**CHECKLIST FOR REVIEW OF METHADONE DRUG ANALYSIS LABORATORY LICENSE APPLICATION**

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<th>Name of the Laboratory</th>
<th>Application for:</th>
<th>Date</th>
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<td>[ ] License</td>
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<td>[ ] Renewal</td>
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<td>[ ] Method Change</td>
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<tr>
<th>Street Address</th>
<th>City</th>
<th>Zip Code</th>
<th>Telephone Number:</th>
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<tr>
<th>Mailing Address (if different from above)</th>
<th>City</th>
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**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.

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**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)

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**I. FORM A: APPLICATION FOR A METHADONE DRUG ANALYSIS LABORATORY LICENSE**

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<thead>
<tr>
<th>Section</th>
<th>Yes</th>
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**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.  
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.)
3. That such person has two years of **practical** experience in performing drug analysis on biological fluids or tissues.

4. That such experience includes experience in
   a. **Interpretation** of *chromatographic* results of tests;
   b. **Interpretation** of *spectrophotometric* results; and
   c. **Interpretation** of *immunochemical* results of tests
   d. On *urine* specimens for drugs named in Section 1186.

b. Clean, dry sample container to be provided to methadone program
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: __________________________)

2. **Method of Analysis**
   a. Methods immediately available to analysts
   b. Laboratory's method is identical to that on file with the Department
c. Calibration data are recorded
d. Sample data are recorded
e. Positive initial test results (except for methadone) are confirmed using alternative method(s). Data are recorded.
   f. Calibrators and reagents specified in approved method are available
g. Analytical instruments and equipment specified in approved method are in good working condition

3. **Quality Control Program**
   a. Suitable reference material for each method (Specify: __________
   __________
   __________)
   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.

*Complete a separate Part C form for each drug (initial and confirmatory test)
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  
   1188
   [Note: If a completely different method was used, terminate further survey for this/these drug(s)]

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

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