



February 22, 2010

To Whom It May Concern:

Many of our clients have contacted us with questions about the Department of Transportation's (DOT) Notice of Proposed Rulemaking (NPRM), CFR Part 40 covering drug testing guidelines for regulated industries. Clinical Reference Laboratory is aware of the NPRM and has thoroughly evaluated the impact of these proposed regulations on the laboratory.

To assist you in the preparation of your specific comments to the DOT, as it also directly impacts your business, we have enclosed a copy of our response to the DOT. Additionally, an electronic copy of the NPRM and our comments are available on our website at [www.crlcorp.com](http://www.crlcorp.com).

All comments must be submitted back to the DOT no later than March 20, 2010.

Sincerely,

A handwritten signature in black ink, appearing to read 'Barry C. Feingold', is written over a light blue background.

Barry C. Feingold  
Sr. V.P. Toxicology & Analytical Services

Encls.



# CLINICAL REFERENCE LABORATORY

February 19, 2010

Mark Snider, Senior Policy Advisor (S-1)  
Office of Drug and Alcohol Policy and Compliance  
1200 New Jersey Ave., SE.,  
Washington, DC 20590

RE: Proposed Procedures for Transportation Workplace Drug and Alcohol Testing Programs (49 CFR Part 40) (Docket OST-2010-0026) (RIN 2105-AD95)

Dear Mr. Snider,

Thank you for the opportunity to comment on the proposed changes to the Department of Transportation CFR Part 40 covering your agency's drug program for regulated industries. Since the proposed rule making is based on the HHS guideline, we felt that comments on these guidelines are appropriate if it affects the validity of the DOT proposed rule making. We have also included our comments submitted on the proposed standardize Chain of Custody Form (CCF), since we feel that these also have an impact on the DOT rule making.

### IITF Comments

We oppose the establishment of these facilities for use by the Department of Transportation Program for the reasons detailed below.

1. Safety
  - a. The purpose of the Department of Transportation Drug Program is the protection of public safety. While Pre-employment, Post Accident and Reasonable Suspicion all require a Negative Drug Test before the individual is allowed to perform a safety sensitive job, a random collection requires a positive test to stop the individual from performing a safety sensitive job. A random collection sample passed through an IITF and then forwarded to a laboratory for screen and confirmation will be delayed 32 to 72 hours. This allows the individual using drugs to continue in their job, placing the public at risk for a longer period of time.

- b. A sample that screens positive just above the cut off at an IITF may screen negative just below the cutoff in the laboratory thereby allowing a positive driver or pilot to continue in their job risking the public's safety. The practice of running a positive initial immunoassay a second time by immunoassay was eliminated from the program many years ago. The proposed implementation of an IITF would return this practice to the program.
  - c. Resealing and shipping unconfirmed positive samples increases the possibility of a shipping accident. Once bottle A has been opened, a bottle A/B re-designation can not be made, so leakage of bottle A in this second shipment would result in a rejected sample. Samples cancelled for this reason would allow an individual to continue performing their job while possibly under the influence of drugs.
2. Chain of Custody
- a. All positives initially tested at an IITF add a greater complexity to the process and greatly increase the opportunity for legal challenge of the Chain of Custody. As currently written, the IITF does not provide the laboratory any of its internal Chain of Custody Forms. This practice is in total conflict with the current requirement that a Certifying Scientist MUST review ALL Chain of Custody documents relating to sample handling (from the time of collection to completion of testing) before Certifying and reporting a result. If a laboratory failed to do this, it would be considered a major program violation requiring corrective action. The proposed guidelines as written would require the laboratory to assume the sample was handled properly at the IITF without any knowledge of these procedures, personnel, or degree of compliance with program requirements. Additionally, if any Chain of Custody or handling problems are discovered at an IITF through NLCP inspections, these problems would affect the validity of the reports from the laboratory.
  - b. The Chain of Custody Form, as proposed, does not provide a legally defensible Chain of Custody document for the sample. The term, Primary Bottle Seal, is used to describe both the seal placed on the bottle at the collection site and the seal used by the IITF to reseal the bottle.
  - c. The current HHS and proposed DOT guidelines do not provide a legally sound nor properly documented/traceable transfer of samples from the IITF to the laboratory. We would recommend that the procedures currently in place for the transfer of B bottle reconfirmations are mandated for this transfer process as well.
  - d. It will be difficult to determine the source of annotations on the Chain of Custody Form such as observations of sample color and odors. This will raise questions in legal challenges.
  - e. The proposed guidance from HHS does not state if the IITF will receive Memorandums of Corrections for non-fatal errors before sending the non-negative samples to the testing laboratory. This will



add further delays to the testing. There may also be duplication of effort if the laboratory has to obtain the same corrective documentation.

3. Consistency of Testing

- a. The test procedures, as currently mandated in the HHS guidelines, would require the confirmation laboratory to retest the sample received from the IITF without knowledge of the results from testing performed by the IITF. This establishes the possibility that the laboratory could report a sample as positive for a drug or SVT while the IITF has legally discoverable test data that could show the sample as negative for that same substance. This most likely would occur around the screening cutoff levels, especially if different immunoassays are used by the IITF and the laboratory.
  - i. For example, consider a sample tested at an IITF that screens positive for Opiates (based on a prescription), is a borderline negative for THC and has a normal Creatinine of 20.1 mg/dL. Based on the Opiate test, the sample is forwarded for testing to the laboratory.
  - ii. Unaware of the IITF results, the laboratory tests the sample and gets a confirmed positive for Codeine/Morphine (based on legal prescription use) but screens the sample THC positive just over the cutoff and confirms a positive THC. It also gets a 19.8 mg/dL for the Creatinine leading to a Dilute sample being reported along with the THC and Opiate positive.
  - iii. The MRO without the knowledge of the test results from the IITF reports the sample as Positive THC and Dilute.
  - iv. If the individual takes this to a legal setting, ALL the test data will be discoverable. In this setting it will be difficult to get a favorable ruling when there is conflicting laboratory data and the MRO would state he was unaware of the IITF data and therefore was not part of their review. This would call into question both the confirming laboratory and the MRO review process.

### Changes in Drugs Tested and Cutoff Levels

#### Cocaine

With the approval of DOT, Clinical Reference Laboratory conducted a study to assess the effect the proposed Guideline changes in Cocaine cutoffs will have on the program. The results of that study are detailed in Table #1. The summary and conclusion are listed below.

1. A total of 5,173 de-identified samples were evaluated using the proposed lower Cocaine screening and confirmation cutoffs. When evaluated against



these cutoffs the number of screened positives samples increased from 9 to 17. All of the samples screened above the 150 ng/mL cutoff were confirmed by GC/MS and confirmed positive above the 100 ng/mL cutoff.

2. This represents an 88% increase in the detection rate for Cocaine.
3. This change does not increase the number of immunoassay tests performed. The increase in confirmation tests resulted in an equal increase in the number of confirmed positives, thus making for a more effective program.

Based on the results from the above study, and the points detailed below, we firmly support lowering the screening and confirmation cutoffs for Cocaine.

1. The available immunoassay kits from several manufactures have the sensitivity to support the lower cutoff without any increase in cross-reactivity. Positive immunoassay samples all confirmed positive using the lower confirmation levels.
2. Based on studies conducted by CRL, the detection rate of Cocaine will increase by 88%.
3. This change will not add any cost to the screening tests, very little to the confirmatory testing and represents an increase in public safety.

### **Amphetamines**

With the approval of DOT, Clinical Reference Laboratory conducted a study to assess the effect the proposed Guideline changes in Amphetamine cutoffs and the addition of MDMA testing will have on the program. The results of that study are detailed in Table #2. The summary and conclusion are listed below.

1. A total of 3,092 de-identified samples were evaluated using the proposed lower Amphetamine screening cutoff. When evaluated against the cutoff the number of screened positives samples increased from 11 to 40 (a 363% increase) with no additional reportable positives for Methamphetamine or Amphetamines. Ephedrine was detected in 10 of these samples.
2. A total of 3,081 de-identified samples were screened for MDMA and resulted in 10 additional screened positives, none of which showed any trace of MDMA, MDEA or MDA through confirmation testing. One sample tested positive for 1-Methamphetamine.
3. Overall the change in the guidelines would result in twice the number of screening tests (addition of MDMA) and increasing the number of confirmations performed from 11 to 51 (a 490% increase) with no additional reportable positive samples.

We completed a data review of confirmation testing performed at Clinical Reference Laboratory over a five day period. These samples were screened and confirmed under the current program cutoffs; however GC/MS data displayed the Methamphetamine/Amphetamine concentration down to the Limit of Quantitation. A summary of this data is detailed in Table #3.



1. Of the 124 samples that screened positive for Amphetamines using the current 1000 ng/mL cutoff, 45 were negative, 53 confirmed positive for Amphetamines only and 26 were positive for Methamphetamine (13 with reportable Amphetamine levels). There were 4 additional samples in the 300 to 400 ng/mL range for both Methamphetamine and Amphetamine that could have been reported as positive by simply lowering the confirmation cutoff to the proposed 250 ng/mL level.
2. This represents a 15% increase in the reportable positive Methamphetamine with no additional costs or delays in reporting.

Based on our study, data review and the well known testing limitations detailed below, we oppose the proposed lowering of the screening cutoff for Amphetamines and the addition of MDMA Screening and Confirmation. Based on the increased confirmation rate demonstrated in the data review, we support the lowering of the confirmation cutoff without any changes to the screening cutoff.

1. The Amphetamine Immunoassay reagents can not support the lower cutoff. At the lower cutoffs, there is a major increase in the screened positive samples due to the increased cross-reactivity from over the counter and other medications such as Ephedrine/Pseudoephedrine/PPA.
2. No additional positives were detected for Methamphetamine or Amphetamine.
3. The MDMA screening reagent did not detect a single confirmable positive for MDMA, MDA or MDEA.
4. Lowering the confirmation cutoff for samples screened positive at 1000 ng/mL resulted in a 15% increase in the detection of Methamphetamine with no additional costs to the laboratory or the program.

### Opiates

Clinical Reference Laboratory conducted a study consisting of 820 non-regulated samples testing for both Opiates and 6-AcetylMorphine (6-AM). With ONE exception, there were no 6-AM immunoassay screens above 3ng/mL that did not have a positive Opiate screen above the 2000 ng/mL level. Therefore there would be no additional positives generated by screening for 6-AM.

The lone exception was a sample that screened positive for 6-AM at 11.7 ng/mL and confirmed positive for 6-AM at 11.8 ng/mL. This sample screened baseline negative for Opiates and was confirmed negative at Limit of Detection for Morphine, Codeine, Hydrocodone, Hydromorphone, Oxycodone or Oxymorphone by GC/MS.

We oppose the addition of 6-AcetylMorphine as a screening test based on the above study that showed no benefits to the program and these additional reasons below.



1. There is no published scientific explanation for the detection of 6-AM without the presence of Morphine. The program must provide guidance to the MRO's and the laboratory on how to handle these samples or require the detection of Morphine before a 6-AM can be reported.
2. There is only one reagent manufacturer with an FDA cleared kit. This forces the laboratories that use an alternative reagent vendor to buy a single reagent from the sole provider at an inflated price or switch manufacturers for all their tests.

#### **Summary of Adverse Effect of IITF**

1. Creates delays in the reporting of any sample that requires confirmatory drug or SVT analysis.
2. Creates problems with Chain of Custody during the transfer of the sample from the IITF and the laboratory.
3. Creates a gap in the Chain of Custody review process related to the handling of the sample at the IITF.
4. Creates a situation where there may be contradictory data for samples reported positive.

#### **Summary of Positive and Negative Effects of Changes to the Testing**

1. The proposed rules would increase the cost of testing by adding two new high priced screens. The cost of the 6-AM and MDMA reagent, in general, cost the same as the current total 5 drugs and SVT testing panel.
2. The addition of these screens reduce the instrument capacity by 20%
3. The lowering of the Amphetamine screening cutoff and the additional MDMA screening increased the number of samples requiring confirmation by over 400% without a single additional reportable positive.
4. The testing and reporting of 6-AM without the detection of Morphine has no scientific basis and forces the MRO to make decisions without scientific basis or guidance from the program.
5. Gains to the program can be accomplished by making the proposed changes to Cocaine testing and lower the Amphetamine confirmation cutoff. These two changes would increase the rate of Cocaine detection by 88% and the Methamphetamine detection rate would increased by 15%.

#### **HHS Statistics**

We concur with the HHS estimate of addition positive samples; however, disagree with the additional testing and costs incurred by the laboratories and the industry to achieve this small (positive) detection increase. The same increase can be achieved by making the proposed changes for Cocaine and lowering only the Methamphetamine/Amphetamine confirmation levels to 250 ng/mL.

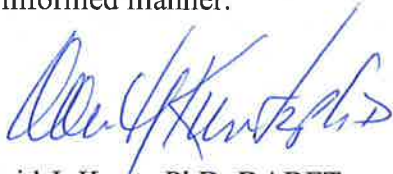
Lowering the Amphetamine screening levels, the addition of MDMA screening and confirmation, and the addition of 6-AM testing results in no additional reportable positive



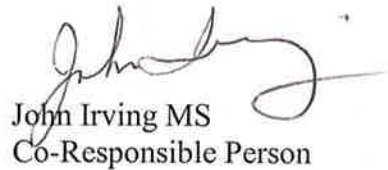
samples. However, these changes create major cost increases and testing delays while questioning one of the basic assumptions of the program. (That the detection of 6-AM and Morphine together proves the use of Heroin.)

### Summary

Clinical Reference Laboratory applauds HHS and DOT for their efforts to continually improve the effectiveness of the Federal Drug Testing Program. We hope that these comments are viewed as our effort to assist in this process. We at Clinical Reference Laboratory stand committed to these same goals as illustrated by our willingness to perform the studies referenced throughout our response. We are willing to assist in future studies or assist with the evaluation of data in an effort to move the program forward in an informed manner.



David J. Kuntz PhD, DABFT  
Co-Responsible Person



John Irving MS  
Co-Responsible Person



Table #1

<b>Regulated Cocaines Tested Under New Guideline Criteria</b>		
Screening	Screening Value	Confirmation Value (ng/mL)
Screened Positive $\geq 150$ but $< 300$	166	134
Screened Positive $\geq 150$ but $< 300$	210	159
Screened Positive $\geq 150$ but $< 300$	211	165
Screened Positive $\geq 150$ but $< 300$	221	209
Screened Positive $\geq 150$ but $< 300$	222	187
Screened Positive $\geq 150$ but $< 300$	250	219
Screened Positive $\geq 150$ but $< 300$	278	262
Screened Positive $\geq 150$ but $< 300$	293	229
Screened Positive $\geq 300$	330	406
Screened Positive $\geq 300$	336	412
Screened Positive $\geq 300$	358	503
Screened Positive $\geq 300$	369	529
Screened Positive $\geq 300$	370	547
Screened Positive $\geq 300$	371	522
Screened Positive $\geq 300$	371	534
Screened Positive $\geq 300$	404	532
Screened Positive $\geq 300$	435	1011

Total Screened	5173
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	Positive Screens	Positive Confirmation
Screened Positive $\geq 300$	9	9
Screened Positive $\geq 150$	17	17



Table #2

**Summary of DOT Samples tested for Amphetamine and MDMA**

	Initial Screening at 1000 ng/mL for Amphetamines	Samples Rescreened at 500 ng/mL for Amphetamines	Samples Rescreened at 500 ng/mL for MDMA
<b>Total Samples</b>	3092	3081	3081
<b>Screening Positives</b>			
Methamphetamine	11	39	N/A
MDMAM/MDA/MDEA	N/A	N/A	10
<b>Confirmations</b>			
Methamphetamine Positive	2	0	1 (L-methamphetamine)
Amphetamine Only Positive	5	0	0
MDMA Positive	N/A	0	0
MDA Positive	N/A	0	0
MDEA Positive	N/A	0	0
Ephedrine/Pseudoephedrine/PPA	N/A	16	0
Reportable as Negative Under the Revised Guidelines	4	39	10

Samples positive screened at 1000 ng/mL were not repeated for tested for MDMA



Table #3

Data Review of Methamphetamine/Amphetamine Confirmation Results

	Reportable Result	Number
Current Confirmation Cutoff (500 ng/mL)		
	Samples Confirmed Negative	45
	Samples Confirmed Amphetamine Positive	53
	Samples Confirmed Methamphetamine Positive	13
	Samples Confirmed Methamphetamine/Amphetamine Positive	13
Proposed Confirmation Cutoff (250 ng/mL)		
	Samples Confirmed Negative	41
	Samples Confirmed Amphetamine Positive	53
	Samples Confirmed Methamphetamine Positive	13
	Samples Confirmed Methamphetamine/Amphetamine Positive	17
Total Positive Screens Tested		124





January 18, 2010

Robert L. Stephenson II, M.P.H.  
Director, Division of Workplace Programs (DWP)  
Center for Substance Abuse Prevention (CSAP)  
1 Coke Cherry Road, Room 2-1035,  
Rockville, MD 20857

RE: Proposed Revisions to Federal Drug Testing Custody and Control Form (OMB NO. 0930-0158)

Dear Mr. Stephenson,

We are responding to your request for comments on the proposed changes to the Custody and Control Form (CCF). The letter contains both comments on the proposed CCF form and a suggested Alternate Procedure for the testing and Chain of Custody for samples forwarded to full service laboratories for testing.

**Comments on the Proposed Changes to the CCF**

We do not see the need to require all Laboratories to waste a substantial amount of space on the CCF for IITF's. We suggest that only IITF's are required to use a form that has space allotted for COC that includes both laboratories. We are submitting an Alternate Proposal for your consideration in the second half of this letter that will maintain the CCF in its current configuration, provides tighter documented control of the samples and addresses the concern of conflicting immunoassay data existing on a sample reported as positive.

If the program does proceed with the concept of the single form then the followed comments are submitted for your consideration.

1. As required by the Guidelines, the identity of both laboratories needs to be on the form and provided to the donor, at the time of collection. This information also needs to be provided to the MRO on their copy.
2. The collection of the additional Testing Authority, places a new requirement for date collection on the laboratories. Laboratories will require time to modify their computer systems to collect this information.

3. We do not agree with the removal of the dashes in the SSN. These are helpful to both the donor and collector when they are filling out the form and to the data entry personnel in the laboratory.
4. Step 4 of the form does not allow for the level of Chain of Custody that has been required by the program.
  - a. There is no place for the IITF to identify which laboratory it is sending the sample, there is only the reduced space box to document the identity of the courier.
  - b. There is no place for the second laboratory to indicate the condition of the resealed bottle. The proposed form only has a space that has Primary Seal Bottle Seal Intact. There has to be additional space to document the condition of resealed bottles.
5. Certifying Scientists (CS) are currently required to review the internal Bottle CCF's as part of the certification process, however if the sample goes through an IITF, the CS can not perform this review. The IITF MUST provide its internal Bottle COC along with the sample.
6. The IITF needs to provide the second laboratory the results of their testing. We believe the possibility of negative immunoassay results for a sample that is tested and reported as positive for the same drug class by the second laboratory will create legal problems for the program. While the laboratories understand the limitations of Immunoassay, this level of understanding does not extend to the MRO or Legal communities. We do not think it is in the best interests of the program to raise the issue of the limitations of the immunoassay testing.
7. The reduction of the width of the security labels will result in more samples rejected for broken seals and make it more difficult for the collectors to seal the bottles without tearing the seals.

### **Alternative Proposal for CCF**

Instead of taking up space and making a more confusing form to handle the limited number of samples that will be sent by IITF's that will require further testing, we believe the following proposal will achieve the intended goals but will also result in a sounder, more defensible system. We propose that the CCF is modified as detailed below and the IITF use a standardized continuation COC form and utilize the tracking procedures now required for bottle B handling to forward samples to the full service laboratory.

### **Modifications of the Current CCF (All other parts of the form remain unchanged)**

1. For IITF's, print the CCF with the name of both the IITF and the Full Service Laboratory. For all other laboratories print only the Full Service Laboratory.
2. Make all the proposed reference changes from laboratory to Test Facility.
3. Add the Testing Authority information boxes.
4. Add the additional drugs to the report section.
5. Add the Certifying Technician to the signature line.

### Procedure for Transfer of Samples

1. The IITF completes a continuation COC that also includes the reason the sample is being forwarded to the Full Service Laboratory.
2. Include a copy of the IITF's Bottle COC.
3. The IITF follows the same notification procedures and notifications that are currently required for Bottle B Testing
4. The IITF notifies the MRO of the transfer.

### Procedure for Full Testing Laboratory

1. Receives the samples and follows the same procedures it uses for the receipt of Bottle B samples including notification of the MRO.
2. Tests the sample ONLY for screened positive drug classes (perform screen and confirmation) or the required SVT tests.

### Advantages of this Alternative

1. Provides the donor and the MRO the name of all laboratories that are involved in the testing of the sample.
2. Prevents the possibility of a reported positive sample that has negative immunoassay results from the IITF. This data would be discoverable in legal proceedings and MRO's will be very uneasy to report the positive not knowing if conflicting data exists on the sample.
3. Provides a better accounting for non-negative samples initial tested by IITF's.
4. Does not reduce the useable space available for the collection and laboratory personnel
5. Maintains the width of the security seals.
6. Maintains the area for reporting Bottle B testing.
7. The laboratories can continue to use their current supply of forms by stamping the additional drugs tested on the bottom of the form and print the boxes to collect the Test Authority information on the form when they print the client and MRO information.

Thank you for the opportunity to submit our comments on the proposed changes. CRL is committed to the continual improvement of the Federal Drug Testing Program.



David J. Kuntz PhD, DABFT  
Co-Responsible Person



John Irving MS  
Co-Responsible Person