



# eCCF Updates 2015

Presented by  
**Charles LoDico, M.S., DABFT**

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Drug Testing Advisory Board



# OMB Notice of Approval

NOTICE OF OFFICE OF MANAGEMENT AND BUDGET ACTION Date 05/28/2014

LIST OF INFORMATION COLLECTIONS:

Department of Health and Human Services/Substance Abuse and Mental Health Services

In accordance with the Paperwork Reduction Act, OMB has taken action on your request received 07/24/2013

ACTION REQUESTED: Revision of a currently approved collection

TYPE OF REVIEW REQUESTED: Regular

TITLE: Mandatory Guidelines for Federal Workplace Drug Testing Programs

OMB ACTION: Approved with change

OMB CONTROL NUMBER: 0930-0158

EXPIRATION DATE: 05/31/2017

# DOT FR Final Rule

- Federal Register (80 FR 19551)
  - Monday, April 13, 2015
    - Expands the DOT's definition of the CCF to include both paper and electronic forms
    - Laboratory eCCF must be reviewed and approved/inspected by NLCP before implementation

# Related eCCF Documents

- HHS/NLCP eCCF Oversight and Requirements
- 2014 Guidance for using the Federal CCF
- Updated MRO Manual
- Updated Collection Hand Book
- Update Checklist and Manual – in progress

# Paper CCF

- A paper Federal CCF may be either:
  - **Option 1:** a preprinted, multiple-part carbonless form, or
  - **Option 2:** a multiple-part CCF that is printed at the collection site, prior to the collection.
- The collector and the donor must sign using wet signatures.
- The hardcopy CCF sent with the specimen is the chain of custody.

# Electronic CCF (eCCF)

- An electronic CCF is an electronic document used to record all CCF events from collection through reporting.
- The eCCF includes electronic (digitized) signatures of the collector, the donor, and the test facility personnel attesting to receipt and certification of test results.
- The electronic CCF is the chain of custody.

# Combination Electronic/Paper CCF

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- The collector uses an electronic CCF to document the collection process then the collector prints Copy 1 and Copy 2-5 on carbonless paper.
- The collector and donor must sign using wet signatures.
- The collector distributes copies of Copy 2-5 (with signatures) to the employer and donor and maintains a copy for the collection site records.
- Copy 1 is sent to the test facility with the specimen.
- The hardcopy CCF sent with the specimen is the chain of custody.

# Getting Started

- Before a Federal eCCF can be used for regulated specimens, the HHS-certified laboratory must:
  - Submit documentation for NLCP Review
  - Undergo an NLCP inspection
  - Obtain HHS/SAMHSA approval to begin using the eCCF
- After implementation of an eCCF system:
  - NLCP inspectors will review procedures, practices, and records including verifying Section P self-assessment
  - Laboratories must notify the NLCP before major changes are made

# Submission to NLCP

1. Process Overview
2. Topic Outline of proposed SOPs for eCCF use
3. Training Plans
4. System/Network Diagram
5. System Security Plan
6. System Validation Plan
7. 3<sup>rd</sup> Party eCCF Provider Agreement
8. Laboratory Information Checklist (e.g., C-16) and Section P Self-Assessment (relevant to eCCF)

# 1. Process Overview

- ALL processes involving the Federal eCCF
- From initiation until final disposition

## 2. Topic Outline of Proposed SOPs

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- Procedures/instructions for eCCF users
  - Laboratory SOP content (accessioning, certification, reporting)
  - Instructions for other eCCF users (collectors, MROs and MRO staff)
- Examples for submission
  - Screenshots
  - Tables of contents

# 3. Training Plans

- eCCF Users
  - Laboratory staff
  - Collectors
  - MROs and MRO staff (as applicable)
- Other individuals given access to regulated specimen data (e.g., IT staff)
  - Security awareness training must address forensic records and regulated specimen donor PII
- RP must document review and approval of training plans and materials

# 4. System/Network Diagram

- Create and provide a logical network diagram that includes, at a minimum, the following:
  - Firewalls
  - Network security devices
  - Servers
  - Workstations
  - Primary routers/switches
  - Remote access device(s)
  - Internet connection(s)

# 5. System Security Plan

- Overview of the security requirements for the system
- May submit:
  - Documentation of compliance with NIST 800-53 (security control families)
  - A report from an independent auditor regarding compliance with relevant industry standards (e.g., SSAE16)
  - A signed HIPAA Business Associate Agreement (BAA) with supporting documentation

# 6. System Validation Plan

- Plan for testing and evaluating information security controls
- Documentation of security control testing and evaluation for review at NLCP inspections
- Examples:
  - Periodic record checks
  - Independent security monitoring by laboratory IT staff
  - Report from an independent auditor regarding compliance with relevant industry standards

# 7. 3<sup>rd</sup> Party Agreements

- Written agreement/contract signed by each RP and authorized representative of the 3rd party eCCF provider
- Agreement specifies responsibilities of the eCCF provider
  - State restrictions and conditions that apply to the eCCF provider with respect to regulated specimen and drug test information
- Agreement must be provided for NLCP review
  - With initial eCCF system submission
  - With other eCCF system documentation at each inspection
- Laboratory is responsible for program compliance – *get it in writing!*

# 8. NLCP Checklist Information

- Completed NLCP Checklist items
  - Laboratory Information Checklist (e.g., Item C-16)
  - Section P Self-Assessment (relevant to eCCF)

# NLCP Checklist and Manual

- Current NLCP Checklist and Manual include requirements applicable to the use of a Federal eCCF:
  - CCF annotation
  - Computer system validation
  - Security
  - Electronic records
  - Electronic signatures
  - Electronic reports
  - Audit trails and logs
  - System monitoring
  - Incident response
  - Disaster recovery
  - Personnel training