

FARC Advisory Subcommittee Meeting 7-16-08

7-16- 08 Advisory Subcommittee Meeting Notes:

San Diego Site:

Jennifer Shen – Public Member, San Diego PD

Patricia Lough, FARC Member

Conference Call In:

Terry Fickies – Public Member, DOJ Sacramento

Keith Scruggs – Public, DOJ Fresno

Heather Lewis – Public, Orange Co.

Greg Gossage – Public, Long Beach PD

Eileen Boyd – Public, Ventura Co. Sheriff's Lab

Tony Agurto, Public, Asst. Division Chief, Ca State FDR

NOTE: Action pending in this document is typed in BLUE.

New Discussion:

Terry Fickies and Jennifer Shen were informed by DHS that members of the subcommittee must appear at the actual location of the conference site. Jennifer Shen was present at the San Diego site location. Terry Fickies is from Sacramento and there was no site available in his area to attend.

Per the request of Pattie Lough, Tony Agurto consulted the DHS legal advisers and was told that Bagley-Keene requires subcommittee members to attend the site location of the meeting or teleconference from a phone location available to the public who may wish to attend. With that information in mind, Jennifer will continue to attend the San Diego site location. Terry Fickies is advised to coordinate with DHS on an available public Sacramento site or DHS funding for a flight to San Diego to attend that meeting.

Meeting Notes:

The subcommittee completed their review of the regulations. Jennifer Shen is in the process of formalizing the comments to justify the modifications

made and/or current language elected to be maintained. Additional information to be provided by subcommittee members is annotated in BLUE. Jennifer will contact Pattie Lough when she is ready for a final subcommittee meeting to review her work product prior to submission to the FARC.

5-21-08 Advisory Subcommittee Meeting Notes:

Teleconference attendance:

Patricia Lough, FARC Member

Jennifer Shen, Public Member

Heather Lewis, Public, Orange County Sheriff

Attendees reviewed prior work and continued working on the product. Changes made have been incorporated. Jennifer Shen is assigned to work on justification language on completed work during the month of June.

Next meeting: The dates of July 14 through 17 have been tentatively set assigned for the 3rd meeting based on availability of a public meeting location.

4-23-08 Advisory Subcommittee Meeting Notes

Teleconference attendance:

Terry Fickies, Public Member, DOJ-Sacramento

Patricia Lough, FARC Member, CACLD (on-site San Diego)

Jennifer Shen, Public Member, San Diego PD

Ron Moore, Public

Notes in red added by Lough 4-24-08 added for consideration. FARC changes from 8th meeting were added per my notes but have not been verified against transcripts. Note: per ISOR format: deleted text lined through, new text underlined. Also added for review within the document

is the wording submitted by the public, Terry Fickies, at the 8th FARC meeting. There are 27 pages in this document.

Lough was assigned to prepare the ISOR Introduction. A Draft has been added below for consideration:

Next teleconference meeting: May 21, 2008

Initial Statement of Reasons (ISOR) DRAFT

INTRODUCTION

Pattie to provide: [prior Bill and vote, State audit]

Senate Bill 1623 (Johnson, Laboratories: licensing and accreditation) was approved and signed into law in August 2004, with the intent to greatly reduce State oversight of forensic alcohol analysis **[Pattie provide: reference Johnson letter, handouts to Legislators]**. This bill resulted in significant changes to the CA Health and Safety Code Sections 100700-100775 and eliminated State licensing of laboratories performing forensic alcohol analysis. A newly appointed Forensic Alcohol Review Committee comprised of scientific, law enforcement, and legal representatives, was given the authority to evaluate the regulations and “determine revisions that will limit those regulations to those that the review committee determines are reasonably necessary to ensure the competence of the laboratories and employees to prepare, analyze, and report the results of the tests and comply with applicable laws”.

State oversight of forensic alcohol analysis began in the 70's. At that time it provided the only source of on-site inspections, proficiency testing, and consistent regulations for laboratories performing forensic alcohol analysis for law enforcement agencies. All other forensic alcohol analysis laboratories were,

and continue to be, exempt from State regulation. **[Pattie provide: ref. State list of functions]**

Forensic testing, unlike clinical or general scientific testing, is unique in that all documentation, test results, and interpretation of those results are subjected to the highest level of scrutiny through the California judicial system **[FARC: ref. evidence code or other legal references?]**. Legal safeguards of forensic analysis include a process for inspection of documentation and facilities, and reanalysis of samples by independent laboratories. Great strides have been made over the last 30+ years in all forensic disciplines, such as DNA testing, firearms and toolmark examinations, drug and toxicology analyses, paint, hair and fiber comparisons, and alcohol analysis. Only forensic alcohol analysis is, and has been, subject to State oversight.

The majority of laboratories originally licensed by the State are now accredited through an internationally recognized forensic accreditation organization, the American Society of Crime Lab Directors/Laboratory Accreditation Board (ASCLD/LAB) **[Jennifer to provide; add ISO information/references, asclD/lab references; advantages]**. Accredited labs are subject to regularly scheduled on-site inspections, including a full review of methods, personnel qualifications, and proficiency testing. A small minority, **___#___**, of labs originally licensed by the State are not accredited by ASCLD/LAB. Although these few labs are not accredited, their work is still subject to scrutiny in the courts. It is not the intent of these regulations to require

laboratory accreditation. **[PL: state cost reduction by reducing oversight of accredited labs, minority of nonaccredited labs]**

The State inspection program **[PL: add record of State inspections of labs]....**

Proficiency testing programs and test providers required in the 2004 revised Health and Safety Code not only duplicate the State proficiency test program, but are superior in scope and design. Laboratories are not required to be accredited through ASCLD/LAB, but must follow the ASCLD/LAB guidelines and the use of ASCLD/LAB approved proficiency test providers. **[reference: number of labs that licensed but not accredited] [PL: note & references: differences between programs: all analysts must be tested annually; state tests always above the legal limit, state tests always one or 2 samples divided into 4 test vials so analysts expect no more than 2 different results; delays in waiting for state test for classification status/upgrades]**

The existing CA Code of Regulations were last updated in 1986 and are not in compliance with the Administrative Procedures Act. They are grossly outdated and inconsistent with California law, current health advisories, and modern instrumentation and technology.

A brief overview of the significant changes is provided below. **[add info]**

Elimination of all references to DPH licensing of forensic alcohol labs

Enhanced academic requirements for personnel:

Requirements for additional controls and standards for analysis:

Advisory Subcommittee Work Product Draft a/o 4-23-08

BARCLAYS OFFICIAL CALIFORNIA CODE OF REGULATIONS
TITLE 17. PUBLIC HEALTH
DIVISION 1. STATE DEPARTMENT OF HEALTH SERVICES
CHAPTER 2. LABORATORIES
SUBCHAPTER 1. SERVICE LABORATORIES
GROUP 8. FORENSIC ALCOHOL ANALYSIS ~~AND BREATH ALCOHOL ANALYSIS~~

Removed because breath alcohol analysis is redundant and is included in the definition of forensic alcohol analysis under 1215.1 B.

ARTICLE 1. GENERAL

This database is current through 05/12/06, Register 2006, No. 19.

s 1215. Authority.

~~Chapter 5 Sections 436.50-436.63 of Part 1 of Division 1 of the Health and Safety Code.~~ Health and Safety Code Division 101, Part 1, Chapter 4, Article 2, Sections 100700-100775.

Rule 100 change; This change would reflect current law.

s 1215.1. Definitions.

(a) "Alcohol" means the unique chemical compound, ethyl alcohol, with the exception that reference in these regulations to compounds to be avoided as skin antiseptics includes the generic class of organic compounds known as alcohols.

(b) "Forensic Alcohol Analysis" means the ~~practical application use~~ of specialized equipment, devices, instruments, and methods by trained laboratory personnel to measure the concentration of ~~ethyl~~ alcohol in samples of blood, breath, urine, or tissue of persons involved in traffic accidents or traffic violations.

Clarity and common language. so the term is understandable in the common language.

Alcohol (ethyl) previously defined in 1215.1 (a)

**New law 100700a now includes the reference to breath. to ... and breath and
NOTE: existing language already includes breath in this definition. We are not adding it here so don't need justification.**

no longer using trained laboratory personnel phrase

NOTE: because... definition restricted to what analysis is; who performs the analysis is defined elsewhere

Equipment: clarity and common language; devices may be confused with use of the term “calibrating devices”; dictionary definition lends itself to more of an instrument than an item; more accurate term.

(c) “Breath Alcohol Analysis Testing means analysis of a sample of a person’s expired breath, using a breath testing instrument designed for this purpose, in order to determine the concentration of ethyl alcohol in the person’s ~~blood~~ breath.”

NOTE: possible add breath sample definition

Testing: prevents definition from being circular;

blood to breath – consistent with existing law

ethyl – redundant, defined as such in 1215.1(a)

Check: McNeil case (Ron Moore ?)

(d) "Concentration" means the weight amount of alcohol contained in a unit volume of liquid or a unit volume of gas under specified conditions of temperature and pressure; in the case of a solid tissue specimen, "concentration" means the weight amount of alcohol contained in a unit weight of specimen.

(e) "Forensic Alcohol Laboratory" means a place at which specialized apparatus, equipment, instruments, and methods are used by trained laboratory personnel forensic alcohol supervisors, forensic alcohol analysts, or forensic alcohol analyst trainees to measure the concentration of alcohol in samples of blood, breath, urine, or tissue of persons involved in traffic accidents or in traffic violations; this may be an activity of a laboratory engaged in activities other than forensic alcohol analysis.

clarity, common language, consistent throughout the regulations

personnel: identifies specifically what a laboratory is and provides clarity as to what personnel are included

forensic added: consistent

(f) "Forensic Alcohol Supervisor" means a person employed by a forensic alcohol laboratory who can perform all aspects of forensic alcohol analysis and can supervise personnel who perform such analysis. ~~can be responsible for all aspects of the performance of forensic alcohol analysis and for the supervision of personnel who perform such analysis.~~

clarifies role of the FAS and allows them to analyze samples, includes performance of analysis by FAS

NOTE: remove wording of supervision (key needed for DMV); misleading definition – FAS implies supervision of personnel; this is not true for majority of labs

(g) "Forensic Alcohol Analyst" means a person employed by a forensic alcohol laboratory who performs the ~~technical procedures~~ methods of forensic alcohol analysis.

Methods: consistent with definition 1215.1(b) and throughout the definitions

NOTE: add supervision to analyst of trainees to be consistent with (h) below?

(h) "Forensic Alcohol Analyst Trainee" means a person employed by a forensic alcohol laboratory for the purpose of receiving comprehensive practical experience and instruction in the ~~technical procedures~~ methods of forensic alcohol analysis under the supervision of a forensic alcohol supervisor or forensic alcohol analyst.

consistency throughout the definitions

(i) "Method" means the ~~steps~~ procedures used by a forensic alcohol supervisor, forensic alcohol analyst, or forensic alcohol analyst trainee to determine the alcohol concentration used in a sample or specimen ~~by a trained person to make a measurement of alcohol concentration.~~

more specific, clarifies who trained people are and what method is reads better

in sample: clarifies, describes what we are measuring in

(j) "Instrument" or "Device" means ~~any item or combination of items of equipment used to make a measurement of alcohol concentration; simple and complex devices are included in this meaning.~~

NOTE: do we have to consider this when we get to breath alcohol; check fed cal device/unit; device common dictionary term / definitions

(k) "License" means a document issued by the State Department of Health to a laboratory to perform the tests referred to in the Health and Safety Code, Sections 436.51 and 436.52.

rule 100 change: need better definition for this term to be used throughout document

(l) "Sample" or "Specimen" means a representative portion of ~~breath,~~ blood,

urine, or tissue, or of an artificially constituted material, ~~taken~~ obtained for the purpose of measuring its alcohol concentration. A sample or specimen may also include that portion of an expired breath which is essentially alveolar in composition.

AS Justification: removed breath, added later to more accurately representate what type of breath we were taking. For clarity – we described exactly what type of breath sample we are taking.

(m) "Alveolar" refers to the smallest air sacs in the lungs and to that portion of the expired breath which is in equilibrium with respect to alcohol with the immediately adjacent pulmonary blood.

~~(n) "Department" means the California State Department of Health and its duly authorized representatives.~~

no longer need to describe because no longer referenced in the document rule 100 change?

AS: PL or FARC interpretation??? or leave in to describe who Department is from deleted text??? Intent of legislature to remove/greatly reduce Department oversight.

(o) "Competency test" means the evaluation of a person's ability to perform work in any functional area prior to the performance of independent casework.

Added to define term used in text.

(p) "Proficiency test" means a test to evaluate the competence of analysts, technical support, and the quality performance of a laboratory.

(q) "Precautionary Checklist: means a guide to assist in the operation of a breath instrument.

js; added to define term used in text

ARTICLE 2. REQUIREMENTS FOR FORENSIC ALCOHOL LABORATORIES

s 1216. Authorization Requirement.

~~(a) Every laboratory performing forensic alcohol analysis shall have a valid license issued in accordance with the provisions of these regulations.~~

rule 100 change

(1) Forensic alcohol analysis shall be performed only by persons who meet the qualifications set forth in ~~these regulations~~ section 1216.1 for forensic alcohol supervisors, forensic alcohol analysts, or forensic alcohol analyst trainees.

clarity

(A) A trainee may perform forensic alcohol analysis only under the supervision of a forensic alcohol supervisor or forensic alcohol analyst.

~~(2) The Department shall not be limited by these regulations in performing functions in administration of the alcohol analysis and licensing program.~~

rule 100 change regarding licensing; other functions???

s 1216.1. Qualifications for ~~Licensing~~ to perform forensic alcohol analysis.

rule 100 change, clarification

(a) A forensic alcohol laboratory meets the qualifications to perform forensic alcohol analysis ~~for licensing~~ by:

rule 100 change, clarification

(1) Employing at least one forensic alcohol supervisor or forensic alcohol analyst. ~~If forensic alcohol analysis is performed by persons other than forensic alcohol supervisors, such persons shall meet the qualifications set forth in these regulations for forensic alcohol analysts or forensic alcohol analyst trainees;~~

NOTE: can a lab run without a supervisor

Removed: redundant, qualifications described in definitions

Repeat: enhanced academic requirements of analyst

(2) Maintaining a quality control program in forensic alcohol analysis procedures as specified in section 1220.3;

clarity

(3) ~~Demonstrating satisfactory performance in a proficiency testing program conducted by or approved by the Department;~~ Meeting the proficiency testing requirements specified in Health and Safety Code Section 100702.

citing code for clarity and to know the code exists, actual requirements not restated in this document to avoid redundancy; current DHS prof sampes do not meet the requirements of Health and Safety Code. (Ref. PL

differences, note HD not interested in becoming an approved provider, per Clay conversations)

~~(4) Passing such on-site inspections as the Department may require;~~

*****Document in references; Past practice of inspections irregular by Department; majority of public labs (x out x) accredited by ASCLD/LAB and subject to regular internal and external inspections – redundant; those remaining minority of labs not accredited , courts review all documents case by case basis, may be impetitus for nonaccredited labs to get on board**

NOTE for FARC: who inspects non accredited labs; does State maintain cost for their inspections

~~(5) Showing ability to meet the requirements set forth in these regulations.~~

vague, redundant

~~(b) These qualifications shall be maintained at all times by each licensed laboratory.~~

vague, redundant, rule 100 change

~~(c) The Department may deny a license or renewal thereof, or take disciplinary action against a licensee, for failure to maintain these qualifications in a manner which meets the Department's standards for approval.~~

rule 100 change

~~(d) Whenever a licensed laboratory employing only one forensic alcohol supervisor loses that person, the Department may upon petition of the laboratory extend the license for a period not exceeding 90 days during which time the laboratory shall hire another forensic alcohol supervisor.~~

FARC discussion: necessary? add time period to 1216.1(a)?

~~(1) Such an extension shall be contingent on the laboratory's having in its employ at least one forensic alcohol analyst and upon the laboratory's successfully demonstrating to the Department continued competence in forensic alcohol analysis through such proficiency tests, examinations, and on-site inspections as the Department may require.~~

FARC: if d is out, 1 not relevant

~~(e) A forensic alcohol supervisor is a person who meets the following qualifications:~~

(1) Possesses a baccalaureate or higher degree, ~~or an equivalent, in chemistry, biochemistry, or other appropriate discipline as determined by the Department; in any applied physical or natural science.~~

other disciplines too vague, biochemistry too narrow, didn't allow others otherwise qualified with sufficient science background (criminalistics, biology, geology, zoology); gives responsibility to laboratory

(2) Has two years of experience in performing forensic alcohol analysis, such experience to include experience in interpretation and correlation of alcohol analyses with subjective observations of the demeanor and behavior of persons who have ingested known amounts of ethyl alcohol; or, in lieu of such two years of experience, satisfactorily completes a training course ~~approved by the Department,~~ such training course to include at minimum the following schedule of subjects:

– intent of legislature to give responsibility to labs, reality Department not best to determine this, Dept. test outdated, insufficient to determine the knowledge, redundant to prove people trained via ASCLD/LAB, minority of labs may not be redundant, service only provides service for a small number of labs, services provided by another agency – accreditation; Dept not approving FAS training, goes to licensing of the laboratory, removing course from DHS purvue, still maintaining course content now under responsibility of labs, gives agencies local control when and how to conduct these courses, content spelled out in regulations, no need for dept to approve what is already spelled out; [used as part of the licensing mechanism which has been deleted by rule 100.]

(A) Value and purpose of forensic alcohol analysis, ~~including breath alcohol analysis;~~

redundant, breath included in forensic alcohol analysis definitions

(B) Physiological action of alcohol;

(C) Pharmacology and toxicology of alcohol;

(D) Laboratory methods of forensic alcohol analysis;

forensic: consistency

(E) Instruments and procedures for breath alcohol testing analysis;

clarify language for consistency testing vs analysis

(F) Practical laboratory demonstration of the student's ability to perform forensic alcohol analysis;

consistency, clear

(G) Interpretation of results of forensic alcohol analysis, including correlation of alcohol analyses with subjective observations of the demeanor and behavior of persons who have ingested known amounts of alcohol;

internal consistency within the regulations

(H) Court testimony;

(I) Court decisions regarding chemical tests of alcohol to determine alcohol influence; and

(J) Requirements of Title 17 of the California Code of Regulations, sections 1215 to 1222.1 these regulations;

clarity

~~(3) Successfully demonstrates accuracy in the analysis of proficiency test samples submitted by the Department, and successfully passes examinations prescribed by the Department;~~

At a minimum, successfully complete a competency test comprised of at least four samples that must:

- (a) have differing, predetermined values
- (b) range from 0 to 0.25 percent alcohol concentration
- (c) have values unknown to the test taker
- (d) be analyzed utilizing the laboratory's forensic alcohol method

NOTE: above language changed from FARC wording
The 25 practical exercise where competence test will actually demonstrate if someone is performing the test properly because values are known and predetermined. We can determine if someone is trained and obtaining a correct answer. Just running 25 samples is just practicable. (use Clay's justification)

(4) Meets the requirements of the laboratory of employment.

Justification:

~~(4) Demonstrates the ability to adhere to the provisions of these regulations; or (in lieu of (1) and (2) above)~~

redundant;

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~~(4) (5) Or in lieu of (1) and (2) above, e~~ Either is a person who, prior to January 1, 1971, qualified as director of a clinical laboratory operating under the provisions of the California Business and Professions Code, or is a person who, for a period of one year prior to January 1, 1971, has been employed in the activities of a forensic alcohol supervisor. or was qualified by the Department of Health Services as a Forensic Alcohol Supervisor on or before (date to be inserted for the expected filing the public notice with OAL).

(f) A forensic alcohol analyst is a person who meets the following qualifications:

~~(1) Successfully completes at least 60 semester hours, or their equivalent in quarter hours, of college level courses, including 8 hours of general chemistry and 3 hours of quantitative analysis;~~

(1) Possesses a baccalaureate or higher degree in any applied physical or natural science.

**other disciplines too vague, biochemistry too narrow, didn't allow others otherwise qualified with sufficient science background (criminalistics, biology, geology, zoology); gives responsibility to laboratory that they consider the individual appropriate for the position
Increased educational requirement for a college degree; consistent with accreditation standards [ascld/lab ref]; eliminates qualifications of current requirements to accept persons social or behavioral sciences, such as psychology or criminology, and several technical disciplines such as math and computer science.**

(2) Successfully completes a training period in forensic alcohol analysis on forensic ~~or clinical~~ specimens in a forensic alcohol laboratory ~~or in a clinical laboratory~~;

Clarifying as a forensic alcohol discipline rather than a clinical discipline.

~~(3) Performs during the training period a minimum of 25 analyses of alcohol concentration in blood samples, at least half of which contain alcohol;~~

At a minimum, successfully complete a competency test comprised of at least four samples that must:

- (a) have differing, predetermined values
- (b) range from 0 to 0.25 percent alcohol concentration
- (c) have values unknown to the test taker
- (d) be analyzed utilizing the laboratory's forensic alcohol method

NOTE: wording above has been changed from FARC wording

The 25 practical exercise where competence test will actually demonstrate if someone is performing the test properly because values are known and predetermined. We can determine if someone is trained and obtaining a correct answer. Just running 25 samples is just practicable. (use Clay's justification)

(4) Meets the requirements of the laboratory of employment.

~~(4) Successfully demonstrates accuracy in the analysis of proficiency test samples submitted by the Department, and successfully passes examinations prescribed by the Department;~~

Incorporated into (3) above; now redundant.

~~(5) Demonstrates ability to adhere to the provisions of these regulations; or (in lieu of (1), (2), and (3) above)~~

Incorporated into (3) above; now redundant

(6) Either is a person who, prior to January 1, 1971, was a clinical laboratory technologist licensed under the provisions of the California Business and Professions Code, or is a person who, for a period of one year prior to January 1, 1971, has been employed in the activities of a forensic alcohol analyst or was qualified by the Department of Health Services as a Forensic Alcohol Analyst on or before *(date to be inserted for the expected filing the public notice with OAL)*.

(g) A forensic alcohol analyst trainee is a person who meets the following qualifications:

(1) Meets the educational qualification set forth in ~~as f~~ (1) for a forensic alcohol analyst;

NOTE: look for 1 year updating of qualification from original Title 17

(2) Is employed by a ~~licensed~~ forensic alcohol laboratory.

(3) Meets the requirements of the laboratory of employment.

Rule 100 change

ARTICLE 3. LICENSING PROCEDURES

Rule 100 change all related to licensing; 98% removed; remaining issues 176b and 177: NOTE: heavy justification data to remove inspection and proficiency testing – Pattie draft emphasize)

~~s 1217. Forensic Alcohol Laboratory License.~~

~~(a) Upon receipt of a completed application which shows ability to meet the requirements set forth in these regulations, and upon payment of any required fee, the Department shall submit such proficiency test samples and perform such examinations as are required for that laboratory to complete the qualifications.~~

~~(b) Upon the laboratory's successfully completing all the qualifications, the Department shall issue to the applicant laboratory a forensic alcohol laboratory license.~~

~~s 1217.1. Renewal of Licenses.~~

~~(a) Licenses under these regulations shall be renewed as required by the Department as long as the activity requiring authorization continues. Renewal shall be contingent upon the laboratory continuing in the qualifications set forth in these regulations.~~

~~(1) A forensic alcohol laboratory license shall be valid from January 1 to December 31 of a calendar year. Applications for renewal and applicable fees shall be submitted to the Department on or before October 1 of each year.~~

~~(2) Failure to apply for renewal shall result in forfeiture after a period of three months from the day on which the application for renewal should have been submitted, with the exception that the Department may grant a temporary extension under special circumstances.~~

~~(3) An application for renewal shall not list as a forensic alcohol analyst trainee any person who fails to comply with the requirements of Section 1216.1 (f) (4) within a period of one year after he was first listed with the Department as a trainee. The Department may extend this period for a justifiable reason, such as illness.~~

~~s 1217.2. Application Forms.~~

~~Application for a license and renewal thereof, shall be made on forms furnished by the Department. The applicant shall set forth all pertinent information called for by the form.~~

~~s 1217.3. Report of Change or Discontinuance.~~

~~(a) A person responsible for the operation of a forensic alcohol laboratory shall report to the Department in writing within 30 days any change in qualified personnel who may be performing forensic alcohol analysis, change of ownership, change of address or change or discontinuance of an activity authorized under these regulations.~~

~~(b) Such reports shall be made on forms furnished by the Department and shall set forth all pertinent information called for by the form.~~

~~(c) Persons who formerly qualified as forensic alcohol supervisors or forensic alcohol analysts in another laboratory may be required to demonstrate again their ability to meet the requirement of Section 1216.1 (e) (3) or 1216.1 (f) (4) using the method, apparatus and facilities of the forensic alcohol laboratory which newly lists them in such a Report of Change or Discontinuance.~~

~~s 1217.4. License Implications.~~

~~Licenses issued under these regulations shall not imply approval of anything carried out by a laboratory other than what is specified on the document.~~

~~s 1217.5. Licensing Records.~~

~~Forensic Alcohol Laboratory Licenses shall become part of permanent records available to the courts for legal proceedings or to the Department.~~

~~s 1217.6. Inspection and Additional Requirements.~~

~~(a) Display of Licenses. Licenses issued under these regulations shall be displayed on request to representatives of the Department.~~

~~(b) Access to Premises. The Department may enter at all reasonable times upon any laboratory for the purpose of determining whether or not there is compliance with the provisions of these regulations.~~

~~§ 1217.7. Surveys and Proficiency Tests.~~

~~(a) Laboratories having been licensed or applying for licensing as forensic alcohol laboratories shall be subject to on-site surveys by representatives of the Department, the results of which must meet the requirements of these regulations, and shall accept periodic evaluation samples, perform analyses and report the results of such analyses to the Department.~~

~~(b) These analytical results shall be used by the Department to evaluate the accuracy of the forensic alcohol analyses performed by the laboratory, and the results must meet the requirements of these regulations.~~

~~§ 1217.8. Fees and Other Procedures.~~

~~The annual application fee for a Forensic Alcohol Laboratory License or its renewal shall be one hundred dollars (\$100). A laboratory operated by the state, city or county or other public organization shall be exempt from the annual application fee requirement. Other procedures in the administration of these regulations shall be carried out as set forth in Chapter 5 (commencing with section 436.50) of Part 1 of Division 1 of the Health and Safety Code. Such other procedures include suspension or revocation of license, denial of license, and disciplinary action.~~

ARTICLE 4. TRAINING OF PERSONNEL

Irrelevant; specifically addresses and is limited to FAS training classes that private organizations or DOJ might give. Removed approval of the Department and placed the responsibility to the individual laboratories to provide the training. The training curriculum is spelled out under e2 a-g so this requirement for State approval is redundant with previous regulations.

~~§ 1218. Training Program Approval.~~

~~Any organization, laboratory, institution, school, or college conducting a course of instruction for persons to qualify under these regulations shall submit a course summary and list of instructors and their qualifications to the Department for approval.~~

~~§ 1218.1. Additional Requirements.~~

~~At the discretion of the Department, any phase or portion of a training program shall be subject to alteration in an effort to update the program as technological advances are made or if a portion has been judged inappropriate.~~

~~s 1218.2. Contracts.~~

~~The Department may contract with persons it deems qualified to administer such practical tests and written or oral examinations as may be required under these regulations. This section shall not be construed to authorize the delegation of any discretionary functions conferred on the Department by law, including, but not limited to, the evaluation of tests and examinations.~~

ARTICLE 5. COLLECTION AND HANDLING OF SAMPLES

s 1219. General.

~~Samples taken for forensic alcohol analysis and breath alcohol testing analysis shall be collected and handled in a manner in which the identity and integrity of the samples shall be maintained ~~approved by the Department.~~ †The identity and integrity of the samples shall be maintained through collection to analysis and reporting.~~

Breath alcohol testing vs analysis consistent with document.

Clarity

Approved by Dept eliminated – compliance with law stated below, not department approval. Dept approval redundant function; manner subject to scrutiny in courts.

s 1219.1. Blood Collection and Retention.

(a) Blood samples shall be collected by venipuncture from living individuals as soon as feasible after an alleged offense and processed ~~and only by persons authorized by Section 13354 of the Vehicle Code,~~ in compliance with CVC Section 23158.

updates section; includes references to Uniform Standards of Collection, chain of custody, persons who may perform venipuncture; incorporating reference to the statute for clarification and direction where to go to show applicable statutes

(b) ~~Sufficient blood shall be collected to permit duplicate determinations.~~

vague language, blood collector has insufficient knowledge to make decision, analyst discretion if sample suitable; up to laboratory to determine how much blood they need for analysis and what supplies they provide and have blood techs use to determine what they take.

(c) Alcohol or other volatile organic disinfectant shall not be used to clean the

skin where a specimen is to be collected. Aqueous benzalkonium chloride (zephiran) is an acceptable ~~aqueous merthiolate or other suitable aqueous~~ disinfectant ~~shall be used.~~

health hazard, DHS advisory date (J has letter) significant warning should be included in regulations

(d) Blood samples shall be collected using sterile, dry hypodermic needles and syringes, or using clean, dry vacuum type containers with sterile needles. Reusable equipment, if used, shall not be cleaned with or kept in alcohol or other volatile organic solvents.

(e) The blood sample shall be deposited into a clean, dry container which is closed with an inert stopper.

(1) Alcohol or other volatile organic solvent shall not be used to clean the container.

(2) The blood shall be mixed with an anticoagulant and a preservative.

(f) When blood samples for forensic alcohol analysis are collected post-mortem, all practical precautions to ~~insure~~ ensure an uncontaminated sample shall be employed, such as:

Justification:

(1) Samples shall be obtained prior to the start of any embalming procedure. Blood samples shall not be collected from the circulatory system effluent during arterial injection of embalming fluid. ~~Coroner's samples do not need a preservative added if stored under refrigeration.~~

outdated procedure, current practice recommends refrigeration

(2) Care shall be taken to avoid contamination by alcohol from the gastrointestinal tract directly or by diffusion therefrom. The sample shall be taken from a major vein or the heart.

(g) In order to allow for analysis by the defendant, the remaining portion of the sample shall be retained for one year after the date of collection.

(1) In coroner's cases, blood samples shall be retained for at least 90 days after date of collection.

(2) Whenever a sample is requested by the defendant for analysis and a sufficient sample remains, the forensic alcohol laboratory, ~~or~~ law enforcement

agency, or coroner/medical examiner office in possession of the original sample shall continue such possession, but shall provide the defendant with a portion of the remaining sample in a clean container together with a copy or transcript of the identifying information carried on the original sample container.

adding coroner/me more accurate and inclusive of current practice

s 1219.2. Urine Collection and Retention.

(a) The ~~only approved~~ urine sample from a living individual shall be ~~a sample~~ collected no sooner than twenty minutes after first voiding the bladder.

state what the sample has to be; getting rid of concept that there is an unapproved sample; added living individual for clarity because the bladder sample is obtained from deceased as is.

(b) The specimen shall be deposited in a clean, dry container which also contains a preservative.

(c) In order to allow for analysis by the defendant, the remaining portion of the sample shall be retained for one year after the date of collection.

(1) Whenever a sample is requested by the defendant for analysis and a sufficient sample remains, the forensic alcohol laboratory, ~~or law enforcement agency,~~ or coroner/medical examiner office in possession of the original sample shall continue such possession, but shall provide the defendant with a portion of the remaining sample in a clean container together with a copy or transcript of the identifying information carried on ~~by~~ the original sample container.

language consistent with 1219.1(g)(2)

s 1219.3. Breath Collection.

A breath sample shall be expired breath which is essentially alveolar in composition. ~~The quantity of the breath sample shall be established by direct volumetric measurement.~~ The breath sample shall be collected only after the subject has been under continuous observation for at least fifteen minutes prior to collection of the breath sample, during which time the subject must not have ingested alcoholic beverages or other fluids, regurgitated, vomited, eaten, or smoked.

outdated; has not been performed for decades; unnecessary language

ARTICLE 6. METHODS OF FORENSIC ALCOHOL ANALYSIS

s 1220. General.

(a) All laboratory methods used for forensic alcohol analysis shall be subject to standards set forth in this Article.

(b) Each ~~licensed~~ forensic alcohol laboratory shall have ~~on file with the Department~~ detailed, up-to-date written descriptions of each method it uses for forensic alcohol analysis.

FARC: rule 100 change; legislative intent to remove Department oversight; public information – mechanism in place for documents to be obtained through the courts

(1) Such descriptions shall be immediately available to the person performing an analysis ~~and shall be available for inspection by the Department on request.~~

FARC: rule 100 change; legislative intent to remove Department oversight; data and methods can be available for inspection at any time by any public person or agency; public freedom of information act; redundant language [ref. public act language; discovery language]

(2) Each such description shall include the calibration procedures and the quality control program for the method.

NOTE: ASCLD/LAB and ISO certification encompasses additional requirements for written methods (ref. include their requirements)

s 1220.1. Standards of Performance.

(a) Methods for forensic alcohol analysis shall meet the following standards of performance:

(1) The method shall be capable of the analysis of a reference sample of known alcohol concentration within accuracy and precision limits of plus or minus 5 percent of the value; these limits shall be applied to alcohol concentrations which are ~~0.10~~ 0.08 grams per 100 milliliters or higher;

change in law 1-1990; include reference?

(2) The method shall be capable of the analysis of ethyl alcohol with a specificity which is adequate and appropriate for traffic law enforcement.

(3) The method should be free from interference from anticoagulants and preservatives added to the sample;

(4) Blood alcohol results on post-mortem samples shall not be reported unless the oxidizable substance is identified as ethyl alcohol by qualitative test;

(5) The method shall give a test result which is always less than 0.01 grams of alcohol per 100 milliliters of blood when living subjects free of alcohol are tested.

(b) The ability of methods to meet the standards of performance set forth in this Section shall be evaluated by ~~the Department~~ a forensic alcohol supervisor or forensic alcohol analyst using a laboratory's proficiency test results and such ability must meet the requirements of these regulations.

Formerly Department performed prof test eval function; rule 100 change follow ASCLD/LAB proficiency test guidelines, added specific individuals to perform that function [PL: demo ASCLD/LAB prof superior to state]

END OF 5-21-08 SUBCOMMITTEE MEETING

s 1220.2. Standards of Procedure.

(a) Methods for forensic alcohol analysis shall meet the following standards of procedure:

Comments:

(1) The ~~method~~ instruments shall be calibrated with standards which are water solutions of alcohol.

js: JUSTIFY METHOD VS INSTRUMENTS

FARC: discussion, suggest 3-point calibration curve; use of a "high" "low" standard; 3 decimal places DISCUSS WITH FARC. (INITIAL DEMONSTRATION OF LINEARITY VS DAILY RUNS)

(A) Such alcohol solutions are secondary standards.

(B) Each forensic alcohol laboratory shall purchase National Institute of Standards and Technology (NIST) traceable secondary alcohol standards, or establish the concentration of each lot of secondary alcohol standards it prepares using uses, whether prepared or acquired, by an a direct oxidimetric method which employs a primary standard, such as ~~United States National Bureau of Standards~~ NIST potassium dichromate;

FARC: "direct" – more specific, emphasizes fact that alcohol is added directly to the oxidizing media in the method (Clay [16])

Lough: NIST references; enhanced standards over prepared NIST VS nbs

(C) The forensic alcohol laboratory shall verify the concentration of any new secondary standards used in the method by analyzing the new secondary standard concurrently with a NIST Standard Reference Material (SRM).

Lough: a NIST Standard Reference Material (SRM) would be better than a previously analyzed secondary standard; in line with Fickies suggestion at FARC meeting; extra cost for laboratories but greatly enhances assurance of accuracy. Establish reference point...clay's comments....

(2) The procedure shall include blank and secondary alcohol standard samples at least once each day that samples are subjected to forensic alcohol analysis.

(A) The blank and secondary alcohol standard samples shall be taken through all steps of the method used for forensic alcohol analysis of samples.

(3) The procedure shall also include analysis of quality control reference samples as described in Section 1220.3 and shall include at least duplicate analyses of samples for forensic alcohol analysis.

(A) A quality control reference sample shall not be taken from the same lot of alcohol solution which is used as a secondary alcohol standard.

(4) Alcohols or other volatile organic solvents shall not be used to wash or rinse glassware and instruments used for alcohol analysis;

~~(5) All instruments used for alcohol analysis shall be in good working order and routinely checked for accuracy and precision.~~

Justification: redundancy

Fickies suggested wording for review submitted to Lough by request at 8th FARC meeting:

Fickies proposed changes:

~~(e) "External alcohol standard" means an alcohol standard that has been obtained from a source outside of the laboratory.~~

NOTE: Fickies to discuss need in full committee.

s 1220.2. Standards of Procedure.

Comment [DoHS1]: Page: 11
OOR: OOR recommends the use of the redraft language from 1/26/06 based on the need to provide necessity for the retention of the vague language in current regulation.

(D) Each laboratory shall purchase external alcohol standards. These standards shall be different than any secondary alcohol standards which have been purchased.

(2) The procedure shall include blank, ~~and~~ secondary alcohol standard and external standard alcohol samples at least once each day that samples are subjected to forensic alcohol analysis.

(A) The blank, ~~and~~ secondary alcohol standard and external standard alcohol samples shall be taken through all steps of the method used for forensic alcohol analysis of samples.

(B) The external standard samples shall agree within 0.010% of its stated value.

End of Fickies suggested wording

s 1220.3. Quality Control Program.

(a) Methods for forensic alcohol analysis shall be performed in accordance with the following quality control program:

(1) For each method of forensic alcohol analysis it performs, each forensic alcohol laboratory shall make or acquire a suitable quality control reference material containing alcohol, a sample of which it shall analyze along with each set of samples; the alcohol concentration in the reference material shall be between ~~0.10~~ 0.08 and 0.20 grams per 100 milliliters of liquid;

JS:

(2) For each lot of quality control reference material, the laboratory shall determine a mean value of at least 20 replicate analyses, at a rate of no more than 2 analyses per day, with the method used for analysis of samples for forensic alcohol analysis;

FARC: to 3 decimal places

(3) Acceptable limits of variation for the method shall be set as follows:

(A) The lower limit shall be calculated by subtracting, from the mean value, 0.010 grams per 100 milliliters;

js:

(B) The higher limit shall be calculated by adding, to the mean value, 0.010 grams per 100 milliliters;

js:

(4) At least one sample of the quality control reference material shall be analyzed with each set of samples analyzed for the purpose of forensic alcohol analysis;

(5) Whenever analysis of the quality control reference material is outside the acceptable limits, the method shall be regarded to be in error, and a forensic alcohol supervisor or forensic alcohol analyst shall take remedial action to investigate and correct the source of error;

js: faa included increased academic requirements and fas not required to be on site

(6) Until such time as the error has been corrected, as shown by return of the analysis of the quality control reference material to values within the acceptable limits, no samples shall be analyzed for the purpose of forensic alcohol analysis.

s 1220.4. Expression of Analytical Results.

JS: clarity; included breath changes

~~(a) With the exception of tissue analysis, all analytical results shall be expressed in terms of the alcohol concentration in blood, based on the number of grams of alcohol per 100 milliliters of blood, or in breath, based on the number of grams of alcohol per 210 liters of breath.~~

(e)(a) Analytical results for blood shall be based on the number of grams of alcohol per 100 milliliters of blood.

(f)(b) Analytical results for breath shall be based on the number of grams of alcohol per 210 liters of breath.

FARC: change in law (specify, date)

(a) ~~(4)~~ The symbols, grams %, %, and % (W/V), shall be regarded as acceptable

abbreviations of the phrase, grams per 100 milliliters of liquid or grams of alcohol per 210 liters of breath.

FARC: consistent with 1220.4(a)

(b) Analytical results shall be reported to the second decimal place, deleting the digit in the third decimal place when it is present.

(c) ~~Blood a~~Alcohol concentrations less than 0.01% in living subjects may be reported as negative.

(d) ~~Blood a~~Alcohol concentrations less than 0.02% on post-mortem blood samples may be reported as negative.

JS: remove reference to blood to be all inclusive for any type of sample

(h) ~~(e)~~ A urine alcohol concentration shall be converted to an equivalent blood alcohol concentration by a calculation based on the relationship: the amount of alcohol in 1.3 milliliters of blood is equivalent to the amount of alcohol in 1 milliliter of urine.

~~(f) A breath alcohol concentration shall be converted to an equivalent blood alcohol concentration by a calculation based on the relationship: the amount of alcohol in 2,100 milliliters of alveolar breath is equivalent to the amount of alcohol in 1 milliliter of blood.~~

FARC: change in law, date____

(g) Tissue analysis results shall be expressed in terms of a weight amount of alcohol in a unit weight of the specimen.

ARTICLE 7. REQUIREMENTS FOR BREATH ALCOHOL ANALYSIS

s 1221. General.

Breath alcohol analysis shall be performed in accordance with standards set forth in this Article.

s 1221.1. Authorized Procedures.

(a) Breath alcohol analysis shall be performed only with instruments and ~~related accessories~~ calibrating units/devices which meets ~~the standards of performance set forth in these regulations~~ the requirements specified in Health and Safety Code Section 100701.

FARC: DOT uses units, H&S uses devices

JS:

(b) Such instruments may be used for the analysis of breath samples in places other than ~~licensed~~ forensic alcohol laboratories and by persons other than forensic alcohol supervisors, forensic alcohol analysts and forensic alcohol analyst trainees only if such places and persons are under the direct jurisdiction of a governmental agency or ~~licensed~~ forensic alcohol laboratory.

js:

(1) Breath alcohol analysis by persons other than forensic alcohol supervisors, forensic alcohol analysts and forensic alcohol analyst trainees shall be restricted to the immediate analysis of breath samples collected by direct expiration by the subject into the instrument in which the measurement of alcohol concentration is performed.

(2) Except for the requirements of Section 1220.4, such immediate analysis shall not be subject to the requirements of Article 6.

~~s 1221.2. Standard of Performance.~~

~~(a) Instruments for breath alcohol analysis shall meet the following standard:~~

~~(1) The instrument and any related accessories shall be capable of conforming to the "Model Specifications for Evidential Breath Testing Devices" of the National Highway Traffic Safety Administration of the U.S. Department of Transportation, which were published in the Federal Register, Vol. 49, No. 242, Pages 48854-48872, December 14, 1984, and are hereby adopted and incorporated.~~

~~(b) The ability of instruments and any related accessories to conform to the standard of performance set forth in this section shall be tested by the U.S. Department of Transportation.~~

FARC: redundant

~~s 1221.3. Approved Instruments.~~

~~(a) Only such types and models of instruments and related accessories as are named in the "Conforming Products List" published in the Federal Register by the National Highway Traffic and Safety Administration of the U.S. Department of Transportation shall be used for breath alcohol analysis in this State.~~

FARC: redundant

s 1221.4. Standards of Procedure.

(a) Procedures for breath alcohol ~~analysis testing~~ shall meet the following standards:

js: consistent with previous AS language

(1) For each person tested, breath alcohol analysis shall include analysis of 2 separate breath samples which result in determinations of ~~blood breath~~ alcohol concentrations which do not differ from each other by more than 0.02 grams per ~~400 210 milliliters~~ liters of breath.

JS: (removing blood references in breath testing)

~~(2) The instrument shall be checked for accuracy calibrated with standards, which are water solutions and or dry-gasses of alcohol.~~

JS:; removing reference to calibrations; misuse of term; actual practice is checking accuracy, not calibrating instrument

~~(2)~~ (3) The accuracy of instruments shall be determined.

(A) Such determination of accuracy shall consist, at a minimum, of periodic analysis of a reference sample of known alcohol concentration within accuracy and precision limits of plus or minus 0.010 grams % of the true value; these limits shall be applied to alcohol water concentrations and or dry-gas standards from ~~0.10 0.08~~ to ~~0.30 0.25~~ grams %. The reference sample shall be provided by a forensic alcohol laboratory.

JS: 3 decimal 0.010; 08 change in law, dry-gas stds advances in technology; allow use of dry gas standards all NIST traceable ; note: check if need to add NIST dry gas or if already added)

1. Such analysis shall be performed by an operator as defined in Section 1221.4 (a)(5), and the results shall be used by a forensic alcohol laboratory to determine if the instrument continues to meet the accuracy set forth in Section 1221.4 (a)(2)(A).

(B) For the purposes of such determinations of accuracy, "periodic" means either a period of time not exceeding 10 days or following the testing of every 150 subjects, whichever comes sooner.

(3) Breath alcohol analysis shall be performed only with instruments for which the operators have received training, such training to include at minimum the

following schedule of subjects:

- (A) Theory of operation;
- (B) Detailed procedure of operation;
- (C) Practical experience;
- (D) Precautionary checklist;
- (E) Written and/or practical examination.

(4) Training in the procedures of breath alcohol **analysis testing** shall be under the supervision of ~~persons who qualify as~~ forensic alcohol supervisors, forensic alcohol analysts or forensic alcohol analyst trainees. ~~in a licensed forensic alcohol laboratory.~~

js: consistent with prior language qualifications redundant in definitions; location removed to allow for off site training, license – rule 100

~~(A) After approval as set forth in Section 1218, the forensic alcohol laboratory is responsible for the training and qualifying of its instructors.~~

1218 removed, Dept. reference eliminated via elimination of oversight; training under supervision of lab

(5) An operator shall be a forensic alcohol supervisor, forensic alcohol analyst, forensic alcohol analyst trainee or a person who has completed successfully the training described under Section 1221.4 (a) (3) and who may be called upon to operate a breath testing instrument in the performance of his duties.

(6) Records shall be kept for each instrument to show the frequency of determination of accuracy and the identity of the person performing ~~the~~ a manual determination of accuracy.

JS: auto cal checks handled in language now; need to revisit language regarding those instruments that perform automatic accuracy checks and the “ID” of the person performing the check.

(A) Records shall be kept for each instrument at a ~~licensed~~ forensic alcohol laboratory showing compliance with this Section.

js: rule 100

(b) A The precautionary checklist to be used by operators of the instrument shall be available at the location of each instrument.

js: 1222.2 removed, replaced here

s 1221.5. Expression of Analytical Results.

Results of breath alcohol ~~analysis~~ **testing** shall be expressed as set forth in Section 1220.4.

js: left in for convenience

ARTICLE 8. RECORDS

s 1222. General.

Forensic alcohol laboratories and law enforcement agencies shall maintain records which clearly represent their activities which are covered by these regulations. ~~Such records shall be available for inspection by the Department on request.~~

js: rule 100 change eliminating licensing; available as public records

PL: add info on inspections:

s 1222.1. Forensic Alcohol Laboratory Records.

(a) Each laboratory which ~~is licensed to~~ performs forensic alcohol analysis shall keep the following records for a period of at least three years:

(1) An up-to-date record of persons in its employ who are qualified as forensic alcohol supervisors and forensic alcohol analysts; the record shall include the qualifications of each ~~such~~ person, including education, experience, training and performance in proficiency tests and examinations;

clarity

(2) A list of persons in its employ who are forensic alcohol analyst trainees, the date on which each ~~such~~ person began ~~his~~ training ~~period~~ and the number and results of analyses performed during the training ~~period~~;

clarity

(3) Records of samples analyzed by that laboratory under these regulations, their

results and the identity of persons performing the analyses;

(4) Records of the quality control program;

(5) Records of laboratory performance evaluation in alcohol analysis as shown by results of proficiency tests;

(6) Records of ~~such~~ determinations of accuracy, maintenance, and/or calibration of breath testing instruments as a laboratory may perform for law enforcement agencies;

JS:

(7) Records of ~~such~~ the training as a laboratory may provide provided to persons who operate breath testing instruments for law enforcement agencies.

clarity

~~s 1222.2. Breath Alcohol Analysis Records.~~

~~(a) Each agency shall keep the following records for breath testing instruments which are under its jurisdiction:~~

~~(1) Records of instrument determinations of accuracy;~~

~~(2) Records of analyses performed, results and identities of the persons performing analyses;~~

~~(3) At the location of each instrument, the precautionary checklist to be used by operators of the instrument.~~