



Drug and Alcohol Testing Industry Association

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Department of Transportation (DOT)
1200 New Jersey Avenue, SE
West Building Ground Floor
Room W12-140
Washington, DC 20590-0001

Docket OST-2010-0026

To Whom It May Concern:

Following are the comments of the Drug & Alcohol Testing Industry Association (DATIA) on the Department of Transportation's (DOT) proposed rulemaking to amend certain provisions of its drug testing procedures dealing with laboratory testing of urine specimens, and the roles and standards for specimen collectors and Medical Review Officers.

DATIA is a 1,500+-member national trade association representing the full spectrum of drug and alcohol testing service agents including laboratories, collection sites, third-party administrators, breath alcohol technicians, medical review officers, substance abuse professionals, employers, and testing device manufacturers. Our members represent over 1,000,000 employers and perform over 65,000,000 drug tests per year. DATIA's mission includes working closely with key policy makers in federal agencies and in congress to ensure that the interests of the industry are heard and taken into account when changes in drug and alcohol testing rules are proposed.

DATIA has mixed thoughts on the changes being proposed by the DOT and will address each proposed change individually.

1. The DOT proposes to modify existing and add new definitions to CFR 49 Part 40. DATIA opposes the addition of new definitions for terms that are not even used in CFR 49 Part 40 (Alternate Responsible Technician, Limit of Detection, and Limit of Quantification). Defining words used in another agency's regulations serves no purpose, will only confuse those reading CFR 49 Part 40, and will require the DOT to issue an NPRM to update its regulations each time the other agency updates their definitions. Since the DOT repeatedly refers to the HHS Guidelines in its CFR 49 Part 40 regulations, DATIA instead suggests that the DOT add a separate definition for HHS Guidelines rather than discussing them in the definition of Initial Instrumented Test Facility (IITF).
2. When SAMHSA initially proposed the addition of IITFs, DATIA expressed concern over the additional transfer of non-negative specimens from the IITF to an HHS certified Laboratory. We do not feel these concerns were addressed in HHS' final Mandatory Guidelines, and again submitted chain of custody concerns to the HHS in January 2010. In CFR 49 Part 40.98 (d), the DOT instructs IITFs to follow the HHS guidelines for packaging and transporting the non-negative result to an HHS Certified Laboratory. Since the HHS Guidelines on this subject are somewhat vague, we suggest that the DOT spell out more in-depth regulations given how important chain of custody is in creating a legally defensible result. In addition, §40.98 is entitled "What does an IITF report and how do they report it." Since (d) of this section refers to chain of custody and transport issues, DATIA suggests creating a new section - §40.99 "What does an IITF do with specimens that tested positive, adulterated, substituted, or invalid."
3. DATIA supports the DOT's proposed changes to drugs to be tested and cutoff levels.

4. DATIA supports the requirement for IITFs to provide semi-annual test reports to employers, as appropriate.
5. In regards to the DOT's request for input on MRO certification, DATIA does not see where having a DOT approval process for certification programs would be beneficial. There are currently two MRO certification programs (AAMRO and MROCC) that have successfully been educating and certifying MROs long before such a regulatory requirement existed. DATIA suggests that rather than placing additional regulatory burdens on the MRO community, the DOT should instead look to these organizations to continue providing the services and programs as they have in the past. Both organizations require recertification every six years for 16 CEUs. The DOT requested comments on whether to require 12 CEUs every three years, or recertification every five for MROs and DATIA suggests neither. DATIA suggests that the current industry standard of recertification every 6 years with 16 CEUs be adopted by the DOT.
6. Finally, the DOT requested comments about what types of MRO records should be covered under the record keeping requirements. DATIA believes this should be limited only to pertinent information that an inspector needs in order to verify the testing process was in compliance with Part 40. For example, the inspector should have access to the laboratory report, the verified report, and only limited access to the interview (only enough to confirm that the donor spoke with the MRO, was offered verification, etc.). In most instances the inspector is not qualified to question the MRO's judgment in regards to medical information obtained during the interview.
7. While the DOT did not ask for comments on §40.205 (b) (1) and (2), DATIA would like to request clarification on these requirement since changes were made to this section in the NPRM. This section states that collectors, laboratories, MROs, employers, and other persons implementing these drug-testing regulations are required to supply certain information to correct a problem in a drug test the same business day in which he/she is notified of the problem. DATIA requests clarification and/or a definition from the DOT on "business day." What if notification of a collection problem (i.e. missing information on the CCF) is sent at 5PM, but the collector that collected that particular specimen has left for the day? Or what about when an office that is open until 8PM notifies a service agent of a problem, but the service agent's office closed at 5PM? As you can see, the use of the term business day without further clarification causes some confusion for all service agents.

DATIA thanks the DOT for the opportunity to comment on these issues. Should you have further questions or need clarification, please feel free to contact me at 800-355-1257 or lshelton@datia.org.

Sincerely,



Laura Shelton
Executive Director