

The U.S. Mandatory Guidelines for Federal Workplace Drug Testing Programs: Current status and future considerations

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Available online 16 April 2007

Abstract

The U.S. Department of Health and Human Services (HHS) drug testing standards were published in 1988 and revised in 1994, 1998, and 2004. In 2004, significant revisions defining, standardizing, and requiring specimen validity testing on Federal employee donor urine specimens were included. In a separate notice, HHS proposed to establish scientific and technical guidelines for the Federal Workplace Drug Testing Program to: (1) permit laboratory testing of hair, oral fluid, and sweat patch specimens in addition to urine specimens for marijuana, cocaine, phencyclidine, opiates (with focus on heroin), and amphetamines [including methylenedioxyamphetamine (MDMA), methylenedioxyethamphetamine (MDEA), methylenedioxyamphetamine (MDA)]; (2) permit use of on-site point of collection test (POCT) devices to test urine and oral fluid at collection sites; (3) permit use of instrumented initial test (screening only) facilities [IITF] to quickly identify negative specimens; and (4) add training requirement for collectors, on-site testers, and MROs. This proposal was published in the Federal Register on 13 April 2004, with a 90-day public comment period. The Substance Abuse and Mental Health Services Administration, HHS, reviewed those comments and is preparing the Final Notice that will define the requirements for such testing, including: specimen collection procedures, custody and control procedures that ensure donor specimen identity and integrity, testing facility, initial and confirmatory test cutoff concentrations, analytical testing methods, result review and reporting, evaluation of alternative medical explanations for presence of drug or metabolite in the donor's specimen, and laboratory certification issues. Voluntary pilot performance testing (PT) programs for each specimen type are on-going since April 2000 to determine how to prepare PT materials for specimens other than urine to evaluate laboratories' ability to routinely achieve accuracy and precision required. Certification programs will be developed using the current urine drug testing National Laboratory Certification Program model. The addition of accurate and reliable workplace drug testing using hair, oral fluid, and sweat patch specimens will complement urine drug testing, and aid in combating industries devoted to suborning drug testing through adulteration, substitution, and dilution. For example, hair testing may detect chronic drug use for up to 90 days and be useful in pre-employment situations; oral fluid testing may detect drug use in past hours and be useful in post-accident situations; sweat patch testing may be useful in follow-up drug testing and treatment programs; POCTs and IITFs may be most useful for quickly identifying specimens that are negative for drugs and indicate that the specimen is valid.

Published by Elsevier Ireland Ltd.

Keywords: Workplace drug testing; Regulatory requirements; Specimen validity testing; Performance testing

1. Introduction

The United States Government established requirements for a Drug-Free Federal Workplace following then-president Reagan's Executive Order (EO) Number 12564 [1] dated 15 September 1986. The Secretary of HHS was authorized to promulgate scientific and technical guidelines for drug testing programs and Federal agencies were required to conduct their

drug testing programs in compliance with these guidelines. The Supplemental Appropriations Act of 1987 (Public Law 100-71, Section 503, 5 U.S.C. 7301 note) further outlined the general provisions for Federal drug testing programs, and directed the Secretary of HHS to set comprehensive standards for all aspects of laboratory drug testing. Today, the authority to develop and promulgate these standards resides with the Substance Abuse and Mental Health Services Administration (SAMHSA), an operational division in HHS. The Division of Workplace Programs (DWP) in SAMHSA administers and directs the National Laboratory Certification Program (NLCP) that oversees laboratories performing drug testing in accordance with

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the “Mandatory Guidelines for Federal Workplace Drug Testing Programs” (Guidelines). These Guidelines were first published by the Secretary of Health and Human Services in the Federal Register on 11 April 1988 [2], and were revised and published on 9 June 1994 [3], 13 November 1998 [4], and most recently on 13 April 2004 [5]. The current Guidelines include specific urine specimen validity testing (SVT) requirements. The intent of these Guidelines is to ensure the accuracy, reliability, and forensic supportability of drug and SVT results as well as protect the privacy of individuals (Federal employees) who are drug tested. The focus of this Federal drug testing program is to deter and detect the use of illicit drugs.

The requirements for a comprehensive drug-free workplace model are outlined in the Guidelines and include: (1) a policy that clearly defines the prohibition of illegal drug use and the consequences directed against drug abuse, (2) employee education regarding the dangers of drug use, (3) supervisor training outlining their responsibilities in a Drug-Free Workplace Program, (4) a helping hand in the form of an Employee Assistance Program for employees who have a drug problem, and (5) provisions for identifying employees who are illegal drug users, including drug testing on a controlled and carefully monitored basis.

The Federal Drug-Free Workplace Program applies to all Federal employees, numbering approximately 1.8 million in July 2005. Of this total number, approximately 400,000 Federal employees and job applicants work in safety-sensitive and security-sensitive positions identified as Testing Designated Positions, and are subject to urine drug testing. The types of drug testing conducted under Federal authority include: job applicant, post-accident/unsafe practice, reasonable suspicion, follow-up to treatment, random, and voluntary testing.

The Federal drug testing Guidelines are used by other programs under separate authority and law. For example, the U.S. Department of Transportation (DOT) developed requirements for its regulated industry that incorporate the scientific and technical aspects of the Guidelines into their drug testing program [6]. Here, DOT requires that its regulated employers use only HHS-certified laboratories when testing their employees. The Nuclear Regulatory Commission’s (NRC), fitness for duty program also requires the use of HHS-certified laboratories for any drug testing performed under its rules [7].

2. Current status: requirements for Federal Workplace Drug Testing Programs

2.1. Urine specimen collection

While urine specimen collection requirements are stated in the Guidelines, a very detailed collection procedure is provided in the Urine Specimen Collection Handbook [8]. A collection site must have the necessary facilities, equipment, trained personnel, collection containers, Federal Custody and Control Forms (CCF), and supervision to provide for specimen collection, security, and temporary storage of the specimen. The collection site must also be able to make arrangements for

the transfer of the specimens, once collected, to a certified laboratory. Additionally, the collection site must provide for the privacy of the donor while he/she provides the unobserved urine specimen. The site must limit access to water that could be used to dilute the specimen (one way is by adding a bluing agent to the water in the toilet), have procedures in place to prevent unauthorized access to the site during the collection, not allow the donor access to items that could be used to adulterate or dilute the specimen (i.e., cleaning agents), and prevent unauthorized access to the specimen after it was collected or to the collection site records.

The donor’s responsibilities include leaving his/her unnecessary outer clothing and other personal belongings, such as a briefcase or purse, in a secured area at the collection site, but away from the actual specimen collection. The donor is asked to empty his/her pockets and display the items to the collector to ensure that no items are present that could be used to adulterate the specimen. The donor is then instructed to wash his/her hands in the presence of the collector. The donor then chooses the collection kit and the actual specimen collection begins.

All urine specimens must be collected using chain of custody procedures to document the integrity and security of the specimen from the time of collection until receipt by the laboratory. To ensure uniformity among all Federal agency and federally regulated workplace drug testing programs, the use of an approved Federal Custody and Control Form (CCF) is required [9]. This CCF is formatted to capture the traditional chain of custody dates, signatures, and annotations necessary for documenting the evidentiary specimen collection process, and also serves as a document for reporting laboratory drug and SVT results to the medical review officer (MRO). This CCF is a 5-page carbonless form, with identified pages each going from the collection site to the laboratory, MRO, collector, employer, and donor. The required statements concerning the privacy of the information provided and instructions for completing the Federal CCF are included on the reverse side of the donor copy of the CCF.

At present, each Federal agency has established a protocol to require the donor’s collected specimen to be transferred to a single container or to two containers to be sent to the laboratory for testing. In the case of a single specimen, at least 30 mL of the urine in the collection cup is decanted into a single specimen bottle. Alternatively, if the specimen is to be collected as a “split specimen,” at least 30 mL of the specimen collected is decanted into one bottle, called the primary specimen or bottle A, and at least 15 mL into a second bottle, called the split specimen or bottle B.

The specimen must be collected from the donor in a single-use collection cup, and then presented to the collector who measures the temperature of the urine within 4 min of collection using the temperature strip attached to the outside of the collection cup. The temperature must read between 90 and 100 °F to be considered a valid specimen. If the temperature reads in the acceptable range, the CCF is completed, the tamper-evident bottle seal(s)/label(s) containing unique specimen identification numbers located at the bottom

of the first page of the CCF are applied to the specimen, and the specimen and CCF prepared for delivery to the laboratory. If the specimen temperature is outside of this range, another specimen must be collected under direct observation. If this occurs, both the first specimen (collected with the temperature out of range) and the second specimen (collected under direct observation) must be transferred to the respective specimen bottles, a separate CCF completed for each specimen, with appropriate annotations describing the circumstances of the collection. Both specimen bottles are sealed with the tamper-evident seals/labels from the bottom of the first page of the CCF and sent to the laboratory for analysis. The collector and the donor must each maintain visual contact with the specimen from the time the specimen is transferred to the collector until the time the specimen bottle(s) have been sealed for shipment to the laboratory. In addition, there may be other circumstances under which the collector has reason to believe that the donor may have altered or substituted the specimen. For example: a suspicious product falling out of the donor's sock, fluid leaking from some container concealed on the donor's person, or bulky items protruding under normal clothing. When there is any reason to believe that a donor is attempting to or has altered or substituted his/her specimen, another specimen must be immediately collected under direct observation.

2.2. Drug testing

From the first publication of the Guidelines in April 1988 until the mid-1990s, the focus was primarily on testing the urine specimen for illicit drugs of abuse. The Guidelines require the use of an FDA-cleared immunoassay test as the initial test on each specimen. If the immunoassay test was negative using these cutoffs, then the laboratory reports the specimen as negative. If the immunoassay was positive, indicating that the donor's specimen presumptively contained one or more drug/drug classes tested, then confirmatory testing using gas

chromatography/mass spectrometry (GC/MS) is required to definitively establish the identity of the drug or drug metabolite and report the specimen as positive. The required cutoffs from the Mandatory Guidelines for the initial and confirmatory tests are found in Table 1.

2.3. Specimen validity testing (SVT)

It has always been clear in the Guidelines that no additional drugs may be tested unless authorized by law, and that a specimen is provided by the donor in an unobserved manner unless there is sufficient reason to believe that the donor is attempting to dilute, adulterate, or substitute his/her specimen. Tests to determine that the specimen submitted is a valid human urine specimen have always been allowed. Since the mid-1990s, many different approaches to mask the drugs present in a specimen have been advertised and become available to the general public. As a consequence, a number of specimens have been identified by the laboratories as having unusual chemical characteristics. In response, general guidance in the form of Program Documents was provided to laboratories by HHS to better define the processes to use when conducting SVT. Further, to standardize the testing performed and to require this testing of all Federal employee specimens, the latest revision to the Guidelines was published in the Federal Register on 13 April 2004, and became effective on 1 November 2004 [5].

In addition to drug testing Federal employee specimens as outlined above, starting 1 November 2004, the laboratory must:

- (1) Determine the creatinine concentration on every specimen;
- (2) Determine the specific gravity on every specimen for which the creatinine concentration is less than 20 mg/dL;
- (3) Determine the pH on every specimen;
- (4) Perform one or more validity tests for oxidizing adulterants on every specimen;

Table 1
Initial and confirmatory cutoff concentrations

Drug/analyte	Urine (ng/mL)	
	Initial drug test concentration	Confirmatory drug test concentration
Marijuana metabolites	50	
THCA (Delta-9-tetrahydrocannabinol-9-carboxylic acid)		15
Cocaine metabolites	300	
Benzoylcegonine		150
Opiate metabolites	2000	
Morphine ^a		2000
Codeine		2000
6-Acetylmorphine		10
Phencyclidine	25	
Phencyclidine		25
Amphetamines	1000	
Amphetamine		500
Methamphetamine ^b		500

^a Test for 6-acetylmorphine when the morphine concentration is greater than or equal to 2000 ng/mL.

^b Specimen must also contain amphetamine at a concentration greater than or equal to 200 ng/mL.

- (5) Perform additional validity tests when the following conditions are observed: (a) abnormal physical characteristics, (b) reactions or responses characteristic of an adulterant obtained during initial or confirmatory drug tests (e.g., non-recovery of internal standards, unusual response); or (c) possible unidentified interfering substance or adulterant.

As of August 2005, the DOT does not yet require SVT to be performed on all its regulated industry specimens, but does allow such testing on a voluntary basis. The requirement is that if SVT is performed, it must be performed in accordance with the requirements of the HHS Guidelines stated above [10].

Results for specimens reported using these SVT criteria are categorized as follows:

- (1) A urine specimen is reported as dilute when the creatinine concentration is greater than or equal to 2 mg/dL but less than 20 mg/dL and the specific gravity is greater than 1.0010 but less than 1.0030 on a single aliquot.
- (2) A urine specimen is reported as substituted when the creatinine concentration is less than 2 mg/dL on both the initial and confirmatory creatinine tests (i.e., the same colorimetric test may be used to test both aliquots) and the specific gravity is less than or equal to 1.0010 or greater than or equal to 1.0200 on both the initial and confirmatory specific gravity tests using a refractometer on two separate aliquots.
- (3) A urine specimen is reported as adulterated when: the pH is less than 3 or greater than or equal to 11; the nitrite concentration is greater than or equal to 500 mcg/mL; the chromium (VI) screened at a concentration greater than or equal to 50 mcg/mL and confirmed using a different analytical test at a concentration greater than or equal to the laboratory's limit of detection.
- (4) The presence of a halogen (e.g., from bleach, iodine, fluoride), glutaraldehyde, pyridine, surfactant, and any other adulterant is verified by using an initial test on the first aliquot and a different confirmatory test on the second aliquot.
- (5) A urine specimen that does not meet one of the criteria above, but is clearly not normal is reported as invalid. Some examples of invalid specimens include: when the creatinine concentration and specific gravity results that are obtained are inconsistent with values expected of a normal human urine or the defined ranges for a substituted specimen; when the pH does not meet the requirements to report the specimen as adulterated, but the values are outside the range required for obtaining an acceptable immunoassay test (pH is greater than or equal to 3 and less than 4.5 or greater than or equal to 9 and less than 11); the nitrite concentration is greater than or equal to 200 mcg/mL but less than the 500 mcg/mL concentration required to report the specimen as adulterated; or there is general oxidant activity that cannot be accounted for by identifying a specific oxidizing adulterant.

The reporting of drug and specimen validity test results is summarized in Table 2. As indicated in Table 2, there are many

combinations of possible drug and specimen validity test results that can be reported for a specimen.

2.4. Medical Review Officer (MRO) reporting

All drug and specimen validity test results must be reported from the laboratory directly to an MRO. The MRO must be a licensed physician (either a doctor of medicine or osteopathy) who has, among other things, knowledge about and clinical experience regarding controlled substance abuse disorders and must have knowledge of alternative medical explanations for laboratory positive drug test results. Additionally, an MRO must have knowledge about specimen adulteration, substitution, and medical reasons why a specimen result may be reported as invalid. It is important to note that a positive result does not automatically identify a donor as an illegal drug user. The MRO must interview the donor and evaluate the medical explanations and medications presented by the donor as the reason for the result reported by the laboratory prior to making a final determination regarding the test result, and report the verified result to the Federal agency. Additional detailed information is provided in the MRO Manual [11].

3. Dilution, adulteration, and substitution products

Marketing products to “beat the drug test” continues to proliferate. In September 2002, a Google search on the phrase “beat a drug test” yielded 158,000 hits in 0.4 s; in May 2005, the same search yielded 1,210,000 hits in 0.06 s. A Google search on the phrase “pass a drug test” yielded 3,570,000 hits in 0.06 s. These growing numbers of websites and messages indexed by Internet search engines to identify ways for illicit substance abusers to go undetected in a drug test are of serious concern to those directed Federal, federally regulated, and private sector drug testing programs. As of May 2005, the NLCP has identified over 400 separate products that are marketed to beat a drug test. These products are available through a variety of sources including magazines, smoking and novelty shops, dietary supplement retailers, and websites. Examples of the types of products marketed to be effective in masking the identity of illicit drugs, particularly marijuana, in urine are of three types: (1) dilution and cleansing products, (2) adulteration additives, and (3) substitute urine products.

The dilution and cleansing products mainly consist of teas and drinks and other diuretics, with instructions to consume them with extremely large quantities of water. The intent of these products is to dilute the urine to such an extent as to reduce the concentration of any tested illicit drug or metabolite in the urine to below the established cutoffs. The phrase “dilution is the solution” is one frequently used to describe the intent of these products. Thus, these products work to dilute the urine while it is still in the urinary bladder, i.e., *in vivo*.

The adulteration additives are chemical compounds marketed to be added to the urine after it is provided in the collection cup, in other words to be added to the urine *in vitro*. These chemicals are generally sold in small containers that are easily concealed in the clothing of the specimen donor and can

Table 2
Drug and SVT test result reporting

Result box(es) checked on Federal CCF (step 5a) or result indicated on electronic report	Note	
Negative	All drug tests are negative and all specimen validity test results are acceptable	
Negative and dilute	For DOT-regulated specimens: provide creatinine and SpGr numerical values (see below)	
Invalid result	State reason for invalid result (see below)	
Positive, specific drug	No comment required	
Positive, specific drug, and dilute	No comment required	
Positive, specific drug, and adulterated	State reason for adulterated result (see below)	
Positive, specific drug, and substituted	Provide creatinine and SpGr numerical values (see below)	
Positive, specific drug, and invalid result	State reason for invalid result (see below)	
Adulterated	State reason for adulterated result (see below)	
Adulterated and invalid result	State reasons for adulterated and invalid results (see below)	
Adulterated and substituted	State reason for adulterated result and provide creatinine and SpGr numerical values (see below)	
Substituted	Provide creatinine and SpGr numerical values (see below)	
Substituted and invalid result	Provide creatinine and SpGr numerical values and state reason for invalid result (see below)	
Rejected for testing	State reason for rejecting specimen (see below)	
Test result	Specific comment required on remarks line (step 5a) of the CCF and on electronic report	Note
Negative and dilute	For DOT-regulated specimens: creatinine = (numerical value) mg/dL and SpGr = (numerical value)	
Substituted	Creatinine = (conf. test numerical value) mg/dL and SpGr = (conf. test numerical value)	
Adulterated	pH = (confirmatory test numerical value) Nitrite = (confirmatory test numerical value) mcg/mL Chromium (VI) = (confirmatory test numerical value) mcg/mL (Specify halogen) present Glutaraldehyde = (confirmatory test numerical value) mcg/mL Pyridine = (confirmatory test numerical value) mcg/mL Surfactant present (Specify adulterant) present	
Invalid result	Creatinine < 2 mg/dL; SpGr acceptable SpGr ≤ 1.0010; creatinine ≥ 2 mg/dL Abnormal pH Possible (characterize as oxidant, halogen, aldehyde, or surfactant) activity ^a Immunoassay interference ^a GC/MS interference ^a Abnormal physical characteristic—(specify) ^a Bottle A and bottle B—different physical appearance ^a	SpGr > 1.0010 and <1.0200
Rejected for testing	Fatal flaw: specimen ID number mismatch/missing Fatal flaw: no collector printed name and no signature Fatal flaw: tamper-evident seal broken Fatal flaw: insufficient specimen volume Uncorrected flaw: wrong CCF used Uncorrected flaw: collector signature not recovered	If redesignation is not possible Wait 5 business days before reporting flaw if uncorrected

^a Laboratory shall contact the MRO to discuss the invalid result.

be easily used by the donor when not directly observed while providing his/her specimen. Some products *are* effective and detectable, while others are not yet detectable or disappear on their own. Some products *are not* effective, but are still marketed and sold as being able to beat a drug test.

The substitute urine products generally consist of devices, reservoirs, catheters, prosthetic devices, and fluids formulated to chemically resemble urine. Some actually deliver the drug

free or synthetic urine though a color-matched fake penis, which makes detection even under direct observation (as is conducted in some judicially required programs and under some workplace conditions) difficult.

Many new adulterants worked when first introduced. However, when they were then detected, identified and procedures put in place to counter their use, the purveyors of the products changed their formulation to one presumably not

detectable. Because of this, there has been a rhythmic sequence to the appearance of these products and an ensuing “cat and mouse” pursuit of identifying the next formulation available. It is interesting to note that in addition to urine, many of the available products are advertised to be effective in masking drugs in other bodily specimens. For hair, there are shampoos and spritzes; for oral fluid, there are mouthwashes and cleaners; for blood and other specimens, whole body cleansers are advocated. At this time, only about one-third of the states have laws in place that make the sale, delivery, possession or use of products marketed to beat the drug test illegal, with varying degrees of consequence, ranging from fines to jail time.

Almost 6,800,000 Federal and federally regulated specimens were tested in the HHS-certified urine drug testing labs from May 2004 through April 2005. Of these, laboratory testing shows that about 140,000 (2.1%) are drug positive, and about 10,000 (0.15%) were found to be adulterated, substituted, or invalid. There were an unknown number of successfully adulterated or substituted specimens submitted to testing and not identified as adulterated or substituted.

4. Future considerations: proposed revisions to the Mandatory Guidelines for Federal Employee Drug Testing Programs

4.1. Testing hair, oral fluid, sweat patch and the use of alternative testing technologies

HHS has remained committed to maintaining the integrity of the Federal Drug-Free Workplace Program by identifying and using the most accurate and reliable drug testing technology available. HHS has historically collaborated with the DOT, NRC, Federal regulators, researchers and the drug testing industry on scientific and program matters. Since 1995, SAMHSA scientific staff and its Drug Testing Advisory Board have been working with hair, oral fluid, sweat patch, and POCT industry working groups in a two-way effort to evaluate the science behind the new testing technologies, and to share SAMHSA drug testing program requirements with the industries. The addition of alternative specimens and drug testing technologies would complement the existing urine drug testing program and aid in combating the threat from counter-industries devoted to beating drug tests. On 13 April 2004, HHS published a notice in the Federal Register proposing to establish: (a) scientific and technical guidelines for the testing of hair, sweat, and oral fluid specimens in addition to urine specimens, (b) the requirement to test each specimen for MDMA, MDEA, and MDA, (c) scientific and technical guidelines for using on-site tests to test urine and oral fluid at the collection site, (d) requirements for the certification of instrumented initial test facilities, and (e) require standards for collectors, on-site testers, and MROs [12]. This notice required a 90-day public comment period that ended 12 July 2004. Comments were received from 285 submitters, and more than 2000 separate comments were included.

This proposal was issued with the fundamental understanding that the window of drug detection for urine, hair, oral

fluid, and sweat patch specimens are neither equal nor identical, but the results from each specimen can be used in a complementary manner. Urine is generally useful for detecting drug ingestion for a 3–5-day interval preceding the specimen collection. Hair is useful for detecting drug use for a longer time period, generally ranging from weeks to months (but not the first week), depending on the length of the hair tested. Drug detection in oral fluid is useful for detecting drugs in the range from less than 1 h to approximately 24 h. The window of drug detection for the sweat patch is a cumulative measure of drug use from shortly before the patch is applied until it is removed, which may be from several days to a week (the maximum time allowed in its FDA-clearance for use).

The proposed alternative matrices cutoff concentrations are listed in Table 3.

4.2. Alternative specimen validity testing

This notice for public comment also included a proposal to require that validity tests be performed on each specimen collected. While hair, oral fluid, and sweat patch specimens are collected under conditions that essentially allow direct observation, many products are marketed and available purporting to mask the drug test. For each specimen, several specimen validity tests were proposed. For a hair specimen: perform a digestion test; a microscopic identification; a dye test; determine the solubility of head hair in methanol; and perform additional validity tests when the specimen displays abnormal physical characteristics (e.g., the split specimens have different hair color, or a mixture of different types of head hair); or when the chemical reactions or responses characteristic of an adulterant are obtained during initial or confirmatory drug tests (e.g., non-recovery of standards, unusual response); or a possible unidentified interfering substance or adulterant is identified. For an oral fluid specimen: determine the immunoglobulin concentration on every specimen; and perform additional validity tests when abnormal physical characteristics are identified (e.g., unusual color or texture, unusual odor, semi-solid characteristics); when the chemical reactions or responses characteristic of an adulterant are obtained during initial or confirmatory drug tests (e.g., non-recovery of standards, unusual response); or a possible unidentified interfering substance or adulterant is identified. For a sweat patch specimen: determine the lactic acid concentration; abnormal physical characteristics (e.g., Patch A and Patch B have different color, unusual odor); and when the chemical reactions or responses characteristic of an adulterant are obtained during initial or confirmatory drug tests (e.g., non-recovery of standards, unusual response); or a possible unidentified interfering substance or adulterant is detected. For a urine specimen: the SVT criteria described earlier in this paper and required as of 1 November 2004 are the standards proposed.

Criteria for reporting hair, oral fluid, and sweat patch specimens as invalid, adulterated, and substituted will be defined after the public comments are evaluated, appropriate changes made to the proposed policies, and the Final Notice is published in the Federal Register. Any necessary refinement in reporting a

Table 3

Proposed initial screening and confirmatory cutoffs for alternative specimens

Drug/analyte (ng/mL)	Hair (pg/mg)		Oral fluid (ng/mL)		Sweat patch (ng/patch)		Urine (ng/mL)	
	Screen	Confirm	Screen	Confirm	Screen	Confirm	Screen	Confirm
Marijuana metabolites	1						50	
Marijuana (parent)			4		4			
THC (parent drug)				2		1		
THCA (metabolite)		0.05						15
Cocaine								
Cocaine metabolites	500		20		25		150	
Cocaine		500 ^a		8 ^b		25 ^b		
Benzoylcegonine		50		8		25		100
Cocaethylene		50						
Norcocaine		50						
Opiate metabolites^c	200		40		25		2000	
Morphine		200		40		25		2000
Codeine		200		40		25		2000
6-Acetylmorphine		200 ^d		4		25		10
Phencyclidine	300		10		20		25	
Phencyclidine		300		10		20		25
Amphetamines^e	500		50		25		500	
MDMA	500		50		25		500	
Amphetamine		300		50		25		250
Methamphetamine		300 ^f		50 ^g		25 ^g		250 ^h
MDMA (ecstasy)		300		50		25		250
MDA		300		50		25		250
MDEA		300		50		25		250

^a Laboratories are permitted to initial test all specimens for 6-acetylmorphine (6-AM) using the appropriate cutoff for each matrix.^b Methamphetamine is the target analyte.^c BZE/cocaine ratio ≥ 0.05 or cocaethylene ≥ 50 pg/mL or norcocaine ≥ 50 pg/mL.^d Specimen must also contain morphine at a concentration ≥ 200 pg/mg.^e Must contain amphetamine ≥ 50 pg/mg.^f A confirmatory test must be performed for either cocaine or BZE.^g Must contain amphetamine $\geq$ LOD.^h Must contain amphetamine ≥ 100 ng/mL.

urine specimen as invalid, adulterated, or substituted will also be published at the same time. For specimens reported as invalid by the laboratory, the Department proposes to allow the MRO to direct the Federal agency to have another specimen collected from the donor. The Department requested comments on whether the same type of specimen or one of the other types of specimens should be collected when this occurs.

4.3. HHS certification requirements

Necessary inspection and certification programs will be developed in accordance with requirements published in the Final Notice, using the current urine drug testing NLCP as a model, where possible. For laboratory certification, this will include quarterly PT sets and semi-annual inspections, at a minimum.

In April 2000, HHS initiated a pilot PT program, with the samples developed and produced at government expense. Voluntary pilot PT programs for each specimen type are ongoing to determine how and if accurate and stable PT materials

can be produced, and if laboratories can routinely achieve the credibility, precision, accuracy, and reliability required in a Federal workplace drug testing program. It appears that valid PT materials can be prepared, although further refinement is needed. Over time, some laboratories participating in this pilot PT program have been able to improve performance. Still, there are three serious concerns: (1) not all participating labs can perform the necessary testing with acceptable accuracy, (2) some drug classes are more difficult to detect than others for any given type of specimen, and (3) the specific drug classes that are difficult to detect vary by the type of specimen.

Testing laboratories and IITFs must be HHS-certified for each type of specimen they test and will include the performance testing program and laboratory or IITF inspections.

4.4. Proposed collector requirements

Specimen collectors must be trained for each type of specimen they collect. This training must be documented by a trainer who monitors and evaluates the trainee's knowledge and

ability to perform error-free collections. Written documentation of this training must be kept by the collector and provided to the Federal agency for which the collector is working.

4.5. Proposed MRO requirements

In addition to current requirements for a doctor of medicine or doctor of osteopathy to serve as MROs, HHS proposed the requirement that the individual have knowledge regarding the pharmacology and toxicology of illicit drugs, complete training, and successfully pass an examination administered by a nationally recognized entity that certifies MROs or for subspecialty boards for physicians performing a review of Federal employee drug test results.

HHS proposed that prior to taking the required examination a physician must receive training that includes a thorough review of: (1) the collection procedures for each type of specimen collected, (2) the procedures for conducting POCT tests, (3) how to interpret test results reported by laboratories, (4) chain of custody, reporting, and recordkeeping requirements for regulated specimens, and (5) the HHS Mandatory Guidelines for Federal Workplace Drug Testing Programs.

Also proposed were the requirements for nationally recognized entities that seek approval by the Secretary to certify MROs or for subspecialty boards for physicians performing a review of Federal employee drug test results to submit their qualifications and sample examination. Based on an annual objective review of the qualifications and content of the examination, the Secretary shall annually publish a list in the Federal Register of those entities and boards that have been approved.

4.6. Proposed initial screening processes

4.6.1. Point of Collection Testing (POCT) devices

HHS proposed to permit the use of an on-site POCT device to test urine and oral fluid at the collection site. These POCT devices are generally non-instrumented immunoassay tests with visually read end-points. There are a few POCT devices that have instrumentally read endpoints. Previously conducted assessment of available products [13] and consultation with other agencies using such technologies have provided sufficient experience and knowledge to propose procedures for the uniform assessment of on-going performance of these devices if they are to be used in Federal workplace drug testing programs. Regardless of the design of the device, it must perform drug and validity tests “like” a laboratory, with the same precision, accuracy, and reliability for each analyte around the cutoff. Additionally, if the validity POCT is separate from the POCT device, the validity tests must also perform “like” a laboratory by testing for creatinine, oxidizing adulterants, and pH. All results generated through POCT must be equal to results generated from an HHS-certified laboratory.

4.6.2. Instrumental Initial Test Facilities (IITFs)

HHS proposed to permit the use of IITFs to quickly identify negative specimens. An IITF is basically the initial test section

of the traditional laboratory which is comprised of both initial and confirmatory testing sections. An IITF would need to fulfill the following requirements: (1) be at a permanent location, (2) meet program forensic standards, (3) participate in open and blind performance testing, (4) have a rigorous quality assurance program, (5) be subject to site inspections, (6) use instrumented initial tests for drugs which meet FDA requirements for commercial distribution, (7) conduct required specimen validity tests, (8) use HHS cutoffs, and (9) submit all non-negative specimens to a full service HHS-certified laboratory for required additional testing. These are the same requirements as those of the initial test section of an HHS-certified laboratory.

IITFs may be established as a way to meet local testing needs in a true laboratory facility, and could be used for the initial drug and specimen validity testing of urine, hair, oral fluid, and sweat patch specimens. The requirement would be to send all specimens that tested presumptively positive for drug(s) and specimens with questionable SVT results to a laboratory with confirmatory testing capabilities.

4.7. Action following closure of public comment period

More than 2000 comments were received from 285 commenters representing drug testing laboratories, manufacturers of testing kits, Federal employees who will be drug tested, Agencies that will choose to use new drug testing methods, private sector employers, and members of the public at large. SAMHSA has reviewed those comments and is now preparing the Final Notice that will define the requirements for such testing, including: specimen collection procedures; specimen custody and control procedures that ensure donor specimen identity and integrity; the testing facility itself; initial and confirmatory test cutoff; analytical testing methods; result review and reporting; and requirements to evaluate alternative medical explanations for the presence of tested drug in that specimen, as well as laboratory certification issues.

5. Summary

The addition of accurate and reliable workplace drug tests for hair, oral fluid, and sweat patch specimens will complement urine drug testing and aid in combating the threat from individuals and industries devoted to suborning drug testing through adulteration, substitution and dilution. These specimens will be complementary to each other and provide information concerning illicit drug use. For example, hair testing may detect chronic drug use for up to 90 days and be useful in pre-employment situations, oral fluid testing may detect drug use in the past hours and be useful in post-accident situations, and sweat patch testing may be useful in follow-up drug testing and treatment programs. POCTs and IITFs may quickly identify pre-employment specimens that are negative for drugs and indicate that such specimens are valid.

An evaluation of the issues that are identified regarding cutoff concentrations, specimen validity testing, alternative specimens and their advantages and disadvantages, training requirements for collectors, MROs, and on-site testers has been

pertinent in the preparing the Final Notice that will define the requirements for alternative specimen testing. The voluntary pilot performance testing program for new specimens has shown promise however, the accuracy and reliability of each laboratory will need to be established through its participation in the NLCP process and laboratory certification. The current urine drug testing National Laboratory Certification Program will be the model for the development of parallel certification programs for other matrices.

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