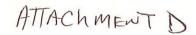
OMB No. 0930-0158

Expiration Date: xx/xx/xxxx



## National Laboratory Certification Program

## **Application Form**

National Laboratory Certification Program
RTI International
Attention: Inspection Department
P.O. Box 12194
3040 Cornwallis Road
Research Triangle Park, North Carolina 27709

#### Paperwork Reduction Act Notice (as required by 5 CFR 1320.21)

Public reporting burden for this collection of information, including the time for reviewing instructions and completing the collection of information, is estimated to average 4 hours per response for an initial certification inspection and 3 hours for subsequent inspections. Federal employees may send comments regarding these burden estimates or any other aspect of this collection of information, including suggestions for reducing this burden, to the SAMHSA Reports Clearance Officer, Paperwork Reduction Project (0930-0158), Room 7-1044, One Choke Cherry Road, Rockville, Maryland 20857. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. The OMB control number for this project is 0930-0158.

# NATIONAL LABORATORY CERTIFICATION PROGRAM APPLICATION FORM

F	A. APPLICANT LABORATORY
1	Laboratory Name:
	Address:
	City, State, ZIP:
	Country:
	Telephone Number:
	FAX Number:
2.	Is your express delivery address the same as listed above?
	□ Yes
	□ No→ ENTER YOUR EXPRESS DELIVERY ADDRESS BELOW
	Name:
	Address:
	City, State, ZIP:
	Country:
3.	Designated Responsible Person:
	Title/Position:
	Telephone Number:
4.	Laboratory Contact Person: (If different from designated RP)
	Title/Position:
	Telephone Number:

## **B. GENERAL LABORATORY INFORMATION**

1.	cor		eligible for certification in this program, your laboratory must perform both initial and rug testing at the same location. If this is not the case, your laboratory is <b>not</b> eligible to rogram.
	1a.	Does your	laboratory perform initial and confirmatory drug testing at the same location?
		☐ Ye	S
		□ No	→ LABORATORY NOT ELIGIBLE TO APPLY
2.	req	uired by the	certified, your laboratory must test for all drugs and specimen validity test analytes Mandatory Guidelines. Your laboratory must use different test methods for the initial bry tests (i.e., for drugs and adulterants).
	2a.	Does you	r laboratory have validated initial test assays for all five drug classes listed in Table 1?
		☐ Ye	3
		☐ No	→ LABORATORY NOT ELIGIBLE TO APPLY
	2b.	Does you	r laboratory use an immunoassay method approved by the FDA for the initial dug tests?
		☐ Yes	
		☐ No	→ LABORATORY NOT ELIGIBLE TO APPLY
	2c.		laboratory have validated GC/MS assays for the confirmatory testing of required drug sted in Table 3? (Note: testing for methamphetamine enantiomers is optional.)
		☐ Yes	
		☐ No	→ LABORATORY NOT ELIGIBLE TO APPLY
	2d.	Mandator	laboratory have validated tests to assess specimen validity as required by the Guidelines (i.e., at a minimum, tests for creatinine, pH, specific gravity, and one or izing adulterants)?
		☐ Yes	
		□ No	→ LABORATORY NOT ELIGIBLE TO APPLY
	2e.	Does your	laboratory perform enantiomeric analysis of methamphetamine?
		☐ Yes	→ COMMENT BELOW
		□ No	
		Briefly desc	ribe the procedure for analysis and reporting of methamphetamine enantiomers.

3.	Is your laboratory registered with the U.S. Drug Enforcement Administration (DEA)?
	$\Box$ Yes → ATTACH PHOTOCOPY OF REGISTRATION CERTIFICATE $\Box$ No → COMMENT BELOW, THEN GO TO QUESTION 7
	If NO, explain how controlled reference materials are acquired:
	3a. What is your laboratory's DEA registration number?
	3b. What type of registration does your laboratory have (e.g., researcher, practitioner)?
4.	In the boxes below, check each schedule covered by your registration.
	□ 1 □ 2 □ 2N □ 3 □ 3N □ 4 □ 4N □ 5
5.	Describe the State licensure requirements for urine forensic toxicology for the State in which your laboratory is located.
6.	Is your laboratory in compliance?
	☐ Yes
	□ No
7.	List your laboratory's licenses and certifications (e.g., CLIA/HCFA, CAP). Attach photocopies of all licenses and certifications.

Table 1: Initial Drug Tests Used by the Laboratory

	Amphetamine / Methamphetamine	Cannabinoide	Cocaine	Softia	17
Immunoassay Method	The second secon			Charles	riencycliquie
Kit Manufacturer					777772
Test Kit Name	TOTAL PROPERTY.		The state of the s		
Concentration of Calibrator(s) (ng/mL)					
Concentration of Controls [Open (O) and Blind (B)] (ng/mL)					
Cutoff				The state of the s	
Make and Model of Analyzer					
Maximum Batch Size					
				7	

NOTE: Define any abbreviation not listed

KIMS - Kinetic Interaction of Microparticles in Solution RIA - Radioimmunoassay

- Enzyme Immunoassay - Fluorescence Polarization Immunoassay

EIA FPIA

Method Abbreviations:

CEDIA - Cloned Enzyme Donor Immunoassay

4

Table 2: Secondary Initial Drug Tests Used by the Laboratory

	Amphetamine / Methamphetamine	Cannabinoids	Cocaine	optoinO	and design of C
Immunoassay Method	7. 11.000			Charles	riieiicyciidine
Kit Manufacturer				7,700	The state of the s
Test Kit Name					
Concentration of Calibrator(s) (ng/mL)					
Concentration of Controls [Open (O) and Blind (B)] (ng/mL)					
Cutoff (ng/ml)					
Make and Model of Analyzer				The state of the s	
Maximum Batch Size					

NOTE: Define any abbreviation not listed

EIA - Enzyme Immunoassay
FPIA - Fluorescence Polarization Immunoassay
KIMS - Kinetic Interaction of Microparticles in Solution
RIA - Radioimmunoassay

CEDIA - Cloned Enzyme Donor Immunoassay

Method Abbreviations:

Table 3: Confirmatory Drug Tests Used by the Laboratory

3						
		Int. Std.				Appendix and a second a second and a second
		Conc'n	LOD	LOQ	ULOL	COL
The state of the s	Internal Standard	(ng/mL)	(na/mL)	(na/mL)	(lm/m)	(lm/nu)
Amphetamine	1984), 19					(1.18,1115)
Methamphetamine	The state of the s					
THC Acid	THE PROPERTY AND THE PR					
Benzoylecgonine	ALL STATES AND THE ST					
Codeine						
Morphine	THE PARTY OF THE P					
6-Acetylmorphine	THE PARTY OF THE P		777.4			
Phencyclidine	TANAN				777786	,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,
d,l-methamphetamine						A CONTRACTOR OF THE CONTRACTOR

 Carryover Limit COL Int. Std. - Internal

Standard - Limit of LOD

Abbreviations:

Detection - Limit of

LOQ

Quantitation ULOL - Upper Limit of Linearity

Table 4: Confirmatory Drug Tests Used by the Laboratory

	D,L-MAMP							
***************************************	PCP	***************************************						
	6-AM							many and the state of the state
THE PARTY OF THE P	COD/MOR						The state of the s	TYPINAL I
	BZE			TOTAL STATE OF THE PARTY OF THE	Section 1. The sectio			
	THCA	THE PARTY OF THE P						
	AMP/MAMP							
		Volume (mL) Used	Extraction Method (L/L or SPE)	Hydrolysis Method (N, Enz, A, B)	Derivatizing Reagent *	Concentration of Calibrator(s) (ng/mL)	Concentration of Controls (ng/mL)**	Cutoff

- Liquid/Liquid

Abbreviations:

Extraction SPE - Solid Phase Extraction N - None Enz - Enzymatic

- Acid - Base

\* For Example: BSTFA, BSA, MSTFA, TFA, PFPA, HFBA, CH3/TMAH, HFIP/PFPA, etc \*\* Open (O) [and Blind (B) if used]

Table 5: Confirmatory Drug Tests Used by the Laboratory

ON V PA	D,L-WAINT								7 7 7 7 7 7 7 7 7 7 7 7 7 7 7 7 7 7 7 7			
٥٥٥	ב							144444				
B.AM												
MOR		ту, караштан										
COD					-							
BZE												
THCA	Water Park											
MAMP			State Control of the				7.17.77.77.11.11.11.11.11.11.11.11.11.11					
AMP	***************************************				7 7 7 7 7 7 7 7 7 7 7 7 7 7 7 7 7 7 7 7							
<b>▼</b>			dι	du	***************************************				(-			
	Make and Model	of GC/MS	Injection Port Ten (°C)	Column Initial Ter (°C)	Interface Temp (°C)	lsothermal or Temperature Program * (°C)	Split or Splitless Injection	Column Type	Column Length (m)	Full Scan Mass Range	Analyte SIM Ions Monitored **	Int.Std. SIM Ions Monitored **

\* For Example: 100(3)15/230(3) Initial temperature 100 degrees, held for 3 minutes, then ramped at 15 degrees/min to 230 degrees which is held for 3 minutes
\*\* Bold or circle quantitative ion

Table 6: Initial Specimen Validity Tests Used by the Laboratory

	Creatinine	ine	Specific	Hd	Nitrite	Other:	Other:	Other:
Method			Gravity					)
1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1								
Kit Manufacturer				7777	TABLE TO THE TABLE			
Test Kit Name								
Unit of Measurement						7,000,000		
Target Analyte								THE PARTY OF THE P
Concentration of Calibrator(s)								The second secon
Concentration of Controls								
ГОР								
LOQ						7,700,000,000		
NLOL								The state of the s
TOO					The state of the s			
Method / Characteristic	CLR -	- Colorimetric	tric	A CANADA A C		- Ion Selective Electrode		
Abbreviations:		- Manual F	Refractometer		<u> </u>			
NOTE: Define any abbreviation not listed	OKET PHM -	Digital Ke PH Meter Disetion	- Digital Refractometer - pH Meter - Director		LOD - Limit of Detection LOQ - Limit of Quantitati	- Limit of Detection - Limit of Quantitation	; ;	
	₹	- Chromatography - Atomic Absorptio	Chromatography Atomic Absorption		ULUL - Upper Limit of L COL - Carryover Limit	- Upper Limit of Linearity/Quantitation - Carryover Limit	/Quantitation	

Table 7: Confirmatory Specimen Validity Tests Used by the Laboratory

	Creatinine	Specific Gravity	Hd	Nitrite	Other:	Other:	Other:
Method	17770000	- constitution of the cons					
Kit Manufacturer				THE	Towns to the second sec		
Test Kit Name	- Thomas						
Unit of Measurement							
Target Analyte							
Concentration of Calibrator(s)							
Concentration of Controls				1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1			
ГОР							
LOQ					THE PARTY OF THE P	7.75.44.5.5.5.5.5.5.5.5.5.5.5.5.5.5.5.5.	
NFOF							
TOO				77,77		10000	TTTTTENTITY TOTAL
Method / Characteristic Abbreviations: NOTE: Define any abbreviation not listed	CRL - Colorime mREF - Manual I DREF - Digital F PHM - pH Mete DS - Dipstick CHRM - Chromat AA - Atomic A	- Colorimetric - Manual Refractometer - Digital Refractometer - pH Meter - Dipstick - Chromatography		ISE - Ion Se CE - Capilla LOD - Lim LOQ - Lim ULOL - Upp COL - Car	ISE - Ion Selective Electrode CE - Capillary Electrophoresis LOD - Limit of Detection LOQ - Limit of Quantitation ULOL - Upper Limit of Linearity/Quantitation COL - Carryover Limit	iis rity/Quantitatior	

Table 8: Screening/Differential Specimen Validity Tests Used by the Laboratory

	Other:	Other:	Other:	Other:	Other:
Method					
Kit Manufacturer		A THE RESIDENCE OF THE PARTY OF			TRANS.
Test Kit Name		A STATE OF THE STA			
Unit of Measurement					
Target Analyte					
Concentration of Calibrator(s)					
Controls					
COD					
ГОО					
NLOL					
COL					
Method / Characteristic Abbreviations: NOTE: Define any abbreviation not listed	CLR - Colorimetric mREF - Manual Refractometer dREF - Digital Refractometer PHM - pH Meter DS - Dipstick CHRM - Chromatography AA - Atomic Absorption	iometer meter y ion		ISE - lon Selective Electrode CE - Capillary Electrophoresis LOD - Limit of Detection LOQ - Limit of Quantitation ULOL - Upper Limit of Linearity COL - Carryover Limit	ectrode phoresis n tion nearity

#### C. STANDARD OPERATING PROCEDURES MANUAL

 For certification, your laboratory must have a complete drug testing procedures manual that will apply to testing of regulated specimens under the Mandatory Guidelines for Federal Workplace Drug Testing Programs (Federal Register, 69 FR 19644, 13 April 2004 effective 1 November 2004).

Note: manufacturers' package inserts or instrument manuals are not considered formal procedures. A written procedure manual is required in order to be eligible to apply for certification and it must be completed before the laboratory is eligible to receive NLCP PT samples.

1a. Does your laboratory have a written drug testing procedures manual?☐ Yes

☐ No → LABORATORY NOT ELIGIBLE TO APPLY

#### LABORATORY SOP INDEX

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

<u>TOPIC</u>	<u>SECTION</u>	PAGE NO.
Accessioning (Specimen receipt) Procedure for receipt and processing of specimens		
Procedure for accessioning specimens or aliquots received from another laboratory		
Procedure for problem/rejected specimens		
Chain-of-Custody Procedure for documenting all transfers of specimens		
Procedure for documenting all transfers of aliquots		
Procedure for maintaining security of specimen bottles		
Procedure for maintaining security of specimen aliquots	***************************************	
Procedure for sending a specimen or aliquot to another laboratory	Manual Ma	

<u>TOPIC</u>	<u>SECTION</u>	PAGE NO
Procedures for documenting all transfers of specimens or aliquots received from another laboratory		
Aliquot Preparation Procedure for preparing initial drug test aliquots		
Procedure for preparing initial specimen validity test aliquots		
Procedure for preparing confirmatory specimen validity test aliquots		
Procedure for preparing confirmatory drug test aliquots		
Procedures for automated aliquotting equipment		
<i>Initial Drug Test</i> Principle of analysis		
Preparation of reagents, calibrators, and controls		
Procedure for set-up and normal operation of instruments		
Procedure for maintenance of instruments	***************************************	
Procedure for assay calibration		
Procedure for calculating results		
Quality control procedure and criteria for acceptable results and corrective actions		
Procedure for validation of initial drug test methods		
References		

<u>TOPIC</u>	<u>SECTION</u>	PAGE N	<u>O.</u>
Secondary Initial Drug Test Criteria for use			_
Principle of analysis			<b></b>
Preparation of reagents, calibrators, and controls		-	-
Procedure for set-up and normal operation of instruments			_
Procedure for maintenance of instruments			-
Procedure for assay calibration			-
Procedure for calculating results		-	-
Quality control procedure and criteria for acceptable results and corrective actions			-
Procedure for validation of secondary initial drug test methods			
References			
Specimen Validity Tests (Initial, Confi	irmatory, S	creening,	Differential)
<b>Creatinine</b> Principle of analysis			
Preparation of reagents, calibrators, and controls			
Procedure for set-up and normal operation of instruments	·		
Procedure for maintenance of instruments			

<u>TOPIC</u>	<u>SECTION</u>	PAGE NO.
Procedure for assay calibration		
Procedures for conducting creatinine tests		***************************************
QC acceptance/rejection criteria and corrective action for creatinine tests		
Procedure for validation of creatinine test methods		
Procedure for periodic reverification of creatinine methods		
References		
Specific Gravity Principle of analysis		
Preparation of calibrators and and controls		-
Procedure for set-up and normal operation of instruments		
Procedure for maintenance of instruments		
Procedure for assay calibration		
Procedures for conducting specific gravity tests		
QC acceptance/rejection criteria and corrective action for specific gravity tests		
Procedure for validation of specific gravity test method		
References		
Criteria for identifying acceptable, dilute, invalid, and substituted specimens based on creatinine and specific gravity test results		

## SECTION PAGE NO. **TOPIC** Hq Principle of analysis Preparation of reagents, calibrators, and controls Procedure for set-up and normal operation of instruments Procedure for maintenance of instruments Procedure for assay calibration Procedures for conducting pH tests QC acceptance/rejection criteria and corrective action for pH tests Criteria for identifying acceptable, invalid, and adulterated specimens based on pH Procedure for validation of pH test methods\_\_\_\_\_ References **Oxidants** Principle of analysis Preparation of reagents, calibrators, and controls Procedure for set-up and normal operation of instruments Procedure for maintenance of instruments Procedure for assay calibration Procedures for conducting oxidant tests QC acceptance/rejection criteria and corrective action for oxidant tests

<u>TOPIC</u>	<u>SECTION</u>	PAGE NO.
Criteria for identifying acceptable, invalid, and adulterated specimens based on oxidant test results		
Procedure for validation of oxidant test methods		
Procedure for periodic reverification of oxidant test methods		
References		
Other Adulterants Principle of analysis		
Preparation of reagents, calibrators, and controls		
Procedure for set-up and normal operation of instruments		<del></del>
Procedure for maintenance of instruments		
Procedure for assay calibration		
Procedures for conducting the adulterant tests		
QC acceptance/rejection criteria and corrective action for the adulterant tests		
Criteria for identifying acceptable, invalid, and adulterated specimens based on the adulterant test results		
Procedure for validation of the adulterant test methods	***************************************	
Procedure for periodic reverification of the adulterant test methods		
References		

## **TOPIC**

## SECTION PAGE NO.

Confirmatory Drug Tests  Principle of each analysis  Marijuana metabolite  Cocaine metabolite  Amphetamines  Opiates  6-Acetylmorphine  Phencyclidine  d,l-methamphetamine		
Preparation of reagents, calibrators, and configuration Marijuana metabolite Cocaine metabolite Amphetamines Opiates 6-Acetylmorphine Phencyclidine d,I-methamphetamine	ontrols	
Description of the extraction procedures Marijuana metabolite Cocaine metabolite Amphetamines Opiates 6-Acetylmorphine Phencyclidine d,I-methamphetamine		
Procedure for maintenance of instruments  Procedure for tuning the instruments		
Procedure for instrument set-up and operated Marijuana metabolite Cocaine metabolite Amphetamines Opiates 6-Acetylmorphine Phencyclidine d,I-methamphetamine	ion	

<u>TOPIC</u>	<u>SECTION</u>	PAGE NO
Procedure for assay calibration Marijuana metabolite Cocaine metabolite Amphetamines Opiates 6-Acetylmorphine Phencyclidine d,I-methamphetamine		
Procedure for calculating results Marijuana metabolite Cocaine metabolite Amphetamines Opiates 6-Acetylmorphine Phencyclidine d,l-methamphetamine		
Procedure when results exceed linearity Marijuana metabolite Cocaine metabolite Amphetamines Opiates 6-Acetylmorphine Phencyclidine d,I-methamphetamine		
Procedure for designating positive results Marijuana metabolite Cocaine metabolite Amphetamines Opiates 6-Acetylmorphine Phencyclidine		
Procedure for designating reconfirmed results and metabolite Cocaine metabolite Amphetamines Opiates 6-Acetylmorphine Phencyclidine	ılts on retest s	pecimens

## **TOPIC**

## SECTION PAGE NO.

	Quality control procedure and criteria for Marijuana metabolite	acceptable res	ults
	Cocaine metabolite		
	Amphetamines		
	Opiates		
	6-Acetylmorphine		
	Phencyclidine		
	d,l-methamphetamine		Exite manufacture to the control of
	Special requirements, etc.		
	Marijuana metabolite		
	Cocaine metabolite		**************************************
	Amphetamines		
	Opiates		
	6-Acetylmorphine		
	Phencyclidine		<del> </del>
	d,I-methamphetamine	-	
	di modiamphotamino		
	References		
	Marijuana metabolite		
	Cocaine metabolite		
	Amphetamines		
	Opiates		
	6-Acetylmorphine		
	Phencyclidine		
	<del>7</del>		
	d,l-methamphetamine		
i	Procedure for validation of confirmatory		
	Procedure for validation of confirmatory		
,	drug test methods		
ı	Procedure for periodic re-verification		
	of confirmatory drug test methods		
•	or communatory drug test memous	<del></del>	·
00	Materials and Passents		
	Materials and Reagents		
	Procedure for preparing stock		
	standards, etc.		
r			
	Procedures for preparing and verifying		
C	alibrators		
-			
	Procedures for preparing and verifying		
C	controls		

<u>TOPIC</u>	<u>SECTION</u>	PAGE NO.
Corrective procedure when QC verification results are out of control limits		
Procedures for preparing and verifying reagents		
Corrective procedure when reagent verification results are unacceptable		
<b>QA Procedures</b> Procedures for monitoring control results		
Corrective procedure when QA review of control results shows problems (e.g., trends, bias)		
<b>Equipment and Maintenance</b> Wash procedures for glassware		
Procedures for determining accuracy and precision of pipetting devices		
Procedures for temperature-dependent equipment		
Procedures for centrifuges		****
Procedures for analytical balances		
Safety procedures		
Administrative/Reporting Procedures Procedure for reviewing/certifying a single/primary specimen test result		
Procedure for reporting a single/primary specimen test result		
Procedure for reviewing/certifying a retest specimen test result		
Procedure for reporting a retest specimen test result		

## SECTION PAGE NO. **TOPIC** Procedure to detect and correct clerical errors Procedure for electronic reporting of results \_\_\_\_\_ Procedure for preparing statistical summary reports Procedure for updating the SOP Procedure for preparation of data packages Procedure for preparation of Non-Negative Specimen List (NNSL) Laboratory Computer System Procedures Computer and LIMS security procedures Computer and LIMS maintenance procedures Procedure for computer and software validation Procedure for requesting, verifying, and implementing software and configuration changes Procedure for LIMS records archiving and retrieval Procedures for system monitoring, incident response, and disaster recovery Procedure for obtaining audit trail reports

#### D. CHAIN OF CUSTODY, ACCESSIONING, AND SECURITY

The laboratory must have chain of custody, accessioning, and security procedures to ensure that integrity is maintained for both the original specimens and their aliquots.

The laboratory must have chain of custody forms and procedures to 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 laboratory must ensure the security of specimens and aliquots during processing and placement in any short-term or long-term storage locations.

1. Provide a TYPED description of the laboratory'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 laboratory accession numbers
- -Handling problems with specimen bottles and/or custody and control forms
- -Location of temporary storage area(s)

#### **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, initial specimen validity tests, confirmatory drug tests, and confirmatory specimen validity tests.
- -Transfer of aliquots from the individuals performing the aliquotting to those who will be testing the aliquots

#### Initial Drug Tests (Primary and Secondary)

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

#### Specimen Validity Tests (Initial, Confirmatory, Screening, Differential)

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

#### **Confirmatory Drug Tests**

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

#### **Disposition of Specimens and Aliquots**

- -Handling of original specimen bottles and aliquots after testing is completed
- -Procedure for transferring non-negative (i.e., positive, adulterated, invalid, substituted) specimens to long-term frozen storage

#### Note: (1) Do not exceed a total of 4 pages.

(2) Attach pages here.

2.	Attach a flowchart and/or examples of chain of custody documents showing how specimens and aliquots are processed and their custody documented (chain of custody documents may be referenced and/or provided as examples for clarification).
3.	Are regulated specimens accessioned in a limited access, secure area?
	<ul><li>☐ Yes</li><li>☐ No → LABORATORY NOT ELIGIBLE TO APPLY</li></ul>
4.	Are regulated specimens tested in a limited access, secure area?
	☐ Yes
	□ No → LABORATORY NOT ELIGIBLE TO APPLY
5.	Attach a floorplan of the laboratory indicating the areas to be used for accessioning, testing of specimens, and storage of specimens 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).
6.	During testing, will the original specimens be maintained in a limited access, secured area at all times?
	☐ Yes
	□ No → LABORATORY NOT ELIGIBLE TO APPLY
	6a. Where will the original specimens be stored?
	6b. Who will have access to the specimen storage area?
7.	When testing is complete, will all non-negative specimens (A and B Bottles) and retest specimens be retained in long-term frozen storage in their original containers?
	☐ Yes→ # of days to be stored:
	□ No → LABORATORY NOT ELIGIBLE TO APPLY
	7a. How will non-negative specimens (A and B Bottles) and retest specimens be stored?

#### E. RECORDS

The laboratory 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 laboratory must also maintain method validation records for past and current procedures, 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 laboratory must have security measures in place to limit access to electronic and hardcopy records to essential authorized personnel.

	·
1.	Will the laboratory maintain records supporting specimen test results for at least two years?
	☐ Yes
	□ No → LABORATORY NOT ELIGIBLE TO APPLY
	1a. Will there be a secured area for the storage of records for reported specimens?
	☐ Yes
	☐ No → LABORATORY NOT ELIGIBLE TO APPLY
2.	Will the laboratory limit records access to authorized personnel?
	☐ Yes
	$\square$ No $\rightarrow$ LABORATORY NOT ELIGIBLE TO APPLY
3.	Attach two data packages using the format described in the Mandatory Guidelines to support (1) a positive drug test result and (2) a non-negative result based on specimen validity testing.

### F. PERSONNEL **Qualifications for a Responsible Person Candidate** 1. RP Candidate's Name: LAST FIRST MIDDLE The candidate must provide the following for review of his/her eligibility: A detailed description of the experience and qualifications specifically addressing the RP requirements as stated in the Mandatory Guidelines; A current résumé or curriculum vitae; and (b) Official copies with raised seal of all academic undergraduate and graduate transcripts. (c) To be eligible for review as an RP, at least one of the following questions must be answered "yes": 2a. Is the candidate certified by the State as a Laboratory Director in forensic toxicology or clinical laboratory toxicology? ☐ Yes→ In which State? □ No 2b. Does the candidate have a Ph.D. in one of the natural sciences? ☐ Yes→ In which field? \_\_\_\_\_\_, GO TO QUESTION 3. $\square$ No $\rightarrow$ GO TO QUESTION 2C. 2c. Does the candidate have training and experience equivalent to a Ph.D. in one of the natural sciences, such as a scientific degree with additional training and laboratory/research experience in biology, chemistry, and pharmacology or toxicology? ☐ Yes→ Describe: □ No 3. An RP must have extensive experience in analytical toxicology. To be eligible for review as an RP, both of the following questions must be answered "yes": 3a. Does the candidate have two years or more of postdoctoral experience or at least six years of experience in analytical toxicology beyond any other degree? ☐ Yes→ **Describe**: □ No→ CANDIDATE NOT ELIGIBLE AS RP

		cology (e.g., court testimon	ning and/or experience in for y, research and publications	
	☐ Yes →D	escribe:		
	 □ No→	CANDIDATE NOT ELIGIBL	E AS RP	
4.	In the table below, e	enter the candidate's educa	ation.	
	Education	Name of School	Major and Minor Fields of Study	Diploma, Certificate or Degree Received
	College or University			
	Other Schools Attended			
	☐ Yes ☐ No	ull-time or part-time employ		
			L. L. V. V. AND MORE MADE TO THE TOTAL PROPERTY OF THE TOTAL PROPE	
6. I	How many hours pe		ork in the Forensic Urine Dr	ug Testing Laboratory?
7. 1	How long has the ca	ndidate been employed by	the laboratory?  YEARS	

## Qualifications for an Alternate Responsible Person Candidate

1.	Alternate	RP Cand	lidate's Name:			
				LAST	FIRST	MIDDLE
	The candi	date mus	st provide the follo	owing for review of	his/her eligibility:	
	(a)			the experience and n the Mandatory Gu		ically addressing the RP
	(b)	A currer	nt résumé or curr	iculum vitae; and		
	(c)	Official	copies with raised	d seal of all academ	ic undergraduate an	d graduate transcripts.
2.	<ol> <li>An alt-RP must be capable of fulfilling RP duties for a limited time (i.e., up to 180 days). An alt-F candidate's qualifications are compared to RP requirements as follow:</li> </ol>				o 180 days). An alt-RP	
		candidat tory toxic		State as a Laborato	ory Director in forensi	ic toxicology or clinical
		Yes→ No	In which State	?		
	2b. Does t	the candi	date have a Ph.C	). in one of the natu	rat sciences?	
		Yes→	In which field?		(	30 TO QUESTION 3.
		No →	GO TO QUEST	ION 2C.		
	scienc	es, such	as a scientific de			n one of the natural ory/research experience
		Yes→	Describe:			
		No				
3.	An alt-RP o	candidate	e must have appr	opriate experience	in analytical toxicolog	gy.
					have in analytical for or drugs of abuse) be	ensic toxicology (including yond any degree?
				YEARS		

		date have appropriate training oratory (i.e., including training		
	☐ Yes			
	□ No→	CANDIDATE NOT ELIGIBLE	AS AN ALT-RP	
4.	In the table below, e	enter the candidate's educat	ion.	
	Education	Name of School	Major and Minor Fields of Study	Diploma, Certificate or Degree Received
	College or University			
	Other Schools Attended			
5.	☐ Yes ☐ No	ill-time or part-time employe		
	, ,	ndidate been employed by t	PER WEEK	ug Testing Laboratory?

#### **Personnel Certifications and Licenses**

1. List the education and certifications/licenses for the following:

NOTE: ATTACH A RÉSUMÉ FOR EACH INDIVIDUAL LISTED BELOW.

Position	Name	Education	License/Certification
Negative Certifying Scientist(s)			
Non-negative Certifying Scientist(s)			
Supervisor(s)			
Other Key Personnel			

	7 da pages de l'ocaca le llet un marriadale in die jes positione in date assere.
2.	Is licensure and/or certification required for any or all of these positions in the State in which the laboratory is located?
	<ul><li>☐ Yes</li><li>☐ No → GO TO SECTION G</li></ul>
3.	Are the Responsible Person Candidate, Certifying Scientist(s), and Supervisor(s) properly licensed or certified?
	☐ Yes
	$\sqcap$ No

G.	OI	JA	LIT	Υ	CC	1(	ΙT	R	OL	
•	~ •	<i>- 1</i> 1			$\sim$	-				

For certification, the laboratory must have clearly defined quality control 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
	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., exceed defined tolerance limits?
	<ul> <li>☐ Yes</li> <li>☐ No → LABORATORY NOT ELIGIBLE TO APPLY</li> </ul>
3.	Are all QC results reviewed by the Certifying Scientist prior to the release of the results?
	<ul> <li>☐ Yes</li> <li>☐ No → LABORATORY NOT ELIGIBLE TO APPLY</li> </ul>
4.	Is the QA/QC program under the direct supervision of a Quality Control Supervisor?
	<ul> <li>☐ Yes</li> <li>☐ No → COMPLETE 4a</li> </ul>
	4a. What is the title and/or position of the person responsible for the QA/QC program?  Title/Position:
5.	Is the QA/QC program reviewed periodically by the Responsible Person Candidate?
	<ul><li>☐ Yes</li><li>☐ No → CANDIDATE NOT ELIGIBLE AS RP</li></ul>
	5a. What is the title and/or 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?
	<ul> <li>☐ Yes</li> <li>☐ No→ LABORATORY NOT ELIGIBLE TO APPLY</li> </ul>
4.	For certification, the laboratory must have a quality control program that includes both blind and open quality control samples. These must, at a minimum, include the number and type of quality control samples described in the Mandatory Guidelines for drug and specimen validity tests.

Provide a TYPED description of the laboratory's quality control program for the following:

#### **Specimen Accessioning**

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

#### Initial Drug Tests (Primary and Secondary)

- 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 source (e.g., in-house, name of supplier), specific drug(s), concentration, and matrix for each QC sample
- 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 (Initial, Confirmatory, Screening, Differential)

- 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 source (e.g., in-house, name of supplier), composition, and matrix for each QC sample
- 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 laboratory's specimen validity testing. The laboratory's submission must identify any "reflex" testing, the use of two separate aliquots, the initial and confirmatory methods for each analytical parameter, and any screening or differential tests.

#### **Confirmatory Drug Tests**

- 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 source (e.g., in-house, name of supplier), specific drug(s), concentration, and matrix for each QC sample
- The procedure and acceptance criteria for calibration, including criteria for exclusion of unsatisfactory calibrators
- 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 a donor specimen result, reextracting the specimen, or reinjecting a specimen

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

(2) Insert pages here.

ŀ	4	RF	=\/	'IF	N	$\Delta N$	n	RF	PO	RTI	NG
	-			I I		$\neg$	_	11			

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

Briefly de title/posit	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).							
•								
	escribe the procedures for reviewing initial and confirmatory specimen validity test							
	escribe the procedures for reviewing confirmatory drug test data and certifying non-negat							
Briefly de reporting	escribe the procedures for the reporting of results. If the laboratory will use electronic for any regulated specimens, describe procedures to ensure confidentiality:							

5.	Is the laboratory's CCF identical to the OMB-approved Federal CCF to be used for all specimens submitted for testing under the Mandatory Guidelines?				
	☐ Yes→ ENCLOSE EXAMPLE OF LABORATORY'S CUSTODY AND CONTROL FORM ☐ No→→ LABORATORY NOT ELIGIBLE TO APPLY				
6.	Will the laboratory use computer-generated electronic reports for specimens submitted for testing under the Mandatory Guidelines?				
	☐ Yes→ ENCLOSE EXAMPLES OF THE LABORATORY'S REPORTS FOR (1) A NEGATIVE SPECIMEN, (2) A DRUG POSITIVE SPECIMEN, AND (3) A SUBSTITUTED OR ADULTERATED SPECIMEN				
	□ No→				

#### I. LABORATORY COMPUTER SYSTEMS

Laboratory 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 quality control data, and reporting final results.

1.	Give a brief description of the computer system to be utilized by the laboratory. Is it a "Stand Alone" system used solely by the laboratory, part of a local system (e.g., a hospital system), or part of a multi-laboratory 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 laboratory plans to use the computer system in regulated specimen					
	processing:					
3.	Is the laboratory computer system maintained in a secure area?					
	☐ Yes ☐ No					
	Attach a floorplan identifying the laboratory 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).					
3.	Does the laboratory limit functional access to the laboratory computer system?					
	☐ Yes ☐ No					

I understand that the answers provided in this application will be used to determine the applicant laboratory'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.					
Signature	Date				
Title	<del>- 1</del>				
NOTE: Any false, fictitious, or fraudulent stat this application form could subject yo penalties, or both. See Sec. 18 U.S.C.	ou to prosecution, monetary				