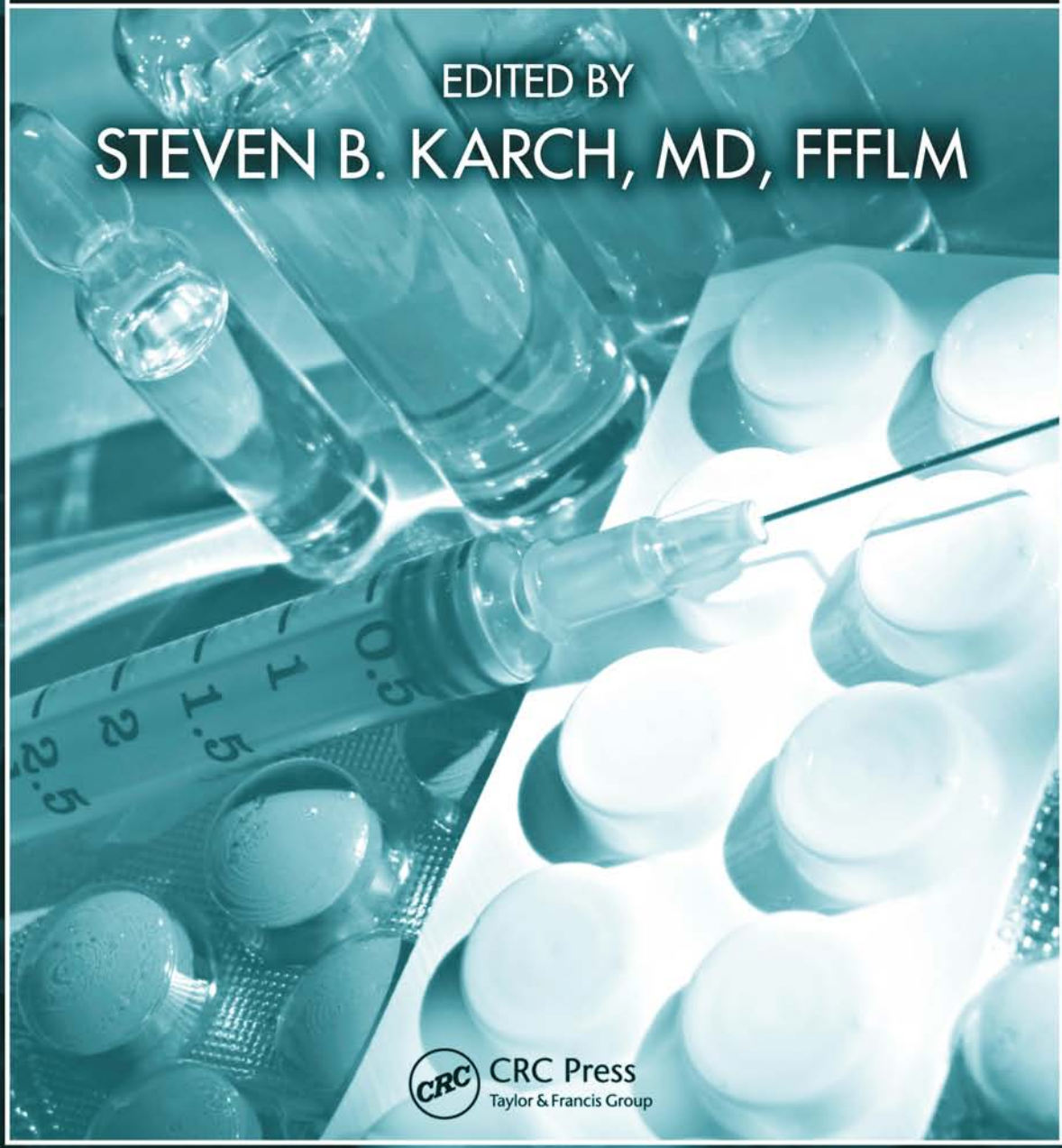
Workplace Drug Testing



EDITED BY

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Preface

Workplace drug and alcohol testing is the latest component to be added to the discipline of forensic toxicology, which now comprises the triad fields of post-mortem, human performance, and workplace drug testing toxicology. Since drug testing is conducted as a deterrent to drug abuse, and society seeks to protect the rights of individuals in the workplace, every effort is necessary to prevent harm to persons through false accusation. Drug testing is a multifaceted process. The accuracy and validity of analysis and the use and application of the reported results are concerns. Multiple factors include the methodologies (initial and confirmatory), cutoff concentrations, administrative or legally mandated rules, and the influence of prescribed drugs or environmental exposure.

Acquiring a full understanding of workplace drug testing is necessary for practitioners (toxicologists, physicians, and others). The tenets of forensic science and regulatory requirements influence workplace drug testing. The right questions must be asked and proper caveats applied. Traditionally in medical practice, the test result is only one part of the diagnostic paradigm that also includes history and physical examination. In workplace testing, the test result is the primary and paramount element. There is no diagnostic paradigm and the result must stand alone, evaluated only after the test event by medical personnel identified as medical review officers (MROs).

Workplace testing is employed to ensure safety and productivity in the workplace. It is complex with myriad elements vital to its success. This book examines workplace drug testing, including its background and current status, its regulatory basis, its application in the U.S. and abroad, analytical approaches, the use of urine and other biological matrices, quality control and validity testing, the role of the MRO, and associated legal issues.

The Editor

Steven B. Karch, M.D., FFFLM, received his undergraduate degree from Brown University. He attended graduate school in anatomy and cell biology at Stanford University. He received his medical degree from Tulane University School of Medicine. Dr. Karch did postgraduate training in neuropathology at the Royal London Hospital and in cardiac pathology at Stanford University. For many years he was a consultant cardiac pathologist to San Francisco's Chief Medical Examiner.

In the U.K., Dr. Karch served as a consultant to the Crown and helped prepare the cases against serial murderer Dr. Harold Shipman, who was subsequently convicted of murdering 248 of his patients. He has testified on drug abuse–related matters in courts around the world. He has a special interest in cases of alleged euthanasia, and in episodes where mothers are accused of murdering their children by the transference of drugs, either *in utero* or by breast feeding.

Dr. Karch is the author of nearly 100 papers and book chapters, most of which are concerned with the effects of drug abuse on the heart. He has published seven books. He is currently completing the fourth edition of *Pathology of Drug Abuse*, a widely used textbook. He is also working on a popular history of Napoleon and his doctors.

Dr. Karch is forensic science editor for Humana Press, and he serves on the editorial boards of the *Journal of Cardiovascular Toxicology*, the *Journal of Clinical Forensic Medicine* (London), *Forensic Science, Medicine and Pathology*, and *Clarke's Analysis of Drugs and Poisons*.

Dr. Karch was elected a fellow of the Faculty of Legal and Forensic Medicine, Royal College of Physicians (London) in 2006. He is also a fellow of the American Academy of Forensic Sciences, the Society of Forensic Toxicologists (SOFT), the National Association of Medical Examiners (NAME), the Royal Society of Medicine in London, and the Forensic Science Society of the U.K. He is a member of The International Association of Forensic Toxicologists (TIAFT).

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CHAPTER 1

Introduction: Drugs in the Workplace

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Substance abuse has been a mainstay of society for the past few millennia. Epidemics come and go in somewhat predictable cycles and the problem has never been resolved. Over the past century, as this cyclic equilibrium has shifted, the magnitude of the problem has generally intensified. The number of euphoric substances has grown and their enhanced distribution has increased abuse. Technology has increased the potency of euphoric compounds, i.e., the synthesis of natural opium to heroin and the *de novo* synthesis of non-natural substances such as PCP, LSD, MDMA, and others. Cocaine has been concentrated and modified from the coca plant to produce freebase and crack cocaine. Improvement in horticulture techniques has increased the content of marijuana to 10 to 15% tetrahydrocannabinol (THC).

Workplace drug and alcohol testing is the latest component to be added to the discipline of forensic toxicology, which now comprises the triad fields of post-mortem, human performance, and workplace drug testing toxicology. Since drug testing is conducted as a deterrent to drug abuse, and society seeks to protect the rights of individuals in the workplace, every effort is necessary to prevent harm to persons through false accusation. Drug testing is a multifaceted process. The accuracy and validity of analysis and the use and application of the reported results are concerns. Multiple factors include the methodologies (initial and confirmatory), cutoff concentrations, administrative or legally mandated rules, and the influence of prescribed drugs or environmental exposure.

Acquiring a full understanding of workplace drug testing is necessary for practitioners (toxicologists, physicians, and others). The tenets of forensic science and regulatory requirements influence workplace drug testing. The right questions must be asked and proper caveats applied.

* Dr. Huestis contributed to this book in her personal capacity. The views expressed are her own and do not necessarily represent the views of the National Institutes of Health or the U.S. government.

Traditionally in medical practice, the test result is only one part of the diagnostic paradigm that also includes history and physical examination. In workplace testing, the test result is the primary and paramount element. There is no diagnostic paradigm and the result must stand alone evaluated only after the test event by medical personnel identified as a medical review officer (MRO).

Workplace testing is employed to ensure safety and productivity in the workplace. It is complex with myriad elements vital to its success. This chapter and those to follow will overview workplace drug testing including its background and current status, its regulatory basis, its application in the U.S. and abroad, analytical approaches, the use of urine and other biological matrices, quality control and validity testing, the role of the MRO, and associated legal issues. Although alcohol testing and on-site (point of collection) testing are practiced in the workplace, they are not included in this chapter.

1.1 HISTORY

Workplace drug testing has grown at a steady rate over the last 20 years. It is recognized that employee/applicant drug testing has become a standard business practice in the U.S. It is likely that almost half of the American workforce will be tested for illegal drugs this year. A more detailed history is provided by Walsh.[1]

The workplace drug-testing phenomenon did not occur overnight, but rather evolved slowly during the 1980s. At the outset, workplace drug testing began in the U.S. military with most of the testing done in military laboratories by military personnel. Testing was highly regimented; however, even within the military programs (Army, Navy, and Air Force), procedures, equipment, and standards varied considerably. As the use of the new immunoassay-based drug-testing technology spread to the private sector in 1982–1983, there were no regulations, no certified laboratories, no standardized procedures, and many of the devices marketed for testing were not cleared by the U.S. Food and Drug Administration. Medical and scientific questions concerning the accuracy and reliability of drug testing were raised continuously by those who opposed testing and often formed the basis of lengthy litigation. As interest in workplace drug testing increased in the public and private sectors, the need for regulations to establish the appropriate science, technology, and practice became obvious.

The beginnings of regulated testing were initiated in 1983 when the National Transportation Safety Board (NTSB) sent a series of specific recommendations to the Secretary of Transportation demanding action in regard to alcohol- and drug-related accidents, particularly in the railroad industry. The report indicated that seven train accidents occurring between June 1982 and May 1983 involved alcohol or other drugs. In response to the NTSB recommendations, the Federal Railroad Administration (FRA) with the assistance of the National Institute on Drug Abuse (NIDA) began to develop the first Department of Transportation (DOT) drug regulations in 1983. However, it was not until early 1986 that legal obstacles were cleared and the rule went into effect and was fully implemented. During the 1983–1986 timeframe, many companies in the oil, chemical, transportation, and nuclear industries voluntarily implemented drug-testing programs. Without standards and recognized procedures, almost every action incurred controversy. Lawsuits and arbitration caseloads mounted rapidly. Reports of laboratory errors in the massive military program raised concerns that the application of this state-of-the-art technology might be premature. Allegations of employees stripped naked and forced to provide specimens in view of other employees were often repeated and added justification for regulations.

In 1986, the federal government became involved in employee drug testing in a significant way. In March 1986, President Reagan's Commission on Organized Crime issued its final report. Among the recommendations were the following:

> The President should direct the heads of all Federal agencies to formulate immediately clear policy statements, with implementing guidelines, including suitable drug testing programs, expressing the

> utter unacceptability of drug abuse by Federal employees. State and local governments and leaders in the private sector should support unequivocally a similar policy that any and all use of drugs is unacceptable. Government contracts should not be awarded to companies that fail to implement drug programs, including suitable drug testing. Government and private sector employers who do not already require drug testing of job applicants and current employees should consider the appropriateness of such a testing program.

NIDA convened a conference in March 1986. The conference was designed to discuss and achieve consensus on drug-testing issues. Prior to the release of the President's Commission on Organized Crime report, the NIDA position advocating testing for critical and sensitive positions was viewed as radical. However, once the recommendation for widespread testing of everyone employed in both the public and private sectors was proposed by the President's Commission, the NIDA position became one of reasonable accommodation. The conference thus focused on prescribing the conditions under which testing could be conducted. After lengthy discussions, consensus was reached on the following points:

1. All individuals tested must be informed.
2. All positive results on an initial screen must be confirmed through the use of an alternate methodology.
3. The confidentiality of test results must be assured.
4. Random screening for drug abuse under a well-defined program is appropriate and legally defensible in certain circumstances.

The consensus reached at this meeting in 1986 on technical, medical, legal, and ethical issues truly served to provide the foundation for the development of the federal regulations that were to evolve over the next decade and continue to evolve. The responsibility for developing technical and scientific guidelines for these drug-testing programs was assigned to the Secretary of Health and Human Services (HHS) and was delegated to NIDA. An informal advisory group produced the initial set of guidelines in a matter of months. On February 19, 1987, HHS Secretary Dr. Otis Bowen issued the required set of technical and scientific guidelines for federal drug-testing programs. Several months later Congress passed a new law (Public Law 100-71 section 503) that set the stage for the widespread regulation of employee drug testing. Enacted on July 7, 1987, the law permitted the President's *Drug Free Federal Workplace* program to go forward only if a number of administrative prerequisites were met. Among the list of required administrative actions was that the Secretary of Health and Human Services publish the HHS technical and scientific guidelines in the *Federal Register* for notice and comment, and to expand the "Guidelines" to include standards for laboratory certification. The NIDA advisory group had been working on the concept of laboratory accreditation since early in 1986 anticipating the eventuality of laboratory certification. This allowed NIDA to revise the "guidelines" quickly and include a proposed scheme of laboratory certification, which was published in the *Federal Register* on August 13, 1987, less than 6 weeks after the passage of the law.

The HHS Guidelines included procedures for collecting urine samples for drug testing, procedures for transmitting the samples to testing laboratories, testing procedures, procedures for evaluating test results, quality control measures applicable to the laboratories, record keeping and reporting requirements, and standards and procedures for HHS certification of drug-testing laboratories. The basic intent of the guidelines was and remains to safeguard the accuracy and integrity of test results and the privacy of individuals who are tested. Following comment and revision, the scientific and technical aspects of the guidelines remained intact as drafted and were published in the *Federal Register* as the "Mandatory Guidelines for Federal Workplace Drug Testing Programs" on April 11, 1988. In July 1988, utilizing the certification standards developed as part of the "Mandatory Guidelines," a National Laboratory Certification Program was implemented by HHS/NIDA and was administered under contract by the Research Triangle Institute. More than 100 laboratories have been certified in this program since 1988 with approximately 50 remaining certified in 2006.

The U.S. DOT published an interim final rule on November 21, 1988 establishing drug-testing procedures applicable to drug testing for transportation employees under six DOT regulations. These six regulations were published on that same date by the Federal Aviation Administration (FAA), Federal Highway Administration (FHWA), Federal Railroad Administration, U.S. Coast Guard, Urban Mass Transportation Administration, and Research and Special Programs Administration. The interim final rule (49 CFR part 40) followed closely the HHS regulation entitled "Mandatory Guidelines for Federal Workplace Drug Testing Programs." DOT issued its final rule on December 1, 1989 with an implementation date of January 2, 1990. These regulations brought the rest of the transportation modes in line with the railroad industry and, in most aspects, standardized the procedures across the industry. The Congress later passed the Omnibus Transportation Employee Drug Testing Act of 1991. This Act was an extremely important piece of legislation that broadly expanded drug testing in the transportation industry. The impetus for the legislation was a very visible subway accident in New York City where the engineer was found to be under the influence of alcohol. The Act required DOT to prescribe regulations within 1 year to expand the existing DOT drug regulations in aviation, rail, highway, and mass transit industries to cover intrastate as well as interstate transportation and to expand the drug-testing program to include alcohol. Final DOT rules were published in the *Federal Register* in February 1994, which continued to incorporate the HHS "Guidelines" and required implementation by January 1, 1995 for large employers (i.e., >50 covered employees) and January 1, 1996 for small employers. Currently the DOT regulations cover more than 12 million transportation workers nationwide.

Drug testing in the workplace has changed considerably over the last 20 years and the changes have improved the program. The development and scope of regulations related to testing have had an important effect not only to improve the accuracy and reliability of employee drug testing but also to establish the credibility of the testing process and the laboratories' capabilities to routinely perform these tests. The stringent laboratory certification standards imposed on forensic drug-testing laboratories have influenced clinical laboratory medicine, with dramatic improvement over the last decade. A real concern is that the federal regulations may have become too rigid, precluding technological advances. The Substance Abuse and Mental Health Services Administration (SAMHSA), which was mandated oversight of workplace drug testing in 1992, has regularly modified regulations and, most recently, proposed new adaptations in technology in a broad sweeping proposal to include the testing of hair, sweat, and oral fluid in addition to urine specimens. It also proposes the use of on-site tests of urine and oral fluid at the collection site, the establishment of instrumented initial test facilities, and changes in operational standards.[2]

1.2 INCIDENCE OF DRUGS IN THE WORKPLACE

Good comprehensive statistics regarding drug use and testing incidence have not been developed. The National Household Survey (2003) shows that 19.5 million people over 12 years of age used drugs during the past month. Of these 54.6% used marijuana, 20.6% marijuana and other drugs, and 24.8% used other drugs. Use was predominately in the 14- to 29-year-old age group as follows: 10.9% (14–15), 19.2% (16–17), 23.3% (18–20), 18.3% (21–25), 13.4% (26–29), and 14.9% (all others).

The only comprehensive compilation of drug test data is published by Quest Diagnostics. Its Drug Testing Index is compiled semiannually. Quest Diagnostics is one of the largest providers of workplace drug tests performing more than 12 million tests annually. Its results are the best available statistical indication of trends in the field. Over the years the drug positivity rates have gone from a high in 1988 (13.6%) when drug-testing programs started to 4.5% in 2004. The number of positives has been relatively consistent since 1997 (5.0 to 4.5%); see Table 1.1. The positivity rates by drug category for the combined workforce for the last 5 years (2000 to 2004) is shown in Table 1.2.

Table 1.1 Annual Positivity Rates for Combined U.S. Workforce (more than 7.2 million tests from January to December 2004)

Year	Drug Positive Rate
1988	13.6%
1989	12.7%
1990	11.0%
1991	8.8%
1992	8.8%
1993	8.4%
1994	7.5%
1995	6.7%
1996	5.8%
1997	5.0%
1998	4.8%
1999	4.6%
2000	4.7%
2001	4.6%
2002	4.4%
2003	4.5%
2004	4.5%

Source: Courtesy of Quest Diagnostics.

Table 1.2 Positivity Rates by Drug Category for Combined U.S. Workforce as a Percentage of All Positives (more than 7.2 million tests from January to December 2004)

Drug Category	2004	2003	2002	2001	2000
Acid/base	0.13%	0.18%	0.27%	0.24%	0.08%
Amphetamines	10.2%	9.3%	7.1%	5.9%	5.1%
Barbiturates	2.5%	2.5%	2.6%	2.9%	3.2%
Benzodiazepines	4.5%	4.7%	4.5%	4.5%	3.9%
Cocaine	14.7%	14.6%	14.6%	13.9%	14.4%
Marijuana	54.8%	54.9%	57.6%	60.6%	62.8%
Methadone	1.5%	1.4%	1.1%	0.88%	0.82%
Methaqualone	0.00%	0.00%	0.00%	0.00%	0.00%
Opiates	6.2%	6.4%	5.5%	5.8%	5.4%
Oxidizing adulterants (incl. nitrites)	0.09%	0.19%	0.52%	0.54%	0.92%
PCP	0.38%	0.61%	0.58%	0.59%	0.56%
Propoxyphene	4.4%	4.5%	5.1%	3.5%	2.3%
Substituted	0.66%	0.73%	0.68%	0.51%	0.58%

Source: Courtesy of Quest Diagnostics.

Updated revisions and more specific breakdowns of these statistics may be found on the Quest Diagnostics Web site www.questdiagnostics.com.

REFERENCES

1. Walsh, J.M., Development and scope of regulated testing. In *Drug Abuse Handbook,* S.B. Karch, Ed. in Chief. CRC Press, Boca Raton, FL, 1998, 729–736.
2. Department of Health and Human Services, Substance Abuse and Mental Health Services Administration, Proposed Revisions to Mandatory Guidelines for Workplace Drug Testing Programs (69 FR 19673), April 13, 2004.

CHAPTER 2

Overview of the Mandatory Guidelines for Federal Workplace Drug Testing Programs

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2.1 HISTORY

"The Federal Government, as the largest employer in the world, can and should show the way towards achieving drug-free workplaces through a program designed to offer drug users a helping hand." These words are part of President Reagan's Executive Order (EO) Number 12564,[1] issued September 15, 1986, which served to launch the Federal Drug-Free Workplace Program. This EO authorized the Secretary of Health and Human Services (HHS) to promulgate scientific and technical guidelines for drug testing programs, and required agencies to conduct their drug testing programs in accordance with these guidelines once promulgated. This Federal Drug-Free Workplace Program covers approximately 1.8 million federal employees. Of this total number, approximately 400,000 federal employees and job applicants work in health- and safety-sensitive positions identified as Testing Designated Positions, and are subject to urine drug testing.