2020

A "Personal" History of Drug Testing

This is the first of a two-part Drug Testing Matters series on the history of workplace drug testing. This part describes the evolution of drug testing from the early days of the military program through the beginning of the Federal Workplace Drug Testing Program.

The Federal Drug-Free Workplace Program and the National Laboratory Certification Program as they exist today achieved a "gold standard" through an extensive evolutionary process. It took efforts from a multitude of people with diverse administrative and scientific backgrounds, successful and unsuccessful planning, adaptation to evolving knowledge and technology, and a lot of trial and error. The evolution of these programs began with the US Military's drug testing program in June 1971 and continued through the military's "War on Drugs" in the early to mid-80s. The evolutionary process advanced through the establishment of testing federal employees and the testing of safety-sensitive employees in federally regulated industries. This was followed by the development of the Mandatory Guidelines for Federal Workplace Drug Testing Programs as the gold standard for workplace drug testing, which ultimately led to the acceptance of drug testing in non-regulated industries.

There are many review articles available that detail the military and federal programs with pertinent technical information, dates, and statistics. These documents recount the true history of these programs from their infancy. To continue to move the federal drug testing program forward, it is important to understand the environment that facilitated the need for drug testing, the state of knowledge and technology available, and most importantly, what we now consider common knowledge and industry standards that have continuously advanced and will continue to do so.

This article is an attempt, in two parts, to tell the history of workplace drug testing through the perspective of individuals in the laboratories and the professionals in the field who developed and used program results to combat drug use. Part one will encompass all military programs but will focus on the Navy's program because many Navy personnel who lived throughout this period were available for consultation and continue to be active participants as consultants and inspectors in workplace drug testing.

Inception: Military Drug Testing (June 1971)

To someone entering the workplace drug testing field today, or even many of those who have been in various parts of the program for the last 20 years, their perception of the military program in the early 70s and what it was like is driven by their experiences today and not the contextual reality.

By the late 60s and early 70s, the military (along with the rest of society) was experiencing major drug use problems. Many of the military personnel returning from Vietnam had developed addictions, primarily heroin use but also marijuana and other drugs. In response to letters from the parents of returning veterans, Congress pushed the Department of Defense (DoD) to address this issue and in June of 1971, President Nixon ordered all returning military personnel be tested for recent drug use and to enter rehabilitation, as necessary, under a program known as Operation Golden Stream.

Program Intent

Operation Golden Stream did not start as either forensic or punitive. The intention was to identify and provide help to service members who were suffering from drug use. The majority of these individuals were not career military personnel but rather young men completing their required military obligation and attempting to return to civilian life. Rehabilitation centers were established to treat individuals identified by the testing or by those who self-reported a drug problem.

With drug use and its negative effect on the discipline and readiness of the armed forces increasing, testing was expanded to cover most active military members. The scope of the testing varied between the different branches, with the Navy and Marine Corps accounting for the majority of testing conducted and the Air Force with the least.

The consequences of having a positive drug test result eventually changed, with the focus no longer on rehabilitation but on more punitive measures. For enlisted personnel, this consisted of non-judicial punishment, typically a loss of pay or rate reduction. For a commissioned officer, however, consequences were more severe—potentially ending their military career with a dishonorable discharge from the service.

The Collection

Urine specimens were collected by both medical and non-medical personnel in a variety of settings, from medical facilities to tents in the field, with little to no direction provided to collectors. They used whatever containers were readily available at the time of collection, from thin-walled plastic containers with paper tops to screw-top glass bottles to pharmacy pill bottles. Most specimens were not sealed with a tamper evident seal, and no transport bags were available. During this time, specimen loss and leakage was a high occurrence.

Upon specimen collection, there was no formal chain of custody (COC) or documentation by the collector. Instead, a specimen inventory list with the service members' identity was sent to the laboratory along with the specimen. The specimen also had the identity information on the container.

Specimens were shipped to laboratories by any means possible, without uniform shipment/transit expectations. That meant specimen handling varied greatly, with some specimens driven directly to the laboratory hours after collection whereas others were transported after weeks, with some specimens sitting in a wooden crate in the heat of a Guam tarmac for extended periods of time.

The Laboratories

Each military service was directed to establish regional Tri-Service testing laboratories both in the United States and overseas. In July 1971, the Navy set up its first laboratory in San Diego, with four additional laboratories set up by March of the following year. The Air Force set up two laboratories, one within the United States and the second in Germany. The Army set up three laboratories, one each in Japan, Maryland, and Hawaii. It also contracted with two private laboratories to provide additional testing.

The type of drug program undertaken by the DoD was unprecedented in the civilian community. There were no models to follow and no expertise available to assist with this mass testing process. Most expert civilian toxicologists worked at state and federal crime laboratories, medical examiner's offices, or in research facilities. Their standard operations consisted of handling one sample at a time and personally completing the testing from cradle to grave. Examples of a mass production drug testing laboratory did not exist.

The initial set up and operation of the military drug testing laboratories were the responsibility of personnel at each location, and the work was primarily assigned to staff from military clinical laboratories.

The initial direction given to the laboratories was essentially "there are specimens coming, test them for drugs." For any enlisted and officer personnel first assigned to these tasks, these directions came as a complete surprise. One Naval Petty Officer First Class said when he was assigned to one of the laboratories, "yesterday I did not know how to spell toxicologist, today I is [sic] one."

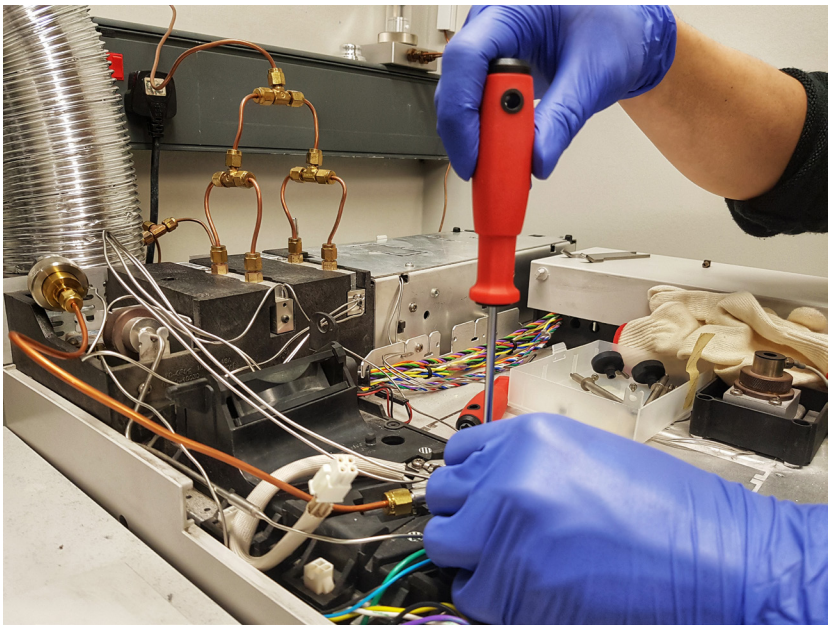
To get an accurate portrayal of what these laboratories looked like, imagine a modern certified laboratory but without any university- or field-trained personnel. There was no air conditioning, computers, autoinjectors, automated screening instruments, mass spectrometry, cutoff levels, deuterated internal standards, COC, or split specimen collections. Additionally, there were no commercially available testing kits, no thin-layer chromatograph systems, no medical review officers, no laboratory inspection and certification programs, no performance testing programs, and no standard operating procedures (SOPs).

These laboratories were set up to detect the presence of drugs in urine specimens. The primary focus of testing was morphine (to detect heroin), cocaine, phencyclidine (PCP), propoxyphene, barbiturates, and amphetamine. The available technology and equipment were vastly different from what is currently used today in all military and Department of Health and Human Services (HHS)-certified laboratories. Because there were no methods available to test for tetrahydrocannabinol (THC), marijuana was not one of the initially included drugs. There were no drug cutoffs established, with the exception of screening for morphine. The only commercially available immunoassay at the time was Free Radical Analytical Technique (FRAT), manufactured by SYVA. The initial FRAT assay only screened for morphine. A kit for cocaine was developed but never put into operation. The other drugs/drug classes were screened using thin-layer chromatography, as described below.

The FRAT assay procedure involved manually drawing up the reagent and the sample into a capillary tube, sealing the bottom of the tube with clay, letting it equilibrate for at least a minute, and then placing the tube in a Varian Electron Spin Resonance Instrument. The results were recorded on a flatbed recorder in the form of a sine wave. The operator would write the specimen number next to the tracing. The size of the wave was proportional to the concentration of morphine present in the sample. Using a ruler, operators manually compared the size of the tracing of the sample with the size of tracing from the "Machine Level Standard" provided by SYVA. A team of three to four operators could run between 60 to 90 samples an hour using two instruments. Specimens determined to be positive were subjected to a "confirmation test" using spectrofluorimetric instrumentation.

The first attempts at urine specimen adulteration were directed toward the FRAT test. Service members would add salt to their specimens. This suppressed the signal below the negative control. Unfortunately for service members trying to beat the test, the effect on the FRAT was too strong, causing a total suppression of the signal and resulting in the first reports of adulterated specimens.

There was very little guidance given to laboratories on how to test for other drugs. A general liquid–liquid extraction scheme was issued by the Armed Forces Institute of Pathology (AFIP), but it was up to laboratory discretion to develop its own methods. The intent was to test the extracts by gas chromatography (GC) using packed columns, a flame ionization detector (FID), temperature programing, and manual injections. Because a limited number of GC-FID instruments were available and because of their long temperature program run times, this method of analysis for the initial testing was quickly abandoned by all the laboratories.

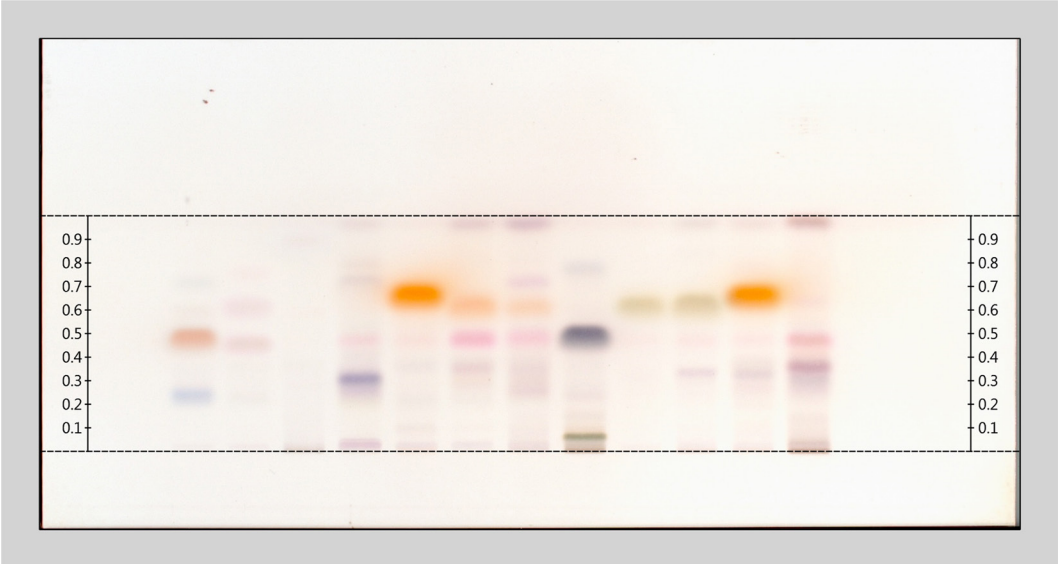


Out of necessity for a "quick" wide-ranging screening procedure and against direction provided from Washington, each of the laboratories developed thin-layer chromatography screening procedures. These required a liquid–liquid extraction using 50-mL conical plastic tubes, multiple transfer steps, and evaporation and reconstitution of the extract. Initially, a saturated borate buffer was used. This required the buffer to be prepared by heating it on a stirring heat plate to keep the salts in solution. The borate buffer was eventually replaced by Tris buffer. Large wooden racks were designed to hold 36 of the conical tubes on a shaker.

The extracts were spotted on 12-by-12-inch silica gel plates using automated spotting machines, allowed to migrate, and then sprayed with several highly toxic developing reagents. Determination of positives was based on the migration distance of the spot and the color reaction to the sprays. There were no cutoffs for this test, and accuracy depended on the skill level of the individual technicians reading the plates. There was no uniform training, and technicians learned on the job. The laboratories continued to use thin-layer chromatography until the introduction and implementation of radioimmunoassay in 1974.

For confirmations of the screened positive samples, an extraction procedure was conducted using a new aliquot of the specimen. There were no derivatizing reagents available or used at this time. Confirmatory testing was performed using the GC-FID with packed columns and manual injections. Initially, integrators were not available, so the chromatograms were printed on simple flat bed or strip chart recorders. As the technician made the injection, they would mark the chart to show the start of the injection and the temperature program in addition to recording the sample number. The retention times and peak height were manually measured using a ruler. A calibration standard with the drug(s) of interest was injected to establish the retention time. Any specimen with a peak at the retention time of the standard was reported as positive. Each laboratory determined how large the peak needed to be to report the specimen as positive.

Results were reported to the command as either negative or positive. Because there were no cutoffs established, drug concentration was not a factor.



The Performance Testing Program

The military established a performance testing/blind quality control program administered by the AFIP. A set of samples was sent to field commands every month. The command would then transfer the samples into whatever type of collection container was used, label them in the same manner, mix them with their command's specimens, and forward them to the laboratory to be tested.

These proficiency samples ranged in composition from negative to high drug concentrations. Threshold concentrations were established for each drug that the laboratory was expected to be able to detect. The lower the laboratory threshold for detection, or the limit of detection (LOD), the better their performance. It became a matter of pride to be able to detect the lowest amounts.

Although this will be discussed later, it should be noted here that this competitive behavior was a major factor in performance issues for the military and commercial laboratories and the reporting of false positives due to non-standardized cutoff values. Ultimately, this led to the establishment of cutoff values—drug concentrations at or above a predetermined threshold that determined if a specimen would be reported as positive. For the military, the initial cutoff levels were based on two factors: what was the lowest possible measurement that could be achieved without eliciting a false positive, and how low could these cutoffs be without losing many service members.

Introduction of Immunoassay and Semi-Automated Initial testing

In early 1974, the military implemented the use of radioimmunoassay (RIA) as a mass screening initial test to replace both the FRAT and thin-layer chromatography. These RIA kits were produced by Roche, and the pipetting and gamma counting equipment was provided by MicroMedics.

Roche initially offered RIA kits for morphine, cocaine, amphetamine, PCP, propoxyphene, and barbiturates. For each drug tested, the laboratories used a MicroMedics pipetting station to pipette urine, the antibody, and the Iodine-125 (^{125}I)-labeled antigen reagents into glass tubes in 12-tube racks. The specimens were incubated, followed by the addition of a precipitating reagent to the mixture. After incubation, the tubes were centrifuged to form a pellet of the bound antibody/antigen complex, leaving the free ^{125}I-labeled antigen in solution. The free antigen solutions were pipetted into clean glass tubes and analyzed on a MicroMedics Gamma Counter. The racks were designed to allow analysts to move them directly to the centrifuge and then to the gamma counter.

The gamma counters were single-well units with an automated arm system to move the tubes one at a time from storage draws to the counter well and back into the storage rack. Often, the instrument would fail to remove a tube and would subsequently break that tube as it attempted to insert the next tube directly on top of it. The result was a contaminated well that needed decontamination and repeat testing for the specimens involved.

The results and tube position number for the measured radioactivity for each tube were printed out using teleprinters. These data were difficult to read because the measured radioactivity and tube position number were printed directly next to each other. Reviewers had to manually identify the positive specimens based on the tube position number. Several laboratories used two different reviewers to review the same data independently so that positive specimens were not missed because of human error.

The use of the automated equipment for screening led to the introduction of several "industry standard practices" as detailed below.

1. The introduction of a standard within each batch. Initially, the LOD was defined by the machine (i.e., "machine level") used for testing. Laboratories would consider specimens as positive if they had measurable activity above the negative. This method of distinguishing positive specimens was driven by laboratory evaluation from the AFIP's performance testing program. As previously mentioned, the AFIP performance test (PT) samples ranged from negative to below the machine level, to at the machine level, and above the machine level (e.g., below the LOD, at the LOD, and above the LOD). The more sensitive the laboratory procedures and equipment were, the higher its PT performance. Later in the program, the machine level was eventually changed to a true cutoff calibrator with specimens at or above the calibrator deemed as positive.
2. The introduction of open positive and negative quality controls with each batch.
3. The introduction of a "blind" quality control starting at the accession process.

The move to RIA also improved testing, but the method still had its problems.

The RIA immunoassay resulted in the following improvements:

1. It greatly increased the volume capacity of laboratories.
2. It eliminated the subjectivity of evaluating the screening results by thin-layer chromatography.
3. It provided a level of standardization among military laboratories.

The RIA immunoassay also introduced a new set of problems:

1. The amphetamines kit was non-specific for just amphetamine and its enantiomers, or mirror images (e.g., levoamphetamine, dextroamphetamine), but was highly cross-reactive with a multitude of phenethylamines (e.g., pseudoephedrine, levomethamphetamine). This ultimately resulted in many false positives that required time-consuming confirmatory testing to report the specimen as negative. The prevalence of these false positives can be attributed to these phenethylamines present in over-the-counter (OTC) medications.
2. The PCP kit produced a high number of false positives because of cross-reactivity with dextromethorphan.
3. The pellet formed after centrifugation was easily disturbed, producing a high number of false positives.
4. The pipetting system caused carryover from sample to sample, eliciting false positives in an otherwise negative specimen.
5. Disposal of the radioactive waste created by laboratories overseas created logistical problems.
6. Attempts were made to manufacture kits with antibodies for multiple classes of drugs. Roche produced a combination kit to detect both morphine and barbiturates in one test. The kit worked well if only one type of drug was present. Unfortunately if both were present in the specimen it resulted in a false negative.
7. The production of the antibody was inconsistent from lot to lot.
    a. The major supplier had quality control issues with the morphine and barbiturate kits, which was discovered by multiple laboratory failures on PT samples.
    b. The Navy briefly used a highly specific free morphine kit with a 10 ng/mL free morphine cutoff. Initially, the antibody had a 0% cross-reactivity to morphine glucuronide or to codeine. However, later lots of this same kit had over 600% cross-reactivity to codeine, making the kit unusable.
    c. This inconsistency in production of the test kits led to the practice of laboratories verifying each new lot of reagents prior to use with specimens.
8. All immunoassay results generated were manually reviewed because there was no computer assistance to highlight or filter the more than 6,000 four- to five-digit numbers typically produced with a batch of 1,000 specimens.

Halt in Military Drug Testing

The DoD published "DoD Instruction 1010.1" in April 1974, which was the military's version of the HHS Mandatory Guidelines and federal agencies' DrugFree Workplace Plans. As such, this document established the first random testing program for drug use in the military. Just as HHS revises the Mandatory Guidelines, DoD continuously updates DoD Instruction 1010.1 to reflect modern changes for drug testing in the military. In an effort to identify active drug users and get them proper treatment, the purpose of this program was described as clinical in nature rather than punitive. This unfortunately was not always the case because once an individual was identified as an active drug user, many military careers were adversely affected, especially Commissioned Officers.

Several months after the initial publication of DoD Instruction 1010.1, a US Army service member was court-martialed for refusal to follow an order to give a urine specimen. When the case was appealed to the Court of Military Appeals (CMA), all drug testing within the military was suspended, and the laboratories shut down until a decision was rendered.

The CMA delivered its decision in early 1975, upholding the military's right to order service members to give a urine specimen for random drug testing. However, the court prohibited punitive actions based on the laboratory results of the random drug tests. The court did decide that the military could employ urine drug testing to screen and eliminate potential new service members from serving in the military based on a positive test result.

Military Program (1975 to 1981)

The military program experienced a period of stagnation between 1975 to 1981 with little improvement. Most of the testing performed was for new recruits, support for rehabilitation centers, and a small number of specimens from commands. The laboratories continued to function as Tri-Service facilities but decreased in size.

During this time, DoD added testing for methaqualone (i.e., brand name Quaalude) in response to the increased popularity and availability of the drug. However, the military ended testing for methaqualone in 1984 because its use decreased significantly when the U.S. Food and Drug Administration (FDA) phased manufacture of this drug out, ultimately discontinuing its production in 1985.

Other minor improvements were made during this time to the gamma counters used for the immunoassay. Autosampler handling was improved, and the number of wells was increased. Most importantly, the data generated from RIA were evaluated by a computer to identify both positive and negative screening results.

For confirmation tests, the data from GC-FID instruments were printed and evaluated using integrators, no longer requiring the data for each sample to be printed on simple flat bed or strip chart recorders.

Although COC procedures were yet to be widely adopted by laboratories, there were great improvements made in overall specimen handling, with more attention on the proper identification of the specimen throughout the testing process.

Unfortunately, there was no standardization of operating procedures or quality control measures in place among laboratories.

The "War on Drugs"

By 1981, it was apparent that drug use by military personnel adversely affected the readiness of all armed services, although to varying degrees. The increase in use in conjunction with a series of events that occurred in 1981 marked the beginning of the expansion in the size, scope, and intent of drug testing within the military:

1. A new CMA ruling now allowed the use of positive drug tests for punitive purposes.
2. An immunoassay to screen for the use of THC and a GC-FID confirmation procedure for tetrahydrocannabinol carboxylic acid (THCA) became available.

3. The crash of an EA-6B Prowler aircraft on the USS Nimitz killed 14 crew members and injured an additional 48. In addition, it caused 150 million dollars in damages to the Nimitz and aircraft, resulting in the loss of this major warship for an extended period of time. Six of the sailors killed during this crash, not including the pilot, had marijuana metabolites in their system.

In 1981, the Navy unilaterally declared a "War on Drugs." In a message to all Naval and Marine Corp commands, Admiral Hayward, the Chief of Naval Operations, authorized all commands to use drug testing to combat the growing drug use within the Navy and Marine Corps. Seeing this as new tool to weed out drug users in their commands, Naval and Marine Corps units quickly started to increase the number of urine specimens collected.

On December 28, 1981, Deputy Secretary of Defense Frank Carlucci issued a memorandum authorizing service-wide use of punitive action, including court-martial and separation from service, based on positive drug test results. The memorandum also directed the testing should include marijuana, opiates, amphetamines, barbiturates, PCP, cocaine, and methaqualone.

Although there was no question that military readiness required a need to increase drug testing, the military laboratories were ill-equipped to handle the influx of testing. Errors that occurred when laboratories were first established in 1971 were about to be repeated but with greater ramifications.

The massive increase in testing was accompanied by other major adjustments that significantly changed the landscape of military (and later workplace) drug testing.

1. The CMA decision to now allow the use of positive drug test results for punitive action significantly changed laboratory operation.
   a. For the first time, forensic policies and procedures were required in a mass production testing environment.
   b. The impact of a positive test result increased significantly. For enlisted personnel, it could lead to legal proceedings resulting in fines, loss of rank, or in extreme cases, dishonorable discharge. For Commissioned Officers, the repercussions were even greater, possibly leading to legal proceedings, the end of a military career, and dishonorable discharge.
   c. All military personnel had the right to appeal positive results, mandating a court-martial with a lawyer provided at no cost to the service member.
   d. Officers in charge of laboratory operation now had to become expert witnesses to defend the laboratory results on trial.
2. The addition of THC testing presented a major technical challenge for the laboratory.
   a. The immunoassay test for THC available at that time was extremely reliable and specific for marijuana use. However, the number of specimens that screened positive for marijuana use was extremely high. The Navy alone reported that over 27% of the specimens received for testing had THC levels above the established THC cutoff limit.
   b. The confirmation procedure developed by Whiting and Manders[1] at the AFIP used GLC-FID instrumentation and was both labor-intensive and time-consuming. The specimen preparation involved hydrolysis, the use of solid-phase columns to separate and concentrate THCA,

[1] Whiting JD, Manders WW. Confirmation of a tetrahydrocannabinol metabolite in urine by gas chromatography. J. Anal Tox 1982; 6:49-52

derivatization of the extract, followed by manual injection of the extract, and manually starting the temperature program. The overall process required an extensive skillset to perform accurately.

c. The identification of the metabolite was based solely on the retention time of the compound.

d. Because retention time was the only method of identification, deuterated internal standards could not be used. Instead, an unrelated compound was used as the internal standard to provide a method to determine the concentration of the sample. This problem was not isolated to confirmation of THCA but occurred for all drugs undergoing confirmatory testing.

The "Flood"

With the release of Admiral Hayward's message, many of the Naval and Marine Corps commands immediately began mass testing their personnel for drug use. The military laboratories were ill-prepared for both the massive influx of tests and the testing requirements. Specimen numbers received daily far exceeded the laboratories' capacity of processing and testing, and they were quickly overrun in the first months with anywhere between 40,000 and 70,000 untested urine specimens in each laboratory.

It was at this point that laboratory oversight was transferred from the Navy's Medical Command to the Operational or "Line" part of the Navy. After an inspection of all five Navy laboratories, Admiral Hughes concluded that the laboratories were both understaffed and underequipped. He ordered the Navy Surgeon General to transfer 50 enlisted military laboratory personnel to each of the five Navy laboratories immediately for a 6-month assignment. He also authorized hiring of civilians to replace the enlisted personnel so they could return to their original stations. Additionally, he had one to two chemists (Commissioned Officers) assigned to each laboratory temporarily, but many of these officers remained with the drug testing laboratory system until the end of their military or professional careers. In addition, new equipment was purchased, including one gas chromatograph mass spectrometer (GC-MS) for each laboratory—a move that changed the future of workplace drug testing.

Because the laboratories were Tri-Service, the other military branches were requested to ramp up their testing capacity. When that request was refused, the Navy unilaterally terminated its testing of any Army or Air Force specimens. A return to Tri-Service testing did not occur until later in the 90s.

With the "Line" oversight of the laboratories, numerous changes were put in place in overall operation.

1. The first SOP was developed and implemented. The concept of the SOP came from the Naval Aviation SOP for the P3 Orion aircraft called Naval Air Training Operating Procedures Standardization (NATOPS). The laboratories were told that the NATOPS contained everything the pilot needed to operate the aircraft and that they were to develop the same type of manual for all laboratory functions. The implementation of SOPs resulted in standardized operation across all the Navy laboratories. The manual went far beyond what was used in clinical laboratories. No longer was it just a set of method procedures and manufacturer's instruction, but it became a comprehensive beginning-to-end laboratory guide, detailing every administrative and technical aspect of laboratory operation.
2. COC procedures were instituted from collection to testing to the retention of positive specimens. This was the first time that forensic standards were applied to a mass production operation.

3. Cutoff concentrations in both the screening and confirmation tests were used.
    a. The screening cutoff for immunoassay tests were determined by the reagent manufacturer.
    b. The confirmation cutoffs were set based, in some part, on the limitation of the assay, with a greater consideration at the time of how many military members the services could afford to lose. Based on this, confirmatory cutoff levels were often set artificially high to prevent unacceptable loss of personnel.

Although the military drug testing program was successful in reducing the overall drug use in the Navy, it came under increased criticism from the civilian technical and legal community. This criticism was fueled by the large number of false or indefensible positive results generated in the laboratories.

An example of this heavy criticism was when the Navy's Drug Testing Laboratory in Oakland, California, had to reverse THCA-positive results reported for 8,000 specimens. This was because the laboratory could not fully resolve the GC-FID peaks for soap from those of THCA, because retention time was the only parameter used for positive identification. The laboratory was also not routinely running negative controls with each batch. Although later examination of the data showed that the majority of these specimens were positive for THCA, the original data would not hold up under legal examination based on aforementioned issues.

Concurrent with this issue, a commission directed by Carlton Turner (President Reagan's "Drug Czar") and headed by Major General David Einsel determined that the combined Army/Air Force testing laboratories were broken. As the laboratories did not meet forensic standards, it was determined that over 10,000 Army and Air Force personnel were improperly discharged.

In both of these situations, the false THCA positives and the review of the Army/Air Force testing laboratories, affected service members were offered reparations, a process that took years to complete. The officers in charge of those laboratories and other high-ranking personnel were relieved of their duties, effectively ending their military careers.

The Dawn of GC-MS

In April 1983, at a high-level Naval meeting chaired by Rear Admiral T.J Hughes, the Head of the Judge Advocate Generals Office (Rear Admiral Thomas E. Flynn), the legal branch of the Navy, concluded that the only thing giving the Navy credibility in court was the GC-MS results. However, with only one GS-MS instrument per laboratory, its use was limited to retesting specimens going to court-martial. He further concluded that using GC-MS only after an individual chose to go to court-martial was illegal. Admiral Hughes, the Line officer overseeing the meeting and program, ordered the immediate purchase of sufficient GC-MS instruments to perform all confirmatory testing. Consequently, he directed the Medical Command to establish a contract with a laboratory with GC-MS capability to execute all the THC confirmation testing until such time that Navy laboratories were ready. The decision to convert, while technically sound, was made based on legal necessity and to improve public perception of the Navy's drug testing.

The introduction of GC-MS produced a new set of problems for the laboratories:

1. In the beginning, there was very little GC-MS expertise in the laboratories.
2. The instrument software was not capable of processing specimens in a batch.
3. All injections were still performed manually, because there had not yet been a method of effectively automating this process.
4. There were no standard acceptance criteria nor was there civilian acceptance for operation of the instrumentation in Selective Ion Monitoring mode.
    a. Many of these standard acceptance criteria were agreed upon in a series of White House meetings hosted by Carlton Turner and attended by civilian experts and representatives of the each of the services.

The Navy's need to quickly institute usage of GC-MS to replace GC-FID, as directed by Admiral Hughes, led to the use of a commercial environmental testing laboratory to confirm THCA-screened positives. Several discoveries for the drug program that would later affect federal testing were made as a consequence of this arrangement. The first was the formulation of positive THCA controls. The Navy contracted with another laboratory, Research Triangle Institute (now RTI International), specifically with Dr. Monroe Wall and Mr. Ken Davis, to formulate controls for THCA to evaluate and monitor the contract laboratory's performance. To everyone's surprise, RTI was unable to formulate a stable control. This led RTI to undertake evaluation of its methods that eventually gave them the ability to formulate stable THCA controls. As an interim solution, the Norfolk Navy Laboratory provided 30 gallons of urine from previously tested positive specimens to other Navy laboratories, so they could formulate the needed controls.

Another problem was discovered when the contract laboratory reported a negative sample as positive for cocaine because of carryover. Consequently, an immediate requirement was implemented that the final reviewer assess the confirmation batch data as it is generated by the instrument, avoiding reliance on computer review of the batch. The private laboratory fed the data from the GC-MS to a central computer that applied the proper rules to evaluate for the possibility of carryover. Unfortunately, before the evaluation was initiated, the computer reorganized the specimens in numerical order rather than the order in which they were injected on the instrument, effectively preventing the evaluation of sample carryover for a sample following a high or overloaded sample.

Accidental Discoveries by the Military Program

Throughout its program, the military ran into unexpected problems. Much of the common knowledge now taken for granted came from these accidental discoveries and solutions afforded by the efforts of the military program. The following is a list of some of the major hurdles that were overcome.

1. Although the military had the ability to order its personnel to stay out of most situations where the possibility of passive inhalation of THC could occur, they could not fully prevent exposure to spouses who used THC. For this reason, the military funded studies showing that the cutoff levels needed to be adjusted to prevent positive results from passive inhalation.

2. It was well known that the enantiomer levomethamphetamine, or L-methamphetamine, was legally available in Vicks inhalers, while dextromethamphetamine or D-methamphetamine is an illicit substance. This was not considered a problem, because the screening kit did not have sufficient cross-reactivity with L-methamphetamine to cause a false positive from OTC use of a Vicks inhaler alone. However, after an officer in a Navy drug testing laboratory tested positive for amphetamines, it was found that other OTC cold medications did cross-react with the amphetamines immunossay kit. In this case, the legal use of OTC products containing sympathomimetic amines such as pseudoephedrine and ephedrine caused a false positive screening result, and use of the Vicks inhaler caused a false positive confirmation result. The legal use of OTC cross-reactive SMA medications caused a false positive on the initial screen, and the Vicks inhaler caused a false positive on the confirmation. The confirmation method employed at the time was not stereospecific for the L- and D-methamphetamine enantiomers; therefore, a positive result on the confirmation test was assumed to be from D-methamphetamine. Consequently, a test was developed for determining which enantiomer was in the specimen, giving the opportunity to allow the service member to challenge the result by employing this stereoselective test. The previously reported methamphetamine positives were reviewed and many were retested, and corrective actions were taken where required.
3. It was not known at the time that normal ingestion of poppy seeds could result in the presence of morphine in an individual's urine specimen. When several officers assigned to nuclear submarines tested positive for morphine, the Navy conducted an investigation that included a study of poppy seed consumption. Through this, it was determined that the source of the positive specimens was traced back to the ingestion of bagels with a heavy coating of poppy seeds, which led to the presence of morphine in urine. As a result, the cutoff for morphine was raised, and laboratories were required to confirm the presence of 6-acetylmorphine, a metabolite of heroin.

The Effect of the Military Program

In 1981, a survey of lower enlisted officers' ranks was conducted to determine the extent of the Navy's drug problem. The survey reported that 48% of those personnel claimed to have used an illegal drug within the past 30 days. The survey was highly questioned among the upper ranks of the Navy, so an anonymous testing survey was conducted on 1,000 east and west coast personnel. The survey showed 52% of the specimens tested had the presence of an illegal drug.

By 1985, the usage rate had dropped to 8.9% for military members, and by 1988, it had been reduced to 4.8%. This downward trend was not reflective of civilian society's drug use. When questioned, military personnel often cited the military testing program as their reason for stopping or limiting their use. Although the program's focus was to prevent drug users from enlisting in the military, the program also had a deterrent effect on active service members, who were subject to random testing at any time.

The Start of the Federal Testing Program

In early 1986, the National Institute for Drug Abuse initiated a voluntary committee to establish standards for private laboratories doing workplace drug testing and the model of the military program was used as a guide. On September 15, 1986, President Reagan issued Executive Order 12564, requiring each executive federal agency to develop a plan to achieve a drug-free workplace, to include a drug testing program for applicants and federal employees in safety-sensitive positions.

In the second part of this narrative, we will go through the struggles to establish the National Laboratory Certification Program, its development and evolution, and challenges that it faces today.

John Irving has over 48 years of experience in the field of military and civilian workplace drug testing. In 1971, he helped establish the first Navy drug testing laboratory in San Diego and went on to run three other Navy laboratories. With the start of the military's "War on Drugs" in the early 1980s, he became the technical consultant for the standardization of the Navy's five laboratories. While assigned to the Navy's Medical Headquarters in Washington, D.C., he helped develop the standard operating procedures for the Navy, including drug cutoffs, use of chain of custody, and the concept of certification of results. He conducted quarterly inspections of all five Navy laboratories and oversaw the conversion of the Navy's confirmation testing from GC to GC-MS. Mr. Irving served as the Navy's representative for the Tri-Service meeting and was the Navy's representative for all White House drug testing meetings. He served as the military member on the National Institute for Drug Abuse (NIDA) committee to establish standards for workplace drug testing. With the publication of President Reagan's 1986 Executive Order, he was assigned as the technical member of the NIDA office overseeing the development of the initial Drug Testing Guidelines and the publication of the Specimen Collection Handbook, Medical Review Officer Manual, and Laboratory Inspection Checklist and Guidance Document. He oversaw the inspection and certification of the initial laboratories in the federal program. After retiring from the Navy, he managed numerous civilian drug testing laboratories, including urine, oral fluid, and hair as the tested matrix. He has been the co-author on numerous papers in the field. Mr. Irving is currently an inspector for the National Laboratory Certification Program (NLCP) and serves as an independent consultant.

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