

**Department of Health and Human Services (HHS)  
Substance Abuse and Mental Health Services Administration (SAMHSA)  
Center for Substance Abuse Prevention (CSAP)**

**Drug Testing Advisory Board**

**February 11, 2013  
Minutes – Open Session**

The CSAP Drug Testing Advisory Board (DTAB) meeting was convened at 10:30 a.m. on February 11, 2013 in the SAMHSA Building (Sugarloaf Conference Room), 1 Choke Cherry Road, Rockville, Maryland 20857.

In accordance with the provisions of Public Law 92-463, the meeting was open to the public on February 11, 2013 from 10:30 a.m. to 5:30 p.m. The meeting was closed to the public on February 12 from 9:00 a.m. to 2:00 p.m.

**Table of Contents**

|  |   |
|--|---|
| Board Members in Attendance .....  | 1 |
| Call to order.....   | 1 |
| Welcome, Introductions, and Opening Remarks.....   | 1 |
| Medical Review Officer.....  | 2 |
| Custody and Control Form (CCF) .....   | 2 |
| Proposed Revisions to the Mandatory Guidelines for Federal Workplace Drug Testing Programs ..... | 3 |
| Department of Transportation (DOT) Drug Testing Update.....                                      | 3 |
| Department of Defense (DoD) Drug Testing Update.....   | 3 |
| U.S. Nuclear Regulatory Commission (NRC) 10 CFR Part 26 Fitness for Duty Program .....           | 3 |
| Federal Workplace Drug Testing Programs .....  | 4 |
| Public Comments .....  | 5 |

**Board Members in Attendance**

Dr. Janine Denis Cook  
Mr. Robert Bonds  
Dr. Lawrence Brown  
Ms. Phyllis Chandler  
Dr. Anthony Costantino  
Ms. Laurel Farrell  
Dr. Greg Grinstead  
Ms. Susan Mills  
Dr. Jasbir Singh  
Dr. Donna Smith  
Mr. Jim Swart

**Call to order**

Dr. Janine Denis Cook, the Designated Federal Official of the DTAB, called the meeting to order at 10:00 a.m. Dr. Cook provided announcements to both the on-site and remote attendees.

**Welcome, Introductions, and Opening Remarks**

Dr. Cook, Acting Chair of the DTAB, thanked the retired DTAB members: Jim Bourland, Larry Bowers, and Barbara Rowland. She welcomed the new Board members: Tony Costantino, Greg Grinstead, Marilyn Huestis, Susie Mills, and Jasbir Singh. She also welcomed the returning Board members: Bobby Bonds, Larry Brown, Phyllis Chandler, Laurel Farrell, Courtney Lias, Donna Smith, Jim Swart, and Steve Wong. The staff of the

Division of Workplace Programs (DWP), other distinguished guests, and the public were welcomed. The tentative dates for the remaining fiscal year 2013 DTAB meetings were announced: April 3-4, July 16-17, and September 10-11, 2013.

Ron Fliegel, Director of DWP, welcomed the public and acknowledged the DWP staff for their support of the Federal Drug-Free Workplace Programs. He provided updates of the proposed revisions for the Mandatory Guidelines for Federal Workplace Drug Testing Programs (MG) for urine and oral fluid and the Medical Review Officer (MRO) Manual.

Fran Harding, Director of CSAP, welcomed the returning and new members to DTAB, our federal partners, the DWP program staff, and the general public. She explained the role of the DTAB and reviewed the progress of the two recommendations by the Board regarding the inclusion of oral fluid as the alternative specimen and additional schedule two prescription medications in the MG. Ms. Harding described the importance of the Federal Workplace Drug Testing Programs and the recommendations proposed by the DTAB in their support of SAMSHA's number one strategic initiative: the prevention of substance abuse and mental illness.

David Mineta, Deputy Director of the Office for Demand Reduction in the White House Office of National Drug Control Policy (ONDCP), thanked our federal partners, the DTAB members, and the stakeholders for attending the meeting. A key priority of the Obama Administration and ONDCP is preventing drug use before it starts and ensuring a drug-free workplace. Drug-free workplace programs are beneficial for our labor force, employers, families, and communities in general. He applauded the DTAB for their hard work on the proposed revisions to the MG and appreciated the scientific updates that the DTAB has guided and the recommendations the Board has developed.

### **Medical Review Officer**

Dr. Jennifer Fan provided a brief overview and update on MROs and MRO entities. MRO entities are approved by the HHS Secretary and the latest approved list was published in a Federal Register on January 14, 2013. The entities that were approved this last cycle for providing both training and certification of MROs are the American Association of Medical Review Officers and the Medical Review Officer Certification Council. The American College of Occupational and Environmental Medicine and American Society of Addiction Medicine were reviewed and approved as training-only organizations; MROs completing training with one of these organizations can sit for the exams that are given by the approved entities. DWP convened a MRO workgroup to aid SAMHSA in determining the steps in the MRO verification process in regard to program objectives, developing specific workplace definitions, reviewing the standards and practices, and advising SAMHSA in drafting guidance for the consistent interpretation of donor drug test results. This group is charged with creating a more comprehensive MRO Manual and updated case studies that will include the newly added synthetic opiates and oral fluid drug test results. The MRO workgroup has also discussed the electronic Custody Control Form (eCCF) and how MROs will be affected by the eCCF.

### **Custody and Control Form (CCF)**

Charlie LoDico provided an update on the 2013 CCF. The current form, referred to as the 2010 Federal CCF, expires on 8.31.2013 and will no longer have OMB approval. SAMHSA was given a provisional approval for the 2010 form with the condition that the next iteration of the form be available as an electronic document. DWP convened a working group to address various issues associated with an eCCF, including electronic signatures, nonrepudiation agreement for digital signatures, third party software for managing the federal CCF information, unique specimen identification numbers, the legal binding equivalents to the traditional handwritten signature in a forensic arena, the security of data transmission, and the integrity of the document content. The outcomes for this working group were focused in three areas: the risks and benefits of an electronic CCF, standardization of terms and definitions, and the operational considerations. For the risks and benefits, the key areas that we focused on were specific to the federal agencies and employers, the collection sites, and the laboratories. We did not want to recreate the wheel but borrowed from existing federal references. With the adoption of the eCCF, the MRO Manual, the Collection Handbook, and the NLCP Laboratory Checklist must be revised.

## **Proposed Revisions to the Mandatory Guidelines for Federal Workplace Drug Testing Programs**

Ron Flegel described the review process for the proposed revisions to the MG to include oral fluid and synthetic opiates.

### **Department of Transportation (DOT) Drug Testing Update**

Cindy Ingrao, Senior Policy Advisor in the Office of Drug and Alcohol Policy and Compliance (ODAPC) within the DOT, provided the DOT program overview. ODAPC is responsible for writing and interpreting the CFR Part 40 regulation, which is the how-to of drug and alcohol testing for the transportation industry. The DOT's number one priority is safety. We are the world's largest regulated drug and alcohol testing program with over 5.5 million tests performed in 2011. Since 2008, the HHS-certified laboratories have been submitting DOT-only data on a semi-annual basis. From January to June 2012, more than 2.9 million tests were conducted. Marijuana continues to be the most prevalent detected drug, amphetamines are on the rise, and cocaine fell in our industry. The increase in the percent positives in 2011 for amphetamine and cocaine are attributed to the new cutoff levels that were instituted with the October 2010 final rule. The MRO downgrades, due to a legitimate medical explanation, are most prominent for amphetamine and opiates.

### **Department of Defense (DoD) Drug Testing Update**

LTC Tom Martin provided a brief overview of DoD drug testing. DoD service members must operate in a drug-free environment so as to not compromise the mission or mission readiness. Our service personnel operate around the world where illegal drugs are either manufactured or readily assessable and are also a high risk population, comprised of 18 to 25 year old males who represent about a third of the overall military force but account for two thirds of the overall positives. The drugs tested in the six DoD drug testing laboratories are marijuana, cocaine, amphetamines, designer amphetamines, heroin, oxycodone, hydrocodone, hydrocodone, codeine, and morphine. Also, benzodiazepine testing is performed at a pulse rate of 10 percent. The overall laboratory drug positive rate stayed steady at around one percent. The emergence of prescription drug abuse has transferred over into the military population. From 2005 to 2008, there was a significant increase in the number of members reporting misuse of prescription drugs. DoD conducts prevalence testing to monitor abused drugs and any drug previously removed from the panel. For a drug to be added to our panel, the prevalence rate must be at least 0.25 percent. For instance, prevalence testing has been performed on LSD, ecstasy (MDMA), oxycodone, and benzodiazepines. For drug demand reduction, especially for misuse of prescription drugs, we enlist the support from the medical community, in particular, those prescribing the medications. We marry up our drug results with the DoD Prescription Drug Portal, which allows us to correlate positive results with service members' prescription history in the Electronic Medical Review Process. A recent hot topic within DoD is synthetic marijuana (cannabinoids or Spice). An Army prevalence study yielded a positive rate of 2.4 percent for synthetic marijuana.

### **U.S. Nuclear Regulatory Commission (NRC) 10 CFR Part 26 Fitness for Duty Program (FFD)**

Paul Harris, Senior Program Manager in the NRC FFD Program, explained why NRC's FFD program helps provide reasonable assurance that persons who have access to NRC licensed facilities are fit for duty and can safely and competently perform their duties. The FFD Program is regulated under the 10 CFR Part 26 rule, which dictates who is subject to drug and alcohol testing, behavioral observation, and fatigue management; aligns FFD requirements and security access authorization, incorporates a defense-in-depth program, and offers employee assistance programs. The NRC can leverage four levels of sanctions against an individual. The first sanction, for a first time drug or alcohol positive test, is a 14 day denial from authorization. For the second positive test, the individual is removed for five years. The third offense is permanent denial. The fourth sanction is criminal sanctions. In the commercial nuclear industry, 76 entities report data to us, of which about 80 percent is submitted electronically. We conduct 178,586 total tests in FY 2011 on the 340,000 to 350,000 people in the commercial nuclear industry. Our overall positivity rate is about 0.6 percent, with ninety percent involving marijuana (52%), alcohol (26%), and cocaine (12%). There were 37 drug and alcohol events involving licensed operators and the supervisors. About three times as many contractor vendors test positive for drugs and alcohol than licensee employees. The trend in positive test rates is sloping downward for the

contractor/vendors; the trend for permanent employees has been relatively steady. The electronically-reported data was categorized as follow-up, post-accident, for cause, random, and pre-access testing. Mostly the same drugs are detected in random testing as in pre-access testing. For post-accident events, contractor/vendors are skewed to significantly more positives. The pre-access positives are about three times larger than the random testing data.

## **Federal Workplace Drug Testing Programs**

Ron Flegel, Division Director of DWP, presented the National Laboratory Certification Program (NLCP) drug testing data through 2012. The number of regulated specimens tested from January 2003 to December 2012 ranged from about 6.6 million in 2003, peaked in 2007 at about 7.99 million, and was a little over 6 million in 2012. For regulated specimens reported as positive, there were about 87,000 specimens reported in 2009 and over 110,000 in 2012. The number of specimens reported as invalid for low pH remained the same in 2009 and 2010, increased in 2011, and then leveled off again in 2012. The number of specimens reported as invalid for pH increased through 2011 and into 2012. In the last part of 2011, laboratories located in specific geographical regions reported increases in the number of low pH invalids. Increasing specimen pH values in winter is a trend that we have not seen in the past. Typically, pH increases with time and temperature. We want to examine both synthetic urine and adulterants as potential causes for this increase in pH invalids and determine whether there is a legitimate medical explanation for these pH invalid results. The slide depicts the number of regulated specimens reported as positive, adulterated, invalid, or substituted and the month and year in which that reporting occurred. From 2009 to 2011 there was a large increase in the number of specimens being tested, especially during the March through the December time period. In 2012, as the economic recovery starts, there was a significant increase in testing numbers in all the regulated laboratories. In October 2010, we had changed the Guidelines, lowering the cutoffs for both methamphetamines and cocaine. After the implementation of the revised Guidelines on October 1<sup>st</sup>, 2010, there was a 5.4 percent reduction of the number of specimens tested, but an increase in the percentage of specimens reported as drug positive. The major drugs responsible for the increase in the number of specimens reported as positive were those whose cutoffs were lowered, specifically cocaine, amphetamine, and methamphetamine. There was a smaller increase observed for morphine and codeine.

DWP has several ongoing projects. Based on the DTAB recommendations, we investigated synthetic opiates. Aliquots of 12,663 regulated specimens were de-identified and tested using DRI, KIMS, CEDIA, and EMIT II reagents using a cutoff at the 300 ng/mL morphine level. Of those initial 266 test positives, 254 were positive by DRI, 162 were positive by KIMS, 253 were positive by CEDIA, and 238 were positive with the EMIT II. These 266 reactive specimens were then confirmed by gas chromatography/mass spectrometry analysis for codeine, morphine, hydrocodone, hydromorphone, oxycodone, and oxymorphone using a 100 ng/mL cutoff. There were 35 specimens in which no drug was found. The number of specimens with hydrocodone only was 40 and hydromorphone only was 13. Both hydrocodone and hydromorphone were present in 116 specimens. Both oxycodone and oxymorphone were found in 29 specimens while codeine and/or morphine were in 33. The concentration distribution of the synthetic opiates in these positive specimens is important in determining appropriate initial as well as the confirmation test cutoffs. This study provided an expectation for the scale of quantitative levels of opiates.

It is important to know the performance of the immunoassay response for detecting the actual drug in a sample. The response rate of the different initial immunoassay tests and how many confirmed positive were determined. Overall, most of the reagents performed equally regarding the confirmatory levels.

In another study, we assessed the identification of oxycodone and oxymorphone with a specific oxycodone assay. We deidentified 2,892 regulated specimens and analyzed them using the oxycodone assay at the 100 ng/mL cutoff. These specimens underwent confirmatory testing for oxycodone and oxymorphone. 14 of these specimens were initial test positive, and 12 confirmed positive for oxycodone and oxymorphone. The positivity rate in this specific subset was 0.42 percent, while the confirmation rate was 85.7 percent.

Individuals in safety-sensitive positions are using semi-synthetic opiates, specifically hydrocodone, hydromorphone, oxycodone, and oxymorphone. The implications of this use, including legal, medical, or

safety-related, can only be implied until the testing for these compounds begins and positive results are verified by an MRO. In our study, these were deidentified specimens, and thus we do not know if these donors had valid prescriptions.

## **Public Comments**

Abigail Potter of the American Trucking Associations (ATA), Inc. praised the DoD for making proactive efforts to identify the new threats and performing testing to stop new abuse and thanked NRC for considering hair testing. ATA is also very concerned about synthetic marijuana and bath salts. Since 2007, ATA has supported the adoption of alternative specimens into DOT's drug testing program, including hair. Companies have found that hair testing, particularly for pre-employment screening, has significant advantages compared to urine testing. With the longer window of detection, up to 90 days, the lifestyle user can be identified. Hair specimens are usually easier to collect, collection is less invasive, and hair is much more difficult to adulterate. Legislation in support of hair testing is expected to be introduced again this year. One of our major carriers conducted 40,000 hair tests since 2007. Their post-accident rate in 2007 was around 2.6 to 3.0 percent; in 2012 it was zero.

Bill Corl, CEO of Omega Laboratories, spoke on behalf of some of his U.S. clients who operate within federally-regulated industries. He voiced their support for the addition of hair testing to the MG. He presented data on the prevalence of synthetic opiates in a large Midwestern carrier population from 2011. The population was comprised of 12,197 donors seeking employment within the transportation industry. Each donor submitted a DOT urine sample and a corresponding hair sample. Hair testing detected 432 synthetic opiate users, of which 111 were found to be positive after MRO review. As the data show, hair testing in general yields a greater number of positive results than its urine testing counterpart. Though urine testing is still effective for post-accident testing, the data suggest that it is no longer effective at screening donors for pre-employment.

The open session adjourned at 11:30 a.m.

I hereby certify that, to the best of my knowledge, the foregoing minutes are accurate and complete.

/SIGNED/

Janine Denis Cook, Ph.D., DABCC, FACB  
Designated Federal Official and Acting Chair, DTAB

These minutes were formally considered, amended, and approved by the DTAB via email.