DEPARTMENT OF HEALTH AND HUMAN SERVICES
SUBSTANCE ABUSE AND MENTAL HEALTH SERVICES ADMINISTRATION
DRUG TESTING ADVISORY BOARD

September 7 - 8, 2005

The Drug Testing Advisory Board was convened for its meeting at 8:30 a.m. on September 7, 2005, in the Residence Inn by Marriott, 7335 Wisconsin Avenue, Bethesda, Maryland.

In accordance with the provisions of Public Law 92-463, the meeting was open to the public on September 7 from 8:30 a.m. to 9:30 a.m. The meeting was closed to the public on September 7 from 9:30 a.m. until adjournment on September 8 at 11:45 a.m. to develop the analytical and administrative policies for the final revisions to the Mandatory Guidelines for Federal Workplace Drug Testing Programs.

Board members present:

Robert Stephenson II, Chairman
Dr. Alberto Gutierrez
Patricia Pizzo
Dr. David Kuntz
Dr. Matthew Slawson
Dr. Sue Brown
Dr. Frederick Fochtman
Dr. William Ferguson Reid
Ann Marie Gordon
Dr. George Jackson

Executive Secretary present:

Dr. Donna Bush, Division of Workplace Programs (DWP), CSAP

Others present for all or a portion of the meeting were:

Dr. Walter Vogl, DWP, CSAP
Charles LoDico, DWP, CSAP
Ron Flegel, DWP, CSAP
Dr. John Mitchell, RTI International
Dr. Mike Baylor, RTI International
George Ellis, Department of Transportation (DOT)
Dr. Yale Caplan, DOT Consultant
Tim McCune, Nuclear Regulatory Commission (NRC)

TOPICS DISCUSSED IN OPEN SESSION

Note: The transcript for the open session is available on the Internet at: http://workplace.samhsa.gov

Opening Remarks

Mr. Stephenson convened the open session of the Board meeting. He stated that the revised Mandatory Guidelines are in internal clearance and, therefore, we are unable to provide any other comments or information.

HHS Update

Dr. Mitchell (RTI International) gave two presentations. The first presentation was an update on the pilot performance testing (PT) program for oral fluids. Dr. Mitchell gave a brief review of the efforts RTI has made since SAMHSA began the initiative to include testing oral fluid specimens in the Federal Workplace Drug Testing Program. He presented the analytical test results from the first three cycles of PT samples that were tested by oral fluid testing laboratories in April 2000, July 2000, and March 2001. The purpose of these samples was to assess the ability of the participating laboratories to meet the proposed cutoffs. He then presented results for the cycles of PT samples tested by the laboratories in October 2003, December 2003, and January 2004. The purpose of these samples was to assess the inter- and intra-laboratory variability over the three cycles. The most recent cycle of PT samples in December 2004 has started an effort to assess collection device variability and analyte stability in PT samples and that effort continues as a work in progress. The lessons learned from these PT samples indicate that it is difficult to collect a sufficient amount of human oral fluid to use a quality assurance (QA)/quality control (QC) material, the dilution of oral fluids with diluents increases the stability and ease of production of QA/QC products, some drug analyte require special precautions, all solutions of drug analytes in human oral fluid should be stored at -20°C, samples should be analyzed soon after thawing, and external QA/QC samples are essential to establishing and maintaining laboratory quantitative performance.

Dr. Mitchell's second presentation was on the results for cycle 8 of the pilot PT program for hair. The objectives of cycle 8 were to determine inter- and intra-laboratory performance, evaluate analyte stability in hair over time, evaluate laboratory efforts to improve performance, and evaluate laboratory performance on liquid spiking solutions over 2 cycles. Nine laboratories participated in cycle 8. Five have had continuous participation in all cycles, two were returning, and two laboratories were new to the program. Dr. Mitchell presented the results reported by the laboratories using a series of bar graphs that showed performance by drug and/or drug metabolite. The conclusions from the results reported by the laboratories suggest that agreement with the batch production target concentrations can be highly variable, overall agreement among the laboratories is not evident because the mean CV varied from 17 to 78%, the drugs having the greatest variability were opiates and THCA, and predictive incorporation of drug into hair remains a challenge.

DOT Update

Mr. Ellis (DOT) stated that the notice of proposed rulemaking regarding specimen validity testing is being circulated for review by the DOT agencies; however, the review process has been affected by the Department's efforts to deal with the recovery efforts from Hurricanes Katrina and Rita. He encouraged everyone to continue using their website to gain immediate access to what is happening within DOT. The website not only gives access to 49 CRF Part 40, but to each agency's rules and access to all of the individuals who are responsible for these programs. In addition, the website maintains a link to the Coast Guard, once a part of DOT, but now in the Department of Homeland Security. The Coast Guard continues to use, at least in great part, 49 CFR Part 40 as part of its drug testing program for merchant mariners.

Mr. Ellis reminded everyone who was interested to sign-up for automated email notification. Every time DOT releases information, including this NPRM, all individuals on the mailing list will receive an email notification.

NRC Update

Mr. McCune (NRC) stated that the proposed revisions to 10 CFR Part 26, the NRC Fitness for Duty (FFD) Program, were published in the Federal Register on August 26th. There is a 120-day public comment period. The comment period will end on December 27th. All indications are that the drug and alcohol portions of the rule are relatively non-controversial. He stated that the NRC is considering to expand the program during the public comment period by holding public meetings in different regions. The first meeting is scheduled for September 21 in Rockville, Maryland. The notice for the meeting is on the NRC website (http://www.nrc.gov).

Mr. McCune also stated that the NRC requires its licensees to report fitness for duty performance data every 6 months. The NRC website now has the FFD performance data through fiscal years 2003 and will shortly include the information and testing rates for fiscal year 2004. To ensure that the information is properly evaluated, a working group has been formed to look at what information is required to measure the health of the program and compliance by the licensees and what additional testing for drugs and analytes not specifically in the HHS panel may be appropriate.

Public Comments

Dr. Christine Moore (Immunalysis Corporation) provided some recent findings with regard to the testing of oral fluid specimens.

Mr. Stephenson stated that the data could be received as part of the public comment period; however, submitting the data to RTI International would be appreciated.

The open session ended at 9:30 a.m.

TOPICS DISCUSSED IN CLOSED SESSION

The Board approved the Minutes for the June 1 - 2 meeting.

The Board discussed the public comments submitted regarding the proposed revisions to the Mandatory Guidelines for Federal Workplace Drug Testing Program (69 FR 19673) and continued preparing the final revisions to the Guidelines.

Adjournment

The meeting adjourned at 11:45 a.m. on September 8.

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

/signed/

Donna M. Bush, Ph.D., D-ABFT
Executive Secretary, DTAB

/signed/

Robert L. Stephenson II, M.P.H.
Chair, DTAB

These minutes will be formally considered by the Board at its next meeting, and any corrections or notations will be incorporated in the minutes of that meeting.