The Electronic Custody and Control Form (eCCF) Process

Presented by:
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Today’s presenters

The Electronic Custody and Control Form (eCCF) Process

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Agenda

The Electronic Custody and Control Form (eCCF) Process

- eCCF background
- FormFox® eCCF
- eScreen® 123 eCCF
- After the collection
- 2017 Federal CCF
eCCF Background
Lifecycle of an eCCF drug test

1. Online drug test order
2. Collection
3. Specimen sent to laboratory
4. Specimen received at lab
5. Chain of custody verified
6. Donor demographics verified
7. Specimen screened
8. Results confirmed (as needed)
9. Certifying Review
10. View status collection to lab
11. Results reported
Definitions

- **Authoritative Copy:** The single printout of the Federal eCCF Copy-1 (i.e., with *printed electronic signature* of the collector) that is sent to the test facility with the specimen and used as the chain of custody form by the test facility.

- **Digitized Signature:** A handwritten signature that has been read by a computer device, which has converted the signature into digital form. A digitized signature is a type of electronic signature (see below).

- **Electronic Signature:** An electronic sound, symbol, or process attached to or logically associated with an electronic record and executed or adopted by a person with the intent to sign the electronic record.

- **Wet (or Wet-Ink) Signature:** A signature subscribed (signed) directly onto the (paper) document in ink (wet-ink) by the person.
Federal CCF

3 Types

- Paper
- Electronic CCF (eCCF)
- Combination Electronic/Paper
Federal CCF: Paper

- Preprinted, multiple-part carbonless form, or
- Multiple-part CCF that is printed at the collection site, prior to the collection (i.e., “print on-demand” form)
Federal CCF: Electronic CCF (eCCF)

- An electronic CCF is an electronic document used to record all CCF events from collection through reporting. The collector and the test facility personnel attesting to receipt and certification of test results sign the eCCF using electronic signatures. The donor signs the eCCF using a digitized signature. The electronic CCF is the chain of custody.
  - Include a printed copy of the Test Facility copy (i.e., Copy 1) of the Federal CCF with the specimen, or
  - When a printed copy is not included, apply a label to the outside of the specimen package, with the specimen identification number, test facility name and contact information, and collection site name and contact information.

The eCCF is the chain of custody. If included, the printed copy of the Test Facility copy is for informational purposes only and cannot serve as the chain of custody.
Federal CCF: combination electronic/paper CCF

2 Types

- Type 1
  - Print-on-demand
  - All five (5) copies printed
  - ‘Wet-Ink’ signature
    - Donor – Copies 2-4
    - Collector – Copies 1-5

- Type 2
  - Print-on-demand
  - Digitized signature (Donor & Collector)
  - One (Copy-1) or more printed copies
## eCCF review and approval process

<table>
<thead>
<tr>
<th>Lab</th>
<th>Submission Received</th>
<th>Lab Response(s) and NLCP Reports</th>
<th>NLCP Final Report</th>
<th>Inspection Date</th>
<th>NLCP Inspection Report</th>
<th>Lab Response(s) and NLCP Reports</th>
<th>NLCP Report &amp; Recommendation to HHS</th>
<th>HHS Letter</th>
</tr>
</thead>
<tbody>
<tr>
<td>C-2</td>
<td>10/19/2015</td>
<td>revised submission</td>
<td>2/12/2016</td>
<td>3/16/2016</td>
<td>4/19/2016</td>
<td>5/2/2016</td>
<td>7/11/2016</td>
<td>Approved</td>
</tr>
</tbody>
</table>

Source: eCCF Updates 2017 by Charles Lodico, MS, F-ABFT, Drug Testing Advisory Board, March 20, 2017
Labs with approved eCCF systems

3 eCCF systems, 4 laboratory networks HHS-certified as of January 2017

- **eScreen (eScreen®123) – Type 2**
  - Alere (Gretna (LA) & Richmond (VA))
  - Clinical Reference Laboratories (Lenexa (KS))

- **FormFox® – Type 2**
  - Quest Diagnostics (Lenexa (KS), Norristown (PA), Tucker (GA) & West Hills (CA))

- **LabCorp – Type 1**
  - Houston (TX), Raritan (NJ), RTP (NC) & Southaven (MS)

Source: [https://www.samhsa.gov/workplace/resources/drug-testing/eccf-approved-list](https://www.samhsa.gov/workplace/resources/drug-testing/eccf-approved-list)
Benefits of eCCF

Implements collection process

- Common recoverable flaws are eliminated
  - Temperature not indicated
  - Missing collector name or signature
- Eliminates most common Fatal Flaw of No Printed and Signed Collector Name
- Compliance with collection protocols through wizard-driven process
- Improved, consistent turnaround time for delivery of the Medical Review Officer (MRO) Copy 2 of the eCCF
- Testing Authority will be marked with an electronic order
- Improved legibility – no need to decipher handwritten CCFs
- Clearly identified collection site demographics and collector name
Benefits of eCCF

Streamlined delivery to MRO

- Clear Copy 2 can be immediately delivered to the current MRO of record with the laboratory
- Legible donor identification and contact information improves MRO review process
Benefits of eCCF

Follows collection protocols

- Step-by-step wizards drive the collection process
- Normal Collections
- Shy Bladder
- Temperature Out of Range
  - Second collection linked to first
Benefits of eCCF

Complies with DOT procedures

- eCCF system ensures compliance with required Direct Observations
- Attempts to tamper with the collection process
- Temperature out of range
- Return to Duty
- Follow-up collections

DOT's Direct Observation Procedures
Office of Drug and Alcohol Policy and Compliance
U.S. Department of Transportation

1. DOT's 49 CFR Part 40 directly observed collections are authorized and required only when:
   - The employee attempts to tamper with his or her specimen at the collection site.
   - The specimen temperature is outside the acceptable range.
   - The specimen shows signs of tampering - unusual color / odor / characteristic:
   - The collector finds an item in the employee's pockets or wallet which appears to be brought into the site to contaminate a specimen or the collector notes conduct suggesting tampering.
   - The Medical Review Officer (MRO) orders the direct observation because:
     - The employee has no legitimate medical reason for certain typical laboratory results, or
     - The employee's positive or negative (postpositive / substituted test result had to be cancelled because the split specimen test would not be performed (for example, the split was not collected).
   - The test is a follow-up test or a Return-to-Duty test.

2. The observer must be the same gender as the employee.

3. If the collector is not the observer, the collector must instruct the observer about the procedures for checking the employee for precast or other devices assigned to carry "clean" urine and urine substituted AND for watching the employee urinate into the collection container:
   - The observer requests the employee to remove his or her shirt, undergarments, or upper clothing, as appropriate, above the waist, and lower clothing and underpants to mid-thigh and show the observer, by turning around, that the employee does not have such devices.
   - If the Employee Has a Device: The observer immediately notifies the collector; the collector stops the collection and the collector thoroughly documents the circumstances surrounding the event in the remarks section of DOT. The collector verifies the SAC. This is a refusal to test.
   - If the Employee Does Not Have a Device: The employee is permitted to return coming to its proper position for the observed collection. The observer must watch the urine go from the employee's body into the collection container. The observer must watch as the employee takes the specimen to the collector. The collector then completes the collection process.

4. Failure of the employee to permit any part of the direct observation procedure is a refusal to test.
Online FormFox®
eCCF demonstration
eScreen® 123 eCCF
eCCF using eScreen® 123

Courtesy of eScreen

- Donor and Collector certification and digitized signatures
eCCF using eScreen® 123

- If an exception occurs like invalid temperature, software enforces the regulations for the exception.
eCCF using eScreen® 123

Fourth collection is added automatically to the waiting list and indicates 2nd collection

<table>
<thead>
<tr>
<th>First Name</th>
<th>Test Type</th>
<th>Date/Time</th>
<th>Status</th>
</tr>
</thead>
<tbody>
<tr>
<td>test test</td>
<td>eCup Instant Test</td>
<td>4/11/2017 09:55 AM</td>
<td>In Process - Beau Norris</td>
</tr>
<tr>
<td>John Doe</td>
<td>DOT Collection • 2 of 2 •</td>
<td>4/12/2017 10:26 AM</td>
<td>Waiting</td>
</tr>
</tbody>
</table>
eCCF using eScreen® 123

Courtesy of eScreen

- Second collection requires collector to indicate observed and automatically references the first collection in comments
After the eCCF collection
Lab process with current approved systems

No change to process after specimen is accessioned (logged-in)

- Lab accessioning
  - Data manually keyed, as per traditional paper process, or
  - eCCF collection system sends specimen and donor demographics to laboratory information management system (LIMS)
    - Lab scans CCF barcode
    - Electronic data pulled into record from LIMS ‘cloud’
    - Accessioner verifies demographic data – Copy-1 vs. LIMS

- CCF Copy-1 signed (wet-ink) by accessioner
  - External chain of custody ends as per traditional paper process

- After testing, Certifying Scientist completes Copy-1 as per traditional paper process
  - Marks results – Negative or Non-negative, remarks
  - Initials (negative) CCF / Signs CCF (non-negative) – Wet-Ink
  - Transmits results to MRO as per traditional paper process
Specimens Received with an Incorrect/Incomplete Custody and Control Form (CCF)

NLCP decision tree April 8, 2016 – Paper / Type 1

5-PART PAPER CCF and COMBINATION ELECTRONIC/PAPER CCF OPTION 1*

No SIGNED CCF Copy 1 in Specimen Package

- No CCF
- Copy 1 missing collector signature and printed name
- Copy 2-5
- Copy 1 missing collector signature, printed name present

Accept and process specimen. Note omission on report

REJECT

Received Explanatory MFR from collector AND Copy 1 with collector wet signature (sent to lab by courier/mail)

- YES
- NO

REJECT**

Received Explanatory MFR from collector

- YES
- NO

Accept and process specimen

* The collector uses an electronic CCF to document the collection process, then prints all copies (Copies 1-5) for wet signatures.

** Wait at least 5 business days while attempting to obtain required documents. If reason for test is post-accident or reasonable suspicion/cause, notify the NLCP and federal agency for guidance before rejecting.
Specimens Received with an Incorrect/Incomplete Custody and Control Form (CCF)

NLCP decision tree April 8, 2016 –Type 2

*The collector uses an electronic CCF to document the collection process; the collector and donor sign using electronic signatures, and the collector prints Copy 1 with his or her electronic signature. The printout of the ECCF Copy 1 must be designated as the single authoritative copy of the ECCF:
- The collector designates the printed Copy 1 as the authoritative copy by signing it using a wet signature, OR
- The copy must be produced as the single authoritative copy using the validated ECCF system.

**MFR not required if collector includes explanatory remarks in Step 2 of the CCF Copy 1 received with the specimen.

***Wait at least 5 business days while attempting to obtain required documents. If reason for test is post-accident or reasonable suspicion/cause, notify the NLCP and federal agency for guidance before rejecting.
Specimens Received with an Incorrect/Incomplete Custody and Control Form (CCF)

NLCP decision tree April 8, 2016 – Upgrade

*The collector uses an electronic CCF to document the collection process, the collector and donor sign using electronic signatures, and the collector prints Copy 1 with his or her electronic signature. The printout of the CCF Copy 1 must be designated as the single authoritative copy of the CCF.

**Same system infrastructure, servers, security, electronic signatures, authoritative copy requirements, etc. as described in the laboratory’s ECCF submission and verified during inspection (e.g., verification and documentation explained in laboratory SOP).
Challenges

Some familiar, some new

- What if the eCCF doesn’t print correctly?
  - Authoritative Copy vs. re-print vs. duplicate

- What if the tamper-evident seals are damaged during application?

- How to ensure ‘uniqueness’ of specimen ID numbers with different collection systems?

- If ‘paperless’ (i.e. true, eCCF), how to identify sending system if no electronic data in LIMS cloud?

- Upgrades/Downgrades
eCCF utilization and flaws

Data from one laboratory testing ~50K Federal CCFs/month

Source: eCCF Updates 2017 by Charles Lodico, MS, F-ABFT, Drug Testing Advisory Board, March 20, 2017
eCCF utilization and flaws

Non-regulated eCCF use at 46%, up 10% since October 2015

Source: Quest Diagnostics
Percentage of Federal eCCF fatal flaws

October 2016 to March 2017

Fatal flaw reason:
- No Authoritative Copy of CCF Received
- Uncorrected Flaw, Wrong CCF used
- Specimen ID Mismatch
- Insufficient Specimen Quantity
- Uncorrected Flaw, Wrong CCF Used
- Uncorrected Flaw, No MFR Received From Collector
- Specimen Leaked in Transit
- Specimen ID Number Missing on Tamper-Evident Seal
- Tamper-Evident Seal Broken
- Specimen Received with No CCF

Source: Quest Diagnostics
Comparison of top Federal fatal flaws (eCCF vs. paper)

January 2015 to March 2017

Source: Quest Diagnostics
Comparison of top Non-Federal fatal flaws (eCCF vs. paper)

January 2015 to March 2017

- Tamper-Evident Seal Missing or Misapplied
- Specimen ID Missing on Tamper-Evident Seal
- Insufficient Specimen Quantity
- Specimen ID Illegible
- Collector’s Printed Name and Signature Missing
- Tamper-Evident Seal Broken
- No specimen submitted with CCF
- Specimen Leaked in Transit
- Specimen Received with No CCF
- Specimen ID Mismatch

Source: Quest Diagnostics
2017 Federal CCF
2017 Federal CCF

2017 Changes to mandatory guidelines and simplification

• Step 1D: Specify Testing Authority
  • Remove the checkbox, the letters “DOT”, and hash line in front of Specify DOT Agency
    • Eliminates need to check both DOT and the mode

• Step 5A: Primary Specimen Report - Completed by Test Facility
  • Addition of four new analytes (oxycodone, oxymorphone, hydrocodone, and hydromorphone)
  • Removal of the analyte MDEA, or methylenedioxyethylamphetamine
  • Consistency with revised Mandatory Guidelines, effective 10/1/2017
### Step 1D
Federal CCF

**STEP 1: COMPLETED BY COLLECTOR OR EMPLOYER REPRESENTATIVE**

A. Employer Name, Address, I.D. No.  
B. MRO Name, Address, Phone No. and Fax No.

C. Donor SSN or Employee I.D. No. ________________________________

D. Specify Testing Authority:  
   - HHS  
   - NRC  
   - Specify DOT Agency:  
     - FMCSA  
     - FAA  
     - FRA  
     - FTA  
     - PHMSA  
     - USCG  

E. Reason for Test:  
   - Pre-employment  
   - Random  
   - Reasonable Suspicion/Cause  
   - Post Accident  
   - Return to Duty  
   - Follow-up  
   - Other (specify) ________________

F. Drug Tests to be Performed:  
   - THC, COC, PCP, OPI, AMP  
   - THC & COC Only  
   - Other (specify) ____________________________

G. Collection Site Address:

Collector Phone No. ________________________________

Collector Fax No. ________________________________
Step 5A

Federal CCF

STEP 5A: PRIMARY SPECIMEN REPORT - COMPLETED BY TEST FACILITY

☐ NEGATIVE  ☐ POSITIVE for:  ☐ Marijuana Metabolite (\(\Delta 9\)-THCA)  ☐ Methamphetamine  ☐ MDMA  ☐ 6-Acetylmorphine  ☐ OXYC  ☐ HYC
☐ Cocaine Metabolite (BZE)  ☐ Amphetamine  ☐ MDA  ☐ Morphine  ☐ OXYM  ☐ HYM
☐ PCP  ☐ REJECTED FOR TESTING  ☐ ADULTERATED  ☐ SUBSTITUTED  ☐ INVALID RESULT

REMARKS:

Test Facility (if different from above):

I certify that the specimen identified on this form was examined upon receipt, handled using chain of custody procedures, analyzed, and reported in accordance with applicable Federal requirements.

X

Signature of Certifying Technician/Scientist  (PRINT) Certifying Technician/Scientist’s Name (First, M, Last)  Date (Mo/Day/Yr)
Timeline for Federal CCF changes

- May 31, 2017
  - Office of Management and Budget (OMB) CCF expires

- June 1, 2017
  - OMB CCF renewed

- October 1, 2017
  - Effective date for MG 2017 (analyte changes)

- Grace period for utilization of 2010 Federal CCF
Thank you

The Electronic Custody and Control Form (eCCF) Process

Q & A