VERMONT
DEPARTMENT OF HEALTH

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ADMINISTRATIVE GUIDELINES FOR

DRUG TESTING LABORATORIES

September 1, 1987 (revised 12/9/91)

A. Scope and Authority

This document implements the provision of 21 V.S.A., Chapter 5, Subchapter 11, Sections 514, 515, 516, 518 and 520 by setting forth guidelines for the Department of Health to approve laboratories which will test body fluids or materials for drugs.

B. Laboratory Approval

I. Laboratories approved by the Vermont Department of Health (Vermont Department of Health) to perform workplace drug testing must meet three criteria.

1. Validate compliance with these guidelines

2. Document continued proficiency in a Vermont Department of Health approved proficiency program (College of American Pathologists, National Institute on Drug Abuse, New York State or equivalent).

3. Successfully demonstrate proper equipment, record keeping, quality assurance, security, etc., at an on-site inspection.

a. Provisional Approval

Each single drug testing laboratory (not a parent corporation) which wishes to obtain Vermont Department of Health approval under these guidelines shall make such a request in writing to the Department. The Department shall acknowledge this request in writing and supply the applicant with a copy of these guidelines, an application form and approval checklist. The applicant must complete the application and checklist forms, sign the statement of compliance and send them along with copies of the laboratories last two proficiency reports and a non-refundable fee of $500 to the Department. The Department will review the information provided, clarify and comment as necessary and upon successful demonstration of compliance will issue a letter of provisional approval. Provisional approval cannot be extended for a period greater than one year.

b. Complete Approval

Complete approval shall be granted for a period of one year after the Department has granted provisional approval, has conducted an on-site observation and evaluation of the laboratory, and has determined that the applicant's laboratory meets the requirements set forth in these guidelines. The costs to the Department for visitation, including travel, food, and lodging, shall be completely at the expense of the party seeking complete approval of the laboratory. Visitation may be waived if the laboratory meets the requirements of alternate approval (Section Ic).

Laboratory approval is extended for a period of one year and is subject to renewal at a yearly fee of $300 per year. Approved laboratories must inform the Vermont Department of Health of any major changes in key personnel identified in the guidelines, and of any substantial technical changes in equipment or methodology. Approved laboratories are responsible for

providing copies of all drug proficiency testing results and written documentation of remedial actions taken to correct poor results. Such information is necessary to maintain approval.

c. Alternate Approval

The Vermont Department of Health will accept National Institute for Drug Abuse (NIDA) accreditation in lieu of the Department's Guidelines; Sections CI, CII, CIII, CIV, CVIc, CVIII and Appendix A. Requirements for Reports, Section CVII, and Confidentiality, Section IX must be met as outlined in these guidelines. Laboratories wishing to operate in Vermont, under this designation must notify the Vermont Department of Health of their intention and submit evidence of their NIDA accreditation, results of the on-site inspection, copies of two sets of proficiency data and an administration fee of $300. There will be a yearly renewal fee of $300.

The Vermont Department of Health will maintain and publish an updated list of all approved laboratories with their approved status, i.e., provisional, complete or alternate.

II. Denial or Loss of Approval

The Commissioner of Health may suspend, modify or revoke any approval issued under these guidelines under the authority granted to the Commissioner of Health. Failure of the laboratory to meet any of the following requirements can result in denial or loss of approval.

1. To meet requirements of the approval guidelines.
2. To supply documentation, including personnel and proficiency test results.
3. To maintain confidentiality.
4. To meet criteria for proficiency testing as outlined in Appendix A.
5. To supply correct information.
6. To have satisfactorily completed two recent Vermont Department of Health recognized proficiency tests.

A laboratory denied approval or who has had their approval revoked shall be notified by certified mail, return recent requested. Within sixty (60) days after receipt of notification, the director of such a laboratory may request that the Vermont Department of Health reconsider its decision.

Any request for reconsideration shall state why the director believes the decision to have been erroneous and shall include documentation of compliance with the approval guidelines.

A request for reconsideration shall not stay the denial or loss of approval.

The director shall be invited to appear at a hearing, with the Commissioner of Health or designee to make a short presentation explaining why the laboratory

Should be approved and shall answer all questions posed by the Vermont Department of Health pertaining to the laboratory.

After the hearing the Commissioner of Health shall determine whether or not to adhere to the original decision to deny approval. Within two (2) weeks after the hearing the laboratory shall be notified by certified mail, return receipt requested. The notification shall include a brief statement of the reasons for the Commissioner's determination.

A laboratory denied approval may reapply for approval demonstrating adherence to the guidelines, or if denial was based on unsatisfactory proficiency results, successful completion of two consecutive proficiency surveys is required for reinstatement.

III. Subcontracting

The laboratory shall perform all work required under these guidelines with its own personnel and equipment, on its own premises.

C. Approval Guidelines

I. Quality Assurance

Urine drug testing laboratories shall have a quality assurance program which encompasses all aspects of the testing process: specimen acquisition, chain of custody, security, and reporting of results, in addition to the screening and confirmation of analytical procedures. Quality control procedures will be designed, implemented, and reviewed to monitor the conduct of each step of the process. These records shall be made available for review at the time of laboratory inspection. Prior to July 1, 1989, laboratories shall document their threshold (cut-off) analytical levels for each drug and drug class and the Commissioner of Health shall be notified as these levels change. After July 1, 1989, the Commissioner of Health shall establish thresholds (cut-off) levels for positive and negative results.

Control urine specimens containing no drugs, and specimens fortified with known standards, will be analyzed with each batch of specimens screened. Some controls with added drug or metabolite at or near the threshold (cut-off) will be included. In addition, internal controls blind to the analyst, shall be tested periodically. Implementation of procedures to ensure that carry-over does not contaminate the testing of a subject's specimen must be documented.

Participation in Vermont Department of Health recognized proficiency testing program (College of American Pathologists or equivalent) for drugs of abuse is mandatory. Acceptable performance in two cycles of this proficiency test program is one of the criteria which must be met before a laboratory becomes eligible for approval.

If any proficiency test results are unsatisfactory according to pre-established criteria, (Appendix A), the cause of the unsatisfactory result must be investigated and corrected

by the laboratory. A report of the investigation findings, together with subsequent corrective actions, will be recorded, dated, and signed by the responsible supervisor and laboratory director. These and all performance reports shall be mailed to the Vermont Department of Health within ten (10) working days. Unsatisfactory performance on Vermont Department of Health recognized proficiency test samples may be sufficient cause to lead to loss of approval by the laboratory.

Many laboratories have applied computer control to various aspects of laboratory operations. In addition, robotics and automation are leading to less human intervention into testing processes. These application present new variables to monitor in order to detect errors, loss of data and maintenance of documentation. All laboratory systems, including data processing and automation systems, must be validated and tested periodically to provide documented evidence of proper function. Specific requirements will be developed to deal with these issues as they arise. The above documentation shall be made available on request.

II. Personnel

The scientific director shall be a doctorate-level individual who has qualified as a clinical chemistry laboratory director under College of American Pathologists (CAP), Health Care Finance Administration (HCFA), or Clinical Laboratory Improvement Act (CLIA) regulations to be a scientific director. This director must be able to demonstrate, at on-site inspections, his competence in the specialized components of urine drug testing, such as chain of custody, security and documentation.

The certifying scientist or responsible person (who may be the scientific director) shall be an individual with documented scientific qualifications comparable to those of a person certified by the National Institute on Drug Abuse.

Supervisors of analysts must posses at least a B.S. degree in chemistry or toxicology and two (2) years of analytical drug screening experience. These too, must have training in the theory and practice of the procedures used, and understanding of quality control concepts. Periodic verification of their skills must be documented.

Other technicians or non-technical staff must posses the necessary training and skills for the task assigned. In-service continuing education programs to meet the needs of all laboratory personnel are desirable. Personnel files must include: resume of training and experience, certification of license if any, references, job descriptions, health records, records of performance evaluation and advancement, and incident reports, as well as results of tests for color blindness where appropriate.

III. Judicial Proceedings

The laboratory must have qualified personnel available to testify and provide expert testimony and documentation in any civil action relating to 21 V.S.A., Chapter 5, Subchapter 11. The laboratory shall provide all services and testing in such a manner that all results and reports shall be developed so as to maximize the likelihood that they

will be admissible evidence in any administrative or civil judicial proceeding. The laboratory must also have processing technicians (and collection site personnel, if under laboratory contract) available for testimony.

The laboratory shall demonstrate an adequate chain of custody. This refers to the methodology of tracking specified materials and/or substances for the purpose of maintaining control and accountability from sample receipt to final disposition for all such materials and/or substances and must provide for accountability at each state in handling, testing, storing specimens, and reporting test results.

IV. Equipment and Instrumentation

The laboratory shall demonstrate that it has the necessary equipment and instrumentation to fully perform both initial and confirmation testing. Maintenance, repair and temperature logs on such equipment shall be maintained and made available on request.

V. Security

The laboratory must be secure not only in the traditional sense of resisting breaking and entering, but also in the sense of limiting access to areas where specimens are being processed and records are stored. Access to these secure areas is limited to specifically authorized individuals whose authorization is documented. Visitors, maintenance and service personnel must be escorted at all times. Documentation of these individuals accessing these areas, dates and time of entry and purpose of entry, must be maintained. Access to computerized data must be limited to authorized individuals whose authorization is documented. Computerized results shall be held in a password protected file.

VI. Methodology

a. Initial Test

The initial screening tests may utilize immunoassay, thin layer, high performance liquid, and/or gas chromatography, or an equivalent technology approved by the Vermont Department of Health. If the initial test utilizes an immunoassay, the immunoassay kit must meet the requirements of the Food and Drug Administration. Only those drugs found in Appendix B are to be reported.

b. Confirmation Test

Only samples which have been tested positive (above threshold or cut-off level) by the initial testing, shall be confirmed by quantitative gas chromatography/mass spectroscopy or a scientifically equivalent technique. In the absence of any accepted quantitative GC/MS assay procedure, preference will be given to a confirmation of qualitative identification by means of full-scan GC/MS analysis and quantification by an alternate chromatographic method. All methods shall meet commonly accepted analytical standards. All confirmations must be performed at the same laboratory that conducted the initial screen.

c. Long Term Storage

Specimens which initially tested negative need not be retained. Specimens tested positive shall be confirmed as described above. All confirmed positive specimens shall then be placed in long-term frozen storage for a period of ninety (90) days. If, at the end of this ninety (90) day period, the laboratory has not bee notified by either the employee/applicant or the employer to retain certain confirmed positive specimens indefinitely, the laboratory shall dispose of these specimens.

VII. Reports

All test results, including screening, confirmation and quality control data must be reviewed by a qualified, responsible scientist before being certified as accurate. The report shall identify the drugs/metabolites tested for, whether positive or negative, and the threshold (or cut-off) concentration for each. No positive results shall be reported on drugs not on the list supplied by the Vermont Department of Health (Appendix B). Starting July 1, 1989, the Vermont Department of Health shall establish the threshold (or cut-off) levels for positive and negative results. Information to be supplied.

The laboratory shall simultaneously provide the employer and the applicant or employee with identical copies of the written report of the drug test result that includes all of the following information from 21 V.S.A., Chapter 5, subchapter 11, Section 9.

a. The name of the person tested.
b. The type of test conducted for both initial screening and confirmation.
c. The results of each test.
d. The detection level, meaning the cut-off or measure used to distinguish positive and negative samples, on both the initial screening and confirmation procedures.
e. The name and address of the laboratory.
f. Any other information provided by the laboratory to the employer concerning that person's test.

VIII. Documentation

Documentation of all aspects of the testing process must be available. This documentation will be maintained for at least three (3) years, and will include: personnel files on analysts, supervisors, directors and all individuals authorized to have access to specimens; chain of custody documents; quality assurance/quality control records; all test data; reports; performance records on proficiency testing; performance on accreditation inspections and hard copies of computer generated data. The laboratory should be prepared to maintain documents for any specimen under legal challenge for an indefinite period.

IX. Confidentiality

(a) "Any information concerning drug test results taken by an employer pursuant to authority under this subchapter shall be confidential and shall not be released to anyone except the employer, applicant or employee, as the case may be, and may not be obtained by court order or process, except as provided in this section.

(b) Employers, laboratories and their agents, who receive or have access to information about drug test results, shall keep all information confidential. Release of such information under any other circumstances shall be solely pursuant to a written consent form signed voluntarily by the person tested, except where such release is compelled by a court of competent jurisdiction in connection with an action brought under this subchapter.

(c) If information about drug test results is released contrary to the provisions of this subchapter, it shall be inadmissible as evidence in judicial or quasi-judicial proceeding, except in a court of competent jurisdiction in connection with an action brought under this subchapter." 21 V.S.A. Chapter 5, Section 516.

Appendix A

Proficiency Testing Criteria

1. For all drugs which the Vermont Department of Health allows to be screened, no false positive drug identifications are acceptable. A false positive result may result in loss of approval.

2. At least 90% of all drugs listed in Appendix B, which are present in the proficiency samples, must be detected.

3. Participant performance will be evaluated for all samples for which drugs were spiked at concentrations above the level for reporting unless the overall participant response indicates that less than 80% of the participants were able to detect a drug.

4. Failure to participate in an approved proficiency program or to participate satisfactorily will result in loss of approval.

5. Once approval is lost, a laboratory must participate in two (2) additional consecutive surveys before reinstatement as an approved laboratory can be considered.

6. Quantitative results reported on confirmation tests must be within 20% of the calculated group mean resulting from all participating laboratories testing the same lot of proficiencies.

Appendix B

Only drugs tested or classified by the Drug Enforcement Administration as Schedule I drugs or their metabolites and the following drugs and/or their metabolites may be reported by laboratories to Vermont employees, applicants and employers.

ethyl alcohol
amitriptyline
amphetamines
barbiturates
benzodiazepines
cannabinoids
cocaine
doxepin
gluethimide
hydromorphone
imipramine
meperidine
methadone
methaqualone
opiates
oxycodone
pentazocine
phenytoin
phencyclidine
phenothiazines
propoxyphene