



2024

Chain of Custody in Federally Regulated Workplace Drug Testing Programs



Chain of custody (COC) is a chronological documentation/process used to track the movement and control of specimens from the collection site through a Department of Health and Human Services (HHS)-certified test facility (i.e., laboratory or Instrumented Initial Test Facility). A complete COC documents each individual person or storage location that has had possession of the specimen or specimen aliquot, the date of handling, and the purpose of the custody transfer^{1,2} from the time of collection through disposal.

To ensure the security and integrity of specimens and aliquots, the laboratory must establish COC procedures and practices that document the identification, security, and integrity of each specimen throughout the drug testing process.^{1,2}

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A break in the COC increases the risk that the integrity of the specimen or aliquot has been compromised and associated results may not be scientifically valid and forensically defensible. The COC documentation must always be maintained and remain intact. Each storage location and individual that handles a specimen or aliquot must be identified, and the date and purpose of access must be documented contemporaneously on an appropriate COC form. Laboratory staff must not backdate COC forms or complete multiple entries before or after performing the documented tasks/actions. If line-of-sight custody cannot be maintained, custody must be transferred to another authorized individual or to an instrument/equipment, locked cabinet/drawer, or defined temporary storage location within the secure area where access is limited to authorized staff.

For federally regulated specimens, the COC begins at the collection site with the Federal Custody and Control Form (CCF), a standardized form developed by HHS and approved by the Office of Management and Budget (OMB).³ The collector documents receipt of the specimen from the donor and release to the Delivery Service (Courier) in Step 4 of the Federal CCF. There is no requirement for transporters or courier personnel to document their custody of the sealed specimen package on the Federal CCF³ because the specimen remains secured in a tamper proof specimen bottle within a sealed specimen bag inside the sealed shipping materials.

The first individual at the laboratory to gain access to the sealed specimen bottle (i.e., opens the shipping materials and sealed specimen bag and handling the sealed specimen bottle) continues the COC by documenting access to the sealed specimen bottle, primary specimen seal condition, and location and handling of the specimen bottles in Step 4 of the Federal CCF. The laboratory documents subsequent transfer of specimen bottles or aliquots on its internal COC forms. Each laboratory develops its own internal COC forms, which may be paper or electronic.^{4,5}

Examples of COC forms include the following:

- External COC form (e.g., OMB-approved Federal CCF)³
- Transmittal COC form for inter-laboratory transfer of specimens and aliquots
- Supplemental CCF (also used for inter-laboratory specimen transfer)
- Internal COC forms for specimen bottles and/or aliquots (e.g., Initial Test Batch Internal COC, Initial Test Aliquot Internal COC, Confirmation Test Batch Internal COC, Confirmation Aliquot Internal COC, and Long-Term Storage Internal COC)

Federal CCF Formats (External COC Form)

- A 5-part paper (hardcopy) Federal CCF
- A combination (electronic and paper) Federal CCF
- A digital Federal CCF

At the time of writing, approximately half of the HHS-certified test facilities use a combination (electronic and paper) or digital Federal CCF in addition to the paper CCF. The Substance Abuse and Mental Health Services Administration (SAMHSA)/HHS has set a deadline of August 31, 2026, for all HHS-certified laboratories to submit a request for approval of a digital Federal CCF.

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Exhibit 1. 2023 Federal CCF, Copy 1

FEDERAL DRUG TESTING CUSTODY AND CONTROL FORM

SPECIMEN ID NO. 0000001 *10/19/2023* ACCESSION NO. CFX123456789

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 (Employee I.D.) or CDL State and No. X244799

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 Contact Info: Phone 199-757-9100
Fax 299-724-85100
Other _____

STEP 2: COMPLETED BY COLLECTOR (make remarks when appropriate). URINE ORAL FLUID

COLLECTION: Split Single None Provided, Enter Remark. URINE: Collector reads urine temperature within 4 minutes. Temperature between 90° and 100° F? Yes No, Enter Remark Observed, Enter Remark

ORAL FLUID: Split Type: Serial Concurrent Subdivided Each Device Within Expiration Date? Yes No Volume Indicator(s) Observed

REMARKS: _____

STEP 3: Collector affixes seal(s) to bottle(s)/tube(s). Collector dates seal(s). Donor completes STEP 5 on Copy 2 (MRO Copy)

STEP 4: CHAIN OF CUSTODY - INITIATED BY COLLECTOR AND COMPLETED BY TEST FACILITY

I certify that the specimen given to me by the donor identified in the certification section on Copy 2 of this form was collected, labeled, sealed and released to the Delivery Service noted in accordance with applicable federal requirements. *VIPER SENGHOR*

SPECIMEN BOTTLE(S)/TUBE(S) RELEASED TO: FedEx **NAME OF DELIVERY SERVICE**

RECEIVED AT LAB OR IITF: *A. Venk* **Signature of Accessorizer** **Primary Specimen Seal Intact** **SPECIMEN BOTTLE(S)/TUBE(S) RELEASED TO:** *Temporary Storage Refrigerator*

RECEIVED AT LAB OR IITF: *A. Venk* **Signature of Accessorizer** **Primary Specimen Seal Intact** **SPECIMEN BOTTLE(S)/TUBE(S) RELEASED TO:** *Temporary Storage Refrigerator*

REMARKS: _____

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

NEGATIVE REJECTED FOR TESTING ADULTERATED SUBSTITUTED INVALID RESULT
 DILUTE
 POSITIVE for: _____ Analyte(s) in ng/mL _____

STEP 5b: COMPLETED BY SPLIT TESTING LABORATORY

RECONFIRMED **FAILED TO RECONFIRM - REASON**
I certify that the split specimen identified on this form was examined upon receipt, handled using chain of custody procedures, analyzed, and reported in accordance with applicable federal requirements.

Laboratory Name _____ **Laboratory Address** _____ **Signature of Certifying Scientist** _____ **(PRINT) Certifying Scientist's Name (First, Mi, Last)** _____ **Date (Mo/Day/Yr)** _____

PLACE OVER CAP

0000001 **0000001** **PLACE OVER CAP**
SPECIMEN A **SPECIMEN B** **PLACE OVER CAP**

COPY 1 - TEST FACILITY COPY

Supplemental CCF

For specimens forwarded for additional/different testing, the sending laboratory must send a Supplemental CCF instead of a transmittal COC form with the specimen. The certifying scientist at the sending laboratory must sign the certification statement on the form. Additionally, the Supplemental CCF must contain, at a minimum, the elements on the example form approved by the program.

Exhibit 2. Supplemental CCF

**Inter-Laboratory Transfer
Supplemental Custody and Control Form**

Specimen I.D. #: 123456287

Sending Laboratory Accession #: 235687T

Laboratory Name: ANGLO LABORATORIES NLCP Lab No.

Laboratory Address: 234, Glasgow Street, Raleigh NC 27607

URINE: Bottle A Bottle B **ORAL FLUID:** Tube A Tube B

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

Kee

Signature of Certifying Scientist

SPECIMEN BOTTLE(S)/TUBE(S)
RELEASED TO:

<u>LAMBERT K. KEE</u> (Print) Certifying Scientist Name (First, M I, Last)	<u>10/17/2023</u> Date (Mo/Day/Yr)
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FedEx

RECEIVED AT LABORATORY

LA Acuna

Signature of Accessioner

**BOTTLE/TUBE
SEAL INTACT**

YES

NO

If NO, enter Remark
below

Laboratory Remarks:

Date	Specimen Released by	Specimen Received by	Purpose
<u>10/18/2023</u>	<u>FedEx</u>	<u>Sign: LA Acuna</u> <u>Name: LISBON ACURA</u>	<u>Spec Seal Intact.</u> <u>Rel'd to IOC</u>

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Internal COC Formats

The National Laboratory Certification Program (NLCP) does not specify the exact format of internal COC forms laboratories should use. However, the “Z-type” format is common. Other formats include task list and linear. When formatting internal COC forms, laboratories must allow space to document unexpected custody transfers (e.g., between personnel or to temporary storage locations during breaks or across shifts). Designations for temporary storage locations must be sufficiently specific to be able to determine which temporary storage location a specimen was in from the COC documentation. Transfers to and from analytical instruments must also be documented.

Exhibit 3. Initial Test Batch Internal COC

Initial Test Batch Chain of Custody			
Date	Released By	Received By	Purpose/Remarks
01/10/2023	Sign: <i>Bis Para</i>	Sign: <i>Bis Para</i>	Perform aliquoting
	Name: Accessioning Temporary Storage	Name: Bis Para	
01/10/2023	Sign: <i>Bis Para</i>	Sign:	Specimens and aliquots to accessioning temporary storage
	Name: Bis Para	Name: Accessioning Temporary Storage	
01/10/2023	Sign: <i>Bis Para</i>	Sign: <i>Bis Para</i>	Transfer aliquots to screening temporary storage
	Name: Accessioning Temporary Storage	Name: Bis Para	
01/10/2023	Sign: <i>Bis Para</i>	Sign:	Transfer aliquots to screening temporary storage
	Name: Bis Para	Name: Screening temporary storage	
01/10/2023	Sign:	Sign: <i>Ortho Meta</i>	Remove aliquots from screening temporary storage
	Name: Screening temporary storage	Name: Ortho Meta	
01/10/2023	Sign: <i>Ortho Meta</i>	Sign:	Initial testing/analysis
	Name: Ortho Meta	Name: Instrument #4	
01/10/2023	Sign:	Sign: <i>Ortho Meta</i>	Remove vials from instrument and discard
	Name: Instrument #4	Name: Ortho Meta	

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Exhibit 4. Initial Test Aliquot Internal COC

Initial Test Aliquot Chain of Custody			
Batch ID 2447822-1116T			
Date	Released By	Received By	Purpose/Remarks
11/16/2023	Sign: <i>Yola Gaba</i>	Sign: <i>Elon Gee</i>	Aliquots received in initial test area
	Name: Yola Gaba	Name: Elon Gee	
11/16/2023	Sign: <i>Elon Gee</i>	Initial test Temp Storage	Storage
	Name: Elon Gee		
11/16/2023	Initial Test Temp Storage	Sign: <i>Mai Ken</i>	Transfer
		Name: Mai Ken	
11/16/2023	Sign: <i>Mai Ken</i>	Olympus AU#74	Analysis
	Name: Mai Ken		
11/16/2023	Olympus AU#74	Sign: <i>Mira Melon</i>	Complete analysis and discard
		Name: Mira Melon	

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Exhibit 5. Confirmation Test Batch Internal COC

Confirmation Batch Chain of Custody			
Batch ID: Opiate231106K			
Date	Released By	Received By	Purpose/Remarks
10/01/2023	Long-Term Cart Storage	Sign: <i>Bis Brown</i>	Transfer specimen bottles from cart storage to confirmation temporary storage.
		Name: Bis Brown	
10/01/2023	Confirmation Temp Storage	Sign: <i>Bis Brown</i>	Match bottle identification and return to confirmation temporary storage.
		Name: Bis Brown	
10/01/2023	Confirmation Temp Storage	Sign: <i>Bis Brown</i>	Perform confirmation aliquoting. Transfer aliquots and bottles to confirmation temporary storage.
		Name: Bis Brown	
10/01/2023	Confirmation Temp Storage	Sign: <i>Bis Brown</i>	Transfer specimen bottles and aliquots to refrigerated storage.
		Name: Bis Brown	
10/01/2023	Refrigerated Storage	Sign: <i>Bis Brown</i>	Transfer aliquots to extraction temporary storage.
		Name:	

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Exhibit 6. Confirmation Aliquot Internal COC

Confirmation Aliquot Chain of Custody			
Batch ID: THCA231116			
Date	Released By	Received By	Purpose/Remarks
11/16/2023	Sign: <i>Eva One</i>		Transfer/storage
	Name: Eva One	Name: Pass-Through Storage (window)	
11/16/2023		Sign: <i>Grant Hill</i>	Transfer
	Name: Pass-Through Storage (window)	Name: Grant Hill	
11/16/2023	Sign: <i>Grant Hill</i>		Transfer to confirmation temp storage
	Name: Grant Hill	Name: Confirmation Temp Storage	
11/16/2023		Sign: <i>Ligand Hu</i>	Perform extraction
	Name: Confirmation Temp Storage	Name: Ligand Hu	
11/16/2023	Sign: <i>Ligand Hu</i>		Transfer extracts to storage
	Name: Ligand Hu	Name: Instrument Temp Storage	
11/16/2023		Sign: <i>Type Re</i>	Remove extracts from storage
	Name: Instrument Temp Storage	Name: Type Re	
11/16/2023	Sign: <i>Type Re</i>		Analysis
	Name: Type Re	Name: Inst #4	
11/16/2023		Sign: <i>Oslo Tea</i>	Remove extracts from instrument and discard
	Name: Inst #4	Name: Oslo Tea	

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Exhibit 7. Long-Term Storage Internal COC

Non-Negative Long-Term Storage Chain of Custody		
Storage Batch ID: TK444244		
SID/Accession Numbers:		
TR447889	TR004266	TR566388
TR122445	TR333565	TR555777
Date	Name	Purpose/Remarks
11/10/2023	Sign: <i>Colan Bite</i>	Bottles removed from Accessioning Bottle Temp Storage, scanned into Long-Term Storage Batch TK444244, and placed in refrigerated storage.
	Print: Colan Bite	
11/16/2023	Sign: <i>Logan Kemp</i>	Bottles removed from refrigerated storage and placed in long-term frozen storage.
	Print: Logan Kemp	

Common Errors on Internal COC Forms**Example 1 – Multiple Errors**

In this example, the accessioner documented receipt of specimen CFX123456789 in Step 4 of the Federal CCF and wrote “Temporary Storage Refrigerator” in the “Released to” section of the CCF to document transfer to temporary storage (**Exhibit 8**).

Exhibit 8. Detail of Step 4 from Federal CCF Example in Exhibit 1

VIREK SENGURK (PRINT) Collector's Name (First, Mi, Last)		04 / 19 / 2023	11:31 PM	FEDEX
RECEIVED AT LAB OR IITF: <input checked="" type="checkbox"/> <i>LOVE AVEENI</i>		Signature of Accessioner		Name of Delivery Service
(PRINT) Accessioner's Name (First, Mi, Last)		Primary Specimen Seal Intact <input checked="" type="checkbox"/> YES <input type="checkbox"/> NO 04 / 20 / 2023	Date (Mo/Day/Yr)	SPECIMEN BOTTLE(S)/TUBE(S) RELEASED TO: <i>Temporary Storage Refrigerator</i>
Primary/Single Specimen Device Expiration Date: / / (Mo/Day/Yr)		Split Specimen Device Expiration Date: / / (Mo/Day/Yr)		
STEP 5A: PRIMARY SPECIMEN REPORT - COMPLETED BY TEST FACILITY				
<input type="checkbox"/> NEGATIVE <input type="checkbox"/> REJECTED FOR TESTING <input type="checkbox"/> ADULTERATED <input type="checkbox"/> SUBSTITUTED <input type="checkbox"/> INVALID RESULT				

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The laboratory used the internal COC below to document subsequent transfer entries.

Exhibit 9. Initial Test Batch COC for Batch X4X4

Initial Test Batch Chain of Custody				
Batch ID: X4X4				
	Date	Released By	Received By	Purpose/Remarks
1	04/20/2023	Sign: <i>Lee Roy</i>	Sign:	Aliquoting ^b
		Name: Lee Roy ^a	Name: Temporary Storage Pass Through	
2	04/20/2023	Sign:	Sign: <i>Baja Semi</i>	Transfer
		Name: Temporary Storage Pass Through	Name: Baja Semi	
3	04/20/2023	Sign: <i>Baja Semi</i>	Sign:	Disposal ^c
		Name: Baja Semi	Name: Olympus Instrument #4	
4	04/20/2023	Sign:	Sign: <i>Baja Semi</i>	Analysis
		Name: Olympus Instrument #4	Name: Baja Semi	

^a The internal transfer COC did not include custody transfer of specimen CFX123456789 from temporary storage refrigerator to Lee Roy (see line 1).

^b Staff used incorrect annotation “Aliquoting” in the “Purpose/Remarks” column to document transfer of aliquot(s) to temporary storage pass through (see line 1).

^c Improper documentation of custody transfers (see lines 3 and 4). Staff documented disposition of aliquots prior to analysis performed on the Olympus instrument #4.

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Example 2 – Missed Transfer of Custody

In this example, the confirmation aliquots in batch OPI2311-123-6 were extracted by Belan Boss, analyzed on instrument 6, reanalyzed on instrument 9, and finally discarded.

Exhibit 10. Confirmation Batch COC

Confirmation Batch Chain of Custody				
				Batch ID:
	Date	Released By	Received By	Purpose/Remarks
1	11/04/2023	Sign: <i>Belan Boss</i>	Sign: <i>Belan Boss</i>	Extraction
		Name: Confirmation Temporary Storage	Name: Belan Boss	
2	11/04/2023	Sign: <i>Belan Boss</i>	Sign: <i>Confirmation Temporary Storage</i>	Temporary storage
		Name: Belan Boss	Name: Confirmation Temporary Storage	
3	11/04/2023	Sign: <i>Land Rover</i>	Sign: <i>Land Rover</i>	Load
		Name: Confirmation Temporary Storage	Name: Land Rover	
4	11/04/2023	Sign: <i>Land Rover</i>	Instrument #6	Analysis
		Name: Land Rover		
5	11/04/2023	Instrument #6	Sign: <i>Gamma Rays</i>	Remove vials from instrument
			Name: Gamma Rays	
6	11/04/2023	Sign: <i>Gamma Rays</i>	Sign: <i>Confirmation Temporary Storage</i>	Temporary storage
		Name: Gamma Rays	Name: Confirmation Temporary Storage	
7	11/05/2023	Sign: <i>Alora Sedan</i>	Sign: <i>Instrument #9</i>	Reanalysis of confirmation batch/batch transfer
		Name: Alora Sedan ^a	Name: Instrument #9	
8	11/05/2023	Sign: <i>Bembo Brake</i>	Sign: <i>Bembo Brake</i>	Remove and discard vials
		Name: Instrument #9	Name: Bembo Brake	

^a Gamma Rays placed extracts in temporary storage (see line 6). However, they did not document transfer of extracts from temporary storage to Alora Sedan on the internal extraction batch COC (see line 7).

References

1. Cybersecurity and Infrastructure Security Agency (CISA). Insights: Chain of custody and critical infrastructure systems. <https://www.cisa.gov/resources-tools/resources/cisa-insights-chain-custody-and-critical-infrastructure-systems>. August 2023.
2. California Department of Pesticide Regulation. Standard operating procedure – creating and completing a chain of custody record. <https://www.cdpr.ca.gov/docs/emon/pubs/sops/admn00602.pdf>. Accessed January 1, 2024.
3. RTI International, Center for Forensic Sciences. *Manual for urine laboratories, National Laboratory Certification Program (NLCP)*, (October 2017, rev. 0222). Research Triangle Park, NC; 2022.
4. Mayo Clinic Laboratories. Chain of custody drug testing. <https://news.mayocliniclabs.com/chain-of-custody-drug-testing/#:~:text=Chain%20of%20custody%20is%20a,clinical%20and%20forensic%20toxicology%20testing>. Accessed January 1, 2024.
5. Monder Law Group. Chain of custody. <https://www.monderlaw.com/news/chain-of-custody/>. Accessed January 1, 2024.

Omoware Osanyintolu is a Research Forensic Scientist in the Center for Forensic Science Application and Advancement at RTI International. He is a subject matter expert on principles, practices, and trends in forensic toxicology and knowledgeable in laboratory analytical methods and principles and quality control and assurance procedures. As an NLCP inspection analyst and inspector, he inspects HHS-certified laboratories and reviews inspection correspondence to verify appropriateness of corrective actions taken in response to deficiencies/issues identified in the inspection and performance testing phases of the program. Before joining RTI in 2018, Mr. Osanyintolu spent more than a decade as an analyst and certifying scientist at an HHS-certified laboratory.

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