State of California
Health and Human Services Agency

Department of Public Health
Food and Drug Laboratory Branch
850 Marina Bay Parkway, G365
Richmond, CA 94804-6403

CHECKLIST FOR REVIEW OF METHADONE DRUG ANALYSIS LABORATORY LICENSE APPLICATION

Name of the Laboratory		Application for: [ ] License [ ] Renewal [ ] Method Change	Date
Street Address	City	Zip Code	Telephone Number: ( )
Mailing Address (if different from above)	City	Zip Code	

INSTRUCTIONS TO REVIEWING OFFICER: Complete this checklist for each application submitted. Mark "X" on the appropriate column against each evaluated item of the application for compliance with the regulations (California Code of Regulations, Title 17, Sections 1160 to 1196). In reviewing the method descriptions, mark "X" on the "N/A" column when an item is not applicable to the cited section of the regulations. Do not make assumptions regarding anything which is not stated explicitly in the written description of the methods.

REVIEW SHOWS:
[ ] Application demonstrates laboratory's ability to meet requirements of the regulations.
[ ] Application fails to demonstrate laboratory's ability to meet requirements of the regulations.

REVIEWED BY: _____ _____ _____
(Print Name) (Signature) (Date)

	Section	Yes	No	N/A
I FORM A: APPLICATION FOR A METHADONE DRUG ANALYSIS LABORATORY LICENSE				
A: THE FORM SUBMITTED INCLUDES:				
1-4 Demonstration of laboratory's identity administration and line of responsibility for methadone drug analysis.	1175	---	---	---
5-6 Demonstration of laboratory's commitment to comply with the regulations governing Methadone Drug Laboratories.	1175	---	---	---
7 Enclosure of all forms and payment of application fee or laboratory's claim for exemption from application fee under Section 1181.	1175	---	---	---
II. FORM B:.QUALIFICATIONS OF PERSONS EMPLOYED AS METHADONE DRUG ANALYSIS SUPERVISORS				
Form B for _____ (Name of Supervisor)				
A. THE FORM SUBMITTED DEMONSTRATES:				
1. laboratory's review and approval of information by a submission of a completed Report of Change form.	1175	---	---	---
2. That the person named has a baccalaureate of higher degree, or equivalent in chemistry, biochemistry, or other appropriate discipline as determined by the Department. (Note: The Department may accept as "other appropriate discipline" a curriculum including at least 25 semester units in the following subject areas: general chemistry, quantitative analysis, introductory organic chemistry, intermediate organic chemistry, physical chemistry, and biochemistry, or life sciences.)	1173(a))	---	---	---

	Section	Yes	No	N/A
3. That such person has two years of practical experience in performing drug analysis on biological fluids or tissues.	1173(b)	---	---	---
4. That such experience includes experience in				
a. Interpretation of chromatographic results of tests;	1173(b)			
b. Interpretation of spectrophotometric results; and	1173(b)			
c. Interpretation of immunochemical results of tests	1173(b)			
d. On urine specimens for drugs named in Section 1186.	1182			
	1183			
b. Clean, dry sample container to be provided to methadone program	1183			
c. Identity and integrity of sample maintained from collection through analysis and reporting				
d. Samples refrigerated or preserved when not being analyzed Preservative used (Specify:_____)	1184			
2. Method of Analysis	1185			
a. Methods immediately available to analysts				
b. Laboratory's method is identical to that on file with the Department				
c. Calibration data are recorded	1196(b)			
d. Sample data are recorded	1186			
e. Positive initial test results (except for methadone) are confirmed using alternative method(s). Data are recorded.	1196(e)			
f. Calibrators and reagents specified in approved method are available	1187			
g. Analytical instruments and equipment specified in approved method are in good working condition	1161			
	1161			
3. Quality Control Program				
a. Suitable reference material for each method (Specify: _____ _____)	1192(a)			
b. At least one QC reference sample analyzed with each set of 50 or fewer patient's specimens. If no control samples are analyzed, terminate further survey of this/these drugs.	1192(a)			

*Complete a separate Part C form for each drug (initial and confirmatory test)

	Section	Yes	No	N/A
c. Quality control samples are prepared in a urine matrix.	1192(a)			
d. Quality control samples contain drugs at or slightly below the concentrations specified in Section 1186 of the regulations	1192(d)			
e. Acceptable limits for the results of the analysis of the quality control samples are defined: _____	1192(a)			
4. Calculation and Expression of Analytical Results				
a. All analytical results expressed in terms of the generic or chemical names of the drugs found to be present	1189			
b. Analytical results expressed in unequivocal terms	1189			
5. Standards of Performance				
a. Method able to detect drug(s) at the minimum sensitivity level(s) specified in the regulations	1186			
b. Calibration data and sample data used to demonstrate sensitivity of the method are recorded	1196(e)			
PART D: VERIFY THAT THE PROFICIENCY TEST SAMPLES SENT BY THE DEPARTMENT WERE ANALYZED IN ACCORDANCE WITH THE APPROVED METHADONE DRUG ANALYSIS METHOD				
1. Records of analysis of samples were available for inspection (report forms, worksheets, chromatograms, print-outs)	1196(c)			
2. Method on file was used for the analysis of proficiency test samples [Note: If a completely different method was used, terminate further survey for this/these drugs(s)]	1188			
3. Integrity and identity of samples maintained from receipt through analysis and reporting	1183			
4. Method calibrated with drug standards	1186			
5. Samples analyzed with at least one quality control reference material in a sample set (Set <= 50 samples)	1192(a)			
6. Quality control reference material analyzed just like the samples	1192(a)			

	Section	Yes	No	N/A
7. The results of the analysis of the quality control samples were within acceptable limits	1192(a)			
8. Analysis of quality control samples outside limits resulted in:				
a. Method regarded in error	1192(a)			
b. Remedial action by Methadone drug analysis supervisor	1192(a)			
c. No analyses results reported until error is corrected and sample set reanalyzed	1192(a)			
9. Clear, definitive expression of what constituted a positive test result included in the record	1192(a)			
10. Identity of analyst(s) included in records	1189			
	1196(c)			

Comments: