

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



SAMHSA
Substance Abuse and Mental Health
Services Administration

Division of Workplace Programs

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- Senior Policy Analyst: Coleen Sanderson
- Policy Oversight Lead: Hyden Shen, J.D.
- Social Science Analyst: Brijet Burton
- Senior Pharmacist: LCDR Joshua Hunt, PharmD, MPH (USPHS)
- Senior Scientist Policy Advisor: CAPT Sean Belouin, PharmD (on detail)
- Program Assistant: Christie Lamb

Drug Testing Advisory Board Members

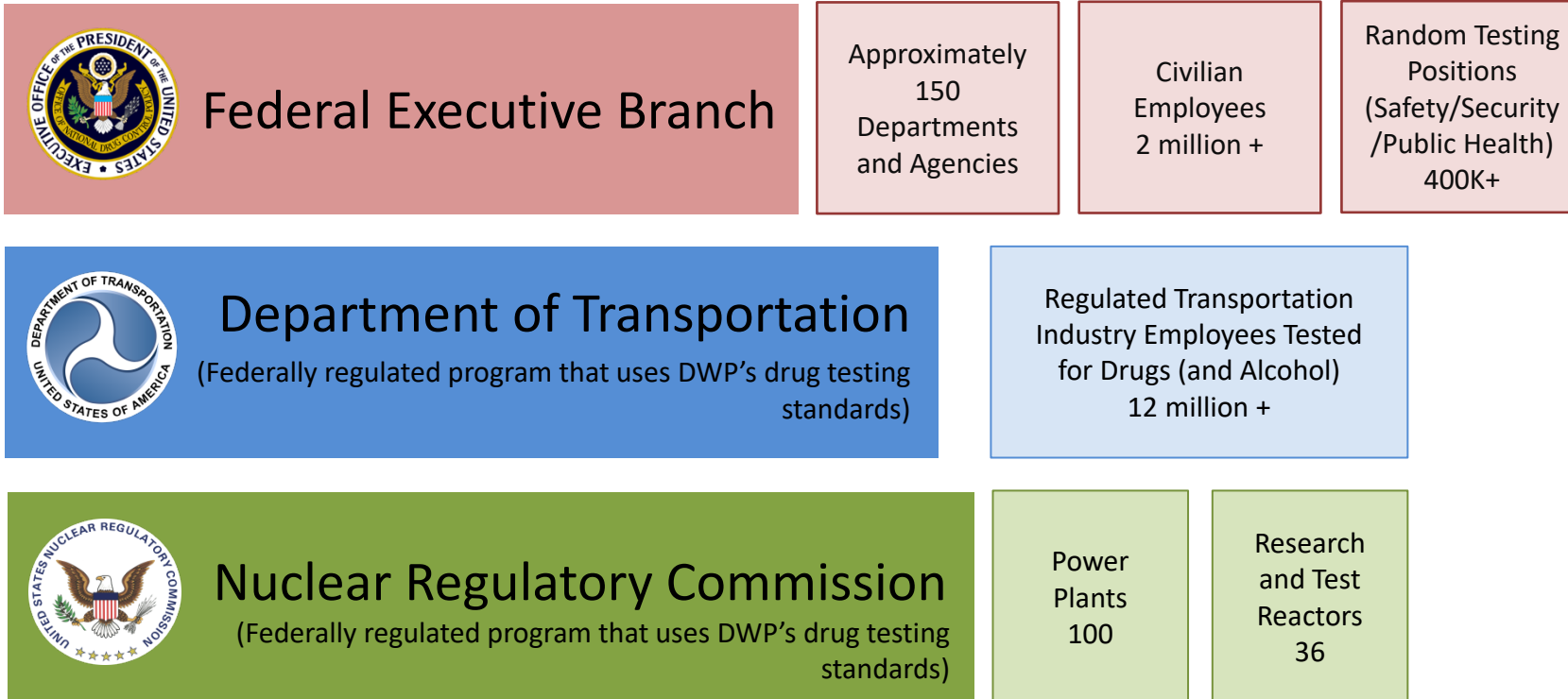
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- David Roberts, Ph.D.
- E. Lindsey Everson, J.D.
- Dawn Hahn
- Bryan Ruggery
- Michael Grommes
- Carl Christensen, MD
- Samantha Tolliver, Ph.D.

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

5



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.



Division of Workplace Programs Legislative Authority and Main Roles



Science Federal Forensic Drug Testing

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1. **Mandatory Guidelines for Federal Drug Testing:** Scientific & Technical Guidelines
 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:**
 - Establishes MRO certification standards
 - Certifies MRO training entities
- * MROs interpret drug testing results on drug use.

Programs Outcomes:

- National drug testing standards
- Alternative specimen testing (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 on implementing the DFWP
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4. **Policies/Legislation:** Evaluating impact of policies and legislation on the DFWP, i.e., Farm bill, state marijuana laws, decriminalization

Program Outcomes:

- Certified DFWP plans for all federal agencies
- DFWP policy and procedures for all federal agencies
- Policy Discussions with ONDCP
- Policy and Legislative Impact on the DFWP

Science and Policy Emerging Issues Group

DWP's Emerging Issues Responsibilities:

1. **Monitor domestic drug prevalence data:** Utilize NFLIS (DEA), NSDUH (SAMHSA), MTF (NIDA), CDC overdose data and MMWRs, and Quest Drug Testing Information to identify new trends and emerging threats of Novel Psychoactive Substances or new adulterants in the illicit supply chain which pose a threat to workplace safety and public health.
 - Monitor international drug misuse trends through WHO, United Nations, DEA, ONDCP, NIDA, and State Department interactions.
2. **Solicit and review drug testing data:** Applicable federal partners include (DoD, DOT, NRC, DEA), HHS-Certified laboratories, research scientists, manufacturers of collection devices/immunoassay kits.
3. **Supports Scientific Studies:** Scientific and technical review of the DFWP.
4. DTAB review for drug analyte addition or removal

Program Outcomes:

- Recommend DFWP analyte table changes (Science)
- Policy Discussions with ONDCP (Policy)
- Policy and Legislation Impact on the DFWP (Policy)
- Recommendations for the addition or removal of an analyte to the Assistant Secretary (Science)

Current Drug-Free Workplace Program

Updated: 29 Jan 24

Total number of Executive Branch agencies thought to be subject to EO 12564204

(Sources: Federal Register (FR), Administrative Conference of the United States (ACUS), USA.gov 2020)

Total number of Executive Branch agencies with certified plans122

(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.....73*

(Source: The CDM Group)

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

Mandatory Guidelines Update

Urine

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

<https://www.govinfo.gov/content/pkg/FR-2022-04-07/pdf/2022-06886.pdf>

Oral Fluid

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

<https://www.govinfo.gov/content/pkg/FR-2022-04-07/pdf/2022-06884.pdf>

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



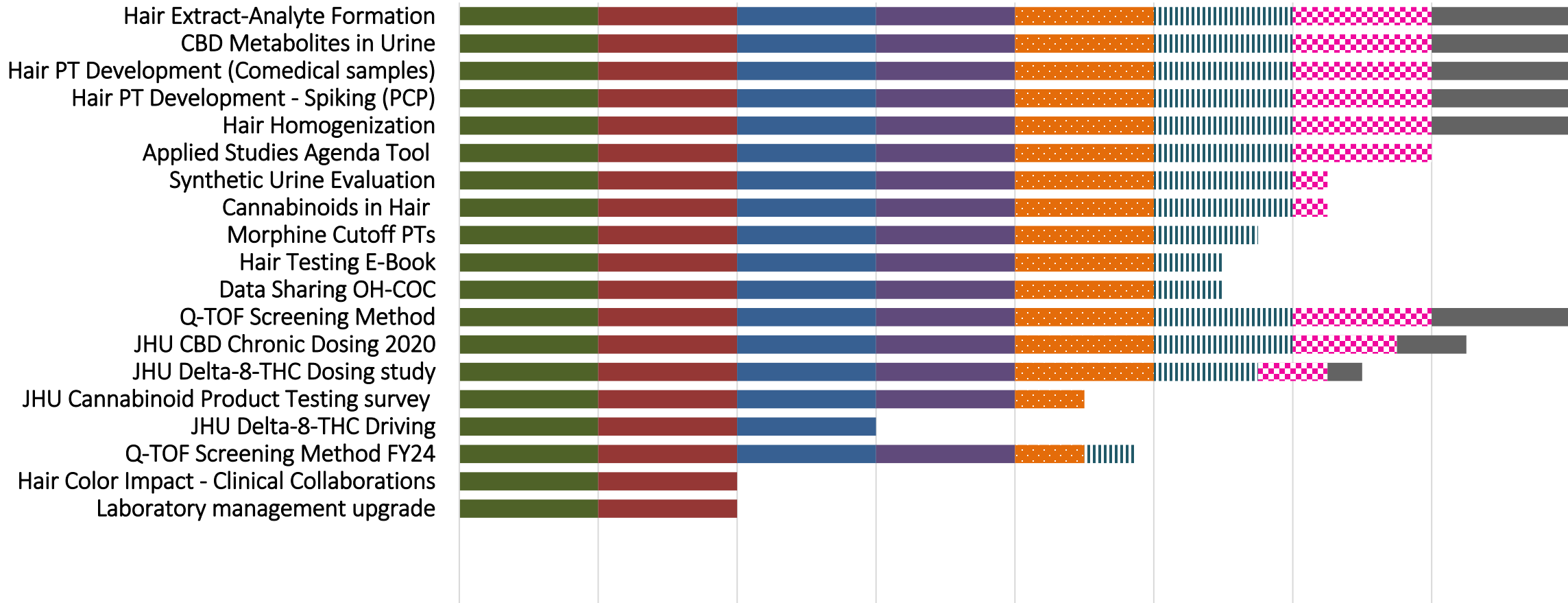
UrMG: Major Revisions Effective Feb 1, 2024

- 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

Current NLCP Applied Studies (In-progress)



- Study plan and budget proposal submission
- Study proposal approval
- Recruit study participants
- Purchase study materials
- Data analysis/Publication

- Regulatory and IRB clearances
- ||| Sample collection

■ Sample analysis

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 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
 - NLCP Manuals for Urine and Oral Fluid Laboratories
 - Guidance for Using the 2023 Federal CCF
- The Revised 2024 MRO Guidance Manual and Case Studies are posted on the SAMHSA website.

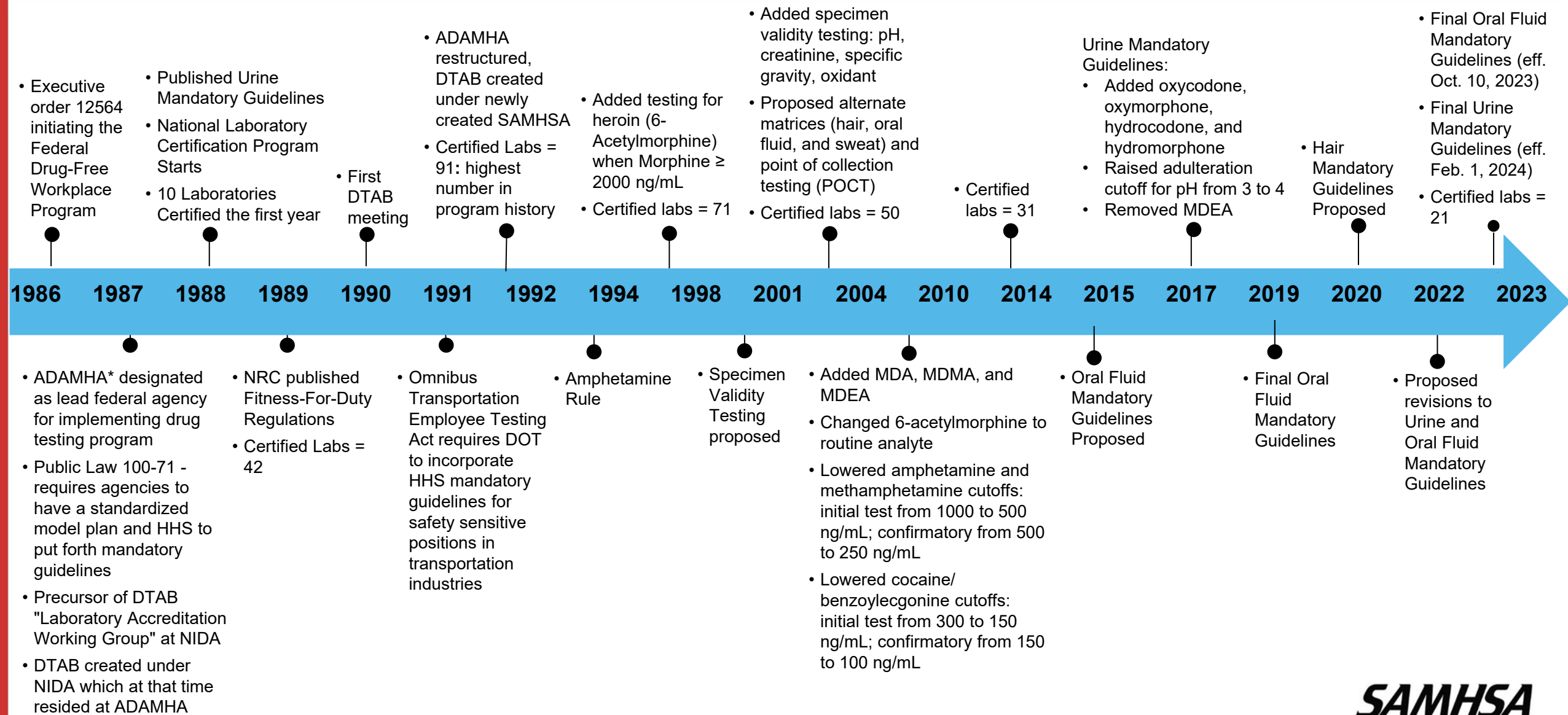
Some Areas of the Program to Examine

- 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 when adding an analyte
- 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 Federal Partners

Federal Drug Free Workplace Program



- 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

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*Alcohol, Drug Abuse and Mental Health Administration

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>