



This document is scheduled to be published in the Federal Register on 05/29/2015 and available online at <http://federalregister.gov/a/2015-12743>, and on FDsys.gov

BILLING CODE 4162-20-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Substance Abuse and Mental Health Services Administration

Mandatory Guidelines for Federal Workplace Drug Testing Programs; Request for Information Regarding Specific Issues Related to the Use of the Hair Specimen for Drug Testing

AGENCY: Substance Abuse and Mental Health Services Administration (SAMHSA), Department of Health and Human Services (DHHS).

ACTION: Request for Information.

SUMMARY: This document is a request for information regarding specific aspects of the regulatory policies and standards that may be applied to the Mandatory Guidelines for Federal Workplace Drug Testing Programs (hair specimen).

DATES: Comment Close Date: To be assured consideration, comments must be received at one of the addresses provided below on or before [INSERT DATE 30 DAYS AFTER PUBLICATION IN THE FEDERAL REGISTER].

ADDRESSES: Because of staff and resource limitations, we cannot accept comments by facsimile (FAX) transmission. You may submit comments in one of four ways (please choose only one of the ways listed):

Electronically: You may submit electronic comments to <http://www.regulations.gov>.

Follow “Submit a comment” instructions.

By regular mail: You may mail written comments to the following address only:
Substance Abuse and Mental Health Services Administration, Attention: Division of Workplace Programs, 1 Choke Cherry Road, Room 7-1029, Rockville, MD 20857. Please allow sufficient time for mailed comments to be received before the close of the comment period.

By express or overnight mail: You may send written comments to the following address only: Substance Abuse and Mental Health Services Administration, Attention: Division of Workplace Programs, 1 Choke Cherry Road, Room 7-1029, Rockville, MD 20850.

By hand or courier: Alternatively, you may deliver (by hand or courier) your written comments only to the following address prior to the close of the comment period:

For delivery in Rockville, MD: Substance Abuse and Mental Health Services Administration, Attention: Division of Workplace Programs, 1 Choke Cherry Road, Room 7-1029, Rockville, MD 20850. To deliver your comments to the Rockville address, call telephone number (240) 276-2600 in advance to schedule your delivery with one of our staff members. Because access to the interior of the Substance Abuse and Mental Health Services Administration Building is not readily available to persons without federal government identification, commenters are encouraged to either schedule your drop off or leave your comments with the security guard in the main lobby of the building.

FOR FURTHER INFORMATION CONTACT: Sean Belouin, Division of Workplace Programs, Center for Substance Abuse Prevention (CSAP), SAMHSA, 1 Choke Cherry Road, Room 7-1029, Rockville, Maryland 20857, (240) 276-2716 (phone), (240) 276-2610 (Fax), or e-mail at sean.belouin@samhsa.hhs.gov.

SUPPLEMENTARY INFORMATION: Inspection of Public Comments: All comments received before the close of the comment period are available for viewing by the public, including any personally identifiable or confidential business information that is included in a comment. We post all comments received before the close of the comment period on the following Web site as soon as possible after they have been received:

<http://www.regulations.gov>. Follow the search instructions on that website to view public comments. Comments received by the deadline will also be available for public inspection at the Substance Abuse and Mental Health Services Administration, Division of Workplace Programs, 1 Choke Cherry Road, Rockville, MD 20850, Monday through Friday of each week from 8:30 a.m. to 4 p.m. To schedule an appointment to view public comments, phone (240) 276-2716.

I. Background: The Department of Health and Human Services (HHS) establishes the standards for Federal Workplace Drug Testing Programs under the authority of Section 503 of Public Law 100-71, 5 U.S.C. Section 7301, and Executive Order No. 12564. As required, HHS published the Mandatory Guidelines for Federal Workplace Drug Testing Programs (Guidelines) in the Federal Register on April 11, 1988 [53 FR 11979]. SAMHSA subsequently revised the Guidelines on June 9, 1994 [59 FR 29908], September 30, 1997 [62 FR 51118], November 13, 1998 [63 FR 63483], April 13, 2004 [69 FR 19644], and on November 25, 2008 [73 FR 71858]. On May 15, 2015, HHS published a notice of proposed revisions to the mandatory guidelines which would provide federal executive branch agencies with the option of collecting and testing an oral fluid specimen in addition to urine specimen. The comment period concludes on July 14, 2015.

Section 503 of Public Law 100-71, 5 U.S.C. Section 7301 note, required the Department to establish scientific and technical guidelines and amendments in accordance with Executive Order 12564 and to publish Mandatory Guidelines which establish comprehensive standards for all aspects of laboratory drug testing and procedures, including standards that require the use of the best available technology for ensuring the full reliability and accuracy of drug tests and strict procedures governing the chain of custody of specimens collected for drug testing. These revisions to the Mandatory Guidelines promote and establish standards that use the best available technology for ensuring the full reliability and accuracy of drug tests, while reflecting the ongoing process of review and evaluation of legal, scientific, and societal concerns.

SAMHSA's chartered CSAP Drug Testing Advisory Board (DTAB) is the vehicle to provide recommendations to the SAMHSA Administrator for proposed changes to the Mandatory Guidelines for Federal Workplace Drug Testing Programs. The DTAB process involves evaluating the scientific supportability of any considered change. To assist the DTAB, we are soliciting written comments and statements from the general public and industry stakeholders regarding a variety of issues related to hair specimen drug testing, including the hair specimen, its collection, specimen preparation, analytes/cutoffs, specimen validity, and initial and confirmatory testing.

II. Solicitation of Comments: We are seeking additional information to inform potential use of hair specimens for drug testing, specifically on the following questions:

Hair Specimen:

- What are the acceptable body locations from which to collect hair for workplace drug testing? What should be done if head hair is not available for collection?

- What hair treatments (i.e., shampoo, conditioning, perm, relaxers, coloring, bleaching, straightening, hair transplant) influence drug concentration in hair and to what degree?
- What are the acceptable reasons for hair testing (i.e., pre-employment, random, reasonable suspicion, post-accident, other (fitness for duty, return to duty, etc.))?

Collection:

- What training should a collector receive prior to collecting the hair specimen?
- What is the best protocol to collect the hair specimen?
- Should the hair collection protocol be standardized, including specific instructions on how close to cut the hair specimen to the skin, how to determine the authenticity of the hair specimen, what cutting instruments to use, how to ensure the cutting instruments are decontaminated, and whether the use of collection kits should be required?
- What is the minimum amount of hair that should be collected?

Specimen Preparation:

- What are acceptable protocols for hair specimen preparation, such as cutting/powdering, initial washing, decontamination, and pre-extraction (i.e., digestion, micro pulverization, etc.)?
- Should the washing and decontamination procedures be analyte specific?
- What criteria should be used to determine the acceptability of a specific wash and decontamination procedure? Are there published research studies, with experimental data included, that demonstrate that a particular wash procedure is

effective at removing external contaminants while not significantly affecting the amount of incorporated drug related to drug use?

- If washing steps are used for decontamination, should adjustments be made for drug concentrations detected in the wash fluids? What calculations are recommended for these adjustments?

Analytes/Cutoffs:

- What analytes should be measured in hair by the initial and confirmatory tests?
- What initial and confirmation cutoffs should be used for the various hair drug testing analytes?
- For each analyte/drug, what criteria (cutoff) should be used to distinguish external contamination from drug use?
- What unique metabolites or other biomarkers exist to confirm use and to distinguish drug use from external contamination for which the drugs are currently tested?

Specimen Validity:

- Are biomarkers or tests needed to verify that the specimen is authentic human hair?
- Are there appropriate biomarkers or tests for the hair specimen that would reveal adulteration and/or substitution? What are the acceptability criteria for these biomarkers or tests?
- Is the “invalid” result category reasonable for hair testing? If so, what criteria are acceptable to classify a specimen result as invalid?

Testing:

- What technologies are available to perform initial and confirmatory testing on hair specimens?
- What is the best sample for valid quality control/proficiency testing material? How should this quality control/proficiency testing material be prepared? What is the best method to prepare a contaminated hair sample versus a sample that represents drug use?

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Chemist

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[FR Doc. 2015-12743 Filed: 5/28/2015 08:45 am; Publication Date: 5/29/2015]