

# Highlighted Changes: Mandatory Guidelines for Federal Workplace Drug Testing Programs (73 FR 75122, November 25, 2008)

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# Mandatory Guidelines for Federal Workplace Drug Testing Programs

- Initial publication in the Federal Register: April 11, 1988 (53 FR 11970)
  - 1st revision June 9, 1994 (59 FR 29908)
  - 2<sup>nd</sup> revision September 30, 1997 (62 FR 51118)
  - 3<sup>rd</sup> revision November 13, 1998 (63 FR 63483)
  - 4<sup>th</sup> revision April 13, 2004 (69 FR 19644)
  - 5<sup>th</sup> revision 2November 25, 2008 (73 FR 71858)
- Focused on current and emerging scientific and technical guidelines for Federal workplace drug testing programs
- Established standards for certification of laboratories engaged in drug testing for Federal agencies

# Revisions to the Mandatory Guidelines published on November 25, 2008

- Three Federal Register Publications:
  - November 25, 2008 (73 FR 71858) with an effective date of May 1, 2010
  - Correct effective date published on December 10, 2008; (73 FR 75122)
  - The effective date was further changed to October 1, 2010 (75 FR 22809) on April 30, 2010.

# Plain Language

- The 2008 MG are a complete revision from the 2004 MG
- The 2008 MG are written in a “plain language regulatory style”
  - Style is easy to read
  - Uses a question and answer format directed at the reader, active voice and shorter sentences
  - When appropriate, uses personal pronouns
  - Generally, pronouns refer to who or what must perform a required action.

# Major Changes

1. Revised requirements for specimen collection
2. Revised standards for collectors and collection sites
3. Revised laboratory testing requirements
  - New analytes, lowered cutoff
4. Allowed new technologies for confirmatory drug testing
5. Added new type of testing facility: Instrumented Initial Test Facility (IITF)
6. Revised qualification for Medical Review Officers (MROs)
7. Revised the Federal Custody and Control Form (CCF)

# Effective Date: October 1, 2010

- The 24-month implementation date allowed time for:
  - Manufacturers of immunoassay test kits to modify/manufacture kits and ensure compliance with any applicable statutory and regulatory requirements before commercialization of the kits
  - HHS-certified laboratories to validate and implement the new immunoassay test kits
  - The NLCP to challenge the HHS-certified laboratories with performance testing (PT) samples to ensure that test kits and test results satisfy the required performance criteria
  - HHS, other Federal agencies, and the various industries to implement new and revised procedures to ensure Guidelines compliance

# Collectors and Collection Sites

# Collection of Specimens

- Collection site
  - Collector Qualification
  - Designation of collection site
  - Security
  - Chain of Custody
- Lab Accessioning
  - Access to Authorized Personnel
  - Privacy
  - Integrity and Identity of Specimen
  - Transport to Test facility

# Urine Specimen Collection Handbook

- Revised for the 2008 Mandatory Guidelines
- Provides additional guidance to the specimen collector in fulfilling his/her function in performance of the duties specified under the “certified” Federal agency plans and the requirements of the “Mandatory Guidelines for Federal Workplace Drug Testing Programs.”
- Copy of 2010 collection Handbook now available at <http://workplace.samhsa.gov> for Federal employee specimen collection

# Specimen Collection Guidelines

- Sections of the MG that address Collector and /or Specimen Collection Guidelines
  - Subpart B-Specimens
  - Subpart D-Collectors
  - Subpart E-Collection Sites
  - Subpart F-Federal CCF
  - Subpart G-Specimen Collection Containers
  - Subpart H-Specimen Collection Procedures

# Subpart B - Specimens

- Type of specimen to be collected
- Reason for test
- How a specimen is collected
- What volume of urine is collected
- How does the collector split the specimen that is collected

# Subpart D - Collectors

- Who may and may not collect a specimen
- Requirements to be a collector
- Requirements to be an observer for a D.O. collection
- Requirements to be a trainer for collectors
- What a Federal agency must do to before an individual is permitted to collect a specimen.

# Subpart E - Collection Sites

## Subpart F - Federal CCF

- Subpart E-Collection Sites
  - Where can a collection take place
  - Requirements for a collection site
  - How long are collection site records stored
  - How does a collector ensure the security and integrity of a specimen at the collection site
- Subpart F-Federal CCF
  - What form is used for collecting a specimen

# Subpart G - Collection Containers

- What is used to collect a urine specimen
- Any Restrictions on the containers and bottles used to collect a urine specimen

# Subpart H - Collection Procedure

- What privacy must a donor be given when providing a specimen
- What must a collector do to prepare a collection site before starting a specimen collection
- Preliminary steps in the collection process
- Steps the collector takes in the collection process **before** donor provides a specimen
- Procedure when donor is unable to provide a specimen
- Steps the collector takes in the collection process **after** donor provides a specimen
- How a collector prepares the specimen

# Drug Testing Facility

## Subpart K – Laboratory

## Subpart L - IITF

# Full Service Urine Drug Testing Lab

# New Confirmatory Test Analytes

- Methylendioxyamphetamine (MDMA)
- Methylendioxyamphetamine (MDA)
- Methylendioxyethylamphetamine (MDEA)

# Lowered Drug Test Cutoffs

## 1. Amphetamines

- Initial test cutoff lowered to **500** ng/mL
- Confirmatory test cutoff lowered to **250** ng/mL for both methamphetamine and amphetamine
- Requirement for amphetamine presence to report methamphetamine: value lowered to **100** ng/mL

## 2. Cocaine

- Initial test cutoff lowered to **150** ng/mL
- Confirmatory test cutoff for cocaine metabolite (benzoylecgonine) lowered to **100** ng/mL

# New Drug and Cutoff Concentration

| Analyte   | Initial Cutoff, ng/mL | Confirmation Cutoff, ng/mL      |
|---|-----------------------|---------------------------------|
| Marijuana metabolite<br>THCA  | 50                    | 15                              |
| Cocaine Metabolite<br>Benzoylecgonine                                 | 150                   | 100                             |
| Opiate Metabolites<br>Morphine<br>Codeine<br>6-AM                     | 2000<br><br>10        | 2000<br>2000<br>10              |
| Phencyclidine   | 25                    | 25                              |
| Amphetamines<br>Amphetamine<br>Methamphetamine<br>MDMA<br>MDA<br>MDEA | 500                   | 250<br>250<br>250<br>250<br>250 |

# New Confirmatory Test Technologies

- The Previous Guidelines allowed GC/MS only
- Revised Guidelines will allow additional analytical methods that combine chromatographic separation with mass spectrometric identification (e.g., GC/MS/MS, LC/MS, LC/MS/MS)
- Federal law requires HHS to establish comprehensive standards for Federal drug testing programs, to include requiring the use of the *best available technology* to ensure the full reliability and accuracy of drug tests

# Instrumented Initial Test Facility (IITF)

- Performs initial drug tests and including tests to determine specimen validity
- Can report specimens as *negative, negative and dilute or rejected*
- Must send specimens to an HHS-certified laboratory for testing when IITF test results indicate the specimen *may be drug positive, adulterated, substituted, or invalid*
- Must be certified under the NLCP to perform Federal employee drug testing

# Federal Workplace Drug Testing Programs using IITFs

- Donor
  - Collector
    - IITF
      - Report
        - Negative
        - Rejected for Testing
        - Negative-Dilute (creatinine >2, <20)
      - Send to Lab
        - Possible Positive, Adulterated Substituted, Invalid
    - IITF and Lab
      - Medical Review Officer (MRO)

# Medical Review Officer (MRO)

## Subpart M-MRO

# Subpart -M

- Who may serve as an MRO?
  - What are the training requirements before a physician can serve as an MRO?
  - What are the responsibilities of an MRO?
  - What must an MRO do when reviewing a test result?
  - What action does an MRO take when a donor cannot provide a sufficient amount of urine?
  - What happens when a donor cannot provide a sufficient amount of specimen due to a permanent or long term medical condition?
  - Who may request a test of a split specimen?
  - How does an MRO report a primary (Bottle A) specimen test result to an agency?
  - What type of relationship is prohibited between an MRO and an HHS-certified laboratory or IITF?

# Medical Review Officer Manual

- Revised for the 2008 Mandatory Guidelines
- Provides additional guidance to the MRO in fulfilling his/her function in performance of the duties specified under the “certified” Federal agency plans and the requirements of the “Mandatory Guidelines for Federal Workplace Drug Testing Programs.”
- Copy of 2010 MRO Handbook now available at <http://workplace.samhsa.gov> for Federal Agency employee

# DWP Website

## MRO Documents

- HHS Approval of Entities that Certify MRO's (FR 75 76478)
- 2010 MRO's Case Studies

# Subpart-N

## Split Specimen Tests

- When may a split specimen be tested
- How does an HHS-certified laboratory test a split (Bottle B) specimen when the primary (Bottle A) specimen was reported positive or adulterated or substituted
- Who receives the split specimen result
- What action does an MRO take after receiving the split (Bottle B) specimen result from the second HHS-certified laboratory
- How does an MRO report a split (Bottle B) specimen test result to an agency
- How long must an HHS-certified laboratory retain a split (Bottle B) specimen

# Subpart-O

## Specimen Rejection Criteria

- What discrepancies require an HHS-certified laboratory or an HHS-certified IITF to report a specimen as rejected for testing
- What discrepancies require an HHS-certified laboratory or an HHS-certified IITF to report a specimen as rejected for testing unless the discrepancy is corrected
- What discrepancies are not sufficient to require an HHS- certified laboratory or an HHS-certified IITF to reject a specimen for testing or an MRO to cancel a test
- What discrepancies may require an MRO to cancel a test?

# Federal Custody and Control Form (CCF)

# Changes to the Federal CCF

- Permit use of Federal CCF by IITF, in addition to labs
- Federal testing authorities under which specimen is collected
- New drug analytes are MDMA,MDA,MDEA
- Revise MRO reporting sections on Copy 2 for primary specimens

# 2010 Federal CCF

- Copy 1 - Test Facility Copy

# Notice of OMB action 2010 Federal CCF

- OMB Control #: 0930-0158
- Expiration Date: 08/31/2013
- A sample of the 2010 Federal CCF is available on the
  - SAMHSA website:  
(<http://www.workplace.samhsa.gov/>).
  - OMB website:  
[http://www.reginfo.gov/public/do/PRAViewIC?ref\\_nbr=201007-0930-002&icID=193835](http://www.reginfo.gov/public/do/PRAViewIC?ref_nbr=201007-0930-002&icID=193835).

# Transition from 2000 to 2010 Federal CCF

- To allow for depletion of existing supplies of the 2000 Federal CCF, OMB permitted the use of this Federal CCF in Federal workplace drug testing programs through September 30, 2011
  - From October 1, 2010 through September 30, 2011, Federal agencies may use either Federal CCF
  - As of October 1, 2011, the 2010 Federal CCF will be the only Federal CCF for regulated specimens. If a regulated specimen is received at a test facility with the 2000 Federal CCF after September 30, 2011, the test facility (IITF or laboratory) must treat this as a correctable flaw

# DWP Website

## Federal CCF Documents

- 2010 Federal Custody and Control Form (75 FR 41488)
- Guidance for using the Federal CCF
- 2000 Federal Custody and Control Form (65 FR 39155)
- CCF Form Suppliers (2010)

# Current/Future Activities concerning Alternative Specimens

From the Summary to the November 25, 2008  
Mandatory Guidelines:

- During the review process, Federal agencies raised significant issues concerning POCT devices and the use of the alternative specimens: oral fluid, sweat patch, and hair
- Additional study and analysis are required
- HHS will issue a notice in the Federal Register requesting information and assistance from the public to provide or identify data and research findings that address specific areas of interest

# Use Our Website – Full of Many Resources

<http://www.workplace.samhsa.gov>

<http://www.drugfreeworkplace.gov>

- Drug Testing
- Federal Workplace Drug Testing Programs
- General Drug-Free Workplace Programs
- Workplace Health, Wellness, and Safety
- Workplace Resource Center