

CLINICAL REFERENCE LABORATORY
8433 Quivira Road
Lenexa, Kansas 66215

January 18, 2010

Robert 1. Stephenson II, M.P.H.
Director, Division of Workplace Programs (DWP)
Center for Substance Abuse Prevention (CSAP)
I 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
1. 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
Responsible Person