DEPARTMENT OF HEALTH AND HUMAN SERVICES (HHS)
SUBSTANCE ABUSE AND MENTAL HEALTH SERVICES ADMINISTRATION (SAMHSA)
DRUG TESTING ADVISORY BOARD (DTAB)
June 2-3, 2009

June 2, 2009

The Drug Testing Advisory Board meeting was convened at 10:00 a.m. on June 2, 2009 in the SAMHSA Building (Sugarloaf and Seneca Conference Rooms), 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 June 2, 2009 from 10:00 a.m. to 4:30 p.m. EDT and on June 3, 2009 from 10:00 a.m. to 1:00 p.m. EDT.

Board members present:

Robert Stephenson II, Chairman
Dr. Louis Baxter
Dr. James Bourland
Dr. Larry Bowers
Dr. Jennifer Collins
Dr. Courtney Harper
Lisa Tarnai-Moak
Dr. Henry Nipper
Barbara Rowland
Dr. Robert Turk

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

Dr. Donna Bush, DWP, CSAP
Charles LoDico, DWP, CSAP
Ronald Flegel, DWP, CSAP
Dr. Sean Belouin, DWP, CSAP
Dr. Janine Cook, DWP, CSAP
Dr. John Mitchell, RTI International
Dr. Michael Baylor, RTI International
Jared Cooper, RTI International
Erica Harbison, RTI International
Jim Swart, DOT
Dr. Yale Caplan, DOT Consultant
Paul Harris, NRC
COL Ron Shippee, DoD
William Sowers, DWP, CSAP
Dr. Deborah Galvin, DWP, CSAP
Barbara Spencer, ONDCP
Lisa Teems, HHS, FOH
Elena Carr, DOL
Dr. James Ferguson
Dr. Donna Smith
Alison Stockdale
Ann Adcook
Barbara Jones
Barry Kurtzer
Bill Corl
Bob Robinson
Carlos Castillo
Charles Johnson
Cynthia Robinson
Dr. David Kuntz
David Paine
Dean Fritch
Dianne Holmes
Gayle Mantello
Heather Harvey
Kathy Petrick
Ken Edgell
Maggie Dunnett
Mary Brown-Ybos
Mary Soffer

N.B. Varlotta
Neil Fortner
Dr. Paula Childs
Dr. Samuel Mathews
Dr. Steven Soifer
Terri Walker
Robert Schoening
Dr. Harvey Graves
Liana Romero
Phyllis Jenkins
Stacey Baughman
Josh Geurian
Mike Neuway
Dr. Peter Stout, RTI
Dr. Jeri Miller, RTI
Patrick Campbell
William Baughman
Peggy Jack
Dr. Murray Lappe
Leslie Rau
Phyllis Alexander
Travis Price
Eric Quilter
Heather Wang
Paul Belyus
Sandy Johnson
Murray
William Lynn
Tom Gluodenis
Robert McCormick
Robert Thompson
Todd Johnson
Vergi Geurian
Vivianne Entz
Alicia Sherrell, HHS
Joseph Whelan
Princetta Ruane, HHS
William Thistle
Autumn Szabo, NRC
Christina Moore
Michael Walsh
Tim Nelson
Alison Stockdale, DOJ
Ted Shults
Michael Vincent
James Soares
Claus Pruemper
Tawanda Williams, BEP
Mary Warren, BEP
Richard Hipkins, DOJ
Nevine Gahed, SAMHSA
Toian Vaughn, SAMHSA
Michael McLendon, SAMHSA
Karen Drumgold, BEP

The Federal Register Notice, the agenda, presentations, minutes, and transcripts for the open session are available on the Internet at: https://www.nac.samhsa.gov/DTAB/meetings.aspx.

Call to Order

Dr. Donna Bush, as the Designated Federal Official, called the Board meeting to order at 10:00 a.m. EDT on June 2, 2009. Ms. Erica Harbison of RTI explained the logistics of this web-based meeting.

Implementation of Web-based and Telephonic Meeting Technologies for DTAB Meetings

Robert L. Stephenson II, M.P.H.
Director, Division of Workplace Programs (DWP)
SAMHSA/HHS

Mr. Bob Stephenson, as Chair of the Board, welcomed all participants and explained

the rationale for conducting this meeting via net conferencing.

Implementation of Revised Mandatory Guidelines

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

The purpose of this meeting was to present the progress on the implementation of the revisions to the Mandatory Guidelines that must be completed in the remaining 11 months before the May 1, 2010 effective date.

The summaries of the day's presentations follow below.

Federal Drug Testing Updates

Department of Transportation (DOT) Drug Testing Update

Jim L. Swart, M.S.S.W.
Director, Office of Drug and Alcohol Policy and Compliance, DOT

The United States Court of Appeals for the District of Columbia Circuit issued a ruling on May 15, 2009 that upheld DOT's direct observation drug testing rules applicable to return-to-duty, safety-sensitive transportation industry employees who have already failed or refused to take a prior drug test. The court found that the rules did not violate the Fourth Amendment constitutional prohibition on unreasonable searches and seizures. Direct observation drug testing was ruled reasonable because of the compelling governmental interest in transportation safety. Because there is an opportunity for the parties to seek a re-hearing of the court's ruling, the court's stay of direct observation rule continues in effect, and the direct observation collections for follow-up and return-to-duty testing will remain an employer's option for the duration of the re-hearing process.

DOT will attempt to harmonize with the HHS Guidelines. A draft notice of proposed rule making is underway which will incorporate the new laboratory requirements and many of the definitions contained in the HHS Mandatory Guidelines that go into effect May 2010.

Department of Defense (DoD) Drug Testing Update

COL Ronald Shippee, Ph.D.
Director, Drug Testing and Program Policy, DoD

The DoD website, http://tricare.mil/tma/ddrp/, contains much information, including policies, the directives that control military and DoD civilian testing, the technical guidance for military laboratories, metrics, and the annual report.

DoD tests about 4.5 million military specimens a year. Annual random testing rates are 100 percent for the Air Force, 200 percent for the Army and the Navy, and 300 percent for the Marines. Overall, the positive rate is one to two percent. There are 145 test-sensitive positions within DoD's Personnel Reliability Program which has about an 80 percent test rate. The goal is to conduct 100 percent random testing of our civilian population.

The DoD drug test panels vary in composition between five to nine analytes, including d-amphetamine, Ecstasy, and oxycodone. There is 100 percent screening for heroin. Prevalence studies, in which negative urine specimens from the labs are tested for other drugs, were recently concluded for benzodiazepines, hydrocodone, and methadone. Based on the findings, DoD is considering adding hydrocodone to its test panel, even though this additional testing will challenge the testing process and the Medical Review Officer (MRO) systems.

The new Guidelines incorporate cutoffs that are closer to DoD's and permit offsite screening laboratories. DoD concurs with the HHS stand on the non-instrumented testing devices and on the alternative matrices. For civilian testing, DoD is switching from contractor collectors to government collectors to ensure better quality assurance in the collection phase.

Nuclear Regulatory Commission (NRC) 10 CFR Part 26 Fitness for Duty Program

Paul Harris
Program Manager, Fitness for Duty Program, NRC

Paul Harris introduced himself as the new senior program manager in the Office of Nuclear Security and Incident Response, NRC. Previously, he was the resident and senior inspector at commercial nuclear power plants.

Fitness for Duty is a key program element for the NRC. Part 26 addresses the NRC's Fitness for Duty requirements that certain NRC licensees are required to follow, primarily for those positions that deal with the nuclear life cycle, to ensure that persons who have unescorted access to commercial power plants are fit for duty. NRC uses a four-pronged approach for fitness for duty, which includes drug testing, alcohol testing, fatigue management, and behavior observation. Part 26 was effective March 30, 2009, while the second half of the rule, which contains the fatigue portion, will be implemented October 1. The March 30 rule includes the cost to implement the fitness for duty requirement. The total industry cost is about $582 million for the 100 nuclear power plants and the 65 major nuclear sites. These costs are absorbed by licensees, who pass it on to the consumer through rate adjustments. NRC will monitor the drug, alcohol, and fatigue portions of rule implementation through frequently asked questions, site inspections, and public meetings.

NRC oversees 64 reactor sites; 6 corporate entities, including the Institute for Nuclear Plant Operations (INPO); two Category 1 fuel facilities; BWXT; and Nuclear Fuel Systems. NRC has a mandated inspection program for all its nuclear facilities; priority number one is responding to inspector calls. Licensees inform the NRC of issues that occur during drug testing, blind performance sampling, and confirmatory sampling. NRC is initiating electronic reporting, which will hopefully improve data evaluation and sharing. One certified lab had five reportable events: an inaccurate pre-access test result and four false positive results on performance sampling. One site reported problems with the random drug testing selection process, resulting in persons not being within the testing pool. NRC requires a 50 percent random testing at commercial nuclear power plants.

Several licensees have voluntarily lowered their drug cutoffs to or below the HHS

Guidelines. One-third of all licensees have lowered their blood alcohol concentrations. Four licensees are testing for drugs that are not required by NRC regulation, including barbiturates, methadone, methaqualone, and others.

NRC, as a user of the HHS guidance, conducted 142,203 drug tests in 2007. Out of those tests, 907 were positive (0.65 percent). These positive results fell into four major categories: pre-access (0.82 percent positivity rate), random (0.23 percent), for-cause (observed behavior: 11.25 percent and post-accident: 0.63 percent), and follow-up (0.62 percent). The catchall category was 2.3 percent. Licensees are required to perform behavior observation of their employees. With abnormal behavior, personnel are subjected to for-cause testing. Overall, contractors at nuclear power plants test positive three times as often as site employees. Similarly, testing from behavior observation showed that contractors tested positive three times more often as plant employees. There were 50 percent more employees than contractors with refusal to test. Contractors tested positive for marijuana and cocaine twice as often than employees. And yet, contractors tested positive for alcohol and amphetamines half as many times as employees.

Currently, in 2009, there have been five significant events: a controlled substance in a protected area of a nuclear power plant, an individual with a controlled substance on his body, a false positive error on a blind sample, a non-licensed employee supervisor testing positive for illegal drugs on a follow-up test, and a confirmed positive for alcohol.

For future new reactor construction, NRC is in negotiations with industry representatives concerning testing and sampling populations. They are nearing an agreement of 50 percent testing of the population for new reactor construction. During the construction of a power plant, there are 2000-4000 people on-site at any one time.

Contact information, including phone numbers and emails were given for the NRC staff.

Review of Significant Changes in the Revised Mandatory Guidelines for Federal Workplace Drug Testing Programs

Donna M. Bush, Ph.D., D-ABFT
Drug Testing Team Leader
DWP/SAMHSA/HHS

The history and mission of the Federal employee workplace drug testing program, beginning with the September 15, 1986 Executive Order 12564, was presented. 120 Federal agencies, representing about 2.12 million Federal employees and job applicants, are covered under this program. There are about 400,000 testing-designated positions, with about 210,000 forensic workplace urine drug tests conducted annually.

The 2008 revisions to the Guidelines, effective May 1, 2010, are restricted to urine drug testing only. Six major changes were published in those revisions to the Guidelines: revised requirements for specimen collections; standards for collections and collection-sites; revised laboratory testing requirements; new technologies allowed for confirmatory drug testing; new type of testing facility, called the instrumented initial test facility; and revised standards for Medical Review Officers.

The 18-month implementation period allows time for the development and FDA-clearance of immunoassay test kits, the laboratory validation and implementation of the new immunoassay test kits, performance testing (PT) challenges of the new analytes and cut-offs, evaluation of additional analytical methods that combine chromatographic separation with mass spectrometric identification and development of minimally acceptable acceptance criteria requirements, the implementation of the Guidelines by Federal agencies and the various industries, revision of the Federal Custody and Control Form (CCF) to include the instrumented initial test facilities (IITF) and clearance through the Office of Management and Budget (OMB), and the creation of IITFs. An IITF, which must be National Laboratory Certification Program (NLCP)-certified, can perform the initial drug tests and the first tests conducted to determine specimen validity. The IITF can report specimen results as negative, negative dilute with creatinine levels between 5 and 20 mg/dL, or rejected. IITF specimens with results indicating drug-positive, adulterated, substituted, invalid, or dilute with a creatinine less than or equal to 5 mg/dL must be sent to a certified laboratory for testing.

Effective May 1, 2010, HHS-certified laboratories will test for two new initial drug test analytes: 6-acetylmorphine (6-AM), which is a heroin marker metabolite, and methylenedioxymethamphetamine (MDMA), which has the street name of Ecstasy. Also, the laboratories will perform initial testing of all specimens for 6-AM, regardless of the morphine concentration. Immunoassay manufacturers must either create new immunoassay kits or retool existing ones to meet new cutoff and analyte requirements. The initial test cutoff for amphetamines is decreased to 500 ng/mL. Confirmatory test cutoffs for both methamphetamine and amphetamine are lowered to 250 ng/mL. The amphetamine presence reporting requirement for methamphetamine in the confirmatory testing process has been lowered to 100 ng/mL. For cocaine, the initial test cutoff has been lowered to 150 ng/mL, while the confirmatory test for the cocaine metabolite benzoylecgonine was lowered to 100 ng/mL. New confirmatory test analytes include MDMA, 3,4-methylenedioxyamphetamine (MDA), and methylenedioxyethylamphetamine (MDEA).

New MRO requirements include training on collection procedures, laboratory test results interpretation, chain of custody reporting, record keeping requirements for Federal agency specimens, and the HHS Mandatory Guidelines. MRO actions when donors do not provide sufficient volume for a drug test are now harmonized with DOT's 49 CFR Part 40. The MRO manual will be updated with the 2010 requirements.

Guidelines revisions clarified how a Federal agency can routinely or on a case by case basis test for additional drugs and addressed situations in which there is no initial test kit available for a drug for which a Federal agency wants to test. For blind samples, an agency must submit three percent of the total specimens, regardless of the age of the drug testing program. There are requirements for supplier validations of blind samples, including sample content and concentration ranges. Lastly, an investigation is required for inconsistent blind sample results.

Additional changes are necessitated because of the revised Guidelines. The collection handbook must be updated to include split specimen collections and revised collector requirements, responsibilities, training, and records. Agencies must annually randomly inspect at least 5 percent, or up to 50, of the collection-sites randomly selected. The NLCP documents, including the checklists and manuals, need revision.

NLCP processes and documents for the IITF must be developed. A procedure for the certification of MRO oversight groups must be developed.

Additional notices will be published in the Federal Register requesting information and assistance from the public in providing or identifying data and research findings that address specific areas of interest concerning point of collection testing devices and the use of alternative specimens, such as oral fluid, sweat patches, and hair.

The DWP website has many resources available on general drug-free workplace programs, young adults going into the workplace, and workplace health, wellness, and safety.

NLCP Planned Implementation of the Revised Mandatory Guidelines for Federal Workplace Drug Testing Programs, May 1, 2010

Michael R. Baylor, Ph.D.
Co-Director, National Laboratory Certification Program (NLCP)
Center for Forensic Sciences
RTI International

The NLCP provides oversight of the HHS-certified drug testing facilities and is responsible for the implementation of the Mandatory Guidelines for Federal Workplace Drug Testing Programs, including the inspection and PT programs, the certification application process, inspector training, and the inspection checklist and manuals.

The December 2008 through May 1, 2010 timeline for laboratory document revisions required by the Guidelines was reviewed. The application is a document that is used by the applicant testing facility to assess its staffing, instrumentation, methodologies, and procedures capabilities. Sections A, B, and C of the inspection checklist describe the testing facility's general layout and staffing. Checklist sections D through U describe the inspection and record audit process. The NLCP manual provides a comment, expectation, or explanation concerning the specific criteria or parameter addressed in a checklist question and defines acceptable technical parameters of performance. NLCP inspectors and auditors must receive annual training and remain active in workplace drug testing and forensic toxicology.

Revisions of the laboratory application and sections A, B, and C of the laboratory checklist began in December 2008 and will be submitted to DWP for review and submission to OMB. The expected release date is January/February 2010. Revision of sections B through U of the revised laboratory initial checklist and sections D through U of the laboratory maintenance checklist began in December 2008 and will be submitted to DWP for review. An October release date is anticipated.

The December 2008 through May 1, 2010 timeline for laboratory PT production and shipping cycles, including practice PT (PPT), special PT (SPT), and maintenance PT (MPT) cycles, was given. The manufacture of the PT challenges will begin in August/September 2009 with reference testing completed by October 2009. These practice, non-scored PPT sets will be shipped in November/December while the SPT sets will be shipped January through April with another SPT set shipped just after the implementation date. The normal MPT cycle, encompassing the new Revised Guidelines, would be issued in July 2010.

The December 2008 through May 1, 2010 timeline for IITF document revisions

required by the Guidelines was reviewed. Checklist sections A through C are the IITF application, which essentially solicits information on the laboratory's procedures, instrumentation, staffing, and training of key staff. The initial IITF maintenance checklist is found in sections D through U.

The IITF urine PT cycles would be manufactured in the months of August and September, with reference-testing occurring in October and availability upon implementation in May 2010.

The creation of the IITF application and IITF checklist sections A, B, and C began in December 2008 and will be submitted to DWP for review and submission to OMB. Availability of the application and checklist sections A through C is expected in January/February 2010. The rest of the IITF checklist is expected to be released in October 2009.

The revision of the NLCP manual was begun in April/May and will be submitted to DWP for review, with an expected release date of October 2009. Inspector training materials are in development, with an anticipated release date of November/December 2009. Inspector web-based training will be available by the end of December 2009 and will be conducted during the first four months of 2010.

The new Federal CCF is expected to be released in early 2010. Revision of the inspection/collection handbook has begun and will be submitted to DWP for review, with an expected November/December 2009 release date.

Initial Testing for New Analytes and New Cutoffs

John M. Mitchell, Ph.D.
Co-Director, NLCP
Center for Forensic Sciences
RTI International

The revised Guidelines added new drug analytes and lowered the positive cutoffs for others. New initial test analytes are MDMA, a designer drug that is a structural analog of methamphetamine, which will have a cutoff at 500 ng/mL, and the opiate 6-acetylmorphine, which will have a cutoff at 10 ng/mL. The revised initial test cutoffs for methamphetamine and amphetamine were decreased from 1000 to 500 ng/mL using d-methamphetamine as the calibrator. For cocaine metabolites, the cutoff was dropped from 300 to 150 ng/mL.

Concerns with implementing these changes include the timeline for the implementation; the awareness of required changes by the laboratories' supporting industries, such as the immunoassay manufacturers; availability of the material for implementing the changes, primarily, the immunoassay tests; and the readiness of the laboratories.

The HHS-certified laboratories are expected to have the new immunoassay kits validated prior to the November 2009 PT shipment. Qualifying PT samples will be shipped between January and May 2010.

Three manufacturers, Roche, Siemens, and Thermo Fisher, currently supply immunoassay reagents to the certified laboratories. Roche currently offers a cocaine immunoassay with a 150 ng/mL cutoff. Roche is developing a single kit which would detect amphetamine, methamphetamine, and MDMA with a 500 ng/mL cutoff. They are

not planning to offer a 6-AM immunoassay at the 10 ng/mL cutoff. Siemens currently offers a MDMA kit and an amphetamine/methamphetamine kit at the 500 ng/mL cutoffs and a cocaine kit at the 100 ng/mL cutoff. They are developing a 6-AM kit at the 10 ng/mL cutoff. Thermo Fisher has kits currently available for all of the new analytes as well as the analytes with the revised cutoffs.

The Thermo Fisher CEDIA amphetamine kit has 100 percent cross-reactivity with d-methamphetamine and d-amphetamine while the cross-reactivity with MDMA/MDA is 69 percent or less. The Thermo Fisher DRI amphetamine kit also exhibits 100 percent cross-reactivity with amphetamine and methamphetamine, whereas MDA and MDEA are at 77 percent.

The Siemens MDMA kit has 100 percent cross-reactivity with MDMA while MDA and MDEA cross reactivities are slightly less than 100 percent. The cross-reactivities with d-amphetamine and d-methamphetamine are negligible.

The Thermo Fisher DRI MDMA assay cross-reactivities are 100 percent for MDMA, 56 percent for MDA, and 83 percent for MDEA. Amphetamine and methamphetamine exhibited no cross-reactivity.

Special PT Program

John M. Mitchell, Ph.D.

Between May and October 2009, the laboratories will validate their immunoassays and confirmatory methods for the revised cutoffs and new analytes. In November 2009, the laboratories will receive PPT sets to verify their validations. This pre-tested, unscored, PPT set will consist of 10 to 12 samples with drug analytes at 0.5 to 1.5 times the immunoassay cutoffs and 1 times and 2 times the confirmatory cutoff concentrations. Between January and March 2010, three rounds of qualifying SPT samples, which will contain 15-20 samples focused on the new analytes and the revised cutoffs, will be shipped to the laboratories and scored. For these SPT sets, the targeted analytes will be tested by the validated immunoassays; the laboratories will be directed as to which samples and analytes are to be tested by confirmatory methods. Laboratories with unsatisfactory scores will be remediated with additional focused SPT testing that must be successfully completed by April 2010. If unable to meet acceptability criteria, laboratories will not be allowed to implement new analyte and revised cutoff testing. Three weeks after implementation, all laboratories will receive a limited set of SPT samples which will assess immunoassay specificity, immunoassay hook effects, performance of each immunoassay at plus or minus 25 percent of the cutoff, quantitative accuracy at analyte concentrations from 40 percent of the cutoff up to 20 times the cutoff, confirmatory specificity, and appropriate reporting.

The new cutoffs for benzoylecgonine, the cocaine metabolite, will be 150 ng/mL for the initial test and 100 ng/mL for the confirmatory test. For 6-AM, the initial test and confirmatory cutoffs will be 10 ng/mL. For methamphetamine, the initial cutoff will be 500 ng/mL, while the confirmatory cutoff will be 250 ng/mL and requires that 100 ng/mL or greater of amphetamine be present for all methamphetamine positives. The cutoff for amphetamine is 250 ng/mL for the confirmatory test. For the designer drugs, the cutoff for the initial test will be 500 ng/mL for Ecstasy or MDMA, with confirmatory cutoffs of 250 ng/mL for MDMA, MDA, and MDEA.

The initial PT sets for IITFs will be available upon implementation of the Revised Guidelines, which is anticipated to be May 1, 2010. The NLCP's MPT program will resume in July 2010 and incorporate challenges for all drugs and all testing as specified in the Revised Guidelines.

Instrumented Initial Test Facilities (IITFs)

Susan D. Crumpton, M.S., D-FTCB
Center for Forensic Sciences
RTI International

An IITF is new type of testing facility that will be allowed to perform Federally-regulated workplace urine drug testing under the 2010 Guidelines. An IITF is defined as the permanent location where initial screening for drugs and specimen validity testing, reporting of results, and record keeping are performed under the supervision of a responsible technician. An IITF will provide quick turnaround times for negative and negative-dilute results, which constitute more than 97 percent of the results reported in Federally-regulated workplace programs overall. An IITF is subject to the same forensic and analytical requirements as a certified laboratory, including open and blind performance testing, quality assurance program, site inspections, the use of instrumented immunoassay drug tests which meet FDA requirements for commercial distribution, performance of the required specimen validity tests, the use of HHS cutoffs, and the submission of all non-negative specimens to a full-service HHS-certified laboratory for initial and confirmatory drug testing and specimen validity determination.

Section 12 of the 2010 Guidelines gives the IITF requirements. Section 12.1 requires the IITF to maintain a standard operating procedure (SOP) manual. Sections 12.2 through 12.6 describe the duties, responsibilities, qualifications, and training of the responsible technician (RT), alternate RT, certifying technician, certifying scientist, and other personnel. Section 12.7 addresses IITF security. Section 12.8 addresses internal chain of custody requirements for an IITF. Section 12.9 describes initial drug testing requirements, including the use of immunoassays that have been approved, cleared, or otherwise recognized by FDA as accurate and reliable for drugs of abuse testing. Section 12.10 specifies the required method validation studies and the requirement to verify new reagent lots prior to use. Section 12.11 described quality control requirements. Sections 12.12 through 12.14 describe specimen validity testing, analytical and batch quality control (QC) requirements, and the method validation requirements. Section 12.15 addresses reporting requirements for an IITF. Sections 12.16 and 12.17 provide the requirements for final specimen disposition by an IITF. Section 12.18 addresses records retention. Section 12.19 requires the IITF to submit a statistical summary report to each Federal agency for which testing is performed. Section 12.20 addresses donor access to his or her drug testing records. Section 12.21 prohibits relationships between an IITF and an MRO. Section 12.22 describes the acceptable relationships between an IITF and an HHS-certified lab.

Section 10 addresses Federal agency blind samples that must be sent to an IITF. Section 9 describes the HHS certification of laboratories and IITFs, including the application process, the PT process, PT scoring criteria, the inspection process, the NLCP inspector requirements, and the program actions when an applicant or certified

IITF fails to meet either the PT or the inspection requirements. HHS will publish a list of certified IITFs each month in the Federal Register. Section 16 details the conditions and procedures for suspension or revocation of certification.

IITF application packages should be available in January 2010. Completed applications will not be accepted until May 2010. Once a completed IITF application is deemed acceptable by the NLCP, the IITF will receive two cycles of initial PT and a third initial PT cycle in conjunction with an on-site inspection. The applicant IITF must perform acceptably on the three initial PT cycles and inspection to be certified by HHS. Once certified, the NLCP will maintain oversight of the IITFs through the PT and inspection processes. The fee schedule for IITF PT and inspection processes, including remedial fees, will be published.

Public Comments

Dr. Steven Soifer, the CEO of the International Paruresis Association and an associate professor of Social Work at the University of Maryland, Baltimore, provided public comment on the impact of the Americans with Disabilities Amendments Act on Shy Bladder Syndrome and the Guidelines.

Adjournment

The first day of this two-day meeting adjourned at 4:30 p.m. on June 2, 2009.

June 3, 2009

The Drug Testing Advisory Board meeting was reconvened at 10:00 a.m. EDT on June 3, 2009 in the SAMHSA Building (Sugarloaf and Seneca Conference Rooms), 1 Choke Cherry Road, Rockville, Maryland 20857.

Call to Order

Dr. Donna Bush, as the Designated Federal Official, called the Board meeting to order at 10:00 a.m. EDT on June 3, 2009.

Opening Remarks

Bob Stephenson, as Chair of the Board, welcomed all participants and requested that RTI provide instructions for those attending the meeting via webcast.

The summaries of the day's presentations follow below.

Revised Federal Custody and Control Form (CCF) Update

Charles LoDico, M.S., D-ABFT
Drug Testing Team, DWP, CSAP, SAMHSA

Every Federal CCF has a three-year expiration date to allow for the reassessment of burden hours. The current form expires in September 2009. On April 22, 2009, a Federal Register Notice was published concerning the CCF renewal with a 60 day public comment period on the estimated burden hours. The CCF will be submitted to OMB for approval prior to the expiration date.

For the May 2010 Mandatory Guidelines, the CCF needs revision, mainly to accommodate the inclusion of the IITF on the form. SAMHSA and DOT are collaborating on the revisions. The CCF must be approved by OMB and given an OMB number. The OMB number for the 2010 CCF will be the same as the current CCF.

The 2010 Federal CCF will be used for urine specimens collected for Federal agencies and regulated industry employers. The CCF is used by specimen collectors and the test facility to document the chain of custody of the primary and split specimens, for the IITF to document the transfer of the specimen to the laboratory for further testing, for the test facility to report primary specimen test results to the MRO, and for the MRO to report drug test results to the Federal agency or employer.

Like the current CCF, the 2010 CCF will use checkboxes, have five copies, be 8.5-by-11 inches in size, and have the bottle seal labels affixed to the bottom of Copy 1.

Changes to the 2010 CCF are: the addition of the new drugs: MDMA, MDA, and MDEA; reporting of split specimen test/retest results by the second split laboratory on the MRO copy; changing the “Lab Accession Number” to the “Accession Number”; the addition of “No.” after “Phone”; the specification of the testing authority and the particular DOT agency; the inclusion of a single line for the reasons for test; the addition of the instructions “Collector reads specimen temperature within four minutes”; deletion of the sentence “Reads specimen temperature within four minutes”; rewording of the phrase to “Temperature between 90 degrees and 100 degrees Fahrenheit”; placement of “Temperature”, “Collection”, and “Observed” on a single line; insertion of more space for the collector’s remarks; changing the phrase to “Completed by Test Facility”; additional space for the “Signature of Collector” block; reduction of the size of the “Specimen bottle(s) released to” area; bolding of the line between the “Chain of Custody” of the collector block and the “Received an IITF” block; the addition of an IITF Chain of Custody section; the insertion of an “IITF name and address, if not above” block; rewording and resizing of the “Primary Specimen Bottle Seal Intact” block; the addition of the “Transfer from the IITF to Lab” block; the bolding of the line between the “Received at IITF” block and the “Received at Lab” block; the addition of a space for “Signature of Accessioner” within the “Received at Lab” Chain of Custody section; the changing of the “Primary Specimen Test Results” to the “Primary Specimen Report”; the changing of the “Primary Laboratory” to “Test Facility”; the inclusion of the new drugs and analytes; the staggering of the results checkboxes; the addition of parentheses “△9-THCA” after the marijuana metabolite and “BZE” after the cocaine metabolite; changing the “Rejected for Testing” to “Rejected”; changing “Test Lab, if different from above” to “Test Facility, if different from above”; changing “Certifying Scientist” to “Certifying Technician/Scientist,” on both the signature and the printed-name lines;

deletion of the split specimen test result section; inclusion of a section for “Completed by Split Testing Laboratory”; the addition of a checkbox to indicate “Split Specimen Tested, See Laboratory Report”; inclusion of a section for the split testing laboratory name, city, and state; the reduction of the width of the of the label seals from 0.75 inch to 0.5 inch; changing the footer to read “Copy 1 - Laboratory” to read “Copy 1 - Test Facility”; changing the first sentence in the instructions after Step 5, “Donor Entries” to “After the medical review officer receives the test results for the specimen identified by this form, he/she may contact you to ask about prescriptions and over-the-counter medications you may have taken”; the bolding of the line before Step 6 to separate the donor section from the MRO section; changing the “Determination/Verification” to “Verification” only; the reposition of the “Results” box; the addition of a checkbox for the MRO to specify drug analytes after “Positive”; the insertion of a line for the MRO to specify the adulterant and the reason after “Adulterated”; the addition of “Other” to “Refusal to Test”; the inclusion of an additional line for the MRO’s remarks; changing “Determination/Verification” to “Verification” only; addition of a line for the MRO to specify reconfirmed drug analyte, substitution, or adulteration after “Reconfirmed”; the addition of a “Test Canceled” box; the addition of a line for the MRO to specify drug analytes, substitution, or adulteration that was not confirmed after “Failed to Reconfirm”; and the addition of a “Remarks” line for the MRO to add reasons for “Failed to Reconfirm Results” or for directed actions.

The order of the information on the back of Copy 5 - Donor Copy of the 2010 CCF is unchanged. The major change is altering the instructions for completing the CCF from using a list of alphabetically identified items to be completed by the collector to a format that uses the Step 1 through 4 order that appears on the front of Copy 1.

To approve the 2010 CCF, a Federal Register notice will be published which announces the proposal to revise the current CCF, followed by a 60-day public comment period. When the comment period is over, SAMHSA will evaluate the public comments received and respond to the individual comments. After this process, a final form format will be produced.

Regulated Industry Urine Collector/Collection Site Procedures

Jim L. Swart, M.S.S.W.

The Federal agencies are responsible for inspecting the collection sites that they use. The DOT agencies have been concerned with collection site issues and have the responsibility for inspecting those collection sites used by Federal transportation employers. There are approximately 23,000 collection sites that collect 6-7 million DOT specimens annually. Inspection of these many sites is a huge endeavor. DOT has increased its number of collection site inspections and the number of inspections that are clandestine. DOT agencies now have access to one another’s collection-site inspection findings. The most prevalent, egregious failures found are: allowing donors easy access to a collection site’s own adulterant and dilution materials; failing to supervise donors throughout the collection process; failing to secure water sources; failing to ensure that donors empty their pockets; allowing unauthorized personnel into the collection area, including friends and coworkers of the donors; and failing to set time limits for urination.

To improve the collection process, DOT provides collection site inspector training. To assist the collection sites and inspectors, DOT offers a poster entitled: “10 Steps to Collection Site Security and Integrity”, available in both English and Spanish, and a collection-site video that details the preparation steps for a DOT collection (http://www.dot.gov/ost/dapc/10_Steps_Video_Final/Start.html).

Gathering Information for Presentation in Open Session Meetings for Implementing the Revisions to the Mandatory Guidelines

Donna M. Bush, Ph.D., D-ABFT

The revisions to the Mandatory Guidelines address medical review officer training, examination, and certification requirements and changes in collector and collection site requirements. Implementing these changes will require the creation of two time-limited ad hoc working groups composed of subject-matter experts to supplement the scientific expertise and technical competencies of the DWP’s technical staff and the DTAB members. Members of the MRO working group have been identified and accepted participation. A similar process is underway for the collection-site issues. These working groups will also provide recommendations about revisions to manuals and guidance documents. The working group process is expected to proceed rapidly with electronic-based meetings. The MRO and collector certification recommendations must be considered by the DTAB in open session.

The mission of the MRO working group will be to discuss these changes in the Mandatory Guidelines, to query MRO training and certifying bodies, and to obtain information on their programmatic approaches, and inform the DTAB membership and SAMHSA, who are charged with developing the process whereby the Secretary of HHS will approve the nationally-recognized entities who train and credential licensed MDs or DOs (doctor of osteopathy) wishing to serve as medical review officers. For approval, these certifying entities must submit to the Secretary their application, applicant qualifications, and sample examination initially and annually thereafter. The Secretary will perform an objective review of the entity’s applicant qualification and examination content and publish the list of approved entities in the Federal Register.

Update on Expanded Confirmatory Test Technologies

Jeri Ropero, Ph.D.
Center for Forensic Sciences
RTI International

Per the Guidelines, a confirmatory drug test must combine chromatographic separation with mass spectrometric identification. The revised Guidelines permit the use of expanded confirmatory testing technologies (ECTT), including liquid chromatography/mass spectrometry (LC/MS), gas chromatography/tandem mass spectrometry (GC/MS/MS), and liquid chromatography/tandem mass spectrometry (LC/MS/MS), for Federally-regulated workplace drug testing. Two projects are underway by the NLCP to evaluate these ECTTs as well as develop minimally accepted criteria for ECTTs which will be published in the NLCP Manual for Urine Laboratories.
The Guidelines require that the laboratory validate the ECTT prior to use. Validation

studies include linearity, limit of detection, limit of quantitation, accuracy and precision at cutoff and 40 percent of cutoff, analytical specificity, and carryover. In addition, the laboratory must re-verify its confirmatory drug test methods at least annually.

To gather information to update the NLCP manual, the NLCP conducted 4 forums, each 3 hours in length, to solicit comments from 20 stakeholders with MS-MS experience in the field of forensic toxicology. Topics discussed included chromatography, the MS/MS detector, and maintenance and validation issues. This group is to gather and provide information on minimal acceptance criteria for the ECTT, such as the quality of the chromatography, including narrow, Gaussian-shaped, well-separated peaks with acceptable signal-to-noise ratios. Sections of the manual requiring revision to include ECTT include Section L-12 (minimal acceptance criteria for all quality-control samples and drug-positive specimens), Section L-12 (relative internal standard), Section L-13 (corrective actions for acceptance criteria failure), and L-14 (corrective actions for carryover).

The second project, which began in August 2008, is a GC/MS - LC/MS/MS comparison study whereby RTI is performing the LC/MS/MS analyses while five HHS-certified laboratories are performing the GC/MS analyses. Experiments performed as part of this project included linearity, precision, accuracy, retention time reproducibility, product ion ratios, target analyte and internal standard responses, interference and matrix-effects studies, and method comparison. A manuscript, describing the evaluation of benzoylecgonine, morphine, codeine, and 6-acetylmorphine, will be published in the October special issue of the Journal of Analytical Toxicology. Analysis of the remaining analytes, including PCP, THCA, amphetamine, methamphetamine, MDA, MDMA, and MDEA, is underway.

Public Comment

Mr. Robert Bard addressed the need for alternative matrices for drug testing and asked why the agencies are not considering alternative matrices at this time.

Ms. N.B. Varlotta inquired as to when the notice in the Federal Register will be published for the CCF. She also wondered whether that notice and the CCF will include a statement that indicates that specimen validity testing is required in the testing process. She wants to make sure that every donor knows that he/she is being tested for pH, creatinine, nitrites, and specific gravity.

Mr. Eric Quilter is president of Compliance Information Systems, a company that provides software, data-management imaging, and data storage services for the drug-testing industry. He suggested that the Federal CCF could benefit from the current industry trend towards generating paper CCFs at the collection site. He expects that this process will dramatically reduce collection-site errors, laboratory data-entry errors, waste, and improve reporting and distribution of information. The software-driven collection process would prompt the collector in the correct collection procedures and could be used to monitor individual collector and collection-site performance. In addition, the software improves the acquisition, management, and protection of donor demographic information, employer information, MRO information, and testing instructions.

Adjournment

The second day of this two-day meeting adjourned at 1:00 p.m. EDT on June 3, 2009.

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
Designated Federal Official, DTAB

/SIGNED/

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

These minutes will be formally considered, amended, and approved by the Board using email.