

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

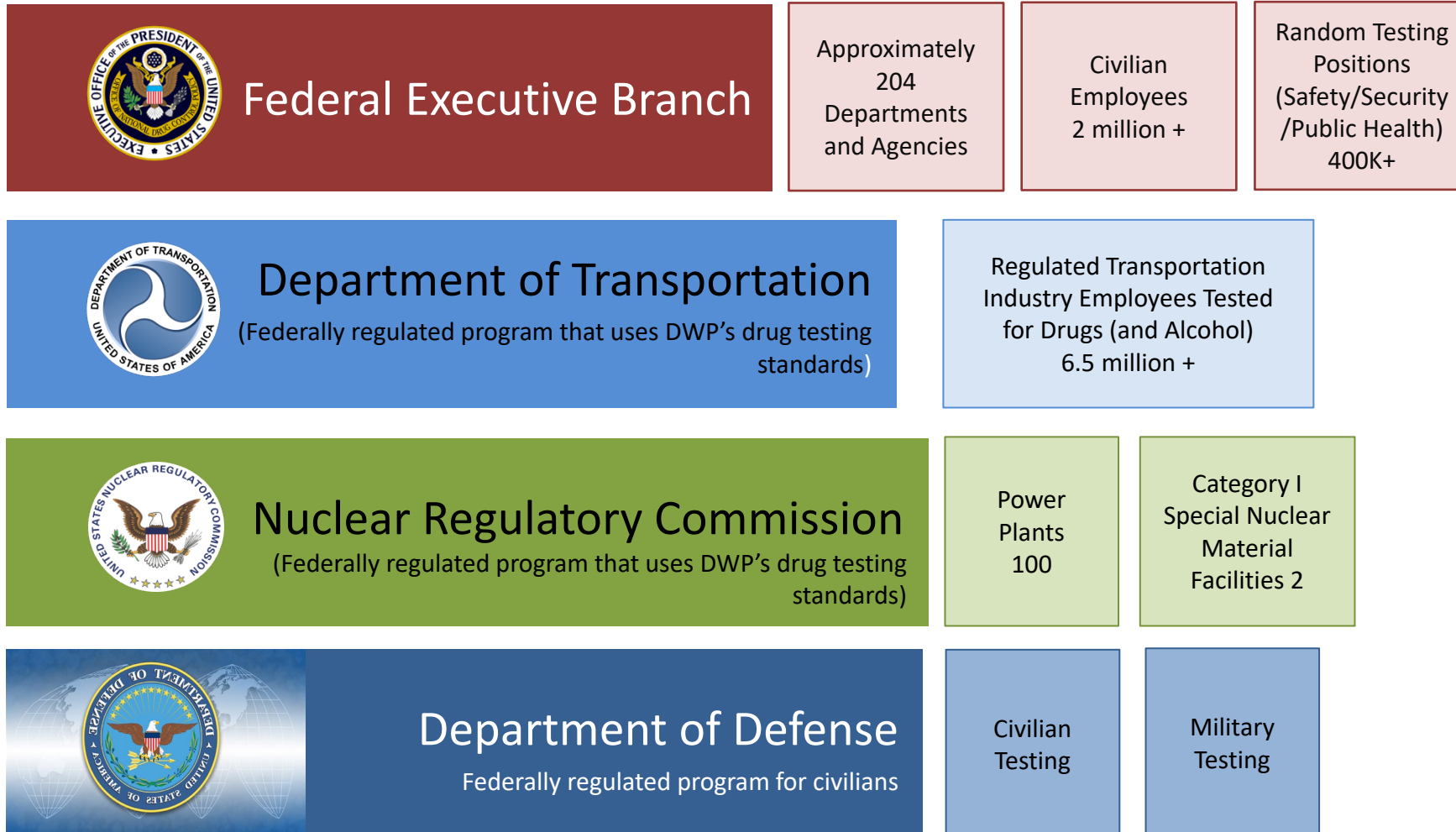
- Director: Ron Flegel, B.S., MT(ASCP), M.S.
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- Senior Scientist Policy Advisor: CAPT Sean Belouin, Pharm.D.
- Program Assistant: Christie Lamb
- Chemist / Toxicologist: Vacancy

Drug Testing Advisory Board Members

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

Drug-Free Workplace Program Impact

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DFWP Program Impacts 14 million+ employees

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.”*
- **Present Goal:** HHS-certification of the first oral fluid testing laboratory.
- **Future Goals:**
 - Address key policy and technical issues for Implementation of the Mandatory Guidelines using hair,
 - Identify and enact enhancements to the Federal Drug Testing Program for urine, oral fluid and hair.



Division of Workplace Programs Legislative Authority and Main Roles



Science

Federal Forensic Drug Testing

DWP's Science Responsibilities:

- 1. Mandatory Guidelines for Federal Drug Testing:** Scientific & Technical Guidelines
- 2. National Laboratory Certification Program (NLCP):** Certifies labs for federal (and federally-regulated) forensic workplace 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)*:**
 - Establishes MRO certification standards
 - Certifies MRO certification entities
 - Issues MRO Guidance Manual and Case Studies

*MROs interpret drug testing results

Program 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
- 2. Plan Certification:** Certify federal agency DFWP plans, transmit agency plans/reports to Congress. Agency plans establish agency policy and procedures.
- 3. Executive Committee:** Interagency Coordinating Group Executive Committee (ICGEC) establishes policy and approves federal Testing Designated Positions (TDP's) of safety-sensitive positions
- 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

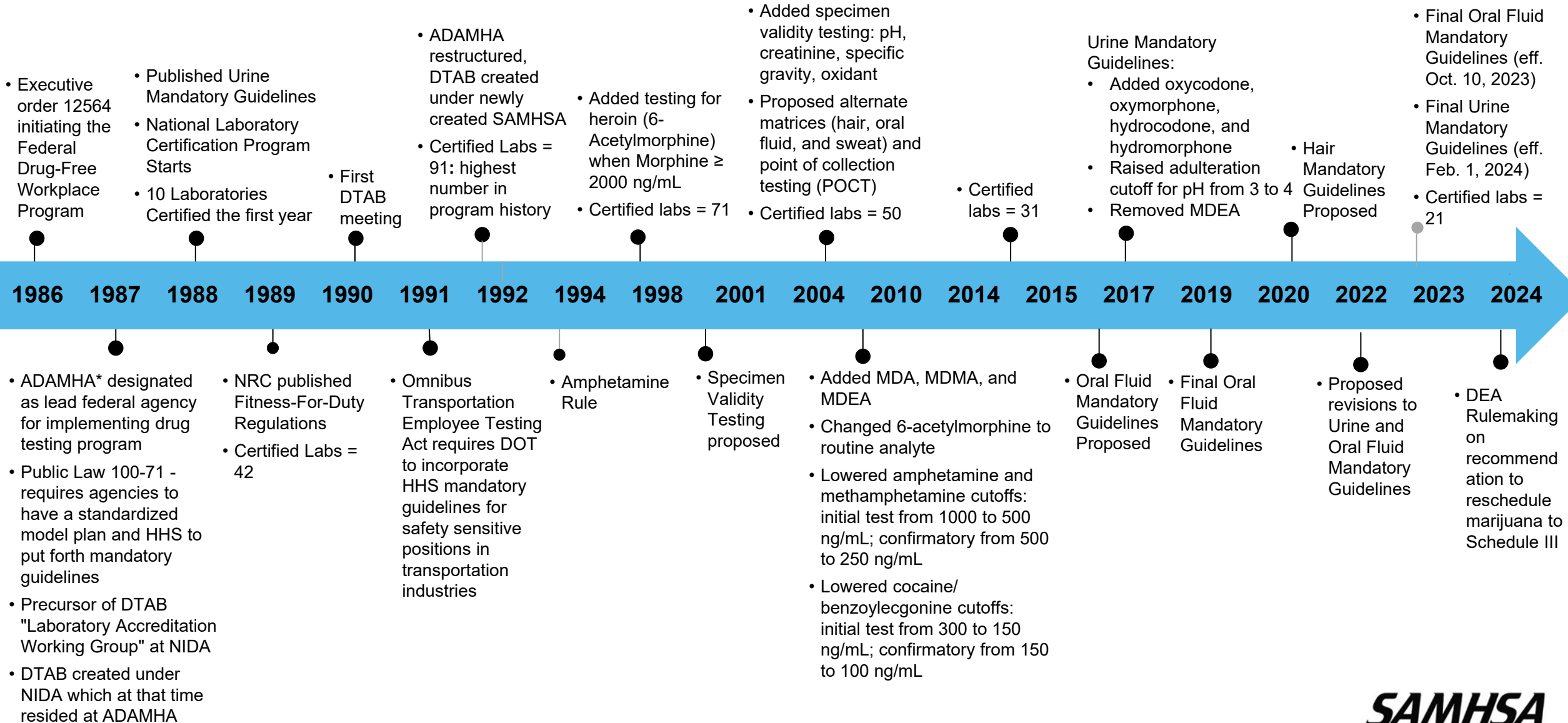
DWP's Emerging Issues Responsibilities:

- 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 (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 and cutoff changes**

Program Outcomes:

- Recommend DFWP analyte and cutoff 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)

Federal Drug Free Workplace Program



*Alcohol, Drug Abuse and Mental Health Administration

Current Drug-Free Workplace Program

Updated: May 2024

Total number of Executive Branch agencies thought to be subject to EO 12564201

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

Total number of Executive Branch agencies with certified plans131

(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.....70*

(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.

[2023-21734.pdf \(govinfo.gov\)](#)

Oral Fluid

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

[2023-21735.pdf \(govinfo.gov\)](#)

Hair

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

[2020-16432.pdf \(govinfo.gov\)](#)

A revised proposal is pending OMB Review

DFWP Objective

DFWP is a Deterrence Program

- One of the largest prevention tools
- Workplace drug testing remains an effective tool.
- Safety Sensitive Positions - Federal partners, Regulated Industry (DOT and NRC) continue to partner with HHS to strengthen their drug-free workplaces.

Authority: Division of Workplace Programs

Executive Order 12564: Drug Free Workplace Program in Executive Branch agencies

- Limits testing authority to Schedule I or II drugs in the Controlled Substances Act
- **Drug-Free Policy:** Address illegal drug use in the workplace. TDP tested for Schedule I and II substances (on and off duty).
- **Agency Responsibilities:** Agencies must create plans for a drug-free workplace, including Employee Assistance Programs and training for supervisors.
- **Drug Testing Programs:** Implement drug testing for all employees and random drug testing for safety sensitive positions (national security, public health and public safety)
- **Personnel Actions:** Refer employees who have tested positive to rehabilitation and /or initiate disciplinary actions, including potential removal from service.

Authority: Division of Workplace Programs

Public Law 100-71: Each agency shall develop a plan for achieving a drug-free workplace

HHS responsibilities:

- Review and certify federal agency DFWP plans
- Publish Mandatory Guidelines which establish scientific and technical guidelines
- Specify the drugs for which Federal employees may be tested (Analyte Table Change)
- National Laboratory Certification Program - Establish comprehensive standards and procedures for certification, periodic review of laboratories, and revocation of certification of laboratories that perform DFWP drug testing

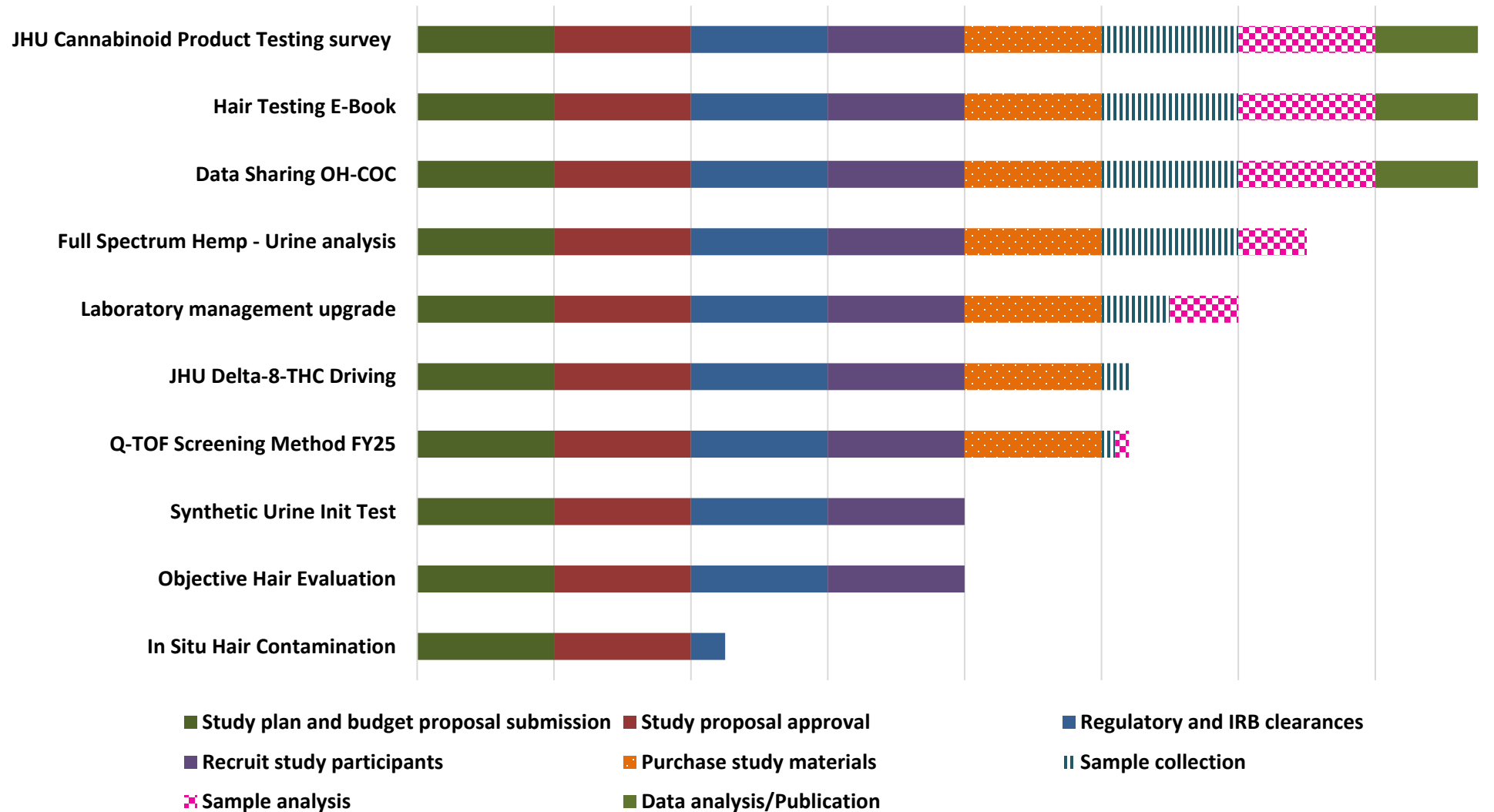
Mandatory Guidelines Routing Process



Hair Mandatory Guidelines – Status

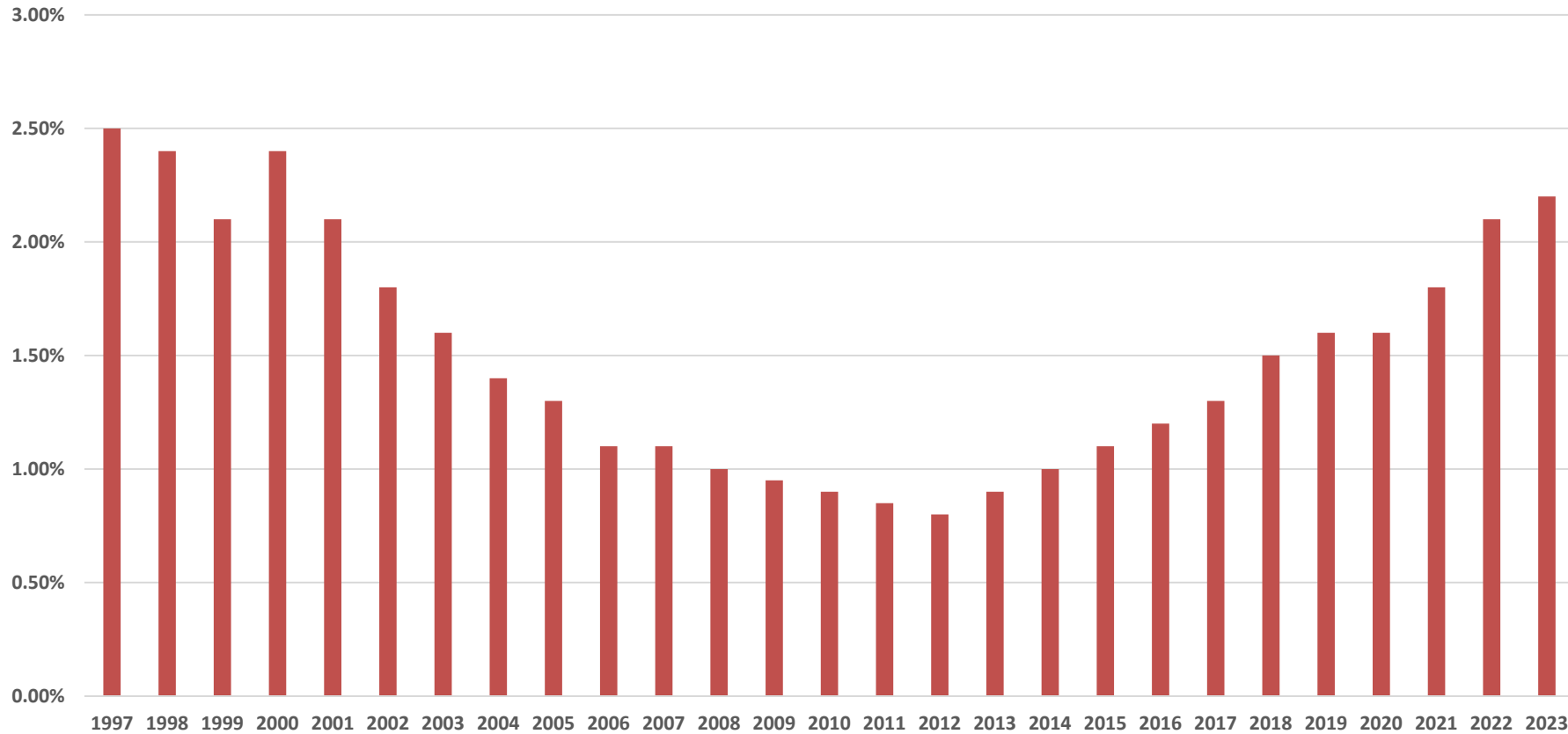
- SAMHSA public comment review:
 - Organized public comments by subject (over 700 individual comments from 213 commenters)
 - Reviewed all comments, submitted information, and scientific studies referenced by commenters – prepared draft HMG
- DTAB review
 - March 2021: summarized public comments presented 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)

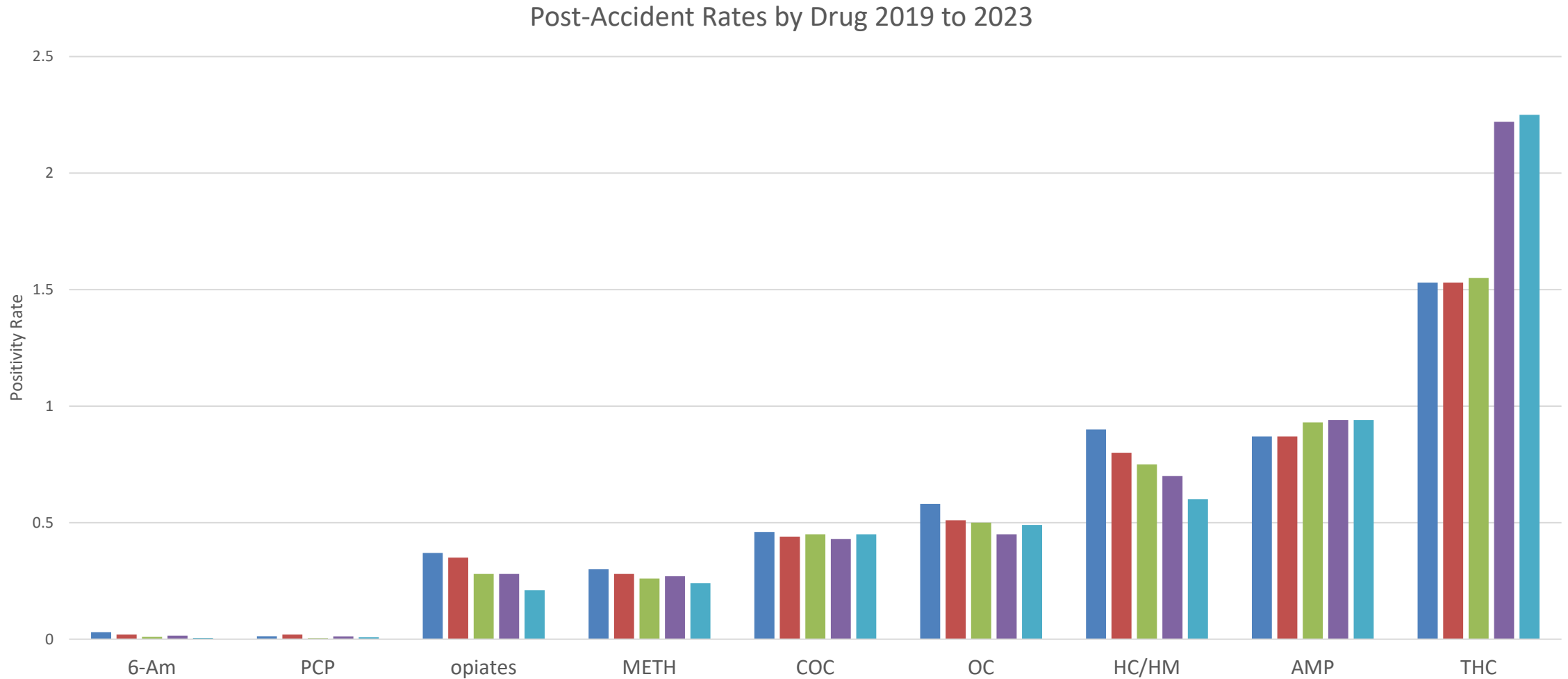


Urine Post-Accident Positivity Rate Marijuana

Urine FMSS Post-Accident Positivity Rate
Marijuana Metabolite



Urine Post-Accident Positivity Rates by Drug Summary



Analyte Table Decisions

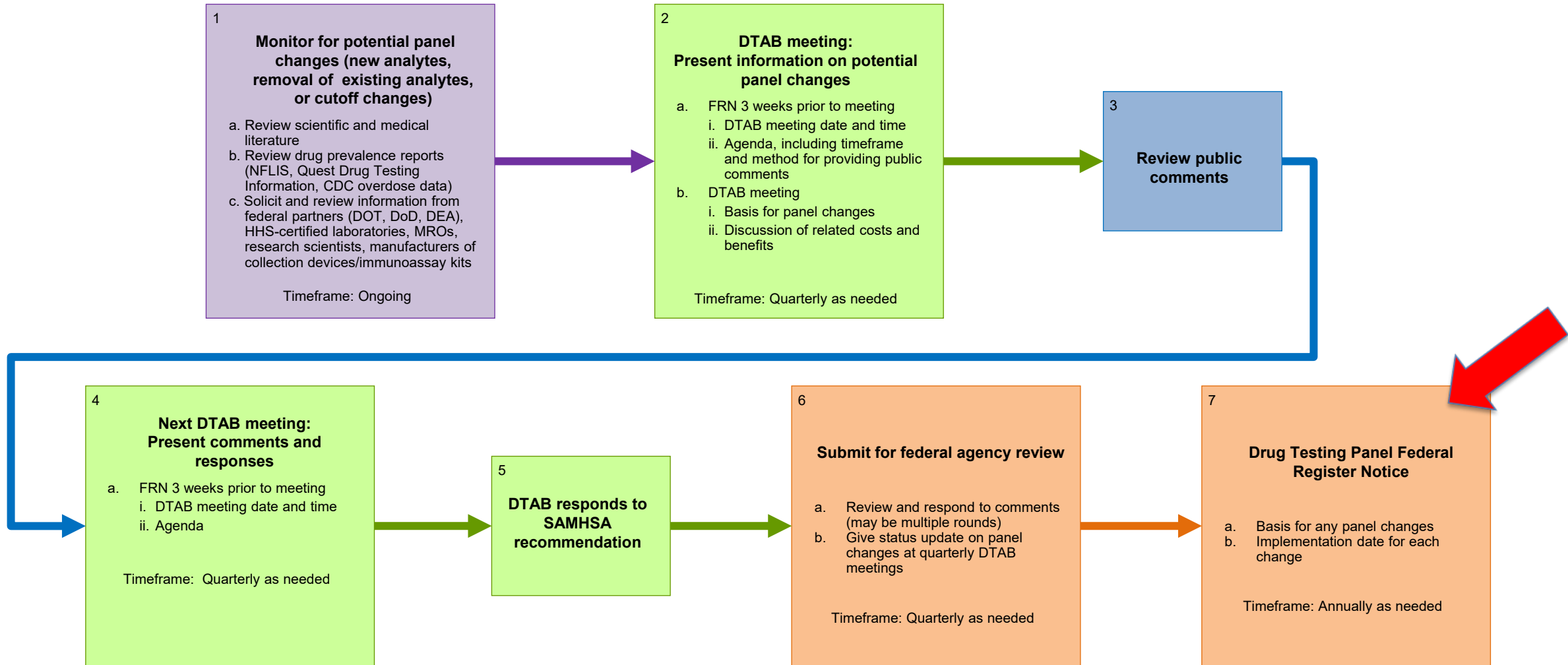
- June 4, 2024 DTAB meeting: Urine remains unchanged

Urine Initial Test Analyte	Initial Test Cutoff	Confirmatory Test Analytes	Confirmation Cutoff
Fentanyl	1 ng/mL	Fentanyl Norfentanyl	1.0 ng/mL

- Raise the initial test cutoff for Fentanyl in Oral Fluid to 4.0 ng/mL

Oral Fluid Analyte	Initial Test Cutoff	Confirmatory Test Analytes	Confirmation Cutoff
Fentanyl	4 ng/mL	Fentanyl	1.0 ng/mL

Process for Drug Testing Panel Changes



Ongoing Challenges

- Implementing the Oral Fluid Mandatory Guidelines
 - Oral fluid collection devices and tests meeting HHS/DOT/FDA requirements
- Ensuring scientifically supported procedures to distinguish drug use from external contamination in hair (decontamination, unique metabolites/biomarkers)
- Addressing emerging issues such as Marijuana/Hemp (CBD), Opioids, Synthetic Drugs, Legislation and State Laws

Comprehensive Review Meeting

Conducted a high-level review of the DFWP to:

- Assess critical issues affecting the program now and in the future;
- Review the state of the art and science;
- Identify key policy and technical challenges; and
- Highlight best practices for the future of DFWP.

Comprehensive Review Roadmap and Action Plan

<u>Action Item</u>	<u>Status</u>
Develop Pulse Analytical Testing Method	Completed
Separate Testing Panels from Mandatory Guidelines	Completed
Meet with FDA to reduce length of time from publication of testing panel to implementation	Ongoing
Align goals and timelines for SAMHSA/DWP and regulated agency partners	Ongoing
Remove requirement for clinical evaluation of opioid addiction	Completed
Reflect regulatory changes in Mandatory Guidelines and MRO Guidance Manual as appropriate	Completed
Provide updated MRO Guidance Documents online	Completed
Review program specimen validity data and change criteria for dilute or pH invalid specimens	Ongoing

MRO Guidance Manual and Case Studies

- Updates based on the 2023 UrMG and OFMG.
 - 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.
 - 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.

Road Map and Action Plans

- Continue to work with FDA and Manufacturers
- Continue to evaluate mechanisms for reducing time required to change the testing panel
- Develop and add new pulse testing (emerging drugs, specimen validity)
- Review and streamline Program processes (inspections and audits)
- Align goals and timelines for SAMHSA/DWP and Federal Partners

Oral Fluid Laboratory Applicant

Bring to your attention:

- 1) HHS / NLCP has their first Applicant Oral Fluid Testing Laboratory
- 2) HHS Certification – Once a laboratory is HHS Certified they can begin to test regulated specimens and will be added to the next monthly lab list
- 3) When a lab is HHS Certified to test both Urine and Oral Fluid the laboratory fee schedule will be revised to a reduced rate. How will that be done and how will that work into the inspection process.
- 4) SAMHSA currently covers all costs for labs applying to the oral fluid program (application, PT's, inspections) through certification. Will there be support beyond that?
- 5) What is the timing of the 3 PT sets for initial certification? How long does a lab have to wait between initial PT rounds prior to certification?
- 6) Note that the OF collection device validation has been revised and updated. Please make sure you refer to the latest notification when performing your validation studies.

Program Overview and Achievements

- NLCP Mission: Ensuring the accuracy, reliability, and consistency of federal workplace drug testing.
 - Key Achievements:
 - Preparation and Management of new Initiatives within the NLCP
 - GAP Analysis Program (Technical Assistance)
 - ECCF Implementation and ECCF Standalone System
 - Applied Studies, Applied Study Agenda Tracking Tool and Study Partnerships
 - Nimonik Inspection Tool Implementation
 - Continuity in Gold Standard Setting
 - Inspection Program Administration
 - PT Program Management
 - Non-Negative Specimen List Maintenance
 - Guidelines Language Drafting

Current Challenges

- Oral Fluid Testing: Overcoming barriers in certifying laboratories for oral fluid testing.
- Knowledge Gaps: Addressing the diminished expertise among junior toxicologists.
- Inspector Training: Ensuring consistent and up-to-date training for all inspectors.
- Panel Agility: Working to make the drug testing panels more flexible and responsive to emerging threats.
- Guidelines Harmonization: Working to harmonize rule-making efforts with the Department of Transportation
- Laboratory Program Participation: Working to decrease cost and burden for certified laboratories with no federal or federally regulated specimens.

Strategic Focus Areas

- Training and Development:
 - Operational Improvements: Streamlining processes to encourage and allow the ECCF program and laboratories to be onboarded.
- Major program activities:
 - Applied Studies Agenda: Focused studies on emerging drugs, testing methodologies, and hair color impact.
 - Stakeholder Engagement: Strengthening communication and collaboration within the program.
 - Program Expansion: Develop and implement guidelines for the certification of international laboratories to expand the program's global reach.
 - Program Efficacy: Continuously optimize processes to achieve greater cost efficiency and time savings.

- Total budget: \$5 million over 5 years
 - *(Approximately \$1 million annually)*
- Collaboration between SAMHSA and Department of Defense (DoD) to leverage expertise and technology for drug use prevention within our programs' authority, monitoring, and intervention
 - Includes a sub-contract with Kansas State University through the NLCP

State of the Program & Looking Forward

- The NLCP program is robust and resilient, making significant strides in maintaining high standards despite emerging challenges. However, continuous improvement and adaptability are crucial to staying ahead in the evolving landscape of workplace drug testing.
- Next Steps:
 - Enhance Flexibility: Continue improving the agility of drug testing panels.
 - Major Program Initiative: Exploring Oral Fluid Alternative Technology for Initial Testing
 - Expand Certifications: Focus on certifying more laboratories, particularly for oral fluid testing and moving internationally.
 - Strengthen Support: Continue technical assistance and communication with stakeholders.
 - Continue Applied Studies: Partner with the field to continue answering questions that directly support the success of the program
- Stay engaged, proactive, and committed to the program's success.

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>