



DTAB's Process for Evaluating the Scientific Supportability of the Hair Specimen for Federal Workplace Drug Testing Programs

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SAMHSA's objective - DTAB

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- SAMHSA's only scientific advisory council
- "SAMHSA seeks to improve the quality of services for forensic workplace drug testing, assess the science and technology used in drug analyses, improve the quality of related laboratory services and systems for drug testing, generate standards for laboratory certification for Federal workplace drug testing programs, and guide national policy in these areas by the establishment of the CSAP DTAB"

DTAB's duties

- Per its charter,
 - “The CSAP DTAB provides advice to the Administrator, SAMHSA, based on an ongoing review of the direction, scope, balance, and emphasis of the Agency's drug testing activities and the drug testing laboratory certification program
 - It shall recommend areas for emphasis or de-emphasis, new or changed directions, and mechanisms or approaches for implementing recommendations
 - Periodically, the CSAP DTAB shall review specific science areas on new drugs of abuse and the methods necessary to detect their presence”

History of alternative specimens

- Notice of Proposed Revisions to the Mandatory Guidelines for Federal Workplace Drug Testing Programs
 - Federal Register, April 13, 2004 (69 FR 19673)
 - “SUMMARY: The Department of Health and Human Services (“HHS” or “Department”) is proposing to establish scientific and technical guidelines for the testing of hair, sweat, and oral fluid specimens in addition to urine specimens”

HHS's decision

- Mandatory Guidelines for Federal Workplace Drug Testing Programs
 - Federal Register, November 25, 2008 (73 FR 71858)
 - Effective 10/1/2010
 - “SUMMARY: This Final Notice of Revisions to the Mandatory Guidelines for Federal Workplace Drug Testing Programs (Revisions to Mandatory Guidelines) addresses collection and testing of urine specimens”

73 FR 71858 background

- <http://www.gpo.gov/fdsys/pkg/FR-2008-11-25/pdf/E8-26726.pdf>

Key issues from the Preamble

- Use of alternative specimens
 - “Submitted **public comments** and additional comments raised by **Federal Agencies** during subsequent internal review of the proposed changes to the Guidelines raised **significant scientific, legal, and public policy concerns** about the use of alternative specimens”

HHS's concern

- “The scientific, legal, and public policy information for drug testing oral fluid, hair, and sweat patch specimens ... is not as complete as it is for the laboratory-based urine drug testing program”

Three issues

- “First, the data from the pilot PT programs to date show that not all participants have developed the capability to test for all required drug classes, nor to perform such tests with acceptable accuracy.
- Second, some drug classes are more difficult to detect than others, for any given type of specimen.
- Third, the specific drug classes that are difficult to detect vary by type of specimen.”

HHS position

- “HHS believes that the addition of alternative specimens to the Federal Workplace Drug Testing Program would complement urine drug testing and aid in combating the risks posed from available methods of suborning urine drug testing through adulteration, substitution, and dilution.”

HHS approach

- HHS approach
 - “Each alternative specimen ... poses different concerns”
 - “Department established a **staggered timeline** for issuing final guidance that allows for **further study and research.**”
 - “Issuing one or more Final Notices in the Federal Register that may require additional **public comment** periods, concerning the use of alternative specimens”

HHS goal

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- “HHS will continue to pursue testing using alternative specimens. HHS anticipates issuing further revisions to the Mandatory Guidelines addressing the use of oral fluid, sweat patch, and hair...”
- “These revisions will be published in the Federal Register, with opportunity for public comment.”

Alternative specimens process

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- DTAB will follow the HHS-recommended staggered timeline for evaluating the scientific supportability of alternative specimens for use in the Federal Workplace Drug Testing Programs
 - The Board has completed its evaluation of oral fluid specimen
 - It has begun its evaluation of the hair specimen

Hair specimen evaluation

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- Since July 2013, the DTAB has been evaluating the science supportability of hair as a potential alternative specimen for inclusion in the Mandatory Guidelines for Federal Workplace Drug Testing Programs

Step 1

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- Task the Drug Testing Advisory Board with assessing the state of the science of hair as an alternative specimen for drug testing within the federal workplace drug testing programs
 - July 15-17, 2013 meeting

Step 2

- Identify scientific experts to assist DWP and the DTAB is assessing the state of the science of hair drug testing

Scientific experts

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- Jim Bourland, Ph.D.
- Yale Caplan, Ph.D.
- Edward J. Cone, Ph.D.
- Dennis J. Crouch, M.B.A.
- Rich Hilderbrand, Ph.D.
- Jeri Roper-Miller, Ph.D.
- *Peter Stout, Ph.D.
- J. Michael Walsh, Ph.D.

Step 3

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- Review the current state of the science of hair
 - July 16-17, 2013 meeting

Review

- A historical perspective of hair as a drug testing matrix
- Specimen characteristics, collection, preparation, and stability
- Drug analytes, analyte stability, analyte cutoffs
- Methodologies: initial and confirmatory
- Proficiency testing
- Best practices experiences
- Hair drug testing data

Step 4

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- Perform an exhaustive hair literature search
 - To date, 1234 peer-reviewed papers in the bibliography

Bibliography

- The purpose of this extensive bibliography is to provide peer-reviewed references for the preamble should proposed hair Mandatory Guidelines be recommended

Step 5

- Identify topic areas in which DWP, the DTAB, and the scientific experts have reached preliminary consensus
 - Subsequent meetings

Step 6

- Identify the topics areas in which further research is required
 - These topic areas, especially hair contamination and preferential binding of basic drugs by melanin, were discussed at length over several DTAB meetings
 - Subsequent meetings

Topics requiring further research

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- Hair Specimen
- Collection
- Specimen Preparation
- Analytes/Cutoffs
- Specimen Validity
- Testing

Topic-related questions

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- For each topic, specific questions were developed
 - For each of these questions, possible outcomes include:
 - Consensus answer
 - Request for more in-depth literature review
 - Request for Information
 - Request for research studies
 - Assignment to the appropriate federal officials for significant scientific, legal, and public policy concerns

Other topics

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- Other significant scientific, legal, and public policy concerns related to the hair specimen have also been identified and are being discussed with the appropriate federal officials

Step 7

- Solicit feedback from industry stakeholders
 - Those laboratories enrolled in the National Laboratory Certification Program (NLCP) hair testing pilot proficiency testing program were asked to attend the February 5-6, 2015 DTAB meeting
 - Those questions identified are requiring further research were posed to laboratory representatives in confidential, one hour sessions

Step 8

- Solicit feedback from the public
 - Those questions identified as needing further research were formulated into a Request for Information (RFI)
 - This RFI was published on May 29, 2015 (80 FR 30689)
 - Public comments will currently be accepted until June 19, 2015 (30 days) at <http://www.regulations.gov>

Step 9

- Review the information submitted by the public
 - June 11-12, 2015 meeting
 - August 6-7, 2015 meeting

Step 10

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- Deliberate on the scientific supportability of the hair specimen for inclusion in the Federal Workplace Drug Testing Programs
 - Proposed for the August 7-8, 2015 meeting

OGC Advice

- At the recommendation of SAMHSA's Office of General Council, DTAB should provide advice to the SAMHSA Administrator in the form of an official written recommendation

Recommendation Process

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- Recommendation must come from a voting member or chair of the DTAB
- The language of the recommendation is clearly proposed in writing
- The Board must deliberate on the recommendation in open session
- A quorum of the Board members must vote by closed ballot on the recommendation in open session with a majority needed for approval
 - Only the tally of the vote will be presented
- If passed, all the voting Board members sign the recommendation letter
- If passed, the signed recommendation is forwarded to the SAMHSA Administrator for her approval/disapproval

Goal

- Based on its evaluation of the scientific supportability of hair as a specimen in the Federal Workplace Drug Testing Programs and after addressing the significant scientific, legal, and public policy concerns raised by public commenters and federal agencies, DTAB will/will not recommend proposed revisions to the Mandatory Guidelines to include hair as an alternative specimen

End Result

- If recommended by the Board and that recommendation is approved by the SAMHSA Administrator, the proposed revisions will be drafted by DWP, reviewed by the Board, and published in the Federal Register for public comment