Regulatory Program Updates and Mandatory Guidelines

Center for Substance Abuse Prevention

Drug Testing Advisory Board

Ron Flegel, BSMT (ASCP), MS
DTAB Chair
Division of Workplace Programs
Substance Abuse and Mental Health Services Administration
U.S. Department of Health and Human Services

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Open Session - Public

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- Policy Oversight Lead: Hyden Shen, J.D.
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- Senior Scientist Policy Advisor: CAPT Sean Belouin, Pharm.D.
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DWP Objectives and Goals

- **Overall Goal:** *"SAMHSA is continually assessing the science and technology used in drug detection to advance national drug policy that is based on the latest scientific findings."*

- **Goal:** Comprehensive Review of the Federal Drug Testing Program and current state of the DFWP, examine the issues affecting the program, outline responses to these critical issues and look at initiatives to address the unanswered questions.

- **Future**: *Identify key policy and technical issues as well as the existing challenges* for Implementation of the Mandatory Guidelines using oral fluid and/or hair, look at ongoing studies for cannabis, and enhancements to the Federal Drug Testing Program.

Drug-Free Workplace Program Impact

Federal Executive Branch

- Approximately 150 Departments and Agencies
- Civilian Employees 2 million +
- Random Testing Positions (Safety/Security /Public Health) 400K+

Department of Transportation

(Federally regulated program that uses DWP's drug testing standards)

- Regulated Transportation Industry Employees Tested for Drugs (and Alcohol) 12 million +

Nuclear Regulatory Commission

(Federally regulated program that uses DWP's drug testing standards)

- Power Plants 100
- Research and Test Reactors 36

DFWP Program Impacts 14 million^{+} employees

Division of Workplace Programs
Legislative Authority and Main Roles

Science
Forensic Drug Testing

DWP's Science Responsibilities:

1. **Mandatory Guidelines for Drug Testing:** Scientific & Technical Guidance
2. **National Laboratory Certification Program (NLCP):** Certifies labs for federal (and federally-regulated) forensic drug testing
3. **Drug Testing Advisory Board (DTAB):** National Advisory Council of experts on federal and federally regulated drug testing activities
4. **Medical Review Officer (MRO)* Training:**
   - Establish MRO certification standards
   - Approve MRO certifying entities

*MROs review and report drug testing results.

Programs Outcomes:

- National drug testing standards
- Multiple specimen types (Urine, Oral Fluid, Hair)
- HHS Certified Laboratories
- DTAB Recommendations for the Assistant Secretary
- National MRO certification standards

Policy
Drug Free Workplace Program

DWP's Policy Responsibilities:

1. **Technical Assistance to all Federal Agencies:** Assistance and review of agency plans in implementing the DFWP
2. **Plan Certification:** Certify federal agency DFWP plans, transmit agency plan Reports to Congress. Agency plans establish agency policy and procedures.
3. **Executive Committee:** Interagency Coordinating Group Executive Committee (ICGEC) established policy and approves federal Testing Designated Positions (TDPs) or safety-sensitive positions
4. **Policies/Legislation:** Evaluating impact of policies and legislation on the DFWP, e.g., Farm bill, state marijuana decriminalization.

Program Outcomes:

- Certified DFWP plans for all federal agencies
- DFWP policy and procedures for all federal agencies
- Policy Discussions with Office of National Drug Control Policy (ONDCP)
- Policy and Legislation Impact on the DFWP

The DWP Emerging Issues group addresses both components of science and policy.

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Current Drug-Free Workplace Program

Updated: 18 May 22

Total number of Executive Branch agencies thought to be subject to EO 12564 ……..208
(Sources: Federal Register (FR), Administrative Conference of the United States (ACUS), USA.gov 2020)

Total number of Executive Branch agencies with certified plans ……..137
(Source: The CDM Group)

Total number of Executive Branch agencies identified without certified plan and without evidence that they are not required to comply with EO 12564……..71*
(Source: The CDM Group)

**Further research/contact is needed to establish status for many of these*

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Mandatory Guidelines Update

Urine

CURRENT Mandatory Guidelines for Federal Workplace Drug Testing using Urine effective February 1, 2024.

https://www.regulations.gov/document/HHS_FRDOC_0001-0914

Oral Fluid

CURRENT Mandatory Guidelines for Federal Workplace Drug Testing using Oral Fluid (OFMG) effective October 10, 2023.

https://www.regulations.gov/document/HHS_FRDOC_0001-0915

Hair

PROPOSED Mandatory Guidelines for Federal Workplace Drug Testing Programs using Hair in September 10, 2020 Federal Register for public comment.

https://www.govinfo.gov/content/pkg/FR-2020-09-10/pdf/2020-16432.pdf

Mandatory Guideline Routing Process

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UrMG: Major Revisions

- Revise the timeline and process for publishing the authorized **drug testing panel** (i.e., drugs, analytes, and cutoffs)
- Revise to report specimens as substituted based on **biomarker testing** (i.e., concentration inconsistent with that established for human specimens)
- Establish a timeline and process for publishing an authorized biomarker testing panel (i.e., biomarker analytes and cutoffs)
- Raise the **morphine** confirmatory test cutoff from **2,000** ng/mL to **4,000** ng/mL in the UrMG
- Revise the Medical Review Officer **(MRO) verification process** for positive codeine and morphine specimens
- Require MROs to submit semiannual reports to HHS or designated representative, on federal agency specimens that were reported as **positive for a drug** or drug metabolite by a laboratory and **verified as negative by the MRO**
- Revised to apply same “refusal to test” criteria for all donors - removed allowance for pre-employment collections

Hair Mandatory Guidelines – Status

- SAMHSA public comment review:
  - Organized public comments by subject (over 700 individual comments from 213 commenters)
  - Reviewed all comments, submitted information, and scientific studies referenced by commenters – prepared draft HMG
- DTAB review
  - March 2021: summarized public comments presented for DTAB discussion
  - June 2021: members reviewed the draft HMG and provided input
- Hair Testing Laboratories – Listening Sessions
  - March – April 2022: SAMHSA listening sessions with 7 hair testing laboratories
  - Topics: proficiency testing requirements, quantitative agreement between labs, reporting criteria, future technical working groups
- Revised HMG has been submitted and is under OMB review

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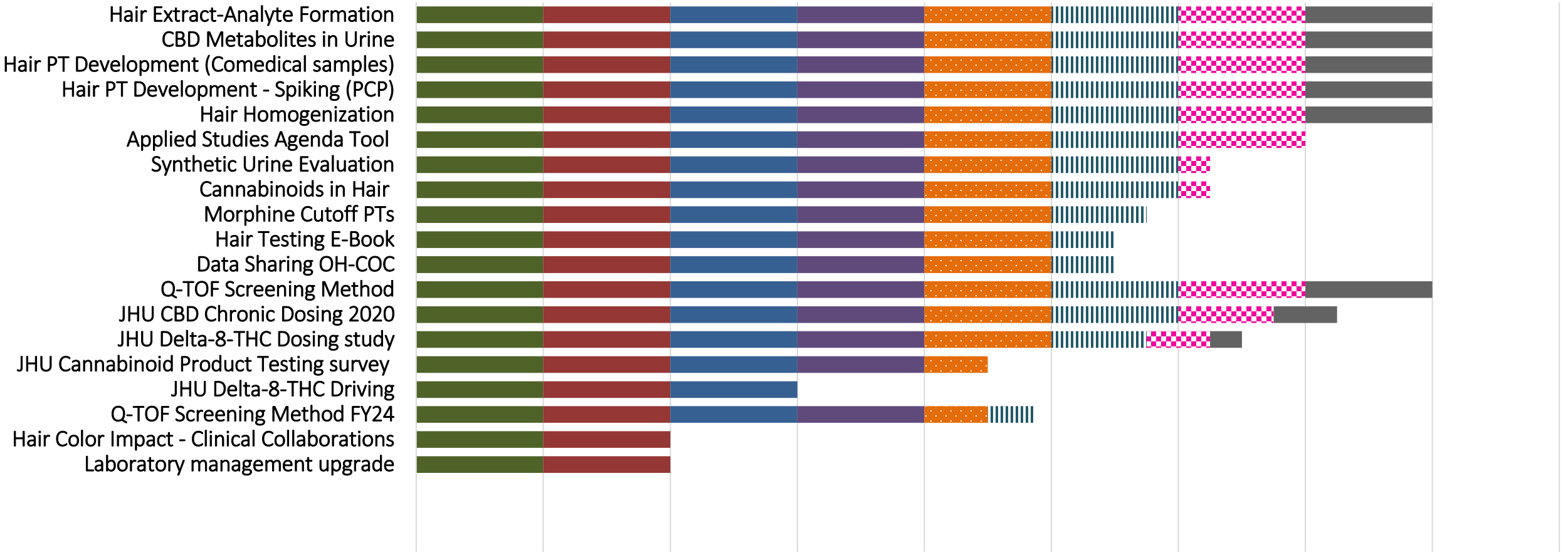
Current NLCP Applied Studies (In-progress)



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DFWP and the Evolving Environment

Emerging Issues - Legislation

- 2015 FAST Act – required development of Scientific and Technical Guidelines for Hair testing while issues of hair color impact and external contamination issues continue to exist
- 2018 Farm Bill – defined hemp and set a legal limit for THC content, making it difficult to discern between legal and illegal sources of THC.
- 2018 Opioids Crisis Response Act

Changes in Science and Technology

- Drug testing and specimen collection technology are improving – Mandatory Guidelines for Federal Workplace Drug Testing Programs using Oral Fluid, effective Jan. 2020

Evolving Environment

- New and novel drug use continues to emerge, e.g., synthetic designer drugs
- Increased public acceptability and availability of marijuana and CBD products and implications for workplace safety/security –e.g., Delta-8-THC or other THC isomers and State initiatives to decriminalize marijuana
- Increased demands on the DFWP – e.g., COVID-19 return-to-office challenges

MRO Guidance Manual and Case Studies

- Updates based on the 2023 UrMG and OFMG. Examples:
  - Revisions to MRO verification process
  - Annual Authorized Drug Testing Panels, Authorized Biomarker Testing Panels, and Required Nomenclature for MRO Reports
  - MRO semi-annual reports to SAMHSA
- Updates based on MRO-relevant information from SAMHSA. Examples:
  - NLCP Notices
  - DRAFT NLCP Manuals for Urine and Oral Fluid Laboratories
  - Guidance for Using the 2023 Federal CCF
  - DRAFT MRO Case Studies
- The 2023 MRO Guidance Manual and Case Studies will be posted on the SAMHSA website.

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Some Areas of the Program to Examine

- State-of-the-art and science
- Maintaining program integrity
  - Drug testing validity and reliability
  - Workplace safety and security (i.e., safety-sensitive positions)
- Issues, challenges, approaches and actions
- Ongoing training needs
- Future studies
- Policy initiatives
- Future direction of the program and desired end state
- Resource needs

Road Map and Action Plans

- Pursue clearance strategy with FDA
- Reduce the length of time required to change the testing panel
- Develop and add a pulse testing (emerging drugs, specimen validity issues)
- Review and streamline Program processes (inspections and audits)
- Align goals and timelines for SAMHSA/DWP and regulated agency partners

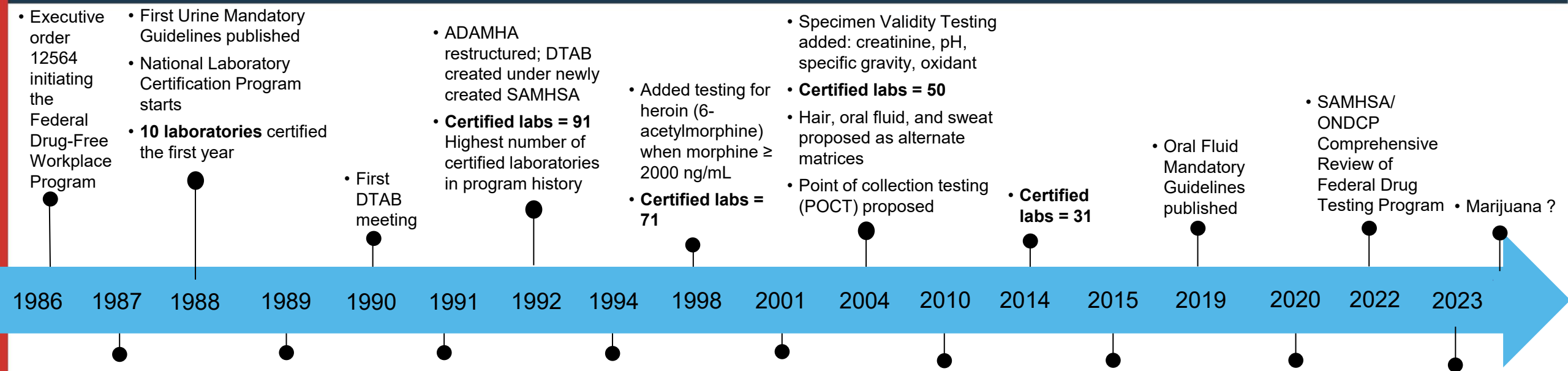
Action Plans

Priority	#	Action	POC	Decision-maker	Actions/Steps
1	***1***	***Pursue emergency clearance strategy with FDA; alternatively, remove FDA clearance requirement and rely on certified laboratory validation of IA kits***	***Lisa***	***FDA/ HHS***	• ***FDA Meeting*** • ***DTAB*** • ***Develop new process*** • ***Recommendations/Changes*** • ***Implement Guidelines changes***
1	2	*Conduct quarterly ICGEC meetings; open some sessions to DPCs; create topic-focused groups of DPCs*	*Ron*	*Asst. Sec.*	• *Amplify message re: cannabis* • *OASH – presentation - Principals' meeting* • *Develop 15-minute summary of DWP data and implications*
1	***3***	***Reduce length of time required to change the testing panel***	***Ron***	***Asst. Sec***	• ***DWP/SMEs/NLCP Meeting*** • ***Implement Surveillance Program*** • ***Develop Criteria for Adding Analytes*** • ***DTAB Presentations*** • ***Align New Process*** • ***Recommendations/Decision/Changes*** • ***Implement Guidelines changes***
1	*4*	*Align goals and timelines for SAMHSA/DWP and federal agency partners*	*Ron*	*DWP*	• *Federal Partners Meeting* • *Align Goals / Regulations / MRO Verification Reporting* • *Develop Process/DTAB* • *Recommendations/Changes* • *Implement Regulatory Changes* • *Ongoing Dialogue*
1	*5*	*Develop and add surveillance program*	*Eugene*	*DWP/ NLCP*	• *DWP/SMEs/NLCP Meeting include DoD* • *Implement Surveillance Program: Drugs and SVT* • *Meets Criteria* • *Align New Process/Data* • *Recommendations/Decision/Changes* • *Implement Guidelines changes*

Action Plans

Priority	#	Action	POC	Decision-maker	Actions/Steps
1	***6***	***Identify and accomplish program process improvements that do not require a regulatory process***	***Ron***	***DWP/ NLCP***	• ***DWP/SMEs/NLCP Meeting*** • ***Program Focus/Fed Partners Meeting*** • ***DTAB Presentation*** • ***Align New Process/ OGC Review*** • ***Recommendations/Decision/Changes*** • ***Implement Guidelines changes if necessary***
2	7	*Review and streamline (where possible) Program requirements (Responsible Person, audits, initial testing, SVT)*	*Lisa/ Eugene*	*DWP/ NLCP*	• *DWP/NLCP Meeting* • *Program Focus* • *Align New Process/ OGC Review* • *Recommendations/Decision/Changes* • *Implement Guidelines changes if necessary*
2	8	*Improve program implementation by providing training on recovery-ready concepts, EAPs, Safe Harbor options, and test scheduling, completion, and reporting; incorporate in DPC Orientation content*	*Hyden*	*DWP/ ONDCP*	• *DWP/ONDCP Meeting* • *DWP / OPM Meeting* • *DTAB Presentation / DPCs* • *Align New Process/ SAMHSA Review* • *Recommendations/Decision/Changes*
3	9	*Identify and relieve (where possible) MRO burdens*	*Josh*	*DWP/ NLCP*	• *DWP/SMEs/NLCP Meeting* • *Program Focus/Fed Partners Meeting* • *DTAB Presentation / Discussion* • *Recommendations/Decision/Changes* • *Implement Guidelines changes if necessary*
3	**10**	***Leverage recovery-ready workplace initiatives to generate more top-down support for and commitment to the Program***	***Hyden***	***DWP/ NLCP***	• ***DWP/ONDCP Meeting*** • ***DWP / OPM Meeting*** • ***DTAB Presentation / DPCs*** • ***Align New Process/ SAMHSA Review***
3	11	*Utilize discussions around cannabis scheduling to focus attention on the Program and its strong rehabilitative intent*	*Ron*	*DWP/Asst Sec*	• *SME / DOJ / SAMHSA Meeting* • *Leg Affairs / OGC Meeting* • *DOJ / OGC Review* • *Recommendations/Decision/Changes*
4	12	*Re-evaluate criteria for dilute and pH invalid*	*Eugene*	*DWP/ NLCP*	• *DWP/ SMEs / NLCP Meeting* • *Program Focus* • *Align New Process/ OGC Review* • *Recommendations/Decision/Changes* • *Implement Guidelines changes if necessary*

Federal Drug Free Workplace Program



1986
- Executive order 12564 initiating the Federal Drug-Free Workplace Program

1987
- ADAMHA* designated as lead federal agency for implementing drug testing program
- Public Law 100-71 requires agencies to have a standardized model plan and HHS to put forth mandatory guidelines
- Precursor of DTAB "Laboratory Accreditation Working Group" at NIDA
- DTAB created under NIDA which at that time resided at ADAMHA

1988
- First Urine Mandatory Guidelines published
- National Laboratory Certification Program starts
- **10 laboratories** certified the first year

1989
- NRC published Fitness-For-Duty Regulations
- **Certified labs = 42**

1990
- First DTAB meeting

1991
- Omnibus Transportation Employee Testing Act requires DOT to incorporate HHS Mandatory Guidelines for safety sensitive positions in transportation industries

1992
- ADAMHA restructured; DTAB created under newly created SAMHSA
- **Certified labs = 91** Highest number of certified laboratories in program history

1994
- Amphetamine Rule

1998
- Added testing for heroin (6-acetylmorphine) when morphine ≥ 2000 ng/mL
- **Certified labs = 71**

2001
- Specimen Validity Testing proposed

2004
- Specimen Validity Testing added: creatinine, pH, specific gravity, oxidant
- **Certified labs = 50**
- Hair, oral fluid, and sweat proposed as alternate matrices
- Point of collection testing (POCT) proposed

2010
- Added oxycodone, oxymorphone, hydrocodone, and hydromorphone
- Raised adulteration cutoff for pH from 3 to 4
- Added MDA and MDMA
- Amphetamine and Methamphetamine cutoffs lowered: initial test from 1000 to 500 ng/mL; confirmatory from 500 to 250 ng/mL
- Cocaine/benzoylecgonine cutoffs lowered: initial test from 300 to 150 ng/mL; confirmatory from 150 to 100 ng/mL

2014
- **Certified labs = 31**

2015
- Oral Fluid Mandatory Guidelines proposed

2019
- Oral Fluid Mandatory Guidelines published

2020
- Hair Mandatory Guidelines proposed

2022
- SAMHSA/ ONDCP Comprehensive Review of Federal Drug Testing Program

2023
- Marijuana ?
- **Certified labs = 21**

*Alcohol, Drug Abuse and Mental Health Administration

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Unanswered Questions

- Will the federal drug testing program continue to be a deterrent program or become fitness-for-duty?
- What will the future of the federal drug testing program look like if marijuana is de-scheduled/rescheduled?
- Will the federal drug testing program continue to test for marijuana?
- Are unique biomarkers for “drug use” achievable?

DFWP Resources

Division of Workplace Programs (DWP) Main Website:
https://www.samhsa.gov/workplace

Executive Order 12564:
https://www.samhsa.gov/sites/default/files/executive_order.pdf

Public Law 100-71:
https://www.samhsa.gov/sites/default/files/workplace/public_law_100.pdf

Model Plan for a Comprehensive Drug-Free Workplace Program:
https://www.samhsa.gov/sites/default/files/workplace/ModelPlan508.pdf

2013 Guidance for Selection of Testing Designated Positions:
https://www.samhsa.gov/sites/default/files/workplace/09-2013-guidance-selection-tdps-2-13-17.pdf

Thank You
Division of Workplace Programs

Please Visit our Website

https://www.samhsa.gov/workplace

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