An internal laboratory quality control program is being initiated. Such a program is indispensable and should be strongly enforced. At least one person is needed full time, and some provision must be made to assure quality control on the second shift. The quality control person should review procedures, check trends, provide control samples for use in runs, maintain documentation on all standards, and prepare blind samples which should enter the system anonymously through the normal accession control area.

- Operator training is currently inadequate to provide uniformly accurate use of gas chromatographs. The equipment on hand and the available procedures should, with proper use, be quite capable of providing fully adequate and sufficient evidentiary records.

- The panel observed that there is no evident control over repeatability and that apparent recovery of samples is quite erratic. Moreover, it is not apparent that any corrective actions are taken to improve these matters. This is an area where immediate attention should give very large improvements in the quality of the records. The panel suggested that each

operator be immediately tasked to pass a training certification as to reproducibility by demonstrating at least + 10-15% accuracy. Similarly, each operator should be tasked to demonstrate his recovery procedures to demonstrate that his procedures approximate the laboratory average percentage recovery to within 15-20%--prior to handling any future samples. Such a procedure for any new operator should be required prior to assignment of actual samples.

- Representative chromatograms were reviewed from each of the months of February, June, September and October 1983. Similar problems were found throughout the period. At least 50% of the February through September chromatograms would not have met the criteria that we developed in Tab B; and, therefore, could not be legally or scientifically defended. The October results, although improved, still would not uniformly be legally sufficient nor scientifically defensible for confirmation of THC in urine. We found no significant evidence of false positive confirmations. This view is supported by the Meade Compuchem GC/MS retest of 816 samples which was completed on 24 October 1983, in which all but four of the submitted specimens showed presence of THC metabolite. A reanalysis of those four samples would be indicated, and if positive confirmation is not attained, these four personnel should be reported as negative.

- In passing, as part of our review of chromatograms, we noticed a number of examples where detergent contamination or contaminated reagents were very evident with no evidence of any effort to retest the samples. Similarly, frequent shifts in baselines, and unusual retention times were far too evident, with similar inattention to correction of the basic problem. This all serves as further indication of the need for better training of operators, more attention by supervisors and reviewers and more attention to quality control throughout the laboratory.

6. The following general observations were made by the panel:

- The limited supervisory assets and the laboratory technicians are hindered by telephone calls, personal visits, and witness requests. Personnel should be identified, designated and be available to handle requests for information by outside sources and be available to testify as expert witnesses on laboratory procedures.

- Better coordination with local staff judge advocate and physical security personnel is recommended. It would seem that these local personnel should visit the laboratory monthly to ascertain whether assistance can be provided, as needed, concerning implementation of the chain of custody SOP and physical security.

- Although it is understood that efforts are underway to expand the laboratory area and there is much evidence of new

equipment initiatives, space still seems inadequate to organize an efficient and productive laboratory. Work areas are crowded. Processing areas are cramped. The GC/MS area and specimen handling room are the worst examples. The laboratory functions seem much too scattered around the building for adequate good security. Overall, the working conditions lend themselves to laboratory errors and accidents. Considering the workload, it would seem that additional extractor and confirmatory equipment is still required. Work areas in the specimen handling room should be separated by functions. Receipt of specimens in the handling room and batch run preparations should be accomplished in separate areas to prevent laboratory accidents, mixing of specimens or inadvertent numbering and labelling errors.

- Authorizations seemed inadequate in both number and skill specialty by type. Increased authorizations should be considered in supervision, quality control and training, at the minimum. Bench supervision was lacking. The laboratory OIC and section supervisors must be trained sufficiently to describe and defend the procedures under their responsibility.

7. In summary, the priority tentative recommendations of our visit are:

- As an immediate measure, confirmation testing should be suspended until problems with reproducibility and sample recovery variations are resolved. (If supervisory and training internal capabilities are knowledgeable, this should require only a matter of several days to correct.) Sample testing could be resumed as soon as the laboratory demonstrates proficiency in reproducibility and recovery procedures.

- Attention to record keeping, supervisory review, and attention to meeting legal sufficiency and scientific credibility should begin immediately (along the lines suggested by Tab B), to assure that future reporting is adequate.

- Should any difficulties remain in the above two areas, several members of this panel can be made available to assist in testing/procedures/review.

- With respect to the June to October 1983 data (where frozen samples remain for about 8000 samples or where reporting of results have been suspended), the Army should provide sufficient chemists, competent in chromatography and approved by this panel, to determine quickly (in a two week period) which chromatograms are adequately documented to satisfy that they can be legally and scientifically supported under the criteria of Tab D. For those chromatograms which are not adequately reported, samples can be rerun to meet the legal sufficiency/technical criteria of Tab B. (Because of the overall laboratory workload, we see little alternative other than going to a commercial laboratory which has GC/MS analytical capability.) Where present GLC

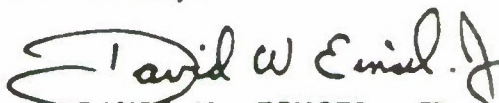
chromatograms are negative, where present GLC chromatograms are sufficient, and after establishing a sufficient record through re-runs, results should begin to be reported to the commands as soon as possible. This panel, or a representative of this panel, would expect to audit the reviewers in their effort as a quality control measure before either proceeding with re-runs or reporting of results to the commands.

- For those samples prior to June 1983, or where there is no possibility of re-runs of a specimen, the records should similarly be reviewed for those cases of positive confirmations since April 1982 when the Carlucci initiatives began in the Army. This review should be done by the same group as above, although it might be at a lesser priority (probably could be done in a matter of weeks). The results of this review should result in providing a listing to the Surgeon General of those personnel, who have been confirmed as positives, but whose records are not legally or scientifically supportable. (As a practical matter, the panel would suggest that, for the above two retrospective reviews of records only, a lesser set of chromatogram criteria be used such as are listed in Tab D. The criteria in Tab D differ from Tab B criteria only in that they allow more variability in baseline interpretation, do not demand the constant retention times, do not require as much excellence in positive control, and recognize the presence of contaminants. True experts, with a bit of calculation can estimate around these existing deficiencies, without sacrificing scientific credibility, although none of the relaxations should be accepted for normal or future testing.)

8. Present plans of the Panel are to visit the remaining laboratories as follows:

4-5 November	Brooks AFB
17-20 November	Wiesbaden Germany Lab
1-5 December	Trippler Army Lab, Hawaii and draft report

- Our final report may readdress some of the above areas in greater detail; however, the recommendations of paragraph 7 deserve immediate attention, support and attention, if the Army is to maintain and regain its credibility in Urinalysis Drug Testing at the Fort Meade Laboratory.


DAVID W. EINSEL, JR.
Major General, USA
Chairman

TAB A

PANEL MEMBERS

REVIEW OF URINALYSIS DRUG TESTING PROGRAM

Major General David W. Einsel, Jr.	Deputy Assistant to the Secretary of Defense (Atomic Energy) and Executive Secretary of the Military Liaison Committee, CHAIRMAN
Brigadier General Joseph L. Ecoppi	Holding Detachment, OCSA, DEPUTY CHAIRMAN
Robert Willette, Ph.D	Former Chief, Research Technical Branch, National Institute for Drug Abuse and Consultant to Research Design, Inc., Naval Material Command and US Courts and Federal Bureau of Prisons
Robert K. Simon, Ph.D	Director, Industrial Operations, American Medical Laboratories and Consultant to Forensic Toxicology
Mahmoud El Sohly, Ph.D	Assistant Director, Research Institute and Associate Professor, School of Pharmacy, University of Mississippi and Director, NIDA Marijuana Project
Major Jerry Lemberger	Office of The Judge Advocate General
Master Sergeant Jesse Del Valle	Medical Laboratory Specialist, US Army Drug and Alcohol Technical Activity, ADMINISTRATIVE ASSISTANT

n.b. A civilian legal expert is to be nominated by the OTJAG, but was not present at the Fort Meade Meetings. When nominated, he should be accompanying the panel to the maximum extent that his personal schedule will permit.

TAB 3

CHROMATOGRAPHY CRITERIA

1. Solvent peak response must return to within 25% of the original baseline before the drug and/or internal standard peaks appear.
2. The negative urine control response at the retention time window of the drug is considered the noise level.
3. The sensitivity control must be greater than three times the negative control (noise) response at the drug retention time to be accepted as the positive cut-off for unknowns.
4. The absolute retention time of the drug substance and the internal standard must remain constant within 0.5 minutes among all chromatographs and/or operators within runs or shifts and between runs and shifts. The relative retention time for a drug and its internal standard must be within $\pm 5\%$ within a shift or run.
5. The in-house positive control must quantitate within $\pm 25\%$ of its stated value to deem a run acceptable.
6. Chromatograms with probable contaminant peaks within $\pm 5\%$ of the drug retention time must be confirmed by GC/MS.

TAB C

ARMY DRUG TESTING LABORATORY ASSAY PARAMETERS

1. The Army Drug Testing Laboratories utilize a bimodal analytical system to detect drugs of abuse. First, a highly selective, drug-class specific radioimmunoassay (RIA) is utilized as the initial screening process to identify negative specimens and to select presumptive positives. Second a highly specific Gas Liquid Chromatography (GLC) procedure is utilized to confirm all RIA - positive specimens.

2. The RIA procedure must be performed in strict compliance with laboratory SOP, and manufacturer instructions, Roche Diagnostics, and ABUSCREEN package inserts. As a minimum requirement the following must be complied with to assure reliability of results:

- a. Reagents stored at 2-8°C and brought to room temperature before use.
- b. Positive and negative controls in duplicate.
- c. Pumps calibrated and recorded.
- d. Reagents added in proper sequence.
- e. Incubation time minimum thirty minutes at room temperature.
- f. Proper mixing of second antibody.
- g. Precipitation of the mixture for ten minutes.
- h. Centrifugation for ten minutes at 1200-2500xg at 20°C.
- i. Proper draining and blotting of supernatant for pellet counting.
- j. Minimum counting time 12 seconds.
- k. Only specimen^s yielding counts per minute (CPM) equal to or less than the CPM of the positive control are to be considered positive.
- l. Positive control level equal to 100 ng/ml of primary urinary metabolite to be used as the cut-off level.
- n. Percentage coefficient of variation for positive control should be less than 7.5%.

- m. All negative controls are negative.
- o. All questionable results will be repeated.

3. The GLC procedure is utilized to confirm the presence of primary urinary metabolite in these specimens yielding RIA - positive results. Recognizing that extraction procedures are highly complex and involve a number of variables, chemists in charge are responsible for final interpretation of results. As a minimum requirement the following must be complied with:

- a. Carrier gas must be of good quality.
- b. Gas flow must be measured and recorded.
- c. Columns must be packed regularly and recorded.
- d. Internal standard must be included with each run.
- e. Positive standard with each run.
- f. Negative control with each run.
- g. Highly positive specimens (200ng/ml or higher) will be followed by an injection of solvent or no injection to allow baseline recovery.
- h. Chromatograms must be resolved of interfering peaks, specimens with "shoulders" on contamination peaks must be repeated.
- i. Peaks must be of adequate height and width to allow discriminatory interpretation of the tracings.
- j. Positive specimens must show a peak greater than 50ng/ml in relation to the peak height of the positive standard.
- k. Negative control must be negative.
- l. Positive standard must have adequate recovery.
- m. Worksheets must be signed after checking results.
- n. Results must be interpreted and certified by supervisory official.
- o. A sensitivity sample should be included at the end of a series and should be within 10-15% of the level of the beginning sensitivity sample.

4. If GC/MS analysis is performed, the following criteria applies:

- a. A negative control is included.

- b. A Delta-9-THC, 100ng/ml standard is included.
- c. A minimum of three selected ions are monitored, ions at mass 313, 357 and 372 (± 0.5 for each), the ion at mass 372 being the molecular ion.
- d. Positive specimens have monitored ion retention times within $\pm .05$ minutes of the positive standard ion retention times.
- e. The ratio of monitored ions in relation to positive standard must be within 20% based on 313 ions.
- f. All three selected ions are present.
- g. Worksheets are signed after checking results.
- h. Results are interpreted and certified by supervisory official.

TAB D

CHROMATOGRAM CRITERIA FOR RETROSPECTIVE REVIEW

1. The negative urine control response at the retention time window of the drug is considered the noise level.
2. The sensitivity control must be greater than three times the negative control (noise) response at the drug retention time to be accepted as the positive cut-off for unknowns.
3. Unknowns that are equal to or greater than 40% of the positive control will be considered positive.
4. Retention times of THC metabolite can not differ by more than ± 0.05 minutes within a shift batch.

APPENDIX D

REPORT OF PANEL OF EXPERTS ON REVIEW OF
FT. MEADE

14 NOV 1983

MEMORANDUM FOR DEPUTY SURGEON GENERAL, U.S. Army

SUBJECT: Resumption of Testing and Reporting at Ft. Meade

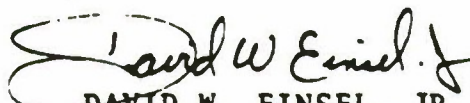
1. Members of my panel have been closely working with the staff of the Ft. Meade Laboratory. The laboratory has instituted a number of quality control measures to assure that operators can repeatedly and accurately reproduce results from known standards. As part of this, they are requiring that each extractor and GLC operator pass a proficiency test. As of this date, four extractors and five GLC operators have met the proficiency test. One other extractor can partially meet the proficiency test and two are in training. Three additional GLC operators are in training but have yet to meet the proficiency test. Two technical members of the panel have reviewed the chromatograms produced by the proficient operators and believe that they would meet requirements for both scientific and legal credibility in determining that the results indicate the presence of THC metabolite in the specimen.

2. With the four certified extractors and five certified operators, it is probable that the lab can successfully handle a throughput of 800-900 presumptive positive samples per month. (Thus, inferring an ability to process about 8,000 specimens with approximately a 10% positive rate.) This estimate also seems reasonable when compared to the 16-18,000 samples that were being processed during the summer by a roughly double number of operators.

3. There is no reason to expect that the laboratory, with its adjusted procedures, should not meet a five-day turn around cycle, except for the period required to "catch up" on the 1200 presumptive positives now awaiting test (approximately a month and a half backlog). Meeting the on-going workload and disposing of this "backlog" would appear to require about six man-months of additional extractor capability and probably about four man-months of additional operator capability. If it is desired to dispose of this backlog within a month, it would appear to the panel that about 10 expert personnel, capable of quickly passing the in-house certification/training, must be provided to the laboratory from other TSG resources or some other equally efficacious remedy must be applied until the

laboratory can train additional operators. Unless such measures are implemented very quickly, the apparent turn around would approximate at least 90 days, the size of the present backlog. It would seem that such a long turn around time would raise serious credibility problems with soldiers, their leaders and the Army.

4. Therefore, I recommend that the laboratory now be cleared to test and report urine results at a rate of about 200 presumption positive samples per trained extractor per month.


DAVID W. EINSEL, JR.
Major General, USA
Chairman

APPENDIX E

REPORT OF VISIT TO BROOKS AFB

14 NOV 1983

MEMORANDUM FOR THE DEPUTY SURGEON GENERAL, USA

SUBJECT: Report of Visit to Brooks Drug Abuse Detection Laboratory by the Blue Ribbon Panel for Review of Urinalysis Drug Testing Program

1. Reference your memo of 24 October 1983 on Requirements for Blue Ribbon Panel Review of Urinalysis Testing Program.
2. The Panel visited the USAF School of Aerospace Medicine's Drug Abuse Detection Laboratory on 4 and 5 November 1983; received a thorough briefing on the operation by the Chief of the Laboratory, Colonel George Lathrop, supported by his operating staff; toured the facility; held a number of detailed technical discussions with each function; and reviewed random chromatograph and technical results over the period from October 1982 to October 1983.
3. Overall the laboratory processes about 22,200 samples per month with a staff of 71 people; tests about 75,000 Army samples per year, tests all samples 100% for THC and 10% are pulsed for one other drug; can test about 500 samples/month for all five other classes of drugs; and meets a turn around time of 5 days. With the exception of one quarter (Oct-Dec 1982 when a new program and new Whiting-Manders AFIP procedures were first introduced), the lab has continuously exceeded AFIP quality control procedures. It has been inspected for certification by the College of American Pathologists (CAP). For both AF and Army THC abuse, approximately a 10% prevalence of THC abuse was being reported in Oct 1983, reflecting a general downward trend from Jan 1983 when Army average was about 23% and AF average was about 18%.
4. Overall, the supervision, attention to technical detail, training, and chain of custody seemed excellent. There was a thorough, detailed, and complete SOP available, and it appears to be used and followed closely. For chain of custody, the SOP is similar to that prescribed by TSG, HQDA, including the forms used, allowing ready compatibility with Army specimens received on Army chain of custody forms. The security of specimens throughout the process is impressive, and the laboratory is periodically inspected by the installation physical security office. The panel was impressed with the in-depth knowledge of the staff in the Drug Urinalysis Program.

The radioimmunoassay (RIA) procedure seems thoroughly credible from a technical viewpoint. Because of laboratory equipment limitations (which will shortly be changed when new

counting equipment arrives), counting is done on the supernatant part of the sample. The procedure involves an excellent statistically based determination of the cutoff levels. Standards are included before, after, and within batches. Tolerance cutoffs are established for each gamma counter and each standard. A WANG tape reader allows the automatic reading of punched encoded values from the gamma counters. By setting parameters through a disc-encoded program, rapid and highly accurate data scanning transcription is done.

The GLC procedure is well documented in current SOPs, and it uses a capillary (DB-5) column versus a glass-packed column. Pooled negative and positive standards are included in each batch run, and are prepared by the quality control group. Prep -1 procedures, including adjustment of pH to 9.0 are used. Oxyphenbutazone is used as the internal standard. Chromatograms were randomly selected by the Panel from October and June 1983 and from the October-November 1982 files. Overall, the Panel's review indicated a very high degree of agreement that the chromatograms would be scientifically credible and legally sufficient. For a batch of October 1983 chromatograms, we would have had some question on about 6.5%, and for June 1983, about 10%. Overall, a very favorable review. Where we felt argumentation of results could result usually involved (1) poor resolution of a post THC contaminant, (2) a THC peak outside the window of the retention time of the Delta-9 standard, or (3) the inadvertant use of a Delta-8 peak as criteria for the judgment of a positive in a real specimen. The greatly improved laboratory performance is evident when one compares the results with those prior to October-November 1982 when packed columns were being used. For that period, the panel found some 37 of 60 (about 60%) which one could find a basis for argumentation as to legal or technical credibility or sufficiency. This period was chosen for review as probably being the most stressful period in that the lab was changing procedures, increasing lab personnel from 35 to the present 71, and increasing their sample throughput, all at the same time.

GC/MS is used only on about 10% of the samples as a confirmatory check and for calibrating negative and positive pool samples. We reviewed the constancy of the MS standards for over a month's period, and it appears to be remarkably constant -- well within the expected standard deviation. Although the mass spectrometer is extremely well run and its credibility is therefore excellent, the panel was of the opinion that the particular MS would give even better sensitivity if it were equipped with a packed column (since it was originally designed for this type of column). A capillary GC/MS unit, however, is needed in 1984 to provide state-of-the-art deuterated THC GC/MS data.

The panel reviewed, as a passing matter, the data available for and the issues raised by the four expert witnesses for the defense at the Homestead AFB, Florida, court-martial of 25-28 October 1983. From the limited summary of information available about the testimony, the issues raised by the expert witnesses apparently centered on:

- (1) The procedures were not developed for forensic purposes.
- (2) Use of DB-5 capillary columns had not been validated to their personal satisfaction or standards.
- (3) Presence of "coelluting peaks" -- THC at 4.05 and another at 4.25.
- (4) GC-MS spectra not calibrated and therefore not correct.

The panel was uniformly convinced that justice would have been better served if the prosecution had been able (possibly, if needed, by employing an expert of equal stature to the defense experts) to address crucial questions such as: (1) Does the internal quality assurance validate the ability to detect 0 concentration and the standard concentration? (It does); (2) Would a peak .20 away from the expected retention time be called a positive? (It would not); (3) How repeatable was the MS when run against standard samples and negative samples? Peak ratios for 357/313 and 372/313 were within the 15 percent guidelines over a two-month review period (August 1983).

This line of reasoning could have disposed of the defense expert witnesses preference for one technique or another and moved the arguments toward the more crucial issue -- Did the sample indicate the presence of THC or not? However, to get such information before the court, the prosecution must understand the scientific issues involved, present expert testimony on behalf of the government and, with expert assistance, ask relevant questions of defense experts. Incidentally, such information should routinely be sought regardless of the column, technique, or procedure used. In summary, the three panel consultants agreed that the specimen in the Homestead AFB case was positive for the THC metabolite based upon a review of the available data.

The laboratory training SOPs were reviewed and personnel queried on how training was done. The SOPs are a model of what should be expected within a lab.

5. Overall, the panel concluded the following:

a. There is no evidence that this laboratory should not continue reporting results to the field.

b. The following issues, none of which themselves would invalidate results, deserve the on-going attention they seem to be receiving.

- There appears to be no reason why the current GC/MS procedures should not continue to be used to support the THC confirmation program. (There was some concern expressed as to whether it should be.)

- Something should be done to remove the fairly constant contaminant peaks seen frequently post THC in GLC's. The most likely source is ethyl acetate reagent contaminant.

- Oxyphenbutazone should be eliminated as the internal standard. This step would improve throughput, since pH balancing would not be needed in Prep I. PBA (pyrene butyric acid) is an alternate and probably more acceptable internal standard although the present DB-5 capillary column would need conversion to a DB-1 column.

- Tighter control at the bench of technicians and more on-the-spot corrections would probably significantly reduce retests and reruns. Participation in a system-wide training program on GC would be beneficial.

- The panel worries whether the manpower evaluation team effort currently underway is a proper priority effort until new equipment and procedures are shaken down.

- The Lab is correct in maintaining a small technology effort to check and chase problems as they arise and to evaluate any change in procedure, before it is installed. This is especially important for AFIP proposed changes, which have not generally been validated in the field.

- Use of Delta-8 THC as a standard is especially unwarranted in a DB-5 capillary column. Delta-9 is the only THC one would expect to see in a true specimen, and its retention time will not match Delta-8 THC.

- Quantification of pool positives and pool negatives are well worth the effort -- whatever it requires.
- The use of TDY personnel proved quite successful in this lab in making a quick change from one workload level to a nearly doubled workload.
- There really should be more technical interchanges among operating laboratory personnel of the various laboratories involved in drug testing.
- Considerably more attention needs to be paid to training legal personnel on the "right questions" to ask in cross examination of expert witnesses. There may be an advantage in securing expert witnesses for the prosecution, particularly if one can secure a board-certified toxicologist.
- As in any secure atmosphere, constant attention should be given to minimizing access to the specimen storage room.
- The present QC/QA unit reports to the Drug Testing Laboratory management. This unit should be independent of the testing unit as also recommended by CAP. Brooks AFB has already undertaken to initiate this change.
- As recommended in our initial review of Ft. Meade, it would seem that consideration should be given to delaying the insertion of SSAN on any intra-lab forms until analysis is complete. (This suggestion, if approved by the Air Force JAG advisors, would reduce hand-written entries and make the specimens more anonymous, thus insulating laboratory personnel from possible coercion from outside sources.)


DAVID W. EINSEL, JR
Major General, USA
Chairman

cc: Dep Surgeon General, USAF

Col George Lathrop, Epidemiology Div
USAF School of Aerospace Medicine

APPENDIX F

REPORT OF VISIT TO WIESBADEN AB LABORATORY

23 NOV 1983

MEMORANDUM FOR THE DEPUTY SURGEON GENERAL, USA

SUBJECT: Report of Visit to US Army Drug Testing Laboratory, Germany, by the Blue Ribbon Panel for Review of Urinalysis Drug Testing Program

1. Reference your memo of 24 October 1983 on Requirements for Blue Ribbon Panel Review of Urinalysis Drug Testing Program.
2. The Panel visited the US Army Drug Testing Laboratory, Wiesbaden, Germany, on 17-19 November 1983; received briefings on the operation by the Commander, Major Stanley Sutton and his staff; toured the facility; reviewed the technical functions of each section; and reviewed random chromatographs and technical results over the period from October 1982 to October 1983. Major John Rucker replaced Major Jerry Lemberger as the OTJAG member of the panel for this visit. Informal outbriefings were provided to the laboratory, to Col Angritt and staff of the 10th Medical Laboratory, and to MG Quinn Becker his deputy and Chief of Staff at 7th Medical Command, Heidelberg.
3. The laboratory provides support to USAREUR and USAFE. It reports through the 10th Medical Laboratory to the 7th Medical Command and is a tenant on the Wiesbaden Army Community (formerly the Wiesbaden Air Force Base). It is currently staffed at 97 personnel (4 Officers, 60 EM, and 33 Civilians), with an authorized strength of 85 personnel (3 Officers, 53 EM, and 29 Civilians). Supervision consists of 4 Officers (1 MAJ, 1 CPT, and 2 1LT's vs Authorized 1 MAJ and 2 CPT), 19 NCOs (4 SFC, 10 SSG and 5 SGT vs an Authorized 5 SFC and 7 SSG) and 3 GS Civilians (2 GS-9 and 1 GS-8 vs an Authorized 2 GS-7). The laboratory processes urine specimens from all of Europe, the Mediterranean and the Middle East, processing about 33,100 specimens in October 1983, averaging about 31,000/month since May 1983, and 28,250/month since October 1982. The range of workload has varied from a low of 21,741 in February 1983 to 49,489 in April 1982. Until October 1982, the Laboratory also processed USNAVEUR's specimens. In October 1983, the breakout of Army vs Air Force specimens was 27,600 to 5,500. The laboratory tests all samples for: amphetamines, barbiturates, morphines, cocaines and THC. Approximately a 3.2% prevalence of THC use was reported in October 1983, reflecting a steady downtrend from the 9.3% reported use in February 1983 when 100% testing for THC began. For October 1983, opiate positive reports were made for 206 specimens (about 0.6%) and cocaine positive reports were made for 102 specimens (about 0.3%). 88 Barbiturate uses and 56 Amphetamine uses were also reported. (All figures are for combined Army and Air Force use.)

4. Overall, the supervision seemed excellent and very dedicated to achieving excellence, (sometimes in spite of the system). Bench level supervision and on-the-spot correction of errors seemed superb. Attention to technical detail was thorough. SOPs were available in each section, although a central updated repository was unavailable. Considerable superb effort has been placed on improving efficiency of throughput through the wise use of automation, dedication of equipment, development of mass-production procedures and use of in-process statistical review of results. Chain of Custody seemed excellent within the laboratory. The quality of reagents and solvents seemed excellent and significantly better than the panel observed at Ft. Meade or Brooks AFB. The laboratory's main shortages are an inadequate GC/MS capability and an apparent low priority in receiving post-engineer and logistical support from the supporting installation.

An impressive and ingenious program has been developed by SFC Perry on the staff for use on a mini Hewlett Packard (Model 9835) computer to assist in the chain of custody, determination of RIA cut-offs, selection of samples for re-RIA analysis, control of sample specimens throughout the process and reporting of the results. Incoming DA 5180-R (test) Chain of Custody forms are key punched into the computer with the unit specimen number, unit code, SSAN, and lab accession number. A computerized receipt is generated from this which shows the date, suppresses the SSAN to prevent possible internal lab coercion, and prints a computerized label for the specimen, along with a batch worksheet for the initial RIA screen. Each sheet has a provision for signature by the aliquoter automatically inserted. As the RIA screen is done, the computer records the positive standards, negative standards, positive QCs, calculates the means and SDs, determines the cutoffs, asterisks possible outlying values, calculates from these factors the desired number of standard deviations to be used for the positive screen, and prints summaries of the results to include listing those samples that are "positive". It simultaneously prints labels in numerical order of the positive samples, a worksheet for the aliquoters to take the samples and provides automatically all of the requisite chain of custody data forms for signatures, times, purpose of aliquot, etc. It also prints automatically the needed worksheets for the reconfirmation, and prints spaces for GLC readings, 2nd readings, and confirmation by the supervisor, along with space for identification of aliquoter, and each operator. Upon completion of reconfirmation, it is capable of printing the outgoing lab message to the commanders; and, since all of the data is stored on discs, provides a ready basis for statistical analysis of internal procedures, variations in SD, variations in percent screening, variations in percent confirmations, and can provide all of this data by Service, by Command, by Unit, by location--all with very little chance of error, since remanipulations of repeated numbers are done by computer in the entire system.

The RIA procedures are well documented. Five initial RIA screens are run in parallel, one for each of the drugs. Standards are included before, after, and within each batch. The outputs of the gamma counters are connected directly to the computer through a floppy disc recorder. As mentioned above, tolerance cut-offs are established for the positive cut and the negative cut on the standards, the RIA mean values of the standards are printed, along with the technician's name, time, number of samples, date and SD. Also listed are the numbers of screened positives, number of low and high counting specimens; and, if the operator believes it is a valid run, necessary paperwork to guide the aliquoters in selecting those samples for re-RIA (along with labels for the re-RIA) are prepared, (each complete with all the necessary chain of custody data spelled out on the form). The panel found no difficulty with the RIA procedures other than suggesting an improvement in the decanting step which should reduce the SD; and suggesting more care in the measuring of the initial aliquot along with more attention to wipers on the automatic pipeters.

The GLC procedures are well-documented, use an OV-17 packed column, and are extremely closely supervised and reviewed throughout their processing. Pooled negative and positive standards are included in each batch run, being prepared by the quality control group. Prep-I procedures, including adjustment to pH 9.0 are used. Oxyphenbutazone is used as the internal standard, although PBA (pyrene butyric acid) has just been received for trial as an internal standard. The quality of the chromatograms was unusually good from the viewpoint that remarkably few contamination peaks were evident -- a tribute to either remarkable care or excellent quality of chemicals -- or both.

In the panel's review of random chromatograms throughout the past year the following summary can be made: From January-February to April 1983, (the period when 100% THC was first being implemented and direct extraction pre-Prep-I procedures were used), more than 75% of the chromatograms would be subject to question as to their scientific or legal credibility. This data rejection was primarily due to poor sample clean-up and inadequate chromatographic resolution. In a review of April 1983 chromatograms (where any peak at the correct RT was called positive), the panel found 7 of 56 (about 12.5%) would have been called negative by the criteria being used at the time and an additional 12 (about 20%) would have needed an MS confirmation to be legally and scientifically credible. Since June 1983, the panel would have found less than 5% which would need an MS confirmation to be credible. Since October when pH 9.0 extraction was implemented, the quality of the chromatograms has noticeably declined, as noted by extra peaks and more frequent operator re-runs. The panel notes that the laboratory uses an extremely conservative criteria especially since August 1983, in view of the overall quality of the THC chromatograms. The panel believes that they could equally confidently support selecting nearly twice as many specimens as

positive--and still be scientifically and legally credible for the period August 1983 to date. Review of the entire period to date does not indicate any reporting of false positives.

The following remarks address GLCs on other drugs, since this laboratory assays all specimens for these other drugs. The cocaine GLC procedures seem extremely accurate. The chromatograms have some contaminant peaks, which although not critical to detection could probably be removed. For opiates, the assay procedures are sound. There were enough chromatograms with coeluting peaks after codeine or overlapping (or incomplete) peaks for morphine that most chromatograms should be reconfirmed by mass spectrography before reporting opiates. (Overall, this is an Army wide problem, requiring review of the guidelines throughout the Army, as to how morphine/codeine chromatograms should be reported. A system to identify which morphine positives are due to its appearance as a codeine metabolite is needed.) For barbiturates, the laboratory is probably not miscalling any of the positive samples, but the present Army-wide procedures need review and revision. The panel believes that the present procedures probably are missing a lot of the barbiturates especially because of the wide use of phenobarbital. The DOD procedure for free acid barbiturate chromatography should be given strong consideration by all laboratories. The laboratory is currently reporting about 50 amphetamine positives a month. The panel's review of these chromatograms raises several concerns. The reasons are: (1) Some negative specimens, when left a long time, show an interfering peak; (2) It is questionable in USAREUR whether methamphetamines would be stable (especially in view of the long ship time from areas such as the Mid-East and in higher temperatures); and (3) A number of the chromatograms reviewed seemed to evidence other peaks which might well be nothing more than decomposition. In general, there is a lack of retention time data on many over-the-counter amphetamines. All of these considerations, lead the panel to question the validity of the currently directed procedures under which the laboratory is performing this analysis. It would seem that the above questions should be resolved by definitive laboratory data and checks prior to placing great reliance on present GLC results, at least without GC/MS supporting data. In passing, the panel noted that the use of nitrogen/phosphorous detectors instead of the FID detectors on the GLC should lead to better detection capability for drugs other than THC. The laboratory has these detectors on hand, and could easily use them on some of the GLC machines which could then be dedicated to the more critical analyses above.

The GC/MS equipment was only installed recently (on about 25 August). It is located in an area without temperature control, contrary to factory specifications, and to date there really has been no adequate operator training, and, obviously, no development of standards, good procedures, or equipment

trend data. GC/MS is used in only about 1% of the samples, instead of the Army suggested 10% for quality control. Establishment of an adequate GC/MS capability is properly recognized as the number one priority effort within the laboratory needing immediate attention. (The panel has already contacted the Hewlett-Packard Company in the US, and they have agreed to resolve the local training problem in Wiesbaden.)

5. Overall, the panel concluded the following:

a. There is no evidence that this laboratory should not continue reporting results to the field; however, we believe some care should be taken by this and all Army labs in following the current procedures on amphetamines, and that Army guidance may be needed on calling Morphine/Codeine results. The laboratory is currently following the Army procedures.

b. Two issues deserve, and will probably require, higher command attention:

- Although it is recognized that the laboratory, in keeping with Army desires to expedite improvements since the beginning of the fiscal year, has had a considerable influx of new GLCs, a new GC/MS which arrived in January, and has had major personnel increases during the year; it seems evident that necessary equal priority has not been provided in achieving facility and logistic support. Electrical outlets and lines have been on order since June; needed barrel storage has been on order since July, installation of the GC/MS did not occur until August, needed environmental control for the GC/MS is not yet in place, a new computer terminal is to begin arriving in January and provisions are not yet scheduled for its installation, and it took a very long time to complete installation of refrigerator units in the receiving area. Moreover, there appears to be building repairs, such as repair of a sewage line in the crawl space which has been on order since April. (At present, there were mosquitos throughout the interior of the building--a feature, not conducive to high quality laboratory procedure.)

- Training for GC/MS operators must be arranged quickly, whether it is done by contract, by bringing instructors in TDY, or by sending personnel on TDY. As a part of this, it is possible that provision might be made for commercial GC/MS support until such training and the equipment installation is complete, (as has been now done by the laboratory on several occasions).

c. The following issues, none of which themselves would invalidate the results of the laboratory, deserve the on-going attention they seem to be receiving.

- SOPs should be more carefully initialled, each page dated, and review procedures should be followed throughout. The plan to place them on word processing equipment, when it arrives, is good.

- The attention to reviewing trends daily for abnormalities in procedures should be encouraged. Reviews of such things as trends of SDs, ratio of screened positives to confirmations, percent recovery of extractors, reproducibility of extractors and shooters, concentration vs. GLC standard values, ratio of presumptive screen results to re-RIAs, trends of GC/MS standards, and determinations of level of detection sensitivities for each GLC are important management indicators and valuable data to have in supporting adversary questions.

- Current efforts in computerization have been so successful and practical, that thought should be given to "exporting" this very successful technique to other Army laboratories.

- Consideration being given to developing a truly lab-wide quality control/assurance group should be continued.

- The efforts of the laboratory to arrange for periodic independent security surveys should be encouraged. While there is no problem with the custody of specimens, general facility security may well be enhanced by these efforts.

- Consideration should be given to performing a quick laboratory experiment to determine whether the use of nitrogen, vs. compressed air, is truly needed for evaporation of solvents in the extraction procedure, in view of the high cost and complexity that installing a large manifolded nitrogen system appears to require.



DAVID W. EINSEL, JR.
Major General, USA
Chairman

cc: Cmdr, 7th Medical Cmd
Cmdr, 10th Medical Lab
Cmdr, USADTL, Wiesbaden, GE

APPENDIX G

REPORT OF VISIT TO TRIPLER AMC LABORATORY

12 December 1983

MEMORANDUM FOR DEPUTY SURGEON GENERAL, US ARMY

SUBJECT: Report of Visit to US Army Drug Urinalysis Laboratory, Tripler Army Medical Center (TAMC), Schofield Barracks, Hawaii, by the Blue Ribbon Panel for Review of Urinalysis Drug Testing Program

1. Reference your memo of 24 October 1983 on Requirements for Blue Ribbon Panel Review of Urinalysis Testing Program.

2. The Panel visited the US Army Urinalysis Laboratory, Schofield Barracks, Hawaii on 2 December 1983; received briefings on the operation by the officer in charge, Captain James P. McCarthy and his staff; toured the facility; reviewed the technical functions, random chromatograms, quality control data and technical results from the period January to October 1983. MAJ John Burton represented the OTJAG for this visit. Informal outbriefings were given to the laboratory and to MG Tracy Strevey, Jr., CG, TAMC.

3. The laboratory provides support to USARPAC Command (Johnston Island, 8th Army, and WESTCOM), USARJ Commands including Okinawa, Alaska Commands, Pacific Coast Guard Elements, Pacific USAF Commands including Korea and Japan, and the western CONUS Commands as far east as Corpus Christi, WSMR, Ft. Bliss, Ft. Huachuca, and Ft. Carson. Over the past six months, it has occasionally supported other CONUS installations such as Ft. Riley and Ft. Benjamin Harrison. It reports to TAMC and is a tenant at Schofield Barracks. It is currently staffed at 35 personnel (18 military and 17 civilians). From June to September 1983, its quota of specimens was 15,000/month. Since October 1983, it has been processing about 11,000/month. For October 1983, the latest month reported, the laboratory received 10,346 specimens (1,570 USAF, 15 Coast Guard, and 8,761 Army). About two-thirds of the Army workload comes from CONUS installations. The range of work load over the past six months varied from nearly 17,000 in August to about 11,000 in November 1983. The laboratory tests 100% of all specimens for THC and does 10% pulse testing for one other drug. For October 1983, the laboratory reported 5.9% confirmed positive THC results, a drop from June 1983 when the reported positives were 19.8%. During the June to October period, the cutoff level for a positive report was increased from 30 to 75 ng/ml. Reported positives for other drugs are very low. For October 1983, only two positive specimens

for cocaine and three for opiates were reported. For the period back to June 1983, the maximum positive specimens reported per month were 20 amphetamines, 10 cocaine, and 4 methamphetamine. (Testing for drugs during the period was only "on request" or on a 10% pulse basis).

4. The RIA procedure was highly credible from a technical and operational consideration. Standards are run adequately with each batch and the data was used properly to substantiate cut off limits. A thorough job in decanting supernatants was evident. Present data handling lends itself to error which could be eliminated with expedited implementation of data reduction systems. Work flow and floor organization were not conducive to efficient specimen throughput due to electrical shortages, internal reorganization and air conditioning requirements. Maintenance records were complete and thorough and maintenance on the automatic pipette machines was noteworthy. There were some questions on the implementation of the Roche package insert instructions which differ from the DA SOP (incubation time 30 or 60 minutes). The laboratory did not violate the manufacturer's procedure, however, the laboratory failed to question the DA proponent on the SOP inaccuracy.

The GC confirmation procedure for THC metabolite appears to be properly performed. Calibration curves for the acid metabolite and internal standard are prepared and the recovery of both compounds is documented. There was careful analytical and statistical evaluation of the cutoff value done by analyzing a series of 75 ng/ml samples. The mean and the standard deviation were derived. If the positive control for a batch was within a ± 2 SD window the batch was accepted. Any urine sample greater than 75 ng/ml was considered positive, with any sample between 50 and 75 ng/ml being re-extracted. Specimens less than 50 ng/ml were reported negative. Even before the 75 ng/ml cutoff was adopted, the laboratory was very conscientious about what was being called a positive. A 30 ng/ml cutoff was used by the laboratory until September 1983 when the 75 ng/ml cutoff was implemented. The Panel feels that the 30 ng/ml value was justified based on review of the chromatograms during that period. The laboratory THC extraction procedure using oxyphenbutazone has had more consistent results than the other laboratories. This is attributed to the close attention to analytical detail and the fact that modifications were evaluated prior to implementation.

The gas chromatographs (HP 5880A) were used to their fullest capability in the laboratory. A computer program was written by laboratory personnel to setup the chain of custody for the GC analysis, document the instrument set-up and conditions, and insert the interpretations and calculation of the GC results. This program helped tremendously in the documentation of GC

data and parameters; however, in some instances, laboratory technicians may have become over-dependent on the quantitative computer program in the calculation of the final result. The Panel believes that chromatogram evaluation must involve increased visual inspection of the chromatograms by the operators with re-injection of some samples to achieve better representative chromatograms. For example, during the period of May-June 1983, the Panel found that about 10% of the chromatograms revealed that the specimens should have been re-extracted or the sample re-injected. In July 1983, when procedures were being changed, a higher rate of poorer quality chromatograms occurred (about 20%). Since then, the quality has been very good with only about a 2% rate that would need further confirmation to be credible and defensible. The deficiencies observed in the GC data during the entire period reviewed were: The internal standard peak was covered by an off-scale solvent front, the solvent peak had not returned to at least 25% of the full scale value, insufficient resolution of peaks existed, or insufficient recovery of the internal standard was evident.

As a quality control measure, positive samples and negative samples are run with every batch for GC confirmation. In addition, as a daily check on reagents and solvents, a water sample is extracted and analyzed to show the lack of any interfering peaks from solvents. The quality of the chromatograms is very good, data is defensible, and the laboratory has developed the best procedures reviewed in any of the four laboratories for analytical evaluation of the cutoff limit. This was done without guidance from outside sources.

The Panel reviewed preliminary data generated by the laboratory using PBA as an alternate internal standard with OV-1 columns. The data looks very promising and, with the proper authorization, the alternate procedure would allow the use of a 50 ng/ml cutoff with continuation of the present Quality Control program.

The situation with GC of other drugs is similar to other laboratories visited by the Panel. The amphetamine procedure has its inherent problems due to urine interference peaks, probably caused by decomposition products. However, amphetamine chromatograms for this laboratory were of good quality with good resolution of the internal standard. It is the Panel's opinion that GC/MS data should be obtained on amphetamine positive samples.

The cocaine procedure currently in use is an old procedure. It is the opinion of the Panel that this cocaine procedure does not allow the laboratory to confirm data obtained from the RIA screen. It is recommended that the laboratory verify the procedure in the Army's SOP for implementation.

The current procedures used for opiates and PCP result in chromatograms of insufficient quality because of lack of peak resolution. Thus GC/MS should be used for confirmation of these samples unless better resolution can be obtained.

There were no positive samples for barbiturates reported during the current year and thus the Panel did not review this procedure.

With respect to GC/MS, a Hewlett-Packard 5995B GC/MS unit was received in May 1983, installed in June 1983 and has been operational for THC since that time. It is currently operated and maintained by CPT McCarthy. The unit is currently housed in a converted bathroom with only general laboratory environmental controls. The GC/MS is currently used only for court-martial cases or re-test requests. The 5995B is performing well, is properly maintained and calibrated (autotuned), and its use is documented in a signed logbook. Review of the data acquired to date shows a very consistent response for the THC metabolite methyl derivative ratios (357/313, 372/313) although the Hewlett-Packard library best peak match algorithm is being used rather than comparing the ratios for specimens vs standards and/or controls run on the same day. The Panel explained the proper use of the THC ratios to CPT McCarthy, and the need for daily use of controls.

Overall, the GC/MS potential in this laboratory for this key program is good. Lack of proper resources (personnel, adequate electrical power, air conditioning, training, and expertise) prevent the proper integration of the GC/MS into the drug testing program. The current approach of using the laboratory OIC as the only qualified GC/MS operator must be changed. At least two full-time operators (for two shifts) are needed now to support the program. Proper training must be received by operators to enable them to provide daily QC support to the GC confirmation program. Long-term training is needed to prepare the laboratory for acquisition of GC/MSD (Mass Selective Detector) units. The laboratory will need bona fide in-house GC/MS expertise and support as well as Hewlett-Packard maintenance contracts during the next year to certify this program. With the proper support, the laboratory will be capable of providing routine GC/MS data that will be scientifically and judicially acceptable. Without this support, the current program will not be able to: (1) maintain an adequate QC program for documentation of GC confirmation against court challenges, (2) prepare for routine use of the programmed Hewlett-Packard bench top GC/MSD units, or (3) achieve the desired 10% GC/MS confirmation rates.

Of particular note to the Panel was the ability of the laboratory to apply solid analytical principles and quality control throughout each processing station in the laboratory. Supervisors and section chiefs understand how to detect trends,

analyze procedures and administer corrective action in THC testing. A major contributing factor to this is the laboratory training program, especially the use of video training aids made in the laboratory by its personnel. Interpretation of results and the practical application of subject matter in laboratory OJT is significant. SOP's are available, kept current and followed closely at each of the processing stations. A master file is maintained, reviewed, corrected and kept up-to-date, and reflects compliance with higher echelon SOP's. Section chiefs are knowledgeable of the Drug Urinalysis Program and have done an excellent job of imparting that knowledge to their personnel. They understand gas chromatography, know how to apply it to laboratory procedures and meet standards. Overall quality is good and reflects application of established standards, analysis of results, calibration curves, and monitoring daily extraction efficiency of the THC metabolite. GC/MS trained personnel are badly needed to ensure initiation of at least 10% confirmation of GC results as QC and to check negative pools. Requests for personnel to appear as court witnesses is excessive and needs control and support from higher headquarters. The absence of the laboratory OIC and up to 25 staff in recent weeks has affected laboratory out-put and turn-around times (a 6,000 unfrozen specimen backlog exists currently).

Data reduction systems assistance from higher headquarters is critically needed. The Panel was unanimous in its concern for lack of automation for in-processing specimens, chain-of-custody procedures, determination of RIA cut-offs, selection of samples for re-RIA analysis, control of specimens throughout the system, and reporting of results. Filling the computer slot, assistance from the Wiesbaden laboratory in personnel and software, and computer engineering assistance from higher headquarters would save significant effort and time in specimen processing. This would permit better utilization of automatic data processing equipment and give the laboratory an opportunity to provide input to data reduction systems use and development. It was noted that the tape systems provided for program management information systems were not compatible with the laboratory equipment.

Shortages in the number of electrical outlets and in electrical power are having an adverse effect on laboratory operations. Freezers are available for positive specimen storage but cannot be placed in the laboratory because of electrical power considerations. Power supply reductions have affected GC/MS operations. This can neutralize court evidence. Lighting and air conditioning are not adequate in all areas of the laboratory and prevent needed internal reorganization to improve the flow of specimens and throughput throughout the laboratory. Improvements in utilities and facilities would permit relocation of the RIA stations, free floor space for freezers, allow for proper air temperature control and circula-

tion for equipment, and reduce the vulnerability of samples to the violation of chain of custody procedures and security. With four additional GC's and four additional MSDs scheduled to arrive in the March-May 1984 time frame, power supply, power outlets, and temperature and humidity concerns will be serious deficiencies. If installed contrary to factory specifications, these units and proposed computer terminal equipment scheduled for future installation will compound operational and productivity problems and directly affect the forensic requirements of this laboratory.

Glass crushers on order are needed quickly. Much time is wasted and operator efficiency is reduced due to present radioactive waste materials handling. Dishwashing procedures, storage consideration, counting, testing and handling procedures impact adversely on laboratory operations. Higher headquarters assistance in this aspect of operations is required. Similar assistance is needed to restore maintenance contracts for Hewlett-Packard equipment. (The laboratory was advised by Medical Maintenance at TAMC to secure funding for this -- a task beyond the laboratory's ability.)

Unfit for Testing (UFT) specimens (altered specimens, altered SSAN's, e.g. KATUSA's in Korea, specimen mismatch, and specimens without numbers on DA Forms 5180 or both) hamper inprocessing procedures and increase processing time. DA assistance is needed to ensure field units and alcohol and drug control officers comply with existing directives and messages to the field outlining corrective measures. (There was evidence that many do not comply promptly, if at all!)

Specimen workload considerations are currently limited by the laboratory's ability to process samples in the evidence handling section. With the implementation of increased quotas (15,000 per month) and possible testing for 100% cocaine, the laboratory has a 6,000 specimen backlog (not frozen). With future program requirements, training demands, cross-training needs, new equipment introduction to the laboratory, and present personnel and fund levels, considerable caution should be used by authorities in allocating the quotas for this laboratory.

Current chain of custody procedures are good and properly documented. Accessions personnel insure that submitting installations comply with external chain of custody procedure requirements before any specimen is processed. Noteworthy was the recording of actual volumes received for each specimen as required by DA. This factor was considered critical in the USAF Homestead case and should be implemented by all laboratories.

As observed at previously inspected laboratories, the chain of custody requirements of Interim Change 2, AR 600-85, were gradually implemented from mid-March through June 1983. Subsequent to July 1983, specimens submitted without properly

documented chain of custody were rejected as unfit for testing (UFT). In a few cases, individuals who hand-carried local specimens to the laboratory did not document how they obtained the specimens, yet the specimens were not rejected as UFT. Closer supervision of hand-carried accessions should resolve the problem. Physical security of the laboratory appeared to be adequate based on two recent inspections by installation security personnel. Such inspections should be conducted frequently and coordinated with the local staff judge advocate. One potentially serious security and chain of custody problem exists. There is no freezer storage space for positive specimens within the laboratory, due to insufficient electrical power and outlets. Freezer storage is essential to prevent degradation of the specimens and to comply with established retention procedures. The installation has provided seven off-the-shelf 18-cubic foot upright freezers in a public access hallway four buildings away (about 300 yards) from the laboratory. Each freezer is locked and secured to the adjacent wall by a "logging chain". However, the exposed hinges of the freezer doors can be removed with a screwdriver. Although the hallway door is locked at night, this arrangement provides marginal physical security of the positive specimens and creates additional chain of custody problems. At a minimum, the laboratory must document each access to a freezer and conduct periodic security patrols of the area.

Overall, this laboratory has the highest rate of confirmations of AFIP samples, has done an excellent job of providing quality control standards, has an excellent training program, is developing good PBA procedures and has the highest percentage of scientific and legally defensible chromatograms.

5. Overall the Panel concluded the following:

a. The Panel found no evidence at all that any false positive results are being reported. The laboratory procedures are scientifically thorough and very conservative in reporting positive results. This laboratory can very confidently report positive results at the current 75 ng/ml level of THC. (In fact, it was doing so confidently at the 30 ng/ml level prior to September 1983.) This results from very dedicated efforts being made in quality control of all potential variables. As with other Army laboratories, considerable caution must be used in reporting amphetamines. The laboratory must validate a new procedure for cocaine confirmation.

b. Several issues deserve and will probably require higher command attention:

- Priority attention must be given to upgrading the electrical power level of the laboratory. The laboratory has been required to store frozen samples under chain of custody

control, but does not yet (after nearly a year) have adequate freezer capacity because of limits on electrical power. Similarly, the laboratory equipment on hand must be physically located now to minimize "brown-outs". With new equipment (GC/MSD) due to arrive in early calendar 1984, there will truly be a power shortage.

- TAMC has advised that maintenance contracts cannot be funded for the Hewlett-Packard equipment. Some provision must be made to assure continuous competent maintenance support if the laboratory is to remain technically above challenge.

- Training for GC/MS operators must become a priority matter to bring the present GC/MS equipment on line for a full two shifts and to provide qualified operators for the arriving GC/MSD equipment.

- There is a requirement for at least a second officer position in the laboratory, particularly in view of frequent TDY requests to appear in court proceedings. (The laboratory presently has an assistant OIC in an overage authorization.)

c. The following issues, none of which would invalidate laboratory results, deserve ongoing attention by the laboratory:

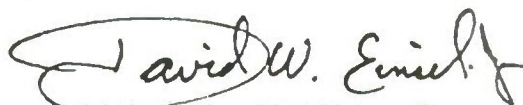
- The laboratory should work closely with the Wiesbaden laboratory to transfer as much of the automation, already developed there, onto their Tripler equipment (which is nearly identical). TDY of the Wiesbaden computer expert to Hawaii is recommended.

- The laboratory should continue its efforts to optimize its physical layout (now controlled largely by electrical power limitations). These efforts will improve overall efficiency, throughput and ease some of the current burdensome chain of custody procedures.

- The laboratory should continue to maintain close relationships with the SJA and physical security staffs to minimize requests for witness support, and ensure that good chain of custody procedures are continuously maintained.

- In the laboratory review of trends of data, consideration should be given to maintaining daily averages of ratios of confirmed GC positive samples to initial RIA screened positives. This would be a good indicator of overall quality control that all procedures, reagents, maintenance and operators

are maintaining constant precision. It will assist the quality control personnel in detecting any unexpected changes before results are sent to the field.

A handwritten signature in dark ink, reading "David W. Einzel, Jr." with a stylized flourish at the end.

DAVID W. EINSEL, JR.
Major General, USA
Chairman

cc: CG, Tripler AMC
OIC, DUL, TAMC, Schofield Barracks

APPENDIX H

REPORT OF VISIT TO ARMED FORCES INSTITUTE OF PATHOLOGY

12 December 1983

MEMORANDUM FOR THE DEPUTY SURGEON GENERAL, USA

SUBJECT: Report of Visit to the Armed Forces Institute of Pathology by the Blue Ribbon Panel for Review of Urinalysis Drug Testing Program

1. Reference your memo of 24 October 1983 on Requirements for Blue Ribbon Panel Review of Urinalysis Drug Testing Program.
2. The Panel visited the Armed Forces Institute of Pathology (AFIP), Washington, DC, on 30 November 1983; received briefings on the role of the Toxicology Section by the Director, AFIP, Colonel William R. Cowan, Colonel William Manders and Dr. John Whiting; and discussed issues relevant to the Panel mission. Major John Burton served as the OTJAG member of the Panel for this visit.
3. AFIP's primary mission is the toxicological evaluation of air and surface accidents for the Armed Services. In addition to other related activities, it has been given the responsibility for conducting the DOD Tri-Service Quality Assurance Program for the services' drug urinalysis program. This presently entails the preparation and distribution of quality control (proficiency testing) samples to the nine military drug urinalysis laboratories and to evaluate and report the test results. The program is designed to submit 36 samples per week to each laboratory in a double-blind manner, through appropriate military submitting units. The samples are prepared at target drug concentrations that are 33 to 150% greater than the DOD RIA minimum sensitivity levels (See Attachment I). Furthermore, by DODD 1010.1, AFIP conducts certification evaluations for new laboratories or methods. AFIP explained its quality assurance program as an evaluation of a laboratory's ability to distinguish positive from negative specimens and to assure that all specimens received by each laboratory are tested.
4. The Panel felt that the QA program accomplished its mission of testing the laboratories' abilities to distinguish positive from negative specimens. The last quarterly report, rendered by AFIP, showed no false positives. (None has been reported, in fact, this year.) AFIP noted that the identification of positive samples has been greater than 90%.

5. The Panel discussed with the AFIP staff some of the problems and limitations of the current QA program. It was agreed that the strongest support that the program provides for the quality of results from the laboratories is the absence of false positive results. The positive samples are spiked at relatively high concentrations and, therefore, do not challenge the laboratories to maintain minimum sensitivity levels. To fully challenge the laboratories sensitivity levels, a fairly extensive review would have to be made as to the levels, variability of levels, effects of transportation and such other factors to "prove" the validity of the quality control samples beyond a shadow of a doubt -- a major effort for which AFIP is not now staffed.

6. Another potential problem noted in some of the laboratories visited by the Panel is the characteristic odor of azide which is added to AFIP samples as a preservative. A more subtle preservative should be sought. The Panel noted that AFIP now uses delta-9-THC-9-acid exclusively in quality assurance samples, thus avoiding the confusion created by use of the delta-8 isomer. Of interest, blind samples for all drugs are currently being sent to all laboratories. However, except for the US Navy and Wiesbaden AB, which test for all drugs, many of the AFIP blind positive samples for drugs other than THC serve no useful purpose, since they are never tested. AFIP pointed out that its current staffing makes it virtually impossible to tailor a double-blind program for positives to match the drugs being analyzed, except for those cases where the laboratories test for all drugs.

7. AFIP initiated a new effort aimed at evaluating the quality of laboratory results by reviewing the actual RIA and GC data on QC samples obtained in Army and Air Force laboratories. This program is relatively new having followed the visit of AFIP personnel to the Fort Meade laboratory in September of this year. The Panel felt that this was a valuable, if not long overdue, aspect of an overall quality assurance program, assuming that AFIP applies a standard written SOP for evaluation of the chromatograms and RIA results. The Panel recommends that this effort be extended to the US Navy laboratories as well.

8. The Panel is concerned about the unclear role and mechanisms through which AFIP provides advice to the laboratories. It is the Panel's understanding that AFIP serves as a technical consultant to The Surgeon General and to the OASD(HA). However, the Panel encountered numerous instances where laboratory personnel sought advice and direction directly from AFIP. The Panel recognizes that AFIP is a valuable resource for the development of new methods and the improvement of existing methods. Nevertheless, such potential changes should be field evaluated and certified before being adopted by any laboratory. A glaring example of a recommendation for an untested change was the recent advisory sent by OTSG, following advice from

AFIP, to all laboratories to adjust the pH of the cannabinoid extraction step to pH 9.0. This caused characteristically "dirtier" chromatograms in the field and was very difficult to implement with the original buffer.

9. Discussion of the facts and data which supported the above advisory lead the Panel to conclude that there is a lack of appreciation by AFIP for the real problems in operating a large scale drug testing laboratory, a lack that is exacerbated by the absence of visits by AFIP to the laboratories in any deliberate or scheduled manner. Overall, the Panel agrees with the oft-termed remark that "AFIP operates in a vacuum" in this respect; however, since they represent an authoritative position their "casual" advice is heeded as "gospel."

10. As a further example, the GC method for cannabinoids published by Whiting and Manders of AFIP (J Anal Tox, Vol. 6, Jan/Feb 1982) is not useful nor workable as a method for routine, high-production type laboratory work. But, as a published method, it is often referred to in courts-martial as the "accepted method." The Panel wishes to emphatically state that such is not the case. In fact, AFIP itself has developed an improved method using a mechanical, resin extraction step which AFIP has "directed" for use in DOD laboratories, although this modification has not been published yet. The Navy has made further refinements on this method, notably in changing to pyrene butyric acid (PBA) as an internal standard and to OV-1 or SE-30 for the column packing. Again, although also unpublished, the experience in the Navy laboratories, coupled with the Panel's observations in the USA/USAF laboratories strongly indicates that PBA gives preferable results over the AFIP-recommended internal standard (oxyphenbutazone), which gives widely varying and erratic recoveries and thus makes quantification more difficult and unreliable. In the Panel's opinion, all the above changes are scientifically justified and definitely improve the so-called "accepted method."

11. During the discussions, AFIP made the following general observations concerning steps that could improve the overall drug testing program. These included the formal recognition that these are Forensic toxicology laboratories dealing with evidence and service personnel's futures. Also the internal quality assurance programs in the laboratories should be strengthened and regular inspections should be made (although by whom was not stated). The Panel agrees strongly with these ideas. The fact was raised that the DOD Biochemical Testing Advisory Committee has been essentially inactive throughout all these major changes in the drug testing program.

12. Also, a lengthy discussion ensued regarding AFIP or its staff's personal opinions on the minimal criteria necessary for the combination of positive RIA, GC, and GC/MS results to be

scientifically and legally defensible. This issue arose in light of court martial testimony by Col Manders and Dr. Whiting questioning such results. AFIP did agree with the Panel that RIA plus GC alone was acceptable, if the method was good (which includes adequate validation), proper positive and negative controls were run with the batch, some appropriate amount of GC/MS quality control conducted as an on-going validation, and the chromatogram in question was fully resolved with the peak at the proper retention time relative to the internal standard.

13. The Panel concluded the following:

a. AFIP has been conducting a blind proficiency testing program in a satisfactory manner, so as to sufficiently evaluate the drug testing laboratories' ability to distinguish positive from negative specimens.

b. For laboratories which do only pulse testing of drugs other than THC, there may be clear advantages in reporting and cost savings to be achieved by submitting only negative AFIP samples to verify that no false positives are being reported. The matter deserves further evaluation.

c. AFIP and the laboratories should be given clear instructions by OASD (HA) and The Surgeon General as to the kind of information that should be exchanged directly. The Panel strongly emphasizes that any change in procedure that deviates from the SOP must receive an appropriate review and validation before it is authorized for adoption.

d. It is clear to the Panel that AFIP is not adequately resourced now to provide a truly comprehensive and necessary effort needed to be an external quality assurance management agency or certifier of DOD drug laboratories. The issue of a comprehensive quality assurance program is addressed in the final Panel report.


DAVID W. EINSEL, JR.
Major General, USA
Chairman

Attachment

cc: Director, AFIP

Radioimmunoassay "Cutoff" Levels for Urinalyses Conducted in
Drug Testing Laboratories

	RIA Minimum Machine Sensitivity Levels ng/mL	AFIP Quality Control Minimum Concentration Levels ng/mL
Opiates	300	500
Barbiturates	200	500
Amphetamines	1,000	1,500
Methaqualone	750	1,000
Cocaine	750	1,000
Phencyclidine	25	50
Cannabincid	100	150

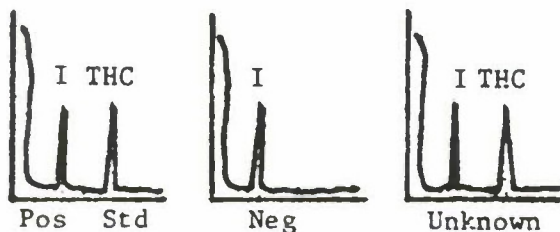
APPENDIX I

INTERPRETATION OF CHROMATOGRAMS

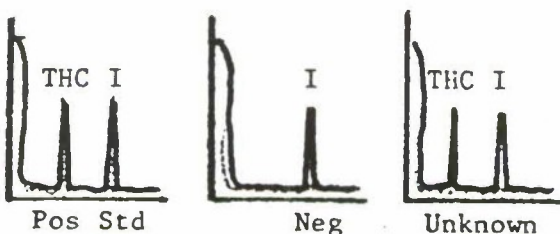
INTERPRETATIONS OF CHROMATOGRAMS

A good chromatogram series would look as follows:

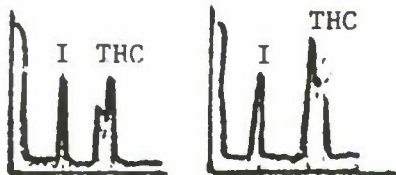
For oxyphenbutazone internal standards:



For pyrene butyric acid internal standards:



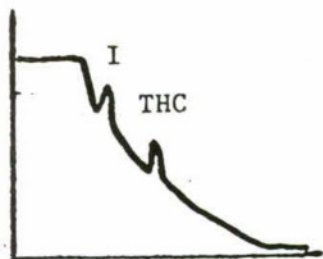
The following are examples of chromatograms which were being accepted, which could have, and should have, required supervisor review, checking, or confirmation by GC/MS or possible re-extraction or re-running of the sample:



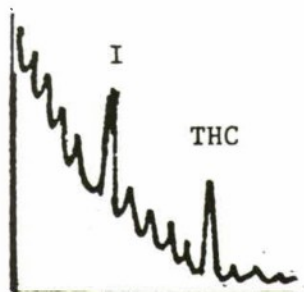
A good internal standard peak, but with a contaminant peak very close to the RT of the THC, such that it is difficult to say confidently that the peak is THC, and not a contaminant. Cleaning of solvents to remove the peak is usually needed here, selecting better grades of reagents, or using GC/MS confirmation for THC would be indicated.



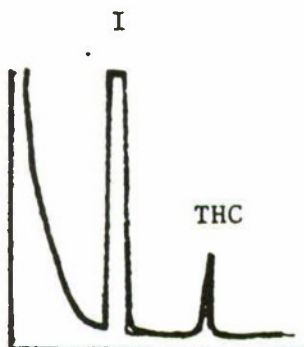
A good internal standard peak, but with a very small (less than three times noise level) peak for the positive standard. This frequently is the result of a poor extraction of the standard.



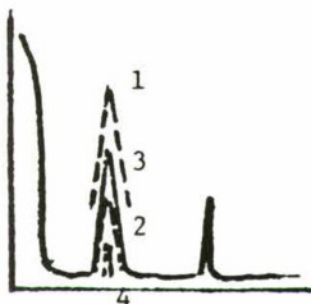
Presence of such an extensive solvent front that either the internal standard or THC peak is almost obscured. This is particularly difficult to interpret when the GLC is set for a baseline Mode Zero integration, when quite obviously the peak is occurring on a tangent to the baseline. Reshooting of the sample, reducing the temperature of the column, or a replacement of the column is indicated to correct this.



Presence of soap on glassware frequently will give a highly scalloped baseline such as this. More attention to dishwashing is indicated. If the samples have strong enough peaks, this need not be considered deleterious, but its frequent presence would indicate a problem area developing.

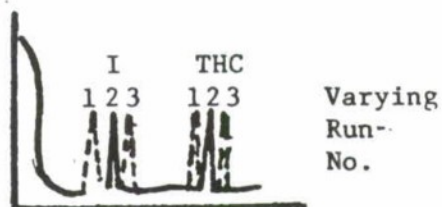


Use of an inappropriate attenuation scale or the shooting of a large enough sample of standard to cause complete overshoot (offscale) of either the internal standard or positive sample. Changing of attenuation or using a smaller sample is indicated (with care to note the fact on the chart!)

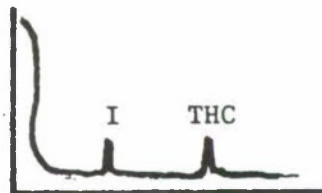


Varying
Run No.

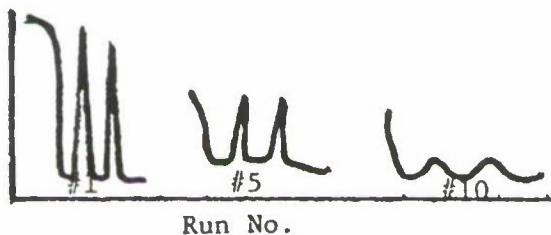
Variations of the internal standard or positive standard over a series of chromatograms. This is usually more frequently observed with oxyphenbutazone internal standards, or where an error (inconsistency) in extraction techniques is occurring.



Variations in retention times, among a series of chromatograms. This can be due to temperature variations in the column.



Very small standard peaks and small THC peaks, hardly above the noise level. Frequently a result of poor extraction technique, poor choice of temperature of column, or choice of too small a sample size. Frequently requires resolution of the sample and reinjection.



Gradual changes throughout a longer series of chromatograms. Possibly indicative of the need to change/repack the column.

APPENDIX J

REVIEW OF CHROMATOGRAMS FOR DETECTION OF MARIJUANA



DEPARTMENT OF THE ARMY
WALTER REED ARMY MEDICAL CENTER
WASHINGTON, D.C. 20307

REPLY TO
ATTENTION OF:

HSHL-UFM

7 November 1983

SUBJECT: Review of Chromatograms for Detection of Marijuana

Major General David W. Einsel, Jr.
Deputy Assistant to the Secretary of Defense
(Atomic Energy) (Military Application)
Office of the Secretary of Defense
Pentagon Rm 3E1074
Washington, DC 20301

1. The Review Committee for the evaluation of Δ^9 THC at the Fort Meade Medical Laboratory was comprised of:

COL Sanders F. Hawkins, Chemical Research and Development Center
LTC Robert O. Pick, Division of Exper Theraps, WRAIR
CPT Stephen R. Missler, Pathophysiology Division, USAMRIID

2. The criteria for the evaluation of Δ^9 THC chromatograms were established for the Review Committee by the Blue Ribbon Panel chaired by MG Einsel. The criteria are:

a. A positive control must be present and be clear with proper retention time for THC peak.

b. A negative control must be present with no peaks at the retention time for THC.

c. The retention time for significant peaks should not vary more than ± 0.05 minutes.

d. To be acceptable a peak should be at least three times the noise level in the chromatogram.

e. The peak height for THC in unknowns must be at least 50% of the 75 ng/ml standard or 40% of the 100 ng/ml standard to be classified as being positive for THC.

f. An internal standard should be present in each chromatogram.

3. Evaluation of chromatograms for the determination of marijuana (Δ^9 THC) at Fort Meade Drug Testing Laboratory during the period of 1 Jan 83 thru

SUBJECT: Review of Chromatograms for Detection of Marijuana

31 Oct 83 has been completed in accordance with the above criteria by the Review Committee. The results of this evaluation are found in Table 1. All chromatograms for THC determinations that were reported as positive by Fort Meade Drug Testing Laboratory were reviewed for August through October 1983. For January thru July 1983, 20% of all positive chromatograms were reviewed.

4. The number of rejected chromatograms previously reported as positive for Δ^9 THC indicate serious problems in the method of gas chromatographic analysis by the Drug Testing Laboratory at Fort Meade. The reviewers agree that the following areas are deficient (listed in order of perceived importance):

- a. Supervisory control and review of analyses.
- b. Training of technicians.
- c. Maintenance of instrumentation.

5. Inadequate supervisory control and review of analyses are considered to be the greatest deficiencies. Supervisors must be knowledgeable in the stringent requirements necessary for acceptable chromatograms and are responsible for insuring that these criteria are met before accepting analyses. Failure to insure this high quality on a daily basis is a signal to laboratory technicians that poor performance is acceptable. It is obvious from Table 1 that when supervisory controls improved in October 1983 the acceptance rate increased by fifty percent.

6. Inadequate training of technicians resulted in production of chromatograms demonstrating:

- a. A lack of proper standards and/or controls with each set of samples. This was the reason for the greatest number of rejections. Analyses were typified by questionable or missing positive and/or negative controls and impure standards (which gave ambiguous retention values for the Δ^9 THC peak).

- b. Contamination of controls and samples with material which interfered with the Δ^9 THC peak or internal standard.

- c. Improper attenuation of signal, thus preventing a good evaluation of the chromatogram.

7. Degradation in GC column efficiency often resulted in loss of resolution between the Δ^9 THC peak and closely eluting contaminants. This caused rejection of potential positives in order to avoid any possible errors in identifying true positives. When column efficiency was good, the problem was less prevalent. Proper maintenance of GC columns through rigorous use of quality controls that would permit observations of column degradation, accompanied with a protocol for replacement of degraded columns would insure a satisfactory level of column efficiency.

Table 1. Representation of Chromatograms (CMGS) for Marijuana
Reviewed IAW Established Blue Ribbon Panel Criteria

Month 1983	Total No. CMGS Screened For Marijuana by GC	No of CMGS		No of CMGS Rejected	No of CMGS Accepted	Percent Rejected
		Reviewed	% of Total			
Jan	2462	602	24	582	20	97
Feb	2944	563	19	534	29	95
Mar	2179	585	27	552	33	94
Apr	2449	503	20	503	0	100
May	2992	599	20	597	2	99
Jun	1547	570	37	556	14	97
Jul	1780	560	31	542	18	96
Aug	2247*	2247	100	2221	26	98
Sep	2081*	2081	100	1966	115	94
Oct	672*	672	100	365	307	54

*100% Chromatograms Reviewed

SUBJECT: Review of Chromatograms for Detection of Marijuana

8. In summary, the Drug Testing Laboratory at Fort Meade was deficient in most areas of good laboratory practices. It is obvious that a rigorous rehabilitation program is warranted to insure future excellence in drug testing. However, it should be realized that this situation may have been precipitated by outside factors beyond the control of the local commander, i.e., lack of trained military personnel which makes up 30 percent of work force and improper programatic funding.

9. Recommendations:

a. Experienced personnel should be provided to the drug testing program (military should be 92B30 or OH1).

b. Provide for the same procedures to be used in all DoD laboratories, if not DoD then DA as a minimum (all administrative procedures, test procedures and test equipment).

c. Provide for central Army-wide administrative and technical supervision of drug testing program.

d. Quality control procedures should be explicit with very little room for personal deviation.

e. Monitoring teams should be established and each drug testing laboratory should be inspected from both a scientific and administrative point of view at least annually.

f. Because of the expense, civilian contractors should represent a last resort for testing. However, when it becomes necessary the scope of work should clearly state what quality control procedures should be followed and what constitutes acceptable results.

g. Frequent site visits should be made to contractors to insure scientific proficiency. Contractors should be made legally responsible for tests performed and, if necessary, appear in court to defend their procedures and test results.

h. Provide for 6.1 and 6.2 funding for validation of current methodologies and future methodologies so that state of art can be maintained.

i. Provide central quality control system to include negative samples.

j. Drug testing laboratories should be complete and separate field operating agencies so that they are not dependant on MEDDAC or MEDCEN for resources and support. They should report directly to HSC thru one

MSHL-UFM

7 November 1983

SUBJECT: Review of Chromatograms for Detection of Marijuana

drug laboratory which will be designated the lead laboratory. This eliminates possible conflict of interest.

10. POC for this action is COL Sanders F. Hawkins, CRDC, AV 584-2318.



SANDERS F. HAWKINS

Colonel, MSC

Committee Chairman

DISTRIBUTION

COL Spiker, HQDA

LTC Pick, WRAIR

CPT Missler, USAMRIID

MAJ Jewell, Ft Meade

APPENDIX K

SUMMARY OF PANEL OBSERVATIONS AND RECOMMENDATIONS

SUMMARY OF PANEL OBSERVATIONS AND RECOMMENDATIONS

Listed below are the Panel's observations and recommendations, arranged by sections in the Report.

- RIA:** Wiesbaden's automation efforts should be exported to other laboratories in the interim, pending an in-depth review of automation needs. This includes giving priority to procuring a disk drive for Tripler AMC and a tape drive for Fort Meade to improve their RIA data processing.
- Visits among laboratories should be more frequent.
- RIA cutoff procedures need to be evaluated more carefully.
- The OTSG has ordered a set of data stations for RIA counters which may unnecessarily duplicate in-house data processing developed at Wiesbaden AB.
- GC:** The internal standard should be changed from oxyphenbutazone to pyrenebutyric acid (PBA) as soon as the laboratories can validate the change.
- The laboratories should upgrade their cocaine procedures by validating the proposed tri-service procedures.
- Methamphetamine analyses should include a GC/MS confirmation.
- A study of degradation of amphetamine samples, if any, versus shipment, storage times, and environmental conditions would be worthwhile.
- A study of the increase in degradation of products from negative specimens, if any, versus storage and shipment times would be worthwhile.
- GC/MS:** There is no OTSG direction for the use of GC/MS as a quality control measure.
- OTSG needs to issue directions in an Army SOP for GC/MS as to how it should be run, interpreted and what data should be maintained.
- OTSG needs to document the apparent high correlation rate between GC/MS positive confirmations and RIA plus GC positive confirmations to provide increased support to the legal sufficiency of RIA plus GC confirmation as a proper test for the presence of THC.
- OTSG needs to provide for operator training on the GC/MS. (Health Services Command may need to include this in its planning.)
- Facility, electrical, and maintenance support are critical needs.
- JAG personnel need to be instructed on using GC/MS data in courts martial.
- A program for operator validation/certification is needed.
- The OTSG needs to perform GC/MS analysis on the large batch of stored positive samples at Fort Meade--it should be good confirmation data on the validity of the GC procedures.
- May need second GC/MS machine at the DTLs.
- The purchase of the new GC/MSD equipment may be premature until proper training and support are available.

- COC: Need freezers at Tripler AMC and Wiesbaden AB laboratories. COC procedures could be simplified greatly if facilities were available to COC custodians to personally lock their own samples upon receipt.
- Management: Need laboratory knowledgeable staff elements in major commands with DTLs. Health Services Command may need a knowledgeable staff element; and needs to provide more assistance in training for the DTLs.
 Fort Meade and Tripler AMC need people support.
 The OTSG needs to have a senior staff officer knowledgeable in forensic methods and full-time staff element.
 DCSPER and USADATA need an officer knowledgeable in DTLs.
 AFIP needs personnel knowledgeable in large-scale laboratory operations if it is to have a significant role in DTL operations.
 There may be a need for a single focal point on technical operations for DTLs.
 Funding and equipment need to follow chain of command and be coordinated with support activities.
 DTLs need better host/tenant support, especially if they are not on medical installations.
 There is a need for technical/professional inspections.
 There is too much "personalized" decisionmaking on automation, GC/MSD and input-output devices.
 Need to encourage testimony by deposition from the DTLs and augment DTLs with additional personnel to support witness requests.
 Need to train JAG officers in technical matters of laboratory operations and chromatography review.
 Plant and physical facilities need improvement.
 Need good first echelon supervision (especially at Fort Meade).
 Need two to three officers per laboratory and adequate NCO/civilian supervision.
 ALF should be highest support priority; need personnel knowledgeable in ADP.
 OTSG needs to correct its direction as to the proper quantity for not sufficient quantity of sample.
 OTSG needs to correct its directions concerning the proper RIA incubation time (to agree with manufacturer's specifications).
- Credibility: Need OTSG professional certification of laboratories.
 Need to develop AF/Army agreement on proficiency and DTLs.
 Policy and technical operations need to be better coordinated among OTSG, ODCSPER, and OTJAG.
 Annual consultant review or peer review is needed.
- QA: Each laboratory must have a fully certifiable QA program and use it as daily control mechanism.
 Need an OTSG system for testing, validating and approving changes in procedures.

Sufficiency: Overall, there is no evidence of false positive reporting by DTLs.

Fort Meade GC/MS confirmations indicate that the GC method is confirmed over 99 percent of the time.

No negative AFIP samples were reported as positive for 1260 samples in first nine months of 1983.

Expect increased positive reporting with recommended PBA standard and OV-1 column.

System overall is conservative in reporting AFIP 150 ng/ml positive THC, since only about 90% are reported as positive.

DTLs should have a proper internal standard before and after a batch of samples.

50 ng/ml GC cutoff should be chosen as standard to improve program credibility in reporting users (when PBA method is validated).

Ft. Meade: Needs space, computer assistance (equipment, programming and operators), supervisors, an operating QC program, facility support; and command support on facilities and personnel.
WRAMC needs to make firm decisions on long-standing arguments on space and personnel.

Wiesbaden: Needs facility support, an adequate GC/MS capability, freezers for COC room, and air conditioning for the GC/MS.
Methamphetamine results need GC/MS confirmation
Should export its successes in computer applications.

Tripler: Needs automation support, computer operator, additional officers, facility support, proper location of freezers, added electrical power.
Must adopt/validate a new cocaine procedure, as will be included in an Army SOP.

AFIP: QC program is good; confirms non-reporting of false positives.
Casual advice is often accepted as gospel.
Needs to visit and become more aware of DTLs operations, if it is to remain in the technical advisory role to DTLs.
Not resourced to provide a full independent QC program.

Overall

Recommendations:

OTSG needs full-time staff element, headed by a senior officer.
DCSPER must improve its coordination of drug policy.
Chain of command for DTLs must be clarified and used.
System of proficiency testing, certification and inspection for the DTLs is needed.
Health Services Command must plan training support for the DTLs.

DA should recommend to OSD greater use of the DOD Biochemical Testing Advisory Committee.

OTSG should expedite short term automation improvements.

DA should consider delaying GC/MSD purchases until training and support is available.

Commanders with DTLs need to review their host/tenant agreements.

DA needs a standard SOP for DTLs.

Each DTL needs an operational QA program.

When training cannot be provided, consideration should be given to using TDY personnel or excess temporary authorizations to accommodate a workload increase.

DTLs need more frequent meetings on a technical level.

AFIPs active role with the laboratories should be clarified.

PBA should be approved by the DA as the internal standard for THC analysis using OV-1 or SE-30 column.

A 50 ng/ml GC cutoff for THC metabolite should be feasible once the laboratories validate the PBA method.

In choosing any cutoff limit for GC, DA should be careful to assure first that each DTL can prove its capability to meet that cutoff with very high confidence of not reporting a false positive.

Automation improvements should be the highest priority, except for validation of procedure matters.

Each DTL needs to have a GC/MS operational capability.

There is no evidence of false positives, using the current Army GC procedure. GC/MS results observed tend to confirm this.

The OTSG should be able to provide increased corroborating data which should lead to acceptability by correlating GC/MS results with RIA plus GC confirmation results.