CHAPTER ~~60~~ 200.
REGULATIONS FOR THE APPROVAL OF INDEPENDENT LABORATORIES TO ANALYZE BLOOD FOR ALCOHOL AND DRUGS IN DRIVING UNDER THE INFLUENCE CASES

PART I.

DEFINITIONS.

~~1 VAC 30-60-10.~~6 VAC 20-200-10. Definitions.

The following words and terms, when used in this chapter, shall have the following meanings unless the context clearly indicates otherwise:

Alcohol means ethyl alcohol, ethanol.

Alcohol determination means a quantitative assay of alcohol in blood in percent by weight by volume, i.e., grams of alcohol per 100 milliLiters (g/100 mL) of blood.

Analysis for drugs in blood means the determination of the presence or absence of drugs in blood, and, if present, their concentration.

"*Analyst*" means a toxicologist, chemist, forensic scientist, or technician who performs an alcohol determination or an analysis for drugs in blood.

~~"*Approval authority*" means the Director of the Division of Forensic Science, the division or his designee.~~

"*Division*" means ~~the Division of Forensic Science,~~ the Department of ~~General~~ Criminal Justice Services, Division of Forensic Science, which is responsible for approval of independent laboratories.

Drug means drug or drug metabolite.

DUI means driving under the influence.

DUID means driving under the influence of drugs.

"*First blood sample*" means the blood sample sent to the division for analysis.

"*Independent laboratory*" means any ~~nongovernment~~ non-division laboratory ~~in Virginia~~.

~~"*List of approved laboratories*~~ Approved laboratory means ~~a list of~~ an independent ~~laboratories~~ laboratory approved by the division to perform analyses for alcohol and drugs in blood ~~analyses which is published by the division and provided to law enforcement agencies in Virginia~~ as set forth in Section 18.2-268.6 of the Code of Virginia. ~~The driver charged with DUI may select any laboratory on this list to analyze the second blood sample for drugs.~~

"*Minimum requirements*" means criteria which are deemed critical to the generation of valid data. These criteria describe the minimum level of capability at which the analyses can be successfully performed.

"*On-site inspection*" means evaluation of the an independent laboratory facilities and procedures by a division team visiting the laboratory premises.

"*Proficiency sample*" means a blood sample prepared or and/or provided by the division or other third party provider acceptable to the division, such as, but not limited to, the College of American Pathologists and the U.S. Department of Transportation, for proficiency evaluation testing of independent laboratories to perform alcohol determinations and/or qualitative and quantitative analyses for drugs in blood drug analyses.

"*Second blood sample*" means the blood sample sent for analysis to an independent approved laboratory at the request of the accused.

1 VAC 30-60-20. 6VAC 20-200-20. Substantial compliance.

This chapter and the steps set forth herein relating to the handling, identification and disposition of blood samples, the testing of such samples, and the completion and filing of any form or record prescribed by these regulations are procedural in nature and not substantive. Substantial compliance therewith shall be deemed sufficient.

PART II.

REGULATIONS.

ARTICLE 1.

GENERAL.

1 VAC 30-60-30. 6 VAC 20-200-30. Authority.

~~Sections 18.2-266 and 18.2-268.6 and 18.2-268.7 of the Code of Virginia have been amended to permit the drug analyses of blood samples from suspected drug-impaired drivers. Portions of these blood samples will be sent for drug analysis to the division and, upon request of accused, to an approved independent laboratory, selected from a list of such laboratories by the accused. When analyses by the division indicate the presence of one or more drugs (listed herein), the approved independent laboratory will be directed to analyze the second sample to confirm or refute the qualitative results of the division and to conduct a quantitative analysis of those drugs (or their metabolites) confirmed.~~ Section 18.2-268.6 of the Code of Virginia provides that the Division of Forensic Science shall approve independent laboratories to perform analyses of blood samples to determine the blood alcohol content and presence and concentration of drugs in the blood of persons arrested for driving a motor vehicle while under the influence of alcohol or drugs.

~~1 VAC 30-60-40.~~ 6 VAC 20-200-40. ~~Expenses.~~ Application fee.

Partial expenses for ~~the~~ proficiency testing, on-site inspection, and other components of the approval ~~processes~~ process and on-going monitoring will be borne by an application fee charged to the applying independent laboratory. ~~A fee to be established by the division for each drug or metabolite tested for may be charged by the approved independent laboratory to the court system. Such fees shall be paid out of the appropriation for criminal charges.~~

~~1 VAC 30-60-50.~~ 6 VAC 20-200-50 Objective.

The objective of this approval process is to ~~establish~~ evaluate each laboratory's ability to consistently produce accurate results when analyzing blood for alcohol and drugs. Documentation is one of the key ~~element~~ elements of this program. Each laboratory shall ~~effectively show~~ maintain objective evidence of its capabilities and ~~substantiate its~~ ongoing performance. ~~Its~~ Such internal record keeping shall be an integral part of its quality assurance program. To assure that each laboratory is producing ~~data of quality~~ accurate results, the division has established a program of ~~reviewing~~ assessing each laboratory's record keeping practices, as well as its equipment-in-use, methods of ~~analyses~~ analysis, personnel, laboratory techniques, and overall quality ~~control~~ assurance program ~~at the time of the on-site evaluation~~ during the approval process. As a continuing ~~evaluation of~~ check on each laboratory's performance, ~~periodic~~ the results of the analyses of proficiency samples will be ~~sent to~~ evaluated, at least annually, for each approved laboratory. Approved laboratories may also be subject to unannounced on-site inspections.

~~1 VAC 30-60-60.~~ 6 VAC 20-200-60. Security.

The laboratory shall be secure not only in the conventional sense of resisting breaking and entering, but also in the sense of limiting access to areas where ~~specimens~~ samples are being processed and records are stored. Access to these secure areas shall be limited to specifically authorized individuals whose authorization is documented. Visitors and maintenance and service personnel shall be escorted at all times. Documentation of such individuals accessing these areas, ~~dates~~ and the date, time, and purpose of each entry shall be maintained.

~~1 VAC 30-60-70.~~ 6 VAC 20-200-70. Record.

A written, signed and dated record of possession of each blood sample ~~for drug determination~~ shall be maintained to document the chain of custody.

ARTICLE 2.

PROCESS OF APPROVAL OF INDEPENDENT LABORATORIES.

~~1 VAC 30-60-80.~~ 6 VAC 20-200-80. ~~Evaluation~~ Process of approval.

To uniformly handle laboratory ~~on-site evaluation and~~ approval, the division will process prospective laboratories ~~for approval~~ in the following sequence:

A. ~~Request~~ Application for approval.

1. The director of a laboratory wishing to be approved to analyze blood for alcohol and drugs shall submit a request in writing to the division.

2. An application packet consisting of ~~the instructions,~~ an application form, a copy of these regulations, ~~and any pertinent information regarding the program~~ and a copy of the laboratory survey form used by inspection teams will then be forwarded by the division to the requesting laboratory.

~~3. The division will administratively review the information provided. The application fee shall accompany this submitted application.~~

3. The laboratory shall return the completed application form, with the documents specified on that form and the application fee, to the division.

~~4. The division will forward proficiency samples.~~

4. The division will review the information provided. If the review of the application materials indicates the laboratory does not have the capability to analyze blood for alcohol and drugs, the division will so inform the laboratory, explain the reason(s) for its decision, and return the application fee.

~~5. The division will then schedule an on-site evaluation if the laboratory proficiency~~ ~~test results are satisfactory.~~

B. Proficiency testing.

1.The division will provide appropriate proficiency samples to the laboratory.

2. The laboratory shall analyze the samples using the procedures to be used on case samples and report the results to the division.

3. The division will assess the reported test results.

a. For alcohol determinations, each result must be within either ± 10%, or 0.010 % by weight by volume, of the target concentration, whichever is greater.

b. For analyses of drugs in blood, each result must be within ±30% of the target concentration to be acceptable.

c. If the results for a sample set are unacceptable, a second set of samples will be issued after the laboratory identifies and corrects the deficiencies which resulted in unsuccessful performance on the first set, and provides documentation of successful corrective action to the division. The laboratory shall analyze the second set of samples and report results as for the first set. If the results for the second set are also unacceptable, the laboratory will be deemed not approved. The laboratory will be informed of such a determination in writing and may reapply for approval after six months.

d. If the results are acceptable, the division will inform the laboratory of its successful performance and may then schedule an on-site inspection.

~~B~~ C. On-site ~~evaluation~~ inspection protocol.

1. The division will notify ~~an independent~~ the laboratory of ~~a pending~~ the on-site ~~evaluation~~ inspection date in writing. ~~at least three weeks in advance of the intended visit; the~~ The notification may include ~~preliminary~~ a request for further information ~~sheets~~ to be ~~completed and returned~~ supplied to the division before the ~~on-site evaluation~~ inspection occurs. ~~The preliminary sheets will include name of laboratory, location, listing of personnel and important vitae, methods of analyses and updated list of equipment.~~

~~2. During the on-site evaluation, the approval team will evaluate the procedures and equipment, review the records and procedure manual for compliance with the criteria stated in these regulations and evaluate the effectiveness of the security system, internal chain of custody procedures, and laboratory's quality control program. The team will use a general laboratory survey form as a working guideline for the evaluation and will review the results of the evaluation at the end of the visit with the appropriate laboratory staff. The review will include observed deviations in procedures and records, recommendations for improvements as necessary, and a discussion of how the division may aid the local laboratory in its attempt to be approved.~~

~~NOTE: A laboratory may be required to perform specific test procedures for a given test parameter during the on-site review.~~

2. a. On arrival at the laboratory, the inspection team will conduct an opening meeting with appropriate laboratory staff at which the team will describe the inspection process and answer any questions the laboratory may have about the inspection or the overall approval process.

b. During the inspection, the team will evaluate the laboratory’s procedures, personnel, equipment and documentation for compliance with these regulations. This will include a determination of the existence and effectiveness of procedures for administration/supervision, personnel qualification, training, and ongoing assessment, security, internal chain of custody, and the laboratory's overall quality assurance program. The team

will use a forensic laboratory survey form as a working guide for, and record of, the inspection.

c. The team will review the results of the evaluation at the end of the inspection with appropriate laboratory staff. The review will include observed deviations from these regulations, discussions of and recommendations for corrective actions, as necessary and appropriate, and a discussion of how the division may aid the laboratory in its attempt to be approved.

~~C~~ D. Approval status.

The ~~approval~~ inspection team will prepare ~~a formal narrative report and action memorandum for the approval authority~~ and provide an inspection report to the division Director. This report will ~~contain all information pertinent to~~ summarize the findings of the ~~evaluation~~ inspection and ~~also~~ recommend the laboratory be placed in one of the following ~~actions~~ categories:

1. An approved laboratory is a laboratory that ~~meets the minimum requirements as determined by the evaluation team using~~ has demonstrated its analytical capabilities by successful analyses of proficiency samples and is in compliance with the criteria listed on the survey form ~~these regulations~~. The approval shall be effective for three years (in the absence of any ~~deficiencies described~~ reasons specified in ~~1 VAC 30-60-110~~ 6 VAC 20-200-100 or 6 VAC 20-200-110).

~~2. Provisionally approved. A laboratory that has demonstrated its analytical capabilities but is deficient in its adherence to one or more of the administrative or procedural requirements of these regulations. A laboratory may be given a grace period of up to one year to correct deficiencies. In no case shall provisional approval be given if the evaluation team believes that the laboratory lacks the capability of performing the analysis. Laboratories placed in this category shall be reevaluated unless they can document in some other acceptable way that the deficiency has been corrected.~~

2. A provisionally approved laboratory is a laboratory that has demonstrated its analytical capabilities by successful analyses of proficiency samples but is not in compliance with the criteria listed on the survey form because of minor deviations which do not affect its analytical capabilities. A laboratory will be given a grace period of up to six months to correct such deviations. Laboratories placed in this category shall be reinspected unless they can demonstrate to the division, with appropriate corrective action documentation, that the deviations have been corrected. A laboratory deemed provisionally approved may analyze samples while it retains that status.

~~3. Not approved. A laboratory that does not meet the minimum requirements as determined by the evaluation team using these regulations. A laboratory in this category may appeal to the approval authority by requesting reevaluation. The results of a reevaluation will be sent to the independent laboratory within 30 days. Should the reevaluation confirm the "not approved" classification, the laboratory may correct the deficiencies noted and then begin the request for approval procedure again, including application fees.~~

3. A not approved laboratory is a laboratory that reported acceptable results from analyses of proficiency samples but is discovered, on inspection, not to be in compliance with the criteria listed on the survey form because of major deviations or deficiencies which may or do impair its capability to consistently produce accurate results and/or are deemed by the inspection team not to be correctable in a six month period. Laboratories placed in this category may correct the deviations or deficiencies noted and then begin the approval process again, including application fees.

The division Director will review the inspection team’s summary and recommendation, and any other materials he deems relevant, decide the laboratory’s status, and issue a formal letter to the laboratory notifying it of his decision.

~~4. Appeals. If a laboratory is deemed "provisionally approved" or "not approved," the laboratory may appeal such status by requesting, in writing, a meeting with the approval authority at which time it may present information to show that it should not be "provisionally approved" or "not approved." The approval authority's final decision, or an order to reevaluate the laboratory should be sent to the laboratory within 30 days; but in no event shall failure of the approval authority to send a final decision on the appeal be deemed to grant the laboratory's appeal.~~

4. Appeals. If a laboratory is deemed provisionally approved or not approved, the laboratory may appeal such status by requesting, in writing to the division Director, a meeting with the division. The letter must be received by the division within 30 days of the division Director’s issuance of the Anotification of status≅ letter to the laboratory. The laboratory may present information at the meeting to show that it had been placed in an inappropriate category. The division will consider all information gathered during the approval process and presented in the meeting when making its decision in response to the appeal. The division may maintain or alter the laboratory’s status, and/or order a repetition of any or all steps of the approval process. The division Director shall inform the laboratory of his decision in writing, but in no event shall failure of the Director to inform the laboratory of its decision be deemed to grant the laboratory's appeal.

5. Change in status. A laboratory which was originally placed in the provisionally approved category and:

a. Is determined to be in compliance with the criteria listed on the survey form upon reinspection or demonstrates appropriate corrective action for identified deviations to the division before expiration of its grace period will subsequently be deemed approved.

b. Is determined not to be in compliance with the criteria listed on the survey form upon reinspection or fails to demonstrate appropriate corrective action for identified deviations to the division before expiration of its grace period will subsequently be deemed not approved.

The division Director shall inform such laboratories of the change in status in writing.

~~1 VAC 30-60-90.~~ 6VAC 20-200-90. ~~Requirements~~ Maintaining approved status.

A laboratory wishing to maintain ~~approval shall continue to meet the requirements listed in these regulations~~ approved status must remain in compliance with the criteria listed on the survey form as well as ~~pass annual performance evaluation studies~~ generate acceptable results on proficiency tests. Proficiency samples may be provided by the division as in 6 VAC 20-200-80, subdivision B. Alternatively, the division may request the laboratory supply its results on other proficiency tests and assess those results against the acceptance criteria for those tests. In addition, ~~these laboratories~~ the laboratory shall be subject to ~~periodic~~ unannounced on-site ~~visits~~ inspections by ~~the approval~~ a division team.

~~1 VAC 30-60-100.~~ 6 VAC 20-200-100. Downgrading to provisionally approved status.

~~An approved~~ A laboratory will be downgraded to ~~a~~ provisionally approved status for any of the following reasons:

~~1. Failure to analyze proficiency samples within the acceptable limits and time frames established by the division. After downgrading to a provisionally approved status, a laboratory may request quality control samples and technical assistance to help identify and resolve the problem. A provisionally approved status will continue until the laboratory's analysis of follow-up performance evaluation sample produces data within the acceptance limits established by the division.~~

~~2. Failure of an approved laboratory to notify the division within 60 days of major changes in personnel, equipment, laboratory location, or methodology which might impair analytical capability.~~

~~3. Failure to satisfy the division that the laboratory is maintaining the required standard of quality based upon an on-site evaluation.~~

~~4. Failure to report results within four weeks of receipt of proficiency samples or four weeks from receipt of the division=s notification on court samples.~~

~~During the provisional status period, which may last up to one year, the laboratory may continue to analyze samples for enforcement purposes until it resolves its deficiencies or is further downgraded to the nonapproved status.~~

1. Failure to generate acceptable results on two proficiency test samples in a single set, or on one sample in each of two consecutive sets. A laboratory downgraded for this reason may request quality control samples and technical assistance from the division in its attempt to identify and correct the deficiencies which resulted in unacceptable performance.

2. The determination, as the result of an unannounced on-site inspection or other information source, that the laboratory should be placed in the provisionally approved category as defined in 6 VAC 20-200-80, subdivision D 2. A laboratory downgraded for this reason will be subsequently processed in the same manner as if it had been placed in the provisionally approved category during its first passage through the approval process.

A laboratory downgraded to provisionally approved status may continue to analyze samples while it retains that status.

~~1 VAC 30-60-110.~~ 6 VAC 20-200-110. ~~Downgrade~~ Downgrading to not approved ~~classification~~ status.

A laboratory will be downgraded ~~from an approved or provisionally approved status~~ to ~~a~~ not approved ~~classification~~ status for any of the following reasons:

~~1. Failure to adhere to acceptable methods of analyses.~~

~~2. Failure to analyze follow-up proficiency samples within the acceptable limits established by the division.~~

~~3. A second failure to report results to the court within the four weeks from the notification by the division.~~

~~4. Submitting a performance evaluation check sample to another laboratory for analysis and reporting data as its own.~~

~~5. Failure to correct identified deviations by the time specified by the approval authority.~~

~~6. Permitting persons other than qualified laboratory personnel to perform and report results to the courts.~~

~~7. Failure to maintain acceptable security or custody of samples.~~

~~8. Falsifying data or using other deceptive practices.~~

1. Use of unacceptable methods of analysis.

2.Failure to generate acceptable results on more than two proficiency test samples in a single set, or on two samples in each of two consecutive sets.

3. Submitting a sample to another laboratory for analysis and reporting the resultant data as its own.

4. Failure to demonstrate appropriate corrective action for identified deviations before expiration of its grace period.

5. Permitting persons other than qualified laboratory personnel to perform analyses and report results.

6. Failure to maintain security and custody of samples.

7. Falsifying data or using other deceptive practices.

8. The determination, as the result of an unannounced on-site inspection or other information source, that the laboratory should be placed in the not approved category as defined in 6 VAC 20-200-80, subdivision D 3, for a reason other than those specified above.

A laboratory downgraded to not approved status may correct the deviations or deficiencies noted and then begin the approval process again, including application fees.

~~1 VAC 30-60-120.~~ 6 VAC 20-200-120. Reinstatement.

~~Approval will be reinstated when and if the laboratory can demonstrate to the approval authority's satisfaction that the deficiencies which produce provisionally approved status or revocation have been corrected. This may include an on-site evaluation, a successful analysis of samples on the next regularly scheduled proficiency study, or any other measure the approval authority deems appropriate.~~

Reinstatement to approved status will occur when and if a laboratory which has been downgraded to provisionally approved status can demonstrate to the division's satisfaction that the deviations which resulted in the downgrade have been corrected. This may require an on-site

inspection, analyses of proficiency samples, provision of laboratory records to the division, or any other measure the division deems appropriate.

~~1 VAC 30-60-130.~~ 6 VAC 20-200-130. ~~Notification~~ Notifications.

~~An approved independent laboratory will be notified in writing by the division of its next on-site evaluation which will be approximately 36 months from the previous approval. The continuing on-site evaluations will be performed essentially the same as the initial visit with emphasis on past deviations and their corrections.~~

1. A Laboratory which is downgraded will be notified by the division Director in writing of its change in status and the reason(s) for the change. Such a laboratory which is subsequently reinstated will similarly be informed of that change in writing.

2. An approved laboratory will be reminded in writing by the division of the expiration date of its approved status period approximately three months prior to that date, and an on-site inspection will be scheduled, if necessary. The continuing on-site inspections will be performed in essentially the same as the initial inspection but with an emphasis on previously identified and reported deviations and deficiencies and their corrections. NOTE: It is the laboratory=s responsibility to formally apply for renewal of approval, including submission of the application fee, before the expiration of its approved status.

6VAC 20-200-140. Publication

The division will periodically publish a list of approved laboratories in The Virginia Register of Regulations. Such list will be published forthwith after any addition or deletion of an approved laboratory to or from the list. The division will also publish the list on its web site, where it will be updated as soon as possible after the publication of an edited list. The division may also provide copies of the list to law enforcement agencies in Virginia. A driver charged with DUI or DUID may select an approved laboratory on this list to perform an analysis of the second blood sample.

ARTICLE 3.

TECHNICAL REQUIREMENTS

~~1 VAC 30-60-140.~~	6 VAC 20-200-150.	Quality ~~Control~~ assurance.
~~1 VAC 30-60-150.~~	6 VAC 20-200-160.	~~Identification~~ Analytical and reporting procedures.
	6 VAC 20-200-170.	Performance and reporting of alcohol determinations.
~~1 VAC 30-60-160.~~	6 VAC 20-200-180.	~~Confirmation~~ Performance and reporting of analyses for drugs.

~~1 VAC 30-60-140.~~ 6 VAC 20-200-150. Quality ~~control~~ assurance.

A written description (quality assurance plan) of a laboratory's quality ~~control~~ assurance program shall be available; this plan and program shall emphasize:

1. The use of approved subsampling, preparatory and analytical procedures.

2. Adequate training of laboratory personnel.

3. a. ~~Calibration~~ Instrument calibration procedures, ~~intervals,~~ frequencies, and ~~standardizations to~~ checks which ensure control of the analytical system.

b. Calibrations performed using a sufficient number of standards to establish instrument linearity across the analytical range.

c. Calibration and calibration check data maintained in a manner which allows its correlation with the results of associated alcohol determinations and/or analyses for drugs in blood.

~~4. Compliance with all sampling criteria.~~

~~5. A current working manual of procedures in an area readily available for the working analyst. The manual shall contain procedures used for each parameter, descriptions of how the procedures are EXACTLY performed (NOT how they should ideally be performed), calibration and standardization procedures, and appropriate references regarding their use.~~

4. a. A current manual of procedures readily available to the working analyst.

b. A manual containing detailed descriptions of all procedures used for alcohol determinations and analyses for drugs in blood.

c. Descriptions of how the procedures shall be performed, not how they should be performed.

~~6. Calibration results and dates.~~

~~7. Preparation of standard curves requiring a sufficient number of known concentrations to establish linearity.~~

~~8~~ 5. ~~Appropriate record of drug and metabolite standards including~~ Records of the source, purity, ~~date of~~ receipt, preparation, quality assurance checks and ~~security measures for~~ secure storage of standards.

~~9~~ 6. Maintenance and repair logs ~~on appropriate~~ for instruments and equipment.

~~10~~ 7. A system of record keeping for the ~~handling, storage,~~ logging, numbering, storage, handling and ~~reporting~~ disposition of samples.

~~11~~ 8. A record of occurrences of situations which could ~~affect~~ negatively impact analytical results, and ~~the~~ an associated corrective ~~actions~~ action system which documents actions taken to identify and resolve the cause of the problem, as well as the correction of the problem by the actions taken. ~~The compilation of these records will develop into a good referencing guide for corrective actions of troubleshooting.~~

~~12. Records of analyses shall be confidential and shall be kept by the laboratory for three years. This includes raw data, calculations, and quality control data. A copy of each actual laboratory report shall be kept on file, including the name of the suspect; date of sample receipt; person receiving sample; date of analysis; person performing the analysis; result of analysis; and date sample returned.~~

~~1 VAC 30-60-150.~~ 6VAC 20-200-160. ~~Identification~~ Analytical and reporting procedures.

~~Each second sample for potential drug or metabolite determination(s) shall be identified as such by the submitting agencies.~~ Upon receipt of a second blood sample, the approved laboratory shall test the sample and report results in the same manner and in accordance with procedures established for the sample sent to the division. Reports must be machine printed, i.e.,

hand written reports are not acceptable. If the laboratory is unsure as to how to process a given sample, the laboratory should contact the division for clarification. ~~by the approved laboratory the container (box) shall be opened, date of receipt and name of the accused recorded, and the sealed blood vial retained under refrigeration. Each vial shall remain sealed and under refrigeration until the division provides written instructions to the laboratory on sample disposition. These instructions will vary depending on the division=s findings on the first blood sample. If the division finds no significant alcohol or drugs, the approved laboratory will be instructed to return the blood vial to the appropriate court unanalyzed. If the division finds only a significant amount of alcohol, the approved laboratory will be instructed to perform only an alcohol determination. If the division finds one or more drugs, metabolites or alcohol, the approved laboratory will be instructed to confirm or refute these findings. In each case the approved laboratory will be appraised of the qualitative, but not quantitative, results of the division before analysis of the second sample is to begin.~~

~~Section 18.2-268.6 of the Code of Virginia specifies that the approved independent laboratory shall analyze the second blood sample only when drugs, metabolites or an elevated concentration of alcohol have been reported by the division. Furthermore, only those drugs or metabolites reported by the division shall be addressed in the report to the court by the approved laboratory. Incidental detection of alcohol, drugs or metabolites other than those reported by the division shall not be reported to the court and are not subject to compensation by the court.~~

6 VAC 20-200-170. Performance and reporting of alcohol determinations

All alcohol determinations shall be performed in duplicate with appropriate controls. Control results must be within ∀5% of the known concentration. Duplicate results must be within ∀ 5%, or 0.005 % by weight by volume, of their mean, whichever is greater. For reporting purposes, duplicate results shall be averaged and the average truncated to two decimal places (e.g., 0.07 % by weight by volume). The analytical technique required for quantitative results for alcohol analyses shall be gas chromatography. Results should be reported within four weeks of receipt of samples.

Records of determinations shall be confidential and shall be kept by the laboratory for a minimum of three years. The records shall include sample tracking and preparation information, raw analytical data, calculations and all associated quality control data. A copy of each laboratory report with the certificate of withdrawal shall also be kept on file.

~~1 VAC 30-60-160.~~ 6 VAC 20-200-180. ~~Confirmation~~ Performance and reporting of analyses for drugs

Analyses for drugs in blood shall consist of screening followed by identification and quantitation of any drugs indicated by the screening. Screening may be performed by immunoassay or similar technique comparable to that performed by the division. The ~~one general~~ recommended analytical technique ~~required~~ for ~~confirmation~~ identification of drugs ~~or metabolites~~ is gas chromatography/mass spectrometry. ~~Selected~~ Both full scan and selected ion monitoring (SIM) modes are acceptable; SIM analyses must include a minimum of three ~~or more~~ ions and their relative ratios ~~is also permitted for confirmation~~ for each drug. Other identification techniques may be used if they are at least as sensitive and specific as gas

chromatography/mass spectrometry. ~~These and other modes of gas chromatography/mass spectrometry, including positive and negative chemical ionization are also permitted for drug and metabolite quantitation. Other acceptable techniques for quantitation are capillary or megabore gas chromatography with flame ionization, nitrogen-phosphorus or electron capture detectors. Likewise, quantitative immunoassays and high performance liquid chromatography with ultraviolet absorbance, fluorescence or electrochemical detectors may be used for drug and metabolite quantitation.~~ Quantitation may be performed using an acceptable identification technique, gas chromatography, liquid chromatography, or any other technique comparable to those performed by the division. For reporting purposes, drugs found to be present above the specified quantitation limit shall be reported in the units as listed on the Fee Schedule. Drug classes found to be below the specified limits shall be reported as ANot Detected≅. Results should be reported within four weeks of receipt of samples. Records of analyses shall be confidential and shall be kept by the laboratory for a minimum of three years. The records shall include sample tracking and preparation information, raw analytical data, calculations and all associated quality control data. A copy of each laboratory report shall be kept on file.

~~1 VAC 30-60-170.~~

~~The following list indicates which drugs and metabolites which an approved laboratory shall be able to detect and the minimum concentration above which each must be quantitated. Drugs and metabolites below these concentrations may be quantitated if the approved laboratory wishes to do so and can document adequate analytical precision at the lower concentrations. Drugs and metabolites detected and confirmed but which are subsequently found to be below minimum measurable concentrations shall be reported as "detected, less than (x) nanograms/milliliter" (i.e. the minimum measurable concentration). If the laboratory does not confirm the presence of a drug or metabolite, the report shall read "none detected" followed by the laboratory's stated limit of detection for that drug or metabolite.~~

~~Category:~~	~~Drug:~~	~~Required Limit of Quantitation (Nanograms per MilliLiter)~~
~~Stimulants~~	~~Cocaine~~	~~100~~
	~~(Benzoylecgonine)~~	~~100~~
	~~Amphetamine~~	~~20~~
	~~Methamphetamine~~	~~20~~
	~~Phenmetrazine~~	~~100~~
~~Barbiturates~~	~~Butalbital~~	~~1000~~
	~~Butabarbital~~	~~1000~~
	~~Amobarbital~~	~~1000~~
	~~Pentobarbital~~	~~1000~~
	~~Secobarbital~~	~~1000~~

	~~Phenobarbital~~	~~1000~~
~~Benzodiazepines~~	~~Diazepam~~	~~100~~
	~~Nordiazepam~~	~~100~~
	~~Chlordiazepoxide~~	~~500~~
~~Antidepressants~~	~~Amitriptyline~~	~~50~~
	~~Nortriptyline~~	~~50~~
	~~Imipramine~~	~~50~~
	~~Desipramine~~	~~50~~
	~~Doxepin~~	~~50~~
~~Antihistamines~~	~~Diphenhydramine~~	~~50~~
	~~Chlorpheniramine~~	~~20~~
	~~Brompheniramine~~	~~20~~
~~Analgesics~~	~~Morphine~~	~~50~~
	~~Codeine~~	~~50~~
	~~Hydrocodone~~	~~50~~
	~~Oxycodone~~	~~50~~
	~~Meperidine~~	~~100~~
	~~Propoxyphene~~	~~100~~
	~~Methadone~~	~~100~~
~~Miscellaneous~~	~~Phencyclidine~~	~~20~~
~~Cannabinoids~~	~~delta-9-Tetrahydrocannabinol~~	~~2.5~~
	~~11-nor-delta-9-Tetrahydro-cannabinol-9-carboxylic acid~~	~~25~~

PART III.

FEES.

~~1 VAC 30-60-180.~~	6VAC 20-200-190.	Fees.
~~1 VAC 30-60-190.~~	~~Handling fee.~~	
~~1 VAC 30-60-200.~~	~~Analysis fee.~~	

~~1 VAC 30-60-180.~~	**6VAC 20-200-190.**	**Fees.**

~~Section 18.2-268.8 of the Code of Virginia, effective April 1, 1988, states, "A fee not to exceed the amount established on a schedule of fees to be published by the Division for the required procedure or procedures shall be allowed the approved laboratory for making an analysis of the second blood sample to determine the presence of a drug or drugs,..."~~Pursuant to ə18.2-268.8 of the Code of Virginia, the division will periodically publish the Fee Schedule in The Virginia Register of Regulations. Such schedule will include fees allowed for specific drugs to be determined, the screening detection limit, the reporting limit for quantitation, as well as directions for the general analytical scheme, and will be published forthwith after any addition, deletion, or change is made. The division will also publish the schedule on its web site, where it will be updated as soon as possible after the publication of an edited schedule.

~~**1 VAC 30-60-190. Handling fee.**~~

~~A fee of $10 shall be allowed an approved laboratory for handling of each second sample, regardless of whether or not an analysis is performed.~~

~~**1 VAC 30-60-200. Analysis fee.**~~

~~In addition, a fee of $80 shall be allowed an approved laboratory for each drug or metabolite analysis performed by the approved laboratory at the instruction of the division. (See 1 VAC 30-60-150)~~

~~FORMS~~

~~Application for Approval to Conduct Independent Analysis in Driving Under the Influence Cases.~~