Effective 1 October 2010
Revised November 2015

Urine
Instrumented Initial Test Facility (IITF)
Application Form

National Laboratory Certification Program (NLCP)

RTI International
Center for Forensic Sciences
3040 Cornwallis Road
P.O. Box 12194
Research Triangle Park, North Carolina 27709

NATIONAL LABORATORY CERTIFICATION PROGRAM
URINE IITF APPLICATION FORM

A. Applicant IITF

1. Name of IITF: _____

   Address: _____

   _____

   City, State, ZIP: _____

   Telephone: (____) ____ - _____ FAX: (____) ____ - _____

   e-Mail: _____

2. Express delivery address *(if different from above)*

   Address: _____

   _____

   City, State, ZIP: _____

3. Designated Responsible Technician (RT): _____
   Title/Position: _____

   Telephone: (____) _____ - _____ Ext. _____

   e-Mail: _____

   If applicable:

   Designated Alternate RT (Alt-RT): _____
   Title/Position: _____

   Telephone: (____) _____ - _____ Ext. _____

   e-Mail: _____

4. **I understand that the answers provided in this application will be used to determine the applicant IITF's potential eligibility for the National Laboratory Certification Program. To the best of my knowledge and belief, the answers recorded herein are true and complete as of this date.**

   Signature, Designated RT Date

NOTE: Any false, fictitious, or fraudulent statements or information presented in this application form could subject you to prosecution, monetary penalties, or both. See Sec. 18 U.S.C. 1001; 31 U.S.C. 3801-812.

B. General IITF Information

The following table is excerpted from Section 3.4 of the Mandatory Guidelines for Federal Workplace Drug Testing Programs (Federal Register, 73 FR 71858, 25 November 2008, effective 1 October 2010). ***Note****: confirmatory test information is not applicable for IITFs.*

Initial Test Analyte	**Initial Test Cutoff Concentration**	**Confirmatory Test Analyte**	**Confirmatory Test Cutoff Concentration**
Marijuana metabolites	50 ng/mL	THCA[1]	15 ng/mL
Cocaine metabolites	150 ng/mL	Benzoylecgonine	100 ng/mL
Opiate metabolites			
Codeine/Morphine[2]	2000 ng/mL	Codeine	2000 ng/mL
		Morphine	2000 ng/mL
6-Acetylmorphine	10 ng/mL	6-Acetylmorphine	10 ng/mL
Phencyclidine	25 ng/mL	Phencyclidine	25 ng/mL
Amphetamines[3]			
AMP/MAMP[4]	500 ng/mL	Amphetamine	250 ng/mL
		Methamphetamine[5]	250 ng/mL
MDMA[6]	500 ng/mL	MDMA	250 ng/mL
		MDA[7]	250 ng/mL
		MDEA[8]	250 ng/mL

[1]Delta-9-tetrahydrocannabinol-9-carboxylic acid (THCA).

[2] Morphine is the target analyte for codeine/morphine testing.

[3] Either a single initial test kit or multiple initial test kits may be used provided the single test kit detects each target analyte independently at the specified cutoff.

[4]Methamphetamine is the target analyte for amphetamine/methamphetamine testing

[5]To be reported positive for methamphetamine, a specimen must also contain amphetamine at a concentration equal to or greater than 100 ng/mL.

[6]Methylenedioxymethamphetamine (MDMA).

[7]Methylenedioxyamphetamine (MDA).

[8]Methylenedioxyethylamphetamine (MDEA).

1. To be eligible for certification, the IITF must test for all initial drug test analytes and initial specimen validity test measurands required by the Mandatory Guidelines for Federal Workplace Drug Testing Programs (*Federal Register*, 73 FR 71858, 25 November 2008, effective 1 October 2010). The IITF must use the test methods specified by the Mandatory Guidelines for screening and initial tests (i.e., drug tests and specimen validity tests). **Note**: the terms "screening specimen validity test" and "initial specimen validity test" are defined in Section J of the NLCP Manual for Urine IITFs.

   1a. Does the IITF have validated initial drug test assays for the drug classes required by the Mandatory Guidelines?

   ___ Yes
   ___ No → **IITF NOT ELIGIBLE TO APPLY**

1b. Does the IITF use an immunoassay method approved, cleared, or otherwise recognized as accurate and reliable by the U.S. Food and Drug Administration (FDA) for the initial drug tests?

___ Yes
___ No → **IITF NOT ELIGIBLE TO APPLY**

1c. Does the IITF have validated tests to assess specimen validity as required by the Mandatory Guidelines (i.e., at a minimum, tests for creatinine, pH, specific gravity, and one or more oxidizing adulterants)?

___ Yes
___ No → **IITF NOT ELIGIBLE TO APPLY**

2. Is the IITF registered with the U.S. Drug Enforcement Agency (DEA)?

___ Yes → **ATTACH PHOTOCOPY OF REGISTRATION CERTIFICATE**
___ No → **COMMENT BELOW**

If YES, which schedules are covered by the registration?

___ 1 ___ 2 ___ 2N ___ 3 ___ 3N ___ 4 ___ 5

If NO, explain how controlled reference materials are acquired: _____

3. Describe the State licensure requirements for urine forensic toxicology for the State in which the IITF is located. _____

4. List IITF certifications/licenses:

____ States (List):_____

____ CLIA/HCFA[1] (List Specialties): _____

____ CAP2 (List Specialties): _____

____ Others (Specify): _____

[1]Clinical Laboratory Improvement Amendments(CLIA)/Health Care Financing Administration (HCFA)
[2]College of American Pathologists (CAP)

4a. **ATTACH PHOTOCOPIES OF ALL LICENSES AND CERTIFICATIONS INDICATED ABOVE.**

5. To be eligible for certification, the IITF must obtain a letter of commitment from one or more HHS-certified laboratories stating that the laboratory will receive, test, and report specimens from the certified IITF. The letter must be signed by each Responsible Person (RP) of the laboratory and by the designated RT of the applicant IITF. The list of currently certified laboratories is published by SAMHSA monthly in the Federal Register and is available on the SAMHSA website, http://workplace.samhsa.gov/.

5a. Does the IITF have a letter of commitment from one or more HHS-certified laboratories?

___ Yes → **ATTACH PHOTOCOPIES OF ALL LABORATORY COMMITMENT LETTERS**
___ No → **IITF NOT ELIGIBLE TO APPLY**

C. IITF Standard Operating Procedures (SOP) Manual

1. For certification, the IITF must have a complete SOP manual that will apply to testing of regulated specimens under the Mandatory Guidelines for Federal Workplace Drug Testing Programs (Federal Register, 73 FR 71858, 25 November 2008, effective 1 October 2010).

   Note: Manufacturers' package inserts or instrument manuals are not considered formal procedures. A written SOP manual is required to be eligible to apply for certification and it must be completed before the IITF is eligible to receive NLCP performance testing (PT) samples.

   1a. Does the IITF have a complete SOP manual for regulated drug testing?

   ___ Yes
   ___ No → **IITF NOT ELIGIBLE TO APPLY**

IITF SOP MANUAL INDEX

Indicate the location for each of these topics in the IITF's SOP manual:

TOPIC	***SECTION***	***PAGE NO.***
Security		
Procedure for controlling access to the drug testing facility	_____	_____
Procedure for controlling access to individual secured areas	_____	_____
Procedure for documenting visitor access	_____	_____
Procedure for using an ECCF System (if applicable)	_____	_____
Accessioning (Specimen receipt)		
Procedure for receipt and processing of specimens	_____	_____
Procedure for problem/rejected specimens	_____	_____
Chain-of-Custody		
Procedure for documenting all transfers of specimens	_____	_____
Procedure for documenting all transfers of aliquots	_____	_____

Other Adulterants

Note: Provide the following information for each adulterant

Adulterant:_____

D. Chain of Custody, Accessioning, and Security

The IITF must have chain of custody, accessioning, and security procedures that ensure integrity is maintained for the original specimens and their aliquots. The chain of custody forms and procedures must account for all individuals who handle the specimens and aliquots. The chain of custody forms and procedures should provide a clear picture of the handling/transfers of specimens and aliquots from initial receipt to final disposition. The IITF must ensure the security of specimens and aliquots during processing and placement in any storage locations.

1. Provide a description of the IITF's chain of custody procedures for the following:

Specimen Receiving/Accessioning

-Receipt of specimen packages, how they are handled, who reviews the accuracy of the information on the custody and control forms and how discrepancies are documented
-Assignment of IITF accession numbers
-Handling and resolution of problems with specimen bottles and/or custody and control forms
-Description of collection kit to be used
- Location of temporary storage area(s)
- Procedures for electronic (digital) or combination (electronic and paper) Federal CCF (if applicable)

Aliquotting Procedures

-Aliquotting from the original specimen bottles (i.e., who and where)
-The aliquotting procedure (pouring or pipetting and amounts) used for preparing aliquots for initial drug tests, screening specimen validity tests, and initial specimen validity tests
-Transfer of aliquots from the individuals performing the aliquotting to those who will be testing the aliquots

Initial Drug Tests (First and Second Tests)

-Handling and testing of aliquots by IITF personnel
-Maintenance of chain of custody and aliquot identity during the testing

Specimen Validity Tests (Screening, Initial)

-Handling and testing of aliquots by IITF personnel
-Maintenance of chain of custody and aliquot identity during the testing
Note: *the terms "screening specimen validity test" and "initial specimen validity test" are defined in Section J of the NLCP Manual for Urine IITFs.*

Disposition of Specimens and Aliquots

-Handling of original specimen bottles and aliquots after testing is completed
-Procedure for transferring specimens to an HHS-certified laboratory

Note: (1) Insert here.
(2) Do not exceed a total of 3 pages.

2. Will the IITF use an electronic (digital) or combination (electronic and paper) Federal CCF?

   ___ Yes → Provide the items on the Electronic CCF System Submission List (attached)
   ___ No

3. Attach a flowchart and/or examples of chain of custody documents showing how regulated specimens and aliquots will be processed and their custody documented (chain of custody documents may be referenced and/or provided as examples for clarification).

4. Will regulated specimens be accessioned in a limited access, secure area?

   ___ Yes
   ___ No → **IITF NOT ELIGIBLE TO APPLY**

5. Will regulated specimens be tested in a limited access, secure area?

   ___ Yes
   ___ No → **IITF NOT ELIGIBLE TO APPLY**

6. Attach a floorplan of the IITF indicating the areas to be used for accessioning, testing of specimens, and storage of specimens, aliquots, and records. Include information to describe how the areas are secured and what security devices are utilized (e.g., which walls are outside walls; which are secured up to the ceiling; the location and type of security devices such as magnetic key cards, cipher locks, padlocks; location of secured storage areas such as refrigerators or freezers and how they are secured).

7. Will the original specimens be maintained in a limited access, secured area at all times?

   ___ Yes
   ___ No → **IITF NOT ELIGIBLE TO APPLY**

   7a. Where will the original specimens be stored?

   Before testing? _____

   During testing? _____

   After testing is complete? _____

   7b. Who will have access to the specimen storage areas?

   Before testing? _____

   During testing? _____

   After testing is complete? _____

E. Records

The IITF must maintain records to support test results (i.e., including but not limited to all associated QC results, analytical data, chain of custody documents and associated administrative records) for at least two years. The IITF must also maintain method validation records for past and current procedures, instrument validation records, records documenting the standard operating procedures used at any given time period, and records of the education, training, and certification of all employees associated with regulated testing. The IITF must have security measures in place to limit access to electronic and hardcopy records to essential authorized personnel.

1. Will the IITF maintain records supporting specimen test results for at least two years?

   ___ Yes
   ___ No → **IITF NOT ELIGIBLE TO APPLY**

   1a. Will there be a secured area for the storage of records supporting specimen test results?

   ___ Yes
   ___ No → **IITF NOT ELIGIBLE TO APPLY**

2. Will the IITF limit records access to authorized personnel?

   ___ Yes
   ___ No → **IITF NOT ELIGIBLE TO APPLY**

3. Attach two data packages using the format described in Section R of the NLCP Manual for Urine Instrumented Initial Test Facilities to support (1) a specimen forwarded to a laboratory based on initial drug test results and (2) a specimen forwarded to a laboratory based on specimen validity test results.

F. Personnel

Qualifications for a Responsible Technician Candidate

1. RT Candidate's Name: _____
   LAST FIRST MIDDLE

   The candidate must provide the following for review of his/her eligibility:

   (a) A detailed description of the experience and qualifications specifically addressing the RT requirements as stated in the Mandatory Guidelines;

   (b) A current résumé or curriculum vitae; and

   (c) Official copies with raised seal of all academic undergraduate and graduate transcripts.

2. To be eligible for review as an RT, at least one of the following questions must be answered "yes":

   2a. Does the candidate have a bachelor's degree in the chemical or biological sciences or medical technology?

   ___ Yes → **In which field?** _____
   GO TO QUESTION 3.

   ___ No → **GO TO QUESTION 2b.**

   2b. Does the candidate have training and experience comparable to a bachelor's degree in the chemical or biological sciences or medical technology, such as a scientific associate degree or certificate, or at least 2 years of university courses in a science curriculum, with additional training and laboratory/research experience in biology, chemistry, and pharmacology or toxicology?

   ___ Yes → **Describe:** _____
   _____
   _____
   _____

   ___ No

3. Does the candidate have training and experience in the analytical methods and forensic procedures used by the IITF that are relevant to the results?

   ___ Yes → **Describe:** _____
   _____
   _____
   _____

   ___ No → **CANDIDATE NOT ELIGIBLE AS RT**

4. Does the candidate have appropriate training and experience in reviewing and reporting forensic test results, maintenance of chain of custody, recordkeeping, and understanding proper remedial action in response to problems that may arise?

___ Yes → **Describe:** _____

_____

_____

_____

___ No→ **CANDIDATE NOT ELIGIBLE AS RT**

4. In the table below, enter the candidate's education.

Education	**Name of School**	**Major and Minor Fields of Study**	**Diploma, Certificate or Degree Received**
College or University			
Other Schools Attended			

5. Is the candidate a full-time or part-time employee of the IITF?

___ Full-time (at least 40 hours per week)

___ Part-time _____ hours per week

If not a full- or part-time employee, what is the relationship between the candidate and the IITF?

_____

_____

_____

_____

6. How many hours per week will the candidate work in the forensic urine drug testing IITF?

_____ HOURS PER WEEK

7. How long has the candidate been associated with the IITF?

_____ YEARS

Qualifications for an Alternate Responsible Technician Candidate

1. Alternate RT Candidate's Name: _____
   LAST FIRST MIDDLE

   The candidate must provide the following for review of his/her eligibility:

   (a) A detailed description of the experience and qualifications specifically addressing the RT requirements as stated in the Mandatory Guidelines;

   (b) A current résumé or curriculum vitae; and

   (c) Official copies with raised seal of all academic undergraduate and graduate transcripts.

2. An alt-RT must be capable of fulfilling RT duties for a limited time (i.e., up to 180 days). An alt-RT candidate's qualifications are compared to RT requirements as follow:

   2a. Does the candidate have a bachelor's degree in the chemical or biological sciences or medical technology?

   ___ Yes → **In which field?** _____
   GO TO QUESTION 3.

   ___ No → **GO TO QUESTION 2b.**

   2b. Does the candidate have training and experience comparable to a bachelor's degree in the chemical or biological sciences or medical technology, such as a scientific associate degree or certificate, or at least 2 years of university courses in a science curriculum, with additional training and laboratory/research experience in biology, chemistry, and pharmacology or toxicology?

   ___ Yes → **Describe:** _____
   _____
   _____
   _____
   ___ No

3. An alt-RT candidate must have appropriate experience in analytical toxicology.

   3a. How many years of experience does the candidate have in analytical forensic toxicology (including experience with the analysis of biological material for drugs of abuse) beyond any degree?

   _____ YEARS

   3b. Does the candidate have appropriate training and/or experience in all operations of the forensic drug testing IITF (i.e., including training and experience as a certifying technician)?

   ___ Yes

   ___ No → **CANDIDATE NOT ELIGIBLE AS AN ALT-RT**

4. In the table below, enter the candidate's education.

Education	Name of School	Major and Minor Fields of Study	Diploma, Certificate or Degree Received
College or University			
Other Schools Attended			

5. Is the candidate a full-time or part-time employee of the IITF?

___ Full-time (at least 40 hours per week)

___ Part-time _____ hours per week

If not a full- or part-time employee, what is the relationship between the candidate and the IITF?

_____
_____
_____
_____

6. How many hours per week will the candidate work in the forensic urine drug testing IITF?

_____ HOURS PER WEEK

7. How long has the candidate been associated with the IITF?

_____ YEARS

Personnel Certifications and Licenses

1. List the name, job title, education, and licenses/certifications for the following key staff:

   Note: (1) Attach a résumé for each individual listed below.

   (2) Attach a separate sheet as needed to list all individuals in these positions.

	Name	Job Title	Education	License/ Certification
Certifying Technician(s)				
Supervisor(s)				
Other Key Staff				

2. Is licensure and/or certification required for any of the above positions in the State in which the IITF is located?

   ___ Yes
   ___ No → **GO TO SECTION G**

   If YES, describe requirements:

   _____
   _____
   _____
   _____

G. Quality Control

For certification, the IITF must have clearly defined QC procedures that are consistently applied, subject to review, and prompt appropriate corrective action upon failure to meet established acceptance criteria.

1. Are instrument function checks reviewed prior to batch analysis?

   ___ Yes → **COMPLETE 1a**
   ___ No

   1a. What is the title and/or position of the person responsible for these checks?

   Title/Position: _____

2. Are corrective actions documented when controls, instrument responses, etc., fail defined acceptance criteria?

   ___ Yes
   ___ No → **IITF NOT ELIGIBLE TO APPLY**

3. Are all QC results reviewed by the Certifying Technician prior to the release of the results?

   ___ Yes
   ___ No → **IITF NOT ELIGIBLE TO APPLY**

4. Is the QA/QC program under the direct supervision of a Quality Control Supervisor?

   ___ Yes
   ___ No → **COMPLETE 4a**

   4a. What is the title/position of the person responsible for the QA/QC program?

   Title/Position: _____

5. Is the QA/QC program reviewed periodically by the Responsible Technician Candidate?

   ___ Yes
   ___ No → **CANDIDATE NOT ELIGIBLE AS RT**

   5a. What is the title/position of the person responsible for the periodic review?

   Title/Position: _____

6. Are there written procedures that are employed to routinely detect clerical and analytical errors prior to reporting results?

   ___ Yes
   ___ No → **IITF NOT ELIGIBLE TO APPLY**

7. For certification, the IITF must have a QC program that includes both blind and open QC samples. At a minimum, these must include the number and type of QC samples described in the Mandatory Guidelines for drug and specimen validity tests.

   Provide a description of the IITF's procedures for the following:

   Specimen Accessioning

   - Introduction and /or aliquotting of blind samples into the test batches by accessioners
   - Content and concentration of each blind sample
   - If applicable, preparation and submission of blind samples as donor specimens from external sources

   Initial Drug Tests (First and Second)

   - How batches are constituted (e.g., how many specimens are in a batch, is it constituted in one session or are specimens added to the batch throughout the day?)
   - The distribution of the donor specimens and QC samples within each batch
   - The procedure(s) and acceptance criteria for calibration and when and by whom the calibration data are evaluated and documented
   - The acceptance criteria for each control (open and blind) in each batch and when and by whom these are evaluated and documented
   - The criteria for accepting all donor specimen results or only a partial number of donor specimens in a batch

   Specimen Validity Tests (Screening, Initial)

   - How batches are constituted (e.g., how many specimens are in a batch, is it constituted in one session or are specimens added to the batch throughout the day?)
   - The distribution of the donor specimens and QC samples within each batch
   - The procedure(s) and acceptance criteria for calibration and when and by whom the calibration data are evaluated and documented
   - The acceptance criteria for each control (open and blind) in each batch and when and by whom these are evaluated and documented
   - The criteria for accepting all donor specimen results or only a partial number of donor specimens in a batch
   - Include an outline or a legible flow chart that comprehensively describes the IITF's specimen validity testing. The IITF's submission must identify any "reflex" testing, the initial test methods for each specimen validity test measurand, and any screening tests.

   Note: (1) Insert here.

   (2) Do not exceed a total of 2 pages.

H. Review and Reporting

The IITF must have adequate procedures to ensure the thorough review and accurate reporting of results.

1. Briefly describe the procedures for reviewing initial drug test data and certifying negative results (i.e., title/position of reviewers, electronic/hardcopy documents reviewed, QC review):

_____

_____

_____

_____

_____

_____

2. Briefly describe the procedures for reviewing specimen validity test data/results (i.e., screening and initial tests): _____

_____

_____

_____

_____

_____

3. Briefly describe the procedures for the reporting of results. If the IITF will use electronic reporting for any regulated specimens, describe procedures to ensure confidentiality: ___

_____

_____

_____

_____

_____

4. Is the IITF's custody and control form (CCF) identical to the OMB-approved Federal CCF to be used for all specimens submitted for testing under the Mandatory Guidelines?

___ Yes→ **ATTACH EXAMPLE OF IITF'S CUSTODY AND CONTROL FORM**
___ No→**IITF NOT ELIGIBLE TO APPLY**

5. Will the IITF use computer-generated electronic reports for specimens submitted for testing under the Mandatory Guidelines?

___ Yes →**ATTACH EXAMPLE REPORTS (SEE BELOW)**
___ No

If YES, attach an example of the IITF's computer-generated electronic report for each of the following IITF results:

- Negative
- Negative, Dilute
- Rejected

6. Will the IITF send a data file report in lieu of a formatted electronic report?

___ Yes → **ATTACH EXAMPLE DATA FILE REPORTS** (reflecting what will be sent)
___ No

7. Does the IITF plan to use an electronic (digital) or combination (electronic and paper) Federal CCF for reporting? Note: Section D of the NLCP Manual for Urine IITFs describes the allowable formats for the Federal CCF.

___ Yes
___ No

If YES, specify the CCF type(s) and supplier(s):

_____
_____
_____

I. IITF Computers and Information Systems

IITF computer systems include any computer system used in processing regulated specimens. Such systems are typically used for accessioning specimens, batch assignment and scheduling, capturing test results, tabulating QC data, and reporting final results. HHS-certified laboratories are prohibited from transmitting data to an IITF through a computer interface. Any computer interface communicating any form of data from an HHS-certified IITF to a laboratory must be approved by the NLCP prior to implementation. The applicant IITF and/or laboratories must submit a detailed plan to the NLCP for review.

1. Give a brief description of the computer system to be utilized by the IITF. Is it a "stand alone" system used solely by the IITF, part of a local system (e.g., a hospital system), or part of a multi-facility corporate system? (If not on-site, provide information on its location and organizational control of the system.)

   _____
   _____
   _____
   _____
   _____
   _____
   _____
   _____

2. Give a brief description of how the IITF plans to use the computer system in regulated specimen processing: _____
   _____
   _____
   _____
   _____
   _____

3. Is the IITF computer system maintained in a secure area?

   ___ Yes
   ___ No

   Attach a floorplan identifying the IITF computer system location. Include information to describe how the area is secured and what security devices are utilized (e.g., which walls are outside walls; which are secured up to the ceiling; the location and type of security devices such as magnetic key cards, cipher locks, padlocks).

4. Does the IITF limit functional access to the computer system?

   ___ Yes
   ___ No

5. Does the IITF have a System Security Plan (SSP) for each information system used for regulated drug testing, including corporate systems and external service provider systems?

___ Yes
___ No → **IITF NOT ELIGIBLE TO APPLY**

6. Will the IITF use an external service provider (e.g., LIMS provider, software service provider, ECCF provider, report provider) to perform services on the IITF's behalf related to regulated drug testing?

___ Yes → **List the names of external service providers, and Complete 6a**
___ No

_____
_____

6a. Does the IITF have a signed contract/agreement with each external service provider that includes the priority elements listed in the Priority Elements for Contracts/Agreements with External Service Providers?

___ Yes
___ No → **IITF NOT ELIGIBLE TO APPLY**

Complete the NLCP Application Tables

Table 1-a. First and Second Initial Drug Test Methods and Instruments

Table 1-b. First Initial Drug Test QC samples

Table 1-c. Second Initial Drug Test QC samples

Table 2-a-1. Initial Specimen Validity Test Methods and Instruments (continued on **Table 2-a-2** as needed)

Table 2-b-1. *not applicable for an IITF*

Table 2-c-1. Screening Specimen Validity Test Methods and Instruments (continued on **Table 2-c-2** as needed)

Table 2-d-1. Initial Specimen Validity Test QC samples (continued on **Table 2-d-2** as needed)

Tables 2-d-3 and 2-d-4. *not applicable for an IITF*

Table 2-d-5. Screening Specimen Validity Test QC samples

Priority Elements for Contracts/Agreements with External Service Providers

1. Limiting access to regulated specimen information

2. Implementing appropriate safeguards to prevent unauthorized use or disclosure of the information, including implementing applicable federal requirements with regard to regulated specimen and drug test information

3. Reporting to the HHS-certified test facility any use or disclosure of the information not provided for by the contract, including incidents that constitute incidents that constitute data breaches of unsecured regulated specimen and drug test information

4. Disclosing information to HHS related to regulated specimens and drug tests

5. Arranging for disposition of regulated specimen data (i.e., disposal in accordance with specified record retention periods; transfer of records to the HHS-certified test facility upon termination of the agreement)

6. Notifying the HHS-certified test facility prior to allowing any subcontractors to have access to regulated specimen and drug test information

7. Ensuring that any subcontractors agree to the same restrictions and conditions that apply to the external service provider with respect to regulated specimen and drug test information.

Electronic CCF System Submission List

Items to be submitted for review:

1. **Process Overview**. A detailed overview of all processes involving the Federal ECCF from initiation until final disposition, including:

    - Assigning unique specimen identification numbers
    - Initiation of the ECCF
    - Collection
    - Specimen shipment (labels/seals for specimen bottles and bags)
    - CCF distribution at the end of collection
    - Collector/collection site records storage and disposal
    - Specimen tracking
    - Test facility accessioning
    - Test facility reporting
    - Test facility records storage and disposal
    - Medical Review Officer review and completion of the CCF
    - MRO reporting
    - MRO records storage and disposal

2. **Topic Outline of Proposed SOPs** An outline of topics to be addressed in:

    - HHS-certified test facility standard operating procedures (SOPs) for accessioning, certification, reporting
    - Procedures/Instructions for other Federal ECCF users including collectors, MROs, and MRO staff

    Note: Proposed Federal ECCF instructions or proposed SOP Table of Contents may be submitted
    Examples: Screenshots, tables of contents

3. **Training Plans** Training for Federal ECCF system users, including:

    - Federal ECCF system users (IITF staff, laboratory staff, collectors, MROs, 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

    Note: RP must document review and approval of training plans and materials

4. **System/Network Diagram** Logical network diagram including, at a minimum:

    - Firewalls
    - Network security devices

Electronic CCF System Submission List

- Servers
- Workstations
- Primary routers/switches
- Remote access devices
- Internet connection(s)

5. **System Security Plan (SSP)** Plan that reflects NIST 800-53 or other recognized security standard, and provides an overview of the security requirements of the system, describes the controls in place or planned for meeting those requirements, and delineates responsibilities and expected behavior of all individuals who access the system.

    - The ability to generate accurate and complete copies of records in both human readable and electronic form suitable for inspection, review, and copying upon request of authorized parties (e.g., the MRO, federal agency, or SAMHSA)
    - Protection of records to enable accurate and ready retrieval through the records retention period
    - Limiting system access to authorized individuals
    - Secure, computer-generated, time-stamped audit trails to independently record the date and time of operator entries and actions that create, modify, or delete records from the time of initiation of the Federal CCF (changes should be evident when reviewing the original record, and any electronic or paper copy of the original record)
    - Use of authority checks to ensure that only authorized individuals can use the system, electronically sign a record, access the operation or computer system input or output device, alter a record, or perform the operation at hand

6. **System Validation Plan** Plan for testing and evaluating information system security controls to ensure effective implementation.

    Note: The HHS-certified test facility must provide documentation of security control testing and evaluation at NLCP inspections.
    Examples of records to be provided include
    - Periodic records checks
    - Independent security monitoring by IITF/laboratory IT staff
    - A report from an independent auditor regarding compliance with relevant industry standards

7. **External ECCF Provider Agreement with HHS-Certified Test Facility** An HHS-certified test facility that plans to use an external ECCF system must have a contract/ agreement signed by each laboratory Responsible Person (RP)/IITF

Electronic CCF System Submission List

Responsible Technician (RT) and an authorized representative of the ECCF provider that:

- Specifies the responsibilities of the ECCF provider and states restrictions and conditions that apply to the ECCF provider with respect to regulated specimen and drug test information
- Establishes the permitted and required uses and disclosures of regulated specimen and drug test information by the ECCF provider
- Addresses, at a minimum, these **priority elements**:
    - Limiting access to regulated specimen information
    - Implementing appropriate safeguards to prevent unauthorized use or disclosure of the information, including implementing applicable federal requirements with regard to regulated specimen and drug test information
    - Reporting to the HHS-certified test facility any use or disclosure of the information not provided for by the contract, including incidents that constitute incidents that constitute data breaches of unsecured regulated specimen and drug test information
    - Disclosing information to HHS related to regulated specimens and drug tests
    - Arranging for disposition of regulated specimen data (i.e., disposal in accordance with specified record retention periods; transfer of records to the HHS-certified test facility upon termination of the agreement)
    - Notifying the HHS-certified test facility prior to allowing any subcontractors to have access to regulated specimen and drug test information
    - Ensuring that any subcontractors agree to the same restrictions and conditions that apply to the ECCF provider with respect to regulated specimen and drug test information.

Note: The agreement/contract must be provided for NLCP review with the initial ECCF submission and with other ECCF system documentation at each inspection.

Table C-1-a

Initial Drug Test
Methods and Instruments

First Initial Drug Test Methods and Instruments							
First Initial Drug Test	THCA (marijuana metabolites)	BZE (cocaine metabolites)	MOR (opiate metabolites)	6-AM	PCP	MAMP (amphetamines)	MDMA
Kit and Manufacturer							
Analyzer and Manufacturer							
Number of Analyzer Units							
Calibration Method							
Maximum Batch Size							
*If "Other" is selected, please specify:							

Second Initial Drug Test Methods and Instruments							
Second Initial Drug Test	THCA (marijuana metabolites)	BZE (cocaine metabolites)	MOR (opiate metabolites)	6-AM	PCP	MAMP (amphetamines)	MDMA
Kit and Manufacturer							
Analyzer and Manufacturer							
Number of Analyzer Units							
Calibration Method							
Maximum Batch Size							
*If "Other" is selected, please specify:							

THCA = ∆9-tetrahydrocannabinol-9-carboxylic acid
BZE = benzoylecgonine
MOR = morphine
PCP = phencyclidine
6-AM = 6-acetylmorphine
MAMP = methamphetamine
MDMA = methylenedioxymethamphetamine

Table C-1-b

First Initial Drug Test
QC Samples

1st initial drug test QC		Cal 1	Cal 2	Cal 3	Cal 4	Cal 5	Control 1	Control 2	Control 3	Control 4	BQC 1	BQC 2
THCA	Conc											
	Matrix											
	Source											
BZE	Conc											
	Matrix											
	Source											
MOR	Conc											
	Matrix											
	Source											
6-AM	Conc											
	Matrix											
	Source											
PCP	Conc											
	Matrix											
	Source											
MAMP	Conc											
	Matrix											
	Source											
MDMA	Conc											
	Matrix											
	Source											
*If "Other" is selected, please specify:												

BQC = blind quality control sample

Table C-1-c

Second Initial Drug Test
QC Samples

2nd initial drug test QC		Cal 1	Cal 2	Cal 3	Cal 4	Control 1	Control 2	Control 3	Control 4	BQC 1	BQC 2
THCA	Conc										
	Matrix										
	Source										
BZE	Conc										
	Matrix										
	Source										
MOR	Conc										
	Matrix										
	Source										
6-AM	Conc										
	Matrix										
	Source										
PCP	Conc										
	Matrix										
	Source										
MAMP	Conc										
	Matrix										
	Source										
MDMA	Conc										
	Matrix										
	Source										
*If "Other" is selected, please specify:											

Table C-2-a-1

Initial Specimen Validity Test Methods and Instruments

Initial SVT	Creatinine	SG	pH	Nitrite	Gen.Oxid.	Other:	Other:
Method		4 dec. place refractometer					
Kit Manufacturer							
Analyzer and Manufacturer							
Number of Analyzer Units							
Unit of Measurement	mg/dL			mcg/mL			
Target Analyte of Assay							
Target Analyte of Calibrator							
Calibration Method							
LOD							
LOQ							
ULOL							
Carryover Limit							
Maximum Batch Size							
*If "Other" is selected, please specify:							

SG = specific gravity
Gen. Oxid. = general oxidant
LOD = limit of detection
LOQ = limit of quantitation
ULOL= upper limit of linearity

Table C-2-a-2

Initial Specimen Validity Test Methods and Instruments

Initial SVT cont.	Other:	Other:	Other:	Other:	Other:	Other:	Other:
Method							
Kit Manufacturer							
Analyzer and Manufacturer							
Number of Analyzer Units							
Unit of Measurement							
Target Analyte of Assay							
Target Analyte of Calibrator							
Calibration Method							
LOD							
LOQ							
ULOL							
Carryover Limit							
Maximum Batch Size							
*If "Other" is selected, please specify:							

Table C-2-c-1

Screening/Differential Specimen Validity Test Methods and Instruments

Screening/Differential SVT	SG	pH	Other:	Other:	Other:
Method					
Kit Manufacturer					
Analyzer and Manufacturer					
Number of Analyzer Units					
Unit of Measurement					
Target Analyte of Assay					
Target Analyte of Calibrator					
Calibration Method					
LOD					
LOQ					
ULOL					
Carryover Limit					
Maximum Batch Size					
*If “Other” is selected, please specify:					

Table C-2-c-2

Screening/Differential Specimen Validity Test Methods and Instruments

Screening/Differential SVT cont.	Other:	Other:	Other:	Other:	Other:
Method					
Kit Manufacturer					
Analyzer and Manufacturer					
Number of Analyzer Units					
Unit of Measurement					
Target Analyte of Assay					
Target Analyte of Calibrator					
Calibration Method					
LOD					
LOQ					
ULOL					
Carryover Limit					
Maximum Batch Size					
*If “Other” is selected, please specify:					

Table C-2-d-1

Initial Specimen Validity Test
QC Samples

Initial SVT QC		Cal 1	Cal 2	Cal 3	Cal 4	Cal 5	Control 1	Control 2	Control 3	Control 4	Control 5
Creatinine	Target value										
	Matrix										
	Source										
SG	Target value										
	Matrix										
	Source										
pH	Target value										
	Matrix										
	Source										
Nitrite	Target value										
	Matrix										
	Source										
Gen Oxid	Target value										
	Matrix										
	Source										
*If “Other” is selected, please specify:											

Table C-2-d-2

Initial Specimen Validity Test
QC Samples

Initial SVT QC cont.		Cal 1	Cal 2	Cal 3	Cal 4	Cal 5	Control 1	Control 2	Control 3	Control 4	Control 5
Other (enter name):	Target Value										
	Matrix										
	Source										
Other (enter name):	Target Value										
	Matrix										
	Source										
Other (enter name):	Target Value										
	Matrix										
	Source										
Other (enter name):	Target Value										
	Matrix										
	Source										
Other (enter name):	Target Value										
	Matrix										
	Source										
Other (enter name):	Target Value										
	Matrix										
	Source										
Other (enter name):	Target Value										
	Matrix										
	Source										
Other (enter name):	Target Value										
	Matrix										
	Source										
*If "Other" is selected, please specify:											

Table C-2-d-5

Screening/Differential Specimen Validity Test
QC Samples

Screening/Differential SVT QC		Cal 1	Cal 2	Cal 3	Cal 4	Cal 5	Control 1	Control 2	Control 3	Control 4	Control 5
Specific Gravity	Target Value										
	Matrix										
	Source										
pH	Target Value										
	Matrix										
	Source										
Other (enter name):	Target Value										
	Matrix										
	Source										
Other (enter name):	Target Value										
	Matrix										
	Source										
Other (enter name):	Target Value										
	Matrix										
	Source										
Other (enter name):	Target Value										
	Matrix										
	Source										
Other (enter name):	Target Value										
	Matrix										
	Source										
Other (enter name):	Target Value										
	Matrix										
	Source										
*If “Other” is selected, please specify:											