

# Behavioral Health is Essential To Health



Prevention Works



Treatment is Effective



People Recover



# *SAMHSA Updates 2016*

Presented by :  
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**Division of Workplace Programs**

**July 26, 2016**

**Drug Testing Advisory Board (DTAB) Meeting**



# Presentation Objective

- Contact Information
- DWP Workplace Helpline
- National Laboratory Certification Program (NLCP)
- Electronic Federal Custody and Control Form (ECCF)
- Specimens With Abnormal Color

# Division of Workplace Programs

4

- Director: Ron Flegel, B.S., MT(ASCP), M.S.
- Sean Belouin, PharmD.
- Anastasia Donovan
- Deborah Galvin, Ph.D.
- Eugene Hayes, Ph.D., M.B.A.
- Charles LoDico, M.S., F-ABFT
- Brian Makela
- Coleen Sanderson
- Hyden Shen, J.D.
- Program Assistant: Giselle Hersh

# We Moved



# We Moved (cont'd)



# How to Reach Us

7

Division of Workplace Programs

5600 Fishers Lane

Rockville, MD 20857

240-276-2600

# History of the Workplace Helpline

- Established in 1987 under NIDA
- 1992 Helpline was transferred to SAMHSA /Center for Substance Abuse Prevention (CSAP)
- Overall purpose of the Workplace Helpline is to assist federal agencies and private organizations with:
  - drug-free workplace policy development
  - workplace drug testing and the Mandatory Guidelines
  - drug and alcohol use prevention and treatment issues in the workplace
  - SAMHSA certified laboratory questions

# DWP Workplace Helpline

- [www.samhsa.gov/workplace](http://www.samhsa.gov/workplace)
- [dwp@samhsa.hhs.gov](mailto:dwp@samhsa.hhs.gov)
- 1-800-967-5752

# The Top 5 Inquiries

- The leading reasons for inquiries are
  - Drug testing
  - Collection site locations
  - DFWP policies & procedures
  - Laboratory certifications
  - Testing anxiety

# 3<sup>rd</sup> Quarter 2016 Data

- 203 inquiries came in to the help line...
  - 174 were phone calls
  - 29 were by e-mail
- 163 inquiries responded on the same day
- 38 inquiries responded within one business day

**Note:** Helpline first quarter in 2015 had 98 inquiries. 3<sup>rd</sup> quarter inquiries represent a 48% increase in call volume.

# Sample Page from Database

**A Client\Inquiry**

Inquiry ID  \*Date/Time  Inquiry Type  Related to Prior  Inquiry Closed Date

**Client ID (New)**

\* First  \* Last

Address1

Address2

City / Zip

Phone  FAX

email

Updated

Agency Type

Agency

Address1

Address2

City / Zip

Phone  FAX

email

Agency Type

**Inquiry:**

Date/Time	Inquiry Type	Consultant	Closed

**Work Helpline**

\* Consultant  \* Response

\* Summary Notes [\(more\)](#)

**Federal Agency Inquiry**

Referred To

SAMHSA Specialty

\* Federal Agency Referred To Comment [\(more\)](#)

**Response**

\* Response Time

\* Inquiry Reasons (check all that apply)

Reason	Select
Alcohol testing	<input type="checkbox"/>
Call outside of program service, (if selected, provide a comment)	<input type="checkbox"/>
Collection site location	<input type="checkbox"/>
Collector training	<input type="checkbox"/>
DFWP policy or procedure	<input type="checkbox"/>
DOT Supervisory Training	<input type="checkbox"/>
Drug testing	<input type="checkbox"/>
EAP related	<input type="checkbox"/>
Legal question regarding substance testing	<input type="checkbox"/>
Need for treatment referrals	<input type="checkbox"/>
Report of illegal activity	<input type="checkbox"/>
Request for brochures or training materials	<input type="checkbox"/>
SAP related	<input type="checkbox"/>
Specific DOT mode question	<input type="checkbox"/>
Supervisor role/how to intervene on impairment	<input type="checkbox"/>
Support Group information	<input type="checkbox"/>

\* Inquiry Reason Comment [\(more\)](#)

**Referral**

\* Referral Made  Yes  No

\* Referral Comment [\(more\)](#)

**Referred to (check all that apply)**

[ReferTo](#)

- Certified Lab
- Commercial Entity
- Community-based Agency
- Federal Agency
- Military Branch Entity
- Publication
- State Agency
- Treatment Directory
- Web site

**Training**

Training Requested  Yes  No \* Duration (Mins)

\* Training Type Requested [\(more\)](#) \* Number of Attendees

**Followup**

\* Followup Date  \* Counselor

Followup Completed  Time Requirement Met

**Results (check all that apply)** \* Followup Comment [\(more\)](#)

Followup Result	Select
Inquiry case complete	<input type="checkbox"/>
Inquiry case continued	<input type="checkbox"/>
No response after 2 attempts	<input type="checkbox"/>

\* Followup Result Comment [\(more\)](#)

# NLCP Contract

13

- National Laboratory Certification Program (NLCP) Contract RTI International
  - 3040 Cornwallis Road
  - P.O. Box 12194
  - Research Triangle Park, NC 27709
- Director: Dr. John M. Mitchell
- Deputy Director - Inspections: Ms. Susan D. Crumpton
- Deputy Director - Performance Testing: Dr. Francis M. Esposito

# Current State of the NLCP

- Certified Laboratories 30
  - Cat 0 2
  - Cat 1 9
  - Cat 2 6
  - Cat 3 3
  - Cat 4 3
  - Cat 5 7
- Candidate Laboratories 1
- Certified IITFs 1

# HHS-certified Laboratories/ HHS-approved ECCF Laboratories

15

- HHS-certified laboratories
  - [www.samhsa.gov/workplace/resources/drug-testing/certified-lab-list](http://www.samhsa.gov/workplace/resources/drug-testing/certified-lab-list)
- HHS-approved ECCF laboratories
  - [www.samhsa.gov/sites/default/files/programs\\_campaigns/division\\_workplace\\_programs/eccf-lab-list-may-2016.pdf](http://www.samhsa.gov/sites/default/files/programs_campaigns/division_workplace_programs/eccf-lab-list-may-2016.pdf)

# Electronic Federal Custody and Control Form (ECCF)

16

- As of May 2016
  - 2 HHS-certified laboratories approved to use ECCF
- As of July, 2016
  - 11 HHS-certified laboratories have submitted ECCF information for NLCP review
  - 8 ECCF inspections completed
  - 1 Pending NLCP Inspection Report
  - 7 Pending Lab Response to ECCF inspection and NLCP review of remediation

# ECCF Review and Approval

## Spring 2016

Lab	Submission Received	Lab Response(s) and NLCP Reports							NLCP Final Report	Inspection Date	NLCP Inspection Report	Lab Response(s) and NLCP Reports			NLCP Report & Recommendation to HHS	HHS Letter
A	4/20/2015	6/2/2015 revised submission	NLCP 6/23/2015	Lab 7/14/2015					9/15/2015	9/21/2015	10/2/2015	10/2/2015	NA	10/9/2015	10/9/2015 Approved	
B	4/21/2015	6/17/2015 revised submission	NLCP 6/30/2015	Lab 11/5/2015	NLCP 11/24/2015	Lab 11/25/2015			12/21/2015	1/26/2016	2/16/2016	3/9/2016	3/17/2016	pending		
C-1	5/26/2015	N/A - Lab provided revised submission														
C-1	6/8/2016 revised submission	N/A - Lab provided revised submission														
C-1	10/19/2015 revised submission	2/1/2016 addtl doc 2/12/16	NLCP 2/12/2016	Lab 3/2/2016	NLCP 3/17/2016	Lab 3/25/2016			3/28/2016	4/28/2016						
C-2	10/19/2015	2/10/16 revised submission	NLCP 2/19/2016	pending												
D	8/6/2015	12/4/2015	NLCP 12/10/2015	Lab 1/21/2016	NLCP 1/29/2016	Lab 2/22/2016	NLCP 3/4/2016	Lab 3/11/2016	3/16/2016	4/19/2016						
E	10/16/2015	12/30/2015	NLCP 2/12/2016	Lab 3/4/2016	NLCP 3/17/2016	Lab 3/25/2016			3/29/2016	4/27/2016						
F	3/22/2016	3/28/2016							3/29/2016	5/3/2016						
G	3/23/2016	3/28/2016							3/29/2016	5/10/2016						
H	3/24/2016	3/30/2016							3/30/2016	5/16/2016						
I	4/1/2016	4/15/2016								6/7/2016						
J	4/1/2016	4/18/2016								6/2/2016						
K	4/1/2016	4/18/2016								6/22/2016						

# ECCF Review and Approval Summer 2016

18

Lab	Submission Received	Lab Response(s) and NLCP Reports							NLCP Final Report	Inspection Date	NLCP Inspection Report	Lab Response(s) and NLCP Reports			NLCP Report & Recommendation to HHS	HHS Letter
A	4/20/2015	6/2/2015 revised submission	NLCP 6/23/2015	Lab 7/14/2015				9/15/2015	9/22/2015	10/2/2015	10/2/2015	NA		10/9/2015	10/9/2015 Approved	
B	4/21/2015	6/17/2015 revised submission	NLCP 6/30/2015	Lab 11/5/2015	NLCP 11/24/2015	Lab 11/25/2015		12/21/2015	1/26/2016	2/16/2016	3/9/2016	3/17/2016	4/20/2016	5/5/2016	5/9/2015 Approved	
C-1	5/26/2016, 6/8/2016 addtl info	N/A - Lab provided revised submission														
C-1	10/19/2015 revised submission	2/1/2016 addtl doc 2/12/16	NLCP 2/12/2016	Lab 3/2/2016	NLCP 3/17/2016	Lab 3/25/2016		3/28/2016	4/28/2016	6/2/2016	6/21/2016	6/30/2016	7/5/2016 in review			
C-2	10/19/2015	2/10/16 revised submission	NLCP 2/19/2016	pending												
D	8/6/2015	12/4/2015	NLCP 12/10/2015	Lab 1/21/2016	NLCP 1/29/2016	Lab 2/22/2016	NLCP 3/4/2016	Lab 3/11/2016	3/16/2016	4/19/2016	5/2/2016	5/11/2016	6/2/2016	pending		
E	10/16/2015	12/30/2015	NLCP 2/12/2016	Lab 3/4/2016	NLCP 3/17/2016	Lab 3/25/2016			3/29/2016	4/27/2016	6/2/2016	6/24/2016	7/1/2016	pending		
F	3/22/2016	3/28/2016							3/29/2016	5/3/2016	6/2/2016	pending				
G	3/23/2016	3/28/2016							3/29/2016	5/10/2016	6/2/2016	pending				
H	3/24/2016	3/30/2016							3/30/2016	5/16/2016	6/8/2016	pending				
I	4/1/2016								4/18/2016	6/2/2016	6/24/2016	pending				
J	4/1/2016								4/15/2016	6/7/2016	7/6/2016	pending				
K	4/1/2016								4/18/2016	6/21/2016	pending					

# % Federally Regulated Specimen Tested Using ECCF 2016

September-15	0.00%
October-15	0.69%
November-15	1.24%
December-15	2.50%
January-16	4.58%
February-16	6.41%
March-16	7.04%
April-16	8.31%
May-16	8.63%
June-16	11.60%

# Comments: Effect of ECCF On Laboratory Process

20

- Pre-Accessioned Data – Reduce Data Entry time and human typo errors
- No altered CCFs (MRO data and Employer data on CCF is not altered, clearly identified)
- Greatly effects MRO changes, as new CCFs are not needed to be shipped, nor do existing CCFs need to be altered
- Legible CCFs
- No hand-writing deciphering
- Reduces amount of CCFs shipped out and storage of CCFs at each clinic

# Standardizing Reporting

Test Result	Required Comment <sup>1</sup>	Note
Negative and Dilute	Creatinine = (numerical value) mg/dL & SpGr = (numerical value)	IITF forwards to lab if creatinine ≤ 5.0 mg/dL
Positive	(Specify drug analyte) = confirmatory test quantitative result	
Positive and Dilute	(Specify drug analyte) = confirmatory test quantitative result; Creatinine = (numerical value) mg/dL & SpGr = (numerical value)	
Adulterated	pH = (conf. test value)	pH < 3.0 or ≥ 11.0 (within the range of controls in the batch)
	Nitrite = (conf. test value) mcg/mL	≥ 500 mcg/mL nitrite
	Surfactant Present; dodecylbenzene sulfonate = (conf. test value) mcg/mL	≥ 100 mcg/mL dodecylbenzene sulfonate
	Chromium (VI) = (conf. test value) mcg/mL	adulterant ≥ LOQ
	(Specify Halogen) = (conf. test value)	
	Glutaraldehyde = (conf. test value) mcg/mL	
Pyridine = (conf. test value) mcg/mL		
(Specify Adulterant) Present = (conf. test value)		
Substituted	Creatinine = (conf. test value) mg/dL & SpGr = (conf. test value)	
Invalid Result	Creatinine < 2 mg/dL & SpGr Acceptable	SpGr > 1.0010 & < 1.0200
	SpGr ≤ 1.0010 & Creatinine ≥ 2 mg/dL	
	Abnormal pH = (pH value supporting the invalid result)	pH ≥ 3.0 & < 4.5 or pH ≥ 9.0 & < 11.0
	Nitrite = (conf. test value) mcg/mL	Nitrite ≥ 200 & < 500 mcg/mL on confirmatory test
	Oxidant Activity = (≥ 200 mcg/mL nitrite-equivalents, ≥ 50 mcg/mL Cr VI-equivalents, or ≥ halogen or other oxidant LOQ) <sup>2</sup>	Oxidant = nitrite, chromium VI, halogen, etc.
	(Specify confirmatory drug test method) interference <sup>2</sup>	Drug analyte(s) must not be included on reports for invalid results based on assay interference
	Immunoassay Interference <sup>2</sup>	
	Possible (characterize as Aldehyde or Surfactant) Activity <sup>2</sup>	
	Abnormal Physical Characteristic - (Specify) <sup>2</sup>	
	Bottle A and Bottle B - Different Physical Appearance <sup>2</sup>	
Uncorrected Flaw: Collector signature not recovered		
Uncorrected Flaw: A & B redesignation not documented by IITF		

<sup>1</sup> Remarks on CCF (Step 5a) & on elec. report for primary specimens; Remarks on Split Specimen Report & on elec. report for split specimens

<sup>2</sup> Lab shall contact the MRO to discuss the Invalid Result in accordance with the HHS Guidelines (73 Fed. Reg. 71858) section 11.19.g.

<sup>3</sup> See NLCP Manual for further guidance: IITF Question E8h and Laboratory Question E9h, CCF Decision Trees)

# Standardizing Reporting (Cont'd)

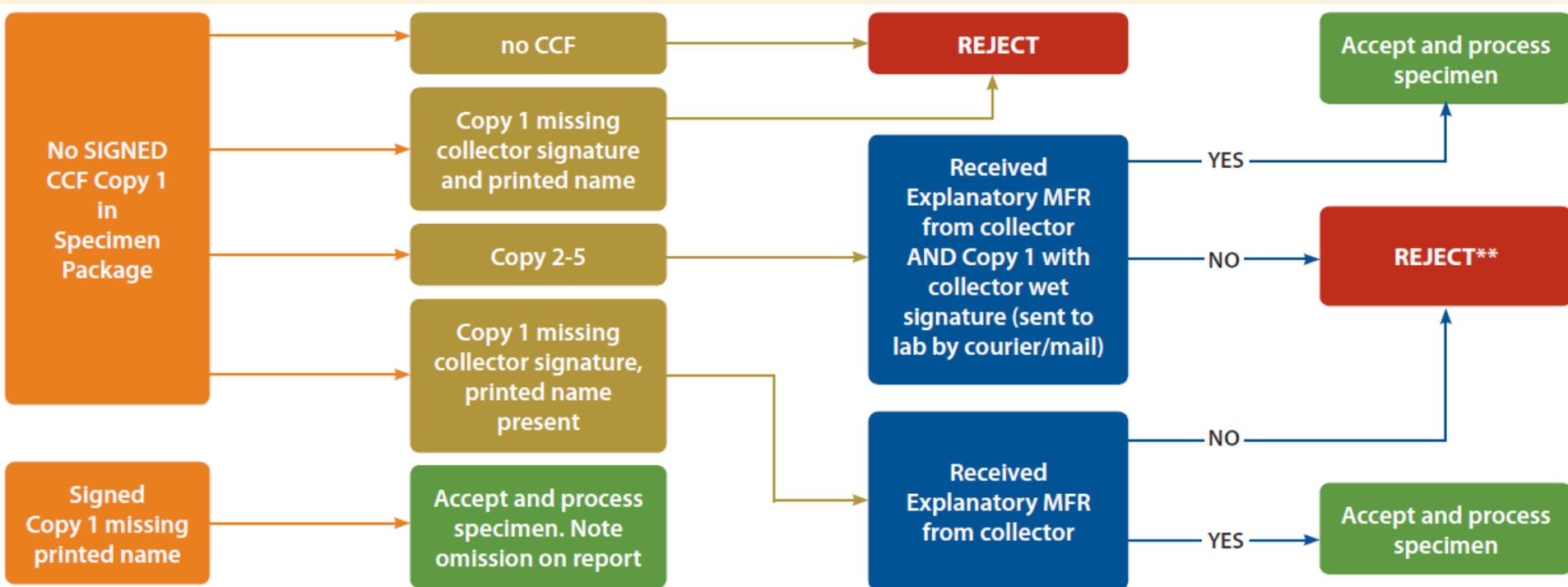
Test Result	Required Comment <sup>1</sup>	Note
Rejected for Testing	Fatal Flaw: Specimen ID number (Specify: mismatch; missing)	ID mismatch/missing on either Bottle A or B
	Fatal Flaw: No collector printed name & No signature	
	Fatal Flaw: No CCF	
	Fatal Flaw: Bottle A label/seal (Specify: missing; broken; shows evidence of tampering)	If redesignation is not possible
	Fatal Flaw: Bottle A insufficient specimen volume	
	Fatal Flaw: Bottle A seal condition not marked on CCF by IITF	
	Uncorrected Flaw: Wrong CCF used <sup>3</sup> (Specify: Expired/Non-Federal CCF; CCF Copy 2-5; ECCF Reprint without collector wet signature)	Wait 5 business days before reporting flaw if not corrected
	Uncorrected Flaw: Collector signature not recovered	
	Uncorrected Flaw: A & B redesignation not documented by IITF	

<sup>1</sup> Remarks on CCF (Step 5a) & on elec. report for primary specimens; Remarks on Split Specimen Report & on elec. report for split specimens

<sup>2</sup> Lab shall contact the MRO to discuss the Invalid Result in accordance with the HHS Guidelines (73 Fed. Reg. 71858) section 11.19.g.

<sup>3</sup> See NLCP Manual for further guidance: IITF Question E8h and Laboratory Question E9h, [CCF Decision Trees](#)

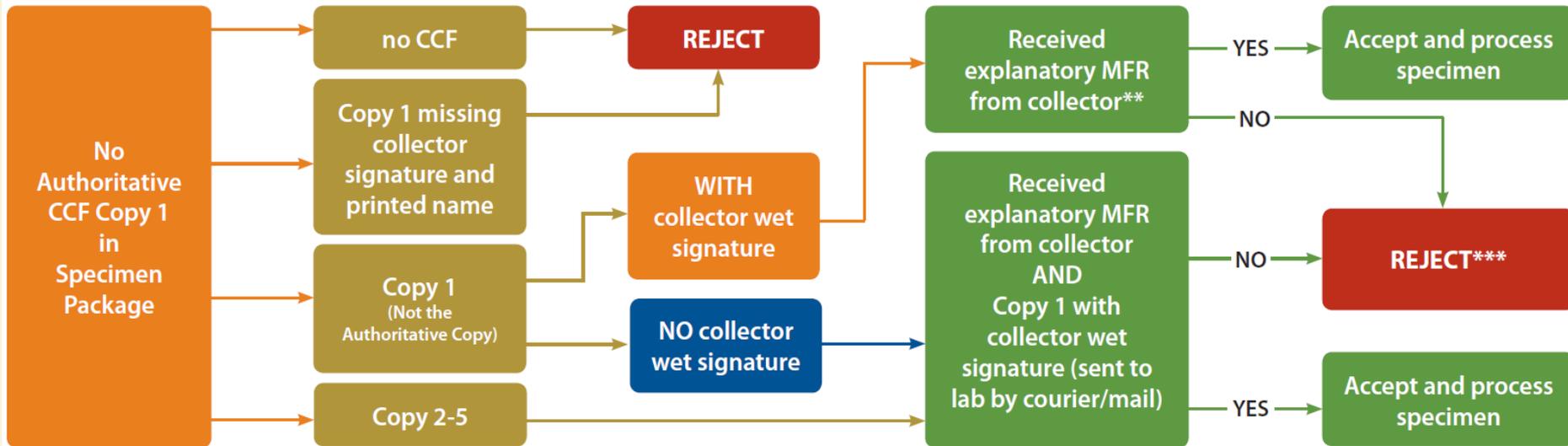
# 5-Part Paper CCF and Combination Electronic/Paper CCF Option 1\*



\*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.

# Combination Electronic/Paper CCF Option 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 ECCF Copy 1 must be designated as the single authoritative copy of the ECCF:

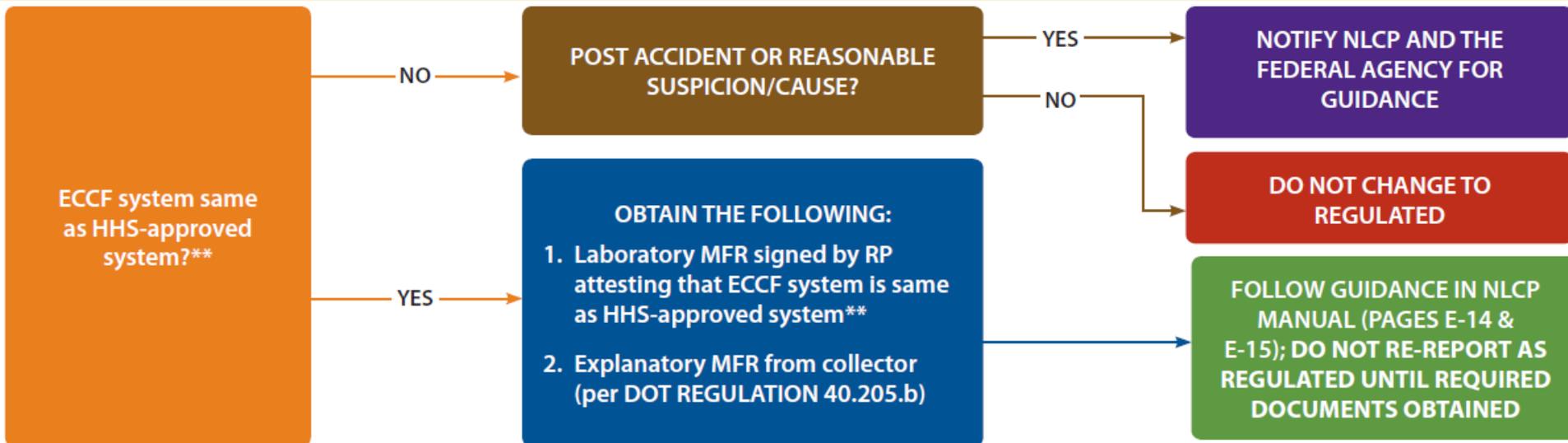
- The collector designates the printed Copy 1 as the authoritative copy by signing it using a wet signature OR
- The copy must be produced as the single authoritative copy using the validated ECCF system.

\*\*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 for guidance prior to rejecting.

# Request to change NON-REGULATED collected with ECCF to REGULATED: COMBINATION ELECTRONIC/PAPER CCF, OPTION 1\*

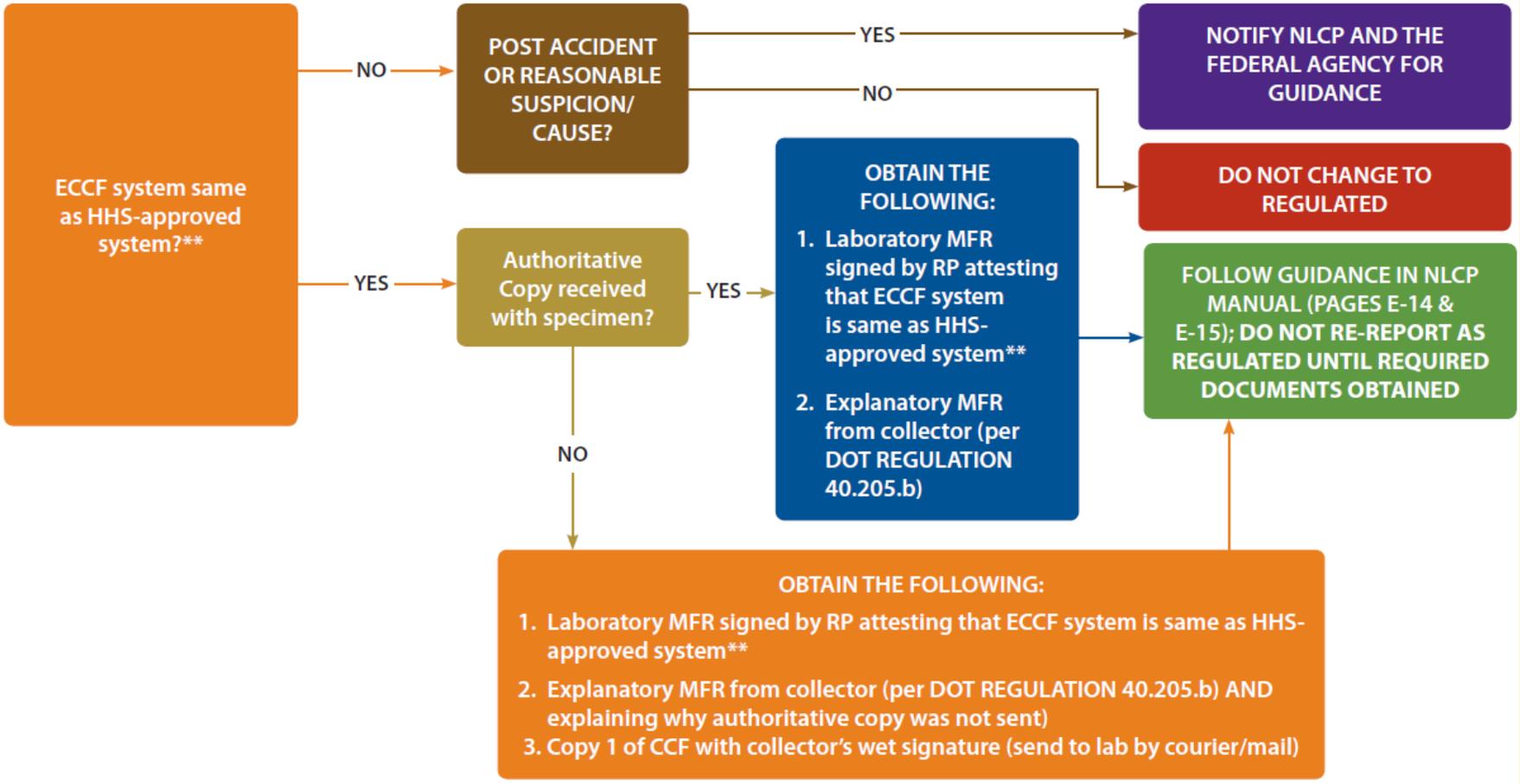
25



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

\*\*Same system infrastructure, servers, security, etc. as described in the laboratory's ECCF submission and verified during inspection (e.g., verification and documentation explained in laboratory SOP).

# Request to change NON-REGULATED collected with ECCF to REGULATED: COMBINATION ELECTRONIC/PAPER CCF, OPTION 2\*



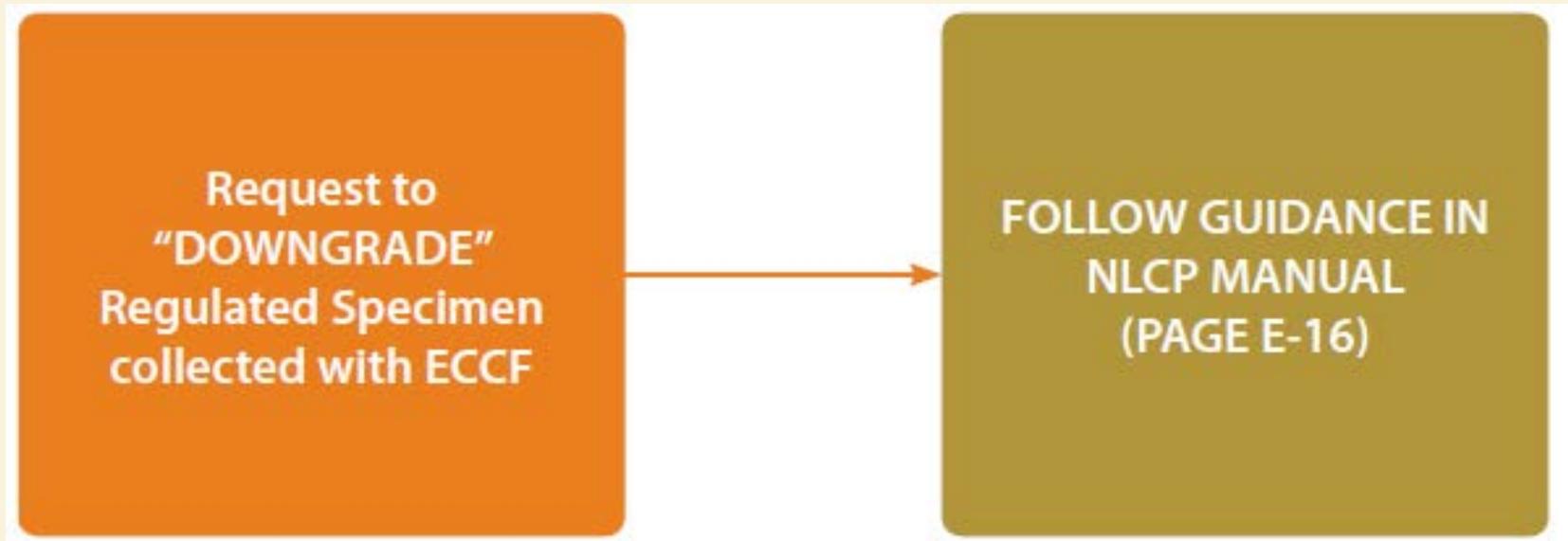
\*The collector uses an ECCF to document the collection process, the collector and donor sign using electronic signatures, and the collector prints Copy 1 with his or her electronic signature. The printout of ECCF Copy 1 must be designated as the single authoritative copy of the ECCF.

\*\*Same system infrastructure, servers, security, etc.



# Request to change REGULATED collected with ECCF to NON-REGULATED

27



- October 2010 NLCP Manual for Urine Laboratories, rev. 1115.1
- October 2010 NLCP Manual for Urine IITFs, rev. 1115

# Specimens with Abnormal Color

## Collector

28

- What does a collector do when a urine specimen exhibits an abnormal color?
  - Note the finding on the CCF, complete the collection, and send the specimen to an HHS-certified laboratory for testing
  - If there is a reason to believe the donor adulterated or substituted the specimen:
    - Complete the collection, perform a direct observed recollection, and send both specimens to an HHS-certified laboratory for testing
    - Note the reason for recollection on both CCFs, including a cross-reference to the associated specimen ID number

# Specimens with Abnormal Color

## Laboratory

29

- Abnormal color alone is not a reason for reporting a specimen as invalid (A and B Bottle same color), **Test if possible**
- Lab must **not** include any comment about the abnormal color on the (CCF), **report based on test results (e.g., negative)**
- Lab must include objective criteria for evaluating specimen color (SOP)
- Abnormal physical characteristics must be verified by at least two individuals, including the CT or CS who signs the CCF
- Lab must document the abnormal color in the internal lab records.

# Specimens with Abnormal Color Laboratory (cont'd)

30

- Abnormal color (A and B Bottle different color)
- Lab Test A Bottle
  - If negative:
    - Report Invalid Result Bottle A and Bottle B – different physical appearance (comment)
  - If positive/adulterated/substituted:
    - Report all results including Invalid Result
    - Ex. Positive for: Drug, Invalid Result Bottle A and Bottle B – different physical appearance (comment)