



Update on Pending Changes to Federal Workplace Drug Testing Guidelines

As you know, a document detailing revisions to the Mandatory Guidelines for Federal Workplace Drug Testing Programs was published in the Federal Register on November 25, 2008 (73 FR, No. 228 pp. 71858 – 71907). The changes are effective on May 1, 2010. There are six major changes impacting various participants in the program:

1. Revised requirements for specimen collection
2. Standards for collectors and collection sites
3. Revised laboratory testing requirements
4. New technologies permitted for laboratory confirmatory testing
5. A new type of testing facility, Instrumented Initial Test Facility (IITF) is permitted
6. Revised standards for Medical Review Officers (MRO's)

As a reminder, the HHS guidelines apply to Federal Employees; employees in Federally-regulated industries, such as transportation and nuclear, follow derivative guidelines that are specific to each group (e.g. DOT – 49CFR Part 40; NRC – 10CFR Part 26). In the case of the DOT, the agency is required by the Omnibus Transportation Employee Act of 1991 to adhere to DHHS laboratory testing protocols, and thus on February 4, 2010 the DOT published a Notice of Proposed Rulemaking (NPRM) in the Federal Register seeking to harmonize it's rules with the revised HHS Mandatory Guidelines (75 FR, No. 23, pp. 5722 – 5732). This notice was published without an implementation timeline and there is a 60 day period during which interested parties may submit public comments. While there is currently no firm implementation date for the revisions to 49CFR Part 40, we are proceeding as if the changes to the laboratory testing protocols will be effective on May 1, 2010, the same time as the effective date of the HHS changes. For detail of all the changes, we refer you to the specific Federal Register documents; the most significant changes impacting MEDTOX and thus your testing programs are summarized below:

Testing changes: new drugs and cutoffs

Initial Testing:

Two new analytes are being added to the initial test panel; 6-Acetylmorphine (6MAM, Heroin Metabolite) at a cutoff of 10 ng/ml, and MDMA (Methylenedioxymethamphetamine, Ecstasy) at a cutoff of 500 ng/ml.

Lower initial test cutoffs for Amphetamines and Cocaine Metabolite will be implemented; Amphetamines will be screened at 500 ng/ml (reduced from 1000 ng/ml) and Cocaine Metabolite (Benzoyllecgonine) will be screened at 150 ng/ml (reduced from 300 ng/ml).

To comply with these changes, MEDTOX will add new tests to appropriate regulated drug screening panels. The specifics of the new panels and associated costs will be provided to you directly if you are a current customer with regulated testing. All relevant HHS and DOT testing panels will automatically convert on May 1, 2010 unless the DOT implementation date is different. If that is the case, implementation of DOT changes will occur as directed by the Department.



Confirmation Testing:

New analytes will be added; MDMA, MDA and MDEA at a cutoff of 250 ng/ml. These are the so-called "Designer Amphetamines" that will be detected with the new MDMA screen.

Lower confirmation cutoffs will be implemented for Amphetamines (amphetamine and methamphetamine at 250 ng/ml) and Benzoyllecgonine (100 ng/ml).

New technologies will be permitted; confirmation testing methodologies can employ some of the newer hybrid techniques such as GC-MS-MS and HPLC-MS-MS.

All confirmation results will be reported quantitatively; this eliminates the requirement for laboratories to maintain documentation from individual MRO's requesting quantitative results.

To comply with these changes, MEDTOX has validated methods consistent with the new analytes and lower cutoffs. New test codes will incorporate the new cutoffs and reporting protocols. Confirmation testing changes will automatically activate on May 1, 2010 (or as directed by the DOT). Sample reports will be available in advance of that date to ensure that the transition is a smooth one. MEDTOX will notify clients as newer methodologies are incorporated into testing paradigms.

New Type of Testing Facilities

The revised HHS guidelines provide for certification of testing facilities that perform only initial screening (Instrumented Initial Test Facility – IITF). These facilities will be certified under the guidelines in a manner similar to certification of full-service laboratories. Negative specimen results may be reported directly from the IITF to an MRO; non-negative specimens must be forwarded to a certified laboratory for re-screening and confirmation.

MEDTOX will remain as a full-service certified laboratory so there are no changes to your current program as a result of this change. If you have questions regarding the IITF's, the revised HHS guidelines lay out requirements for these new facilities in detail.

Revised Federal Custody and Control Form

Because of the addition of the IITF component, changes to the Federal CCF have been proposed to incorporate the potential use of these facilities. The proposed revisions were published in the Federal Register on November 17, 2009 (74 FR, No. 220, pp. 59196 – 59205); the comment period closed on January 19, 2010. Following review of all submitted public comments, the Department (DHHS) will respond and publish the final format.

Because the changes have not yet been finalized, new CCF's cannot be printed. MEDTOX is working with our forms provider to ensure that new forms will be available as quickly as possible after the CCF is finalized. We will make sure that our clients are fully updated as information related to the form becomes available.



We will continue to monitor any further developments and updates related to the implementation of the revised workplace drug testing guidelines for both HHS and DOT. Watch this site for the latest information!