pennsylvania
DEPARTMENT OF HEALTH

Bureau of Laboratories

Requirements for Approval of Laboratories that Perform Analyses of Urine for the Determination of Controlled Substances

The Department of Health has the responsibility for approving laboratories that perform analyses of human urine for drugs subject to abuse in accordance with regulations in Section 5.50 of Title 28, *Pennsylvania Code*, promulgated under the Commonwealth's Clinical Laboratory Act (25 P.S. § §2151 et seq.). The following is a brief outline of the present approval requirements:

- An applicant, after obtaining a permit to operate a clinical laboratory under Pennsylvania law, must submit a description of the analytical work that will be performed and a detailed description of methodologies for all pertinent urine drug analysis procedures.

- In addition, the applicant must submit Laboratory Personnel Qualification Appraisal Forms for personnel engaged in urine drug analysis. A current fee schedule for this service should also be submitted.

- If the laboratory is located outside the Commonwealth of Pennsylvania, it is required that the person making application submit a certification from the health department of the state in which the facility is located, indicating that the applicant has satisfied all pertinent clinical laboratory laws of that state if such laws exist.

- In addition, such laboratories must submit evidence that they are licensed under the Clinical Laboratory Improvement Amendments of 1988 (CLIA '88). Laboratories located in the Commonwealth must also be licensed in accordance with the federal statutes.

- The facility must be registered with the Drug Enforcement Administration (DEA) of the United States Department of Justice as an analytical laboratory, and must hold a currently valid registration number. Laboratories employing procedures which utilize DEA exempt chemical preparations for standardization and quality assurance purposes may request an exception to this requirement.

When these prerequisite requirements have been met, the laboratory will be evaluated using proficiency testing specimens to ascertain that the facility can reliably perform urine drug determinations.

The proficiency testing process utilizes urine specimens containing drugs subject to abuse and other substances as explained in the following paragraph. Contingent upon the correct analysis of the test specimens, the facility will be issued an approval to conduct urine drug analyses for Pennsylvania clients. This approval then remains in effect provided the laboratory's analysts are able to demonstrate an acceptable level of proficiency when examining test samples that will be forwarded to them periodically.

The Bureau of Laboratories' proficiency testing program for the determination of substances subject to abuse in urine consists of three surveys a year. Each survey utilizes 60-ml urine samples containing varying amounts and combinations of the following drugs: amphetamines, barbiturates, benzodiazepines, cannabinoids, cocaine, codeine, ethanol, fentanyl, glutethimide, LSD, methadone, methaqualone, morphine, phencyclidine, phenothiazines, propoxyphene, quinine, and their respective metabolites where applicable. Urines containing medications or other substances that may be incorrectly identified as drugs of abuse are also frequently incorporated into the samples.

The Bureau's Division of Chemistry and Toxicology carefully monitors the stability of the analytes in each lot of test samples during the course of the proficiency evaluations to insure that no significant changes occur. In addition to these intra-laboratory studies, the Bureau also obtains the services of a number of reference laboratories to verify the presence and detectability of the substances of interest. These facilities are selected on the basis of their expertise in the field of toxicology.

Laboratories that perform unsatisfactorily in a proficiency survey are placed in probationary status and may receive additional test specimens following the receipt of their corrective action report if a serious deficiency is discovered or the corrective action report is inadequate. Perfect performance in the next regularly scheduled survey is required to regain regular approval status when a laboratory is on probation. If a laboratory fails two consecutive proficiency tests, the

approval is removed. Reinstatement in the program will then require unequivocal demonstration that proficiency has again been achieved.

Lists of approved laboratories are published semiannually as notices in the *Pennsylvania Bulletin* at approximately six-month intervals. Commonwealth courts utilize these lists to determine that laboratories meet the Department of Health's standards before admitting their drug analysis findings into evidence.

Please contact Jennifer Okraska for any questions you may have regarding this program at 484-870-6405 or jokraska@pa.gov.