

NAUIAP 2018 Annual Conference: Recent Developments and Trends in Drug Testing Technology and Methodology

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I. The Legal Environment

A. Controlled Substances Laws

1. Federal Controlled Substances Act

The Controlled Substances Act was adopted as part of the Comprehensive Drug Abuse Prevention and Control Act of 1970. The law contains five separate schedules of substances the use of which is prohibited or controlled; the substances are rated in decreasing level of control. Schedule I substances are those that are generally prohibited from legal use as (1) having a high potential for abuse; (2) has no currently accepted medical use in treatment in the United States; and (3) a lack of accepted safety for use of the drug or other substance under medical supervision. Marijuana and other cannabinoids (other than Marinol) are Schedule I substances.

The remaining schedules include drugs or other substances that may have medical use but also have varying potential for abuse or addiction. Marinol, a synthetically made THC compound, is listed in Schedule III.

Several classes of prescription medications are included in the schedules, such as narcotics, stimulants, depressants, and anabolic steroids. Alcoholic beverages and tobacco are excluded from the Controlled Substances Act.

Schedule	Description	Examples
Schedule I	No currently accepted medical use and a high potential for abuse.	Heroin, LSD, marijuana
Schedule II	High potential for abuse, with use potentially leading to severe psychological or physical dependence.	Cocaine, Methamphetamine, Adderall
Schedule III	Moderate to low potential for physical or psychological dependence.	Tylenol with codeine, anabolic steroids, testosterone

Schedule IV	Low potential for abuse and low risk of dependence	Xanax, Valium, Ambien
Schedule V	Lower potential for abuse than Schedule IV and consists of preparations containing limited quantities of certain narcotics	Robitussin AC, Lomitol, Motofen

2. State Drug Laws

States also have controlled substances laws, either regulatory or criminal in nature, or both. These tend to mirror the federal law but may have different penalties and may have different schedules. For example, some states have added a sixth schedule in which medical marijuana (other than Marinol) is included.

Twenty-nine states and the District of Columbia have adopted laws legalizing or decriminalizing some form of marijuana usage. Nine states and the District of Columbia have legalized or decriminalized recreational usage.

B. Drug Testing laws

1. Federal

A variety of federal laws require drug-testing for classes of employees:

- a. Federal employees performing law enforcement, national security, or similar functions are required to be drug-tested by Executive Order 12564 and its implementing legislation P.L. 100-71, adopted July 11, 1987.
- b. Some federal contractors and all federal grantees must implement drug-free workplace programs as required by the [Drug-free Workplace Act of 1988](#). Employees covered under the act include any person who works on any activity under the grant or contract and who is on the payroll. The act does not mandate testing, however.
- c. A number of industry specific laws exist. The broadest is the [Omnibus Transportation Employee Testing Act of 1991](#). Employers are covered by this act if they are regulated by any of the following federal agencies:

[Federal Aviation Administration \(FAA\)](#)

[Federal Motor Carrier Safety Administration \(FMCSA\)](#)

[Federal Railroad Administration \(FRA\)](#)

[Federal Transit Administration \(FTA\)](#)

[National Highway Traffic Safety Administration \(NHTSA\)](#)

[Pipeline and Hazardous Materials Safety Administration \(PHMSA\)](#)

[U.S. Coast Guard](#)

The Act generally requires these agencies to implement drug and alcohol testing of “safety-sensitive” employees.

Agency-specific regulations establish which employees are subject to testing.

The Department of Defense requires drug-testing for defense contractors having access to sensitive, classified data in [Title 48 C.F.R., Subpart 223.5](#).

A drug-testing program is also required in the Nuclear Regulatory Agency’s “Fitness for Duty” regulations in [Title 10 C.F.R, Part 26](#).

- d. Other relevant federal provisions are the amendments to Section 303 of the Social Security Act contained in the Middle Class Tax Relief And Job Creation Act of 2012. These amendments authorized states to drug-test UI recipients (1) who were discharged for drug use, or (2) for whom suitable work exists only in an occupation requiring drug testing. Regulations identifying such occupations are still being prepared as of this time.

2. State laws

States have a wide variety of Drug-Free Workplace laws. Most common are those adopted for workers’ compensation benefits or government employees, particularly for safety-sensitive positions such as law enforcement or fire-rescue departments.

C. Constitutional Issues

Governmentally mandated drug-testing for government employees, contractors, or for specific industries has constitutional implications. Drug testing implicates privacy issues and constitutes a government search. The Fourth Amendment protects citizens from unreasonable searches. Generally, for searches to be reasonable, they must be conducted with individualized suspicion of misconduct. The first U.S. Supreme Court cases to address employee drug testing without any level of suspicion as a prerequisite were *Skinner v. Railway Labor Exec. Ass'n*, 489 U.S. 602 (1989), and *Nat'l Treasury Emp. Union v. Von Raab*, 489 U.S. 656 (1989). *Skinner* involved drug testing by the Federal Railroad Administration (FRA) of private employees involved in railroad accidents, and *Von Raab* involved drug testing by the U.S. Customs Service of federal employees seeking promotion to positions that directly involved drug interdiction or the carrying of firearms. While the Court concluded that the challenged governmental policies implicated Fourth Amendment searches, the Court upheld the policies on the ground that the government's "special needs" outweighed the employees' reasonable expectations of privacy.

In *Skinner*, FRA regulations provided for mandatory drug testing of private employees in "safety-sensitive positions" who were involved with serious on the job accidents. Although the tests in question would be administered only after an accident, the tests were administered without any particularized evidence that the tested employee was under the influence of drugs or alcohol at the time of the accident. Thus, the testing program did not require a basis of individualized suspicion. The Court found, however, evidence indicating that alcohol and drug abuse by railroad employees had previously contributed to a number of significant train accidents.

Significantly, the Court first determined that, even though private companies employed the covered workers, the railroad industry is heavily regulated by the government and the mandated program was intrusive enough to implicate Fourth Amendment protection. As to whether the program was unreasonable under the Fourth Amendment, the Court balanced the employees' interests in a reasonable expectation of privacy against the government's interest in conducting the search. Focusing on the loss of life and property in train accidents, the Court held that the government's interest in ensuring public safety presented a special need that made the program reasonable. The Court further determined that the covered employees' expectations of privacy were diminished by reason of their participation in an industry that is heavily regulated by the government to ensure safety. The Court therefore upheld the testing program.

In *Von Raab*, the Court goes even further toward the elimination of the requirement of individualized suspicion. In that case, the Court considered the validity of the U.S. Customs Service drug-testing program, which tested employees seeking promotion to positions involving drug interdiction and possession of firearms. However, unlike *Skinner*, the testing was not post-accident and there was no evidence of a history of drug or alcohol abuse among the employees of the Customs Service.

In a 5-4 decision, the Court upheld the U.S. Customs Service's drug testing policy. In doing so, the Court stressed the epidemic of drug abuse, the danger that service personnel using drugs could be bribed, and the danger inherent in drug-using service agents misusing their firearm. The Court held that the government interest in testing and ensuring that drug users are not promoted to these positions, thereby adding to the safety of the borders and to the integrity of the agency, outweighed the diminished privacy interests of those employees seeking promotion and was sufficiently compelling to validate the search in the absence of individualized suspicion. *Von Raab* is significant because it eliminates any level of suspicion as a prerequisite for finding a search justified so long as the government can show that its need to search outweighs the individual's reasonable expectation of privacy.

II. The Technical Environment

A. Drug Testing Standards

1. [Federal Drug-free Workplace Mandatory Testing Guidelines](#)

- Regulated by the United States Department of Health and Human Services (HHS)
 - The HHS, among other things, establishes scientific and technical guidelines for federal workplace drug-testing programs and standards for certified labs that conduct urine specimen testing for federal agencies.
 - Its recommendations are based on scientific research and input from the federal Drug Testing Advisory Board (DTAB).
- The Mandatory Guidelines are applicable to:
 - All civilian employees in the executive branch agencies
 - The Uniformed Services (excluding the Armed Forces)
 - Any other employing unit or authority of the federal government except the USPS, the Postal Rate Commission, and employing units or authorities in the judicial and legislative branches
 - The intelligence community (e.g., CIA, National Security Agency, Defense Intelligence Agency)
- DOT
 - The Mandatory Guidelines do not apply to transportation industry drug testing.
 - DOT is responsible for establishing and administering the *Procedures for Transportation Workplace Drug and Alcohol Testing Programs* (49 CFR Part 40).

- However, DOT is required to follow HHS Mandatory Guidelines for the categories of drugs for which DOT tests.
- Therefore, when HHS changes the drugs to be tested, DOT must make a corresponding change in the Part 40 regulations.

- State Standards
 - Other than federal testing, all drug testing is regulated by the states.

- Sample Types
 - In federally regulated programs, only urine samples are collected.
 - However, the Secretary of HHS has released proposed guidelines for the inclusion of oral fluid (saliva) specimens.

- Types of Tests
 - Pre-employment Test
 - Random Test
 - Only “testing-designated positions” are subject to random testing.
 - These include any positions where a momentary lapse in judgment could result in a catastrophic event.
 - These are positions with public health, public safety, and national security responsibilities.
 - According to a SAMHSA fact sheet, there are approximately 400,000 employees in testing-designated positions.
 - Reasonable suspicion/cause test
 - Post-accident test
 - Return to duty test
 - Follow-up test

- Authorized Drugs to be Tested:
 - Marijuana (THC)
 - Cocaine
 - Amphetamines
 - Opiates
 - Phencyclidine (PCP)
 - In addition, the revised Mandatory Guidelines, effective 10/1/17, added four additional opioids to the testing panel:
 - Oxycodone
 - Oxymorphone
 - Hydrocodone
 - Hyrdomorphone

C. What's New?

1. Two sets of changes to the Mandatory Guidelines – One Adopted, One Proposed

■ Urine Drug Testing Program (incorporated in current Mandatory Guidelines)

- Effective October 1, 2017:
 - Federal agencies are now required to test for four additional DEA Schedule II substances:
 - Oxycodone
 - Oxymorphone
 - Hydrocodone
 - Hydromorphone

***** The inclusion of these drugs was recommended by the DTAB and is supported by various data on drug abuse trends.

 - MDEA (Methylenedioxyethylamphetamine) has been removed from the standard testing panel because its usage was determined to be too low to justify the cost of testing.
 - The pH cutoff level is increased from three to four for identifying urine specimens as adulterated.
 - Medical Review Officer (MRO) re-qualification training and re-examination is required at least every 5 years after initial certification.
 - Collection of an alternate specimen (e.g., oral fluid) will be allowed with MRO authorization when a donor is unable to provide a sufficient amount of urine at the collection site.
- Effective January 1, 2018, DOT amended its drug testing program to correspond to these revisions.

■ [Proposed Oral Fluids Adoption](#)

- Oral Fluid Mandatory Guidelines have been proposed on May 15, 2015 as the first alternative test medium.
- Why Oral Fluids?
 - Enhances Flexibility
 - Provides flexibility in addressing workplace drug testing needs
 - Enhances Versatility
 - Medical conditions exist that may prevent an employee or applicant from providing sufficient urine or oral fluid for a drug test.

- In the event an individual is unable to provide a urine specimen, the federal agency may authorize the collection of an oral fluid specimen and vice versa.
 - Urine collection requires use of a specialized collection facility, secure restrooms, the same gender, and other special requirements. Oral fluid may be collected in various settings.
- Decreases Invalid Tests
 - Oral fluid collections will occur under observation, which should substantially lessen the risks of specimen substitution and adulteration.
- Saves time
 - Oral fluid collection can require less time than urine collection, reducing employee time away from the workplace and, therefore, reducing costs to the federal agency employer.
 - Oral fluid collection does not require a facility that provides visual privacy during the collection.
 - It is expected that many oral fluid collections will occur at or near the workplace.
- Versatility in Detection
 - The time course of drugs and metabolites differs between oral fluid or urine, resulting in some differences in analytes and detection times.
 - Oral fluid tests generally are positive as soon as the drug is absorbed into the body.
 - In contrast, urine tests that are based solely on detection of a metabolite are dependent upon the rate and extent of metabolite formation.
 - Thus, oral fluid may permit more interpretative insight into recent drug use drug-induced effects that may be present shortly before or at the time the specimen is collected.
- Advances in Oral Fluid Drug Testing
 - Some issues that previously deterred the use of oral fluid for drug testing have been resolved by advances in oral fluid testing and collection technology, thus making it possible to more accurately quantify drug test results.
- In a nutshell, the proposal:
 - Allows federal agencies to collect oral fluid specimens
 - Establishes standards and technical requirements for oral fluid collection devices

- Details initial oral fluid drug test analytes and methods
 - Establishes processes for review by a MRO, and
 - Outlines requirements for federal agency actions
 - At this time, final Guidelines have not been published.
 - Thus, oral fluid testing is not yet approved as a federal drug testing specimen.
 - And references to the use of an alternate specimen type (e.g., oral fluid) in the Mandatory Guidelines are not applicable until final Guidelines have been implemented (See UrMG “Background” Section and Section 8.7).

- Electronic Custody & Control Form
 - HHS, in developing the federal workplace drug testing program, have created chain of custody procedures designed to ensure the integrity and security of specimens from the time they are collected until the time the testing results are reported by the lab.
 - The Federal Drug Testing Custody and Control Form (CCF) is a five-part form used to identify a specimen and to document its handling at the collection site.
 - It consists of the following five copies:
 - Copy 1: Test Facility Copy
 - Copy 2: MRO Copy
 - Copy 3: Collector Copy
 - Copy 4: Employer Copy
 - Copy 5: Donor Copy
 - On May 28, 2014, OMB approved the use of both a paper form CCF and an eCCF under the HHS Mandatory Guidelines
 - An eCCF is the digital version of the traditional, paper CCF.
 - Before implementing an eCCF, HHS-certified labs must provide a detailed plan and proposed standard operating procedures for SAMHSA to review and approve.