

Vermont Forensic Laboratory

Alcohol Testing Program Needs Assessment

Final Report

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The National Forensic Science Technology Center, Inc. (NFSTC) is pleased to submit this needs assessment final report to the State of Vermont Department of Public Safety, Division of Criminal Justice Services.

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INTRODUCTION

In response to Request for Proposals (RFP) #DSP1161 from the State of Vermont Department of Public Safety, the National Forensic Science Technology Center, Inc. (NFSTC) submitted a proposal and was subsequently awarded Contract #20506. The purpose of the award is to provide a needs assessment for the Alcohol Testing Program, which is being transitioned from the Department of Health (DOH) to the Vermont Forensic Laboratory (VFL) opened by the Department of Public Safety in October 2010. The presentation of this final report to the Criminal Justice Services Division of the Department of Public Safety will conclude the project.

Objectives

The objectives of the needs assessment are to conduct an analysis of the current program and staff and to evaluate the resources and space available in the laboratory. This assessment will determine if additional resources are necessary to run the program, establish the prosecutorial and justice needs/expectations for the program, and facilitate a smooth transition from the DOH to the VFL.

In addition, the VFL is an accredited agency and will require assistance in analyzing and revising the transferred Alcohol Testing Program processes and procedures to meet ISO 17025 accreditation standards.

Methods

The methodology being utilized to meet the above-listed objectives includes the following:

- Collect and analyze all processes, procedures, methodologies, workflow or process maps, quality assurance processes, and training used by DOH in operating the Alcohol Testing Program and provide assessment of documents as compared to good laboratory practices and ISO 17025 standards.
- Provide detailed reporting on all areas that meet current standards, provide recommendations to bring any deficiencies into approved practices, and provide an overview of the resources needed to bring the program up to ISO standards.
- Evaluate the DOH program including equipment, personnel, procedures, methods, etc., and provide a report that details the adequacy of the program to meet general standards in the field when the operation is moved to the VFL.
- Estimate the physical space and infrastructure, personnel and resources required to successfully operate the program at ISO 17025 standards, allowing space for 20% growth over 5 years, and evaluate the current space and infrastructure within the VFL to accommodate the program or provide an estimate of space needs if adequate space is not available within the laboratory.
- Provide expert recommendations to facilitate an effective and timely transition of the program.

- Detail the necessary requirements and needed technology for transferring information from the program to prosecutors, defense attorneys and the public to ensure proper administration of justice.
- Assist in writing or revising protocols and procedures needed to meet ISO 17025 standards.

PRE-SITE PREPARATION

Upon reception in mid-November 2011 of the DOH Alcohol Testing Program procedures and policies, a review was conducted by the project team, which includes two technical subject matter experts with extensive experience in forensic science, including alcohol testing. (The two other members of the team have a wealth of experience in supervising, managing, directing and/or evaluating publicly funded forensic laboratories.) The purpose of this review was to compare the in-place DOH Alcohol Testing Program to industry standards and determine a course of action for transfer to the VFL. The following 35 documents were comprehensively reviewed by the project team:

23 V.S.A. Section 1203
Breath and Blood Alcohol Analysis Regulations
P-Alc-120 Rev 0 Feb 2009 DataMaster DMT APM.doc
P-ALC-101 Rev 1 Nov 2011 SAMPLE PREP for Alcohol Analysis by.doc
P-ALC-102 Rev 1 Nov 2011 Alcohol and related VOC Analysis b.doc
P-ALC-116 Rev 1 June 2011 DataMaster DMT Power up procedure.docm
P-Alc-117 Rev 1 August 2011 DataMaster DMT Calibration.doc
P-Alc-118 Rev 1 August 2011 DataMaster DMT Certification.doc
P-Alc-119 Rev 1 August 2011 DataMaster DMT Installation.docm
ALC 301 Rev 1 June 2011 Evidentiary Blood Alcohol Rpt Affida.doc
ALC 501 Rev 3 June 11 DataMaster Supplies Request Form.doc
ALC 603 Rev 3 August 2011 DataMaster Operator Use Log.doc
ALC 626 Rev 3 June 2011 DataMaster Technical Support Inquiry.doc
ALC 668 Rev 2 Oct 2011 DataMaster Calibration Logbook.xls
ALC 668A Rev 1 Oct 2011 DataMaster Calibration Logbook Entry.doc
ALC 670 Rev 0 Jan 2011 Alcohol Standards Logbook.doc
ALC 803 Rev 3 August 2011 Check-up Maintenance log.doc
ALC 902 Rev 1 Feb 2011 CERTIFICATE OF ANALYSIS.doc

ALC 907 October 2011 RPC Review Instructions .doc
CHEM 642 Rev 2 July 2011 Simulator solution Preparation Log.xls
D-ALC-011 Addendum A 5_20_2011.pdf
D-ALC-011 Rev 1 Aug 2011 DataMaster DMT Supervisor Administr.doc
DataMaster Operator logbook instructions August 2011 .doc
DMT Practical Questions.doc
RPC Review Instructions.doc
VCJTC DataMaster DMT Infrared Breath Testing Manual Version .doc
ALC 402 rev 1 March 2009 Evidentiary Blood Kit Instructions.doc
ALC 403 Rev 1 March 2009 Independent Blood Kit Instructions.doc
ALC 906 Rev 0 Sept 10 Discovery Request Cover Sheet.doc
ALC 950 Rev 2 Feb 2008 Blood ALC Analysis Training form.doc
Blood and Breath testing Rules.pdf
P-ALC-105 Rev 2 Nov 2011 Independent Blood Sample Accession.doc
P-ALC-106 Rev 0 April 2007 Independent blood alcohol sample.doc
P-ALC-115 rev.0 July99 blood spill cleanup.doc
P-ALC-204 rev.0 Mar09 Simulator Solution Preparation.doc

The results of the review concluded that the policies and procedures were appropriate for the task, but that some clarification of forms could be made. The policies and procedures were also considered to be in alignment with currently accepted practices observed within the alcohol testing community. The DOH Quality System Manual was also reviewed and found to contain a rudimentary outline of a quality system that is compliant with ISO 17025.

ON-SITE REVIEW: DECEMBER 13-14, 2011

For the first on-site review, NFSTC traveled to Vermont to meet with staff members from the DOH, tour the DOH facility in Burlington, Vermont, and interview Alcohol Testing Program staff in particular. The goal of the tour was to see the current operation and the processes/equipment that are in use.

The re-staging of some DataMaster DMT™ instrumentation was observed. These instruments were recently returned from the manufacturer and were being performance-checked prior to field installation.

DOH personnel were also able to provide a detailed description of the functions of the Alcohol Testing Program. Additionally, statistics were produced to enable the team to conduct cost estimates, spacing estimates and personnel planning for the transition.

This first on-site visit also included detailed assessment of the infrastructure at the VFL in Waterbury, Vermont, for supporting the Alcohol Testing Program, potential space needs, impacts on evidence handling, supply handling, personnel requirements and modification of DOH procedures.

The team concluded that the DOH procedures were scientifically sound and could form an initial foundation for the VFL to assume alcohol testing duties. The team also concluded that the procedures could be transitioned to ISO 17025 requirements after initial casework was begun. The team discussed details of the review of the procedures with the VFL staff.

Given that time was of the essence, the VFL administration asked that preliminary reports be written on current and future space requirements and on budget and equipment issues with the assumption of the Alcohol Testing Program. These documents were provided in draft form for review on January 01, 2012, and final copies were furnished on January 30, 2012 (see attached).

Additional correspondence took place between the team and the VFL staff following the first site visit. The general consensus was that the conversion of the DOH protocols for use by the VFL would be scientifically acceptable and would produce accurate and precise results.

A discussion was held regarding issues reported in the newspaper about the DOH Alcohol Testing Program. These included personnel conflicts, alleged staff impropriety and claims of inadequate DOH quality control procedures. The resulting investigation and findings were discussed with the team so that they would have complete awareness of the needs of the Vermont criminal justice community.

DOH procedures were reviewed again by the team prior to the second on-site meeting, which was scheduled to be held February 07-08, 2012. Additional implementation guidelines were given to the VFL staff so they could convert documents to their requirements.

ON-SITE REVIEW: FEBRUARY 07-08, 2012

For the second on-site review, the team returned to the VFL. During this visit, site preparedness was reviewed. The equipment for alcohol analysis had been delivered but was not yet operational. The team provided some suggestions for readiness, including a detailed review of the validation that is recommended for initiation of blood alcohol analysis.

Policies and procedures from DOH were reviewed and discussed with the VFL staff for transition to their use. This included the need for control of the documents and logo, other

changes and other transition impacts. Enabling legislation was reviewed to ensure the VFL's compliance.

During the team's visit, a detailed transition plan was developed and discussed with the VFL staff. The plan detailed the steps required to assume the alcohol analysis responsibilities for the state (see attached).

There were also extensive discussions on the assumption of DataMaster™ DMT instrumentation responsibilities and the need to "touch" all the instruments to provide additional quality assurance since the instruments would become the responsibility of the VFL.

Subsequent to the site visit, the team reviewed a recently developed DataMaster™ DMT instrumentation checklist with Alcohol Testing Program staff, and revisions were suggested.

ON-SITE REVIEW: MARCH 27-28, 2012

With the initiation of the Alcohol Testing Program by the VFL, NFSTC project team members made a third site visit on March 26-28, 2012, in order to:

- Review the transition of this program and any opportunities for refinement of the program, and make any recommendations during the site visit.
- Update the Transition Plan, and identify additional action items.
- Conduct an ISO 17025 document interpretation review, and generate a roadmap to compliance.
- Address any issues that may arise.
- Determine the status of additional site visits, based on the progress and status of the VFL.

AN ISO ROADMAP

This document was developed as a result of the third site visit and is intended to provide a practical guideline for the implementation of an ISO 17025 accredited quality system in the Vermont Forensic Laboratory, as a testing and calibration laboratory. Since VFL currently maintains a quality assurance program through ASCLD/LAB, the establishment of a calibration laboratory program for the Alcohol Testing Unit, or the expansion of the quality management program to all the analytical sections of the laboratory, is quite capable of being accomplished.

The development of an ISO 17025 compliant laboratory requires the creation of, or modification of, quality manuals, management and technical policies and procedures, implementation and review of these policies and procedures, and auditing of the implementation. However, the speed with which this can be accomplished is proportional to the resources made available to accomplish this goal.

This guidance will focus on the practical aspects of establishing the ISO 17025 program:

1. Accreditation Options
2. Preparation for ISO 17025 Accreditation
3. Top-Ten Non-Conformities for Laboratories Seeking Initial ISO 17025 Accreditation
4. Specific ISO Requirements requiring extensive documentation, which need to be adopted for ISO 17025
 - a. Development of a Document Control System
 - b. Expansion of Corrective/Preventative Actions Policies and Procedures
 - c. Management Reviews
 - d. Uncertainty of Measurement

1. Accreditation Options

The Vermont Forensic Laboratory has three (3) options for obtaining accreditation for the Alcohol Testing unit (ATU):

- a. Request expansion of accredited disciplines by the current accrediting body, ASCLD/LAB, under the auspices of their Legacy accreditation system. This would be the quickest, lowest-cost option since much of the management aspects of the accreditation standards already exist. However, the Legacy accreditation system, while credible and worthwhile, does not meet International Standards.
- b. Request accreditation by an ISO 17025 accreditation body of only the ATU. ASCLD/LAB may not be able to provide this service under their current policies; other accrediting bodies would be able to provide ATU-only accreditation. The preparation for ISO 17025 for only the ATU would involve much of the same effort as meeting ISO 17025 for the entire scope of the laboratory's operation. The Management portion of 17025 would have to be met, yet only the ATU portion of the technical operation would need to be met. This would also be a lower-cost option than Option C since fewer assessors would be needed for the assessment. When the remaining laboratory operations are required to become ISO 17025 accredited in 30 months, the two accreditations can be synched up into one event.
- c. Request accreditation by an ISO 17025 accreditation body for all the laboratory operations. This would require all of the effort of Option B as well as meeting the technical aspects of ISO 17025 for the entire operation. This would extend any effort to become accredited many months beyond the time frame of Option B. This would also be the costliest option since fees paid for the current legacy accreditation may not be refundable.

Each option has its own policy, cost and implementation impacts. The preparation and timeline for ISO 17025 accreditation is ultimately a question of resources brought to bear, either internally or externally, on the effort. It is ultimately a policy decision of the VFL and its management to decide which accreditation option to pursue.

2. Preparation for ISO 17025 Accreditation

The preparation for an ISO 17025 compliant quality system involves the adoption of management policies and procedures which meet all the clauses of ISO 17025, meet generally accepted good laboratory practices, the specific supplemental or other requirements of the accrediting body and meet all applicable federal, state and local statutes.

In order to meet accreditation standards, a laboratory must demonstrate its ability to comply with requirements on a continuing basis. The Vermont Forensic Laboratory, with its history of successfully meeting the requirements of the ASCLD/LAB legacy program, has established a record of continued compliance with good laboratory practices.

The transition to ISO 17025 can be built on the framework of the earlier legacy accreditation. While many of the technical procedures and practices will be easily transitioned to ISO accreditation, there are specific requirements that must be met.

These include specific policies and procedures that must be developed or modified, documented and placed into practice. These include the following:

POLICIES

Policies must state the overall direction of the organization with regard to the subject activity.

ISO Clause Description

4.1.5c	ensure the protection of its customers' confidential information
4.1.5d	avoid involvement in any activities that would diminish confidence in activities
4.2.2	policies related to quality, including a quality policy statement, shall be defined in a quality manual
4.4.1	policies for reviews leading to a contract must be defined
4.6.1	a policy for the selection and purchasing of services and supplies must exist
4.8	resolution of complaints received from customers or other parties must be made
4.9.1	control of nonconforming testing and/or calibration work must be defined
4.11.1	policy on corrective action must be defined
5.2.2	identifying training needs and providing training of personnel

PROCEDURES

Procedures must specify a way to perform an activity and must usually contain the purpose and scope of the activity, what shall be done and by whom, when, where and how it shall be done. The procedure must also address what materials, equipment and documents shall be used and how it shall be controlled and recorded.

4.1.5c	ensure the protection of its customers' confidential information
4.1.5d	avoid involvement in any activities that would diminish confidence in activities
4.3.1	establish and maintain procedures to control all documents that form part of its management system
4.3.2.2	establish and maintain procedures to control all documents, including subsections a-d

4.3.3.3	If the agency's documentation control system allows for the amendment of documents by hand pending the re-issue of the documents, the procedures and authorities for such amendments shall be defined.
4.3.3.4	procedures shall be established to describe how changes in documents maintained in computerized systems are made and controlled
4.4.1	procedures for these reviews leading to a contract must be defined
4.6.1	procedures for the selection and purchasing of services and supplies must exist
4.8	resolution of complaints received from customers or other parties must be made
4.9.1	procedures for control of nonconforming testing and/or calibration work
4.11.1	procedures for corrective action
4.12.2	Procedures for preventative action
4.13.1.1	establish and maintain procedures for identification, collection, indexing, access, filing, storage, maintenance and disposal of quality and technical records
4.13.1.4	establish procedures to protect and back-up records stored electronically and to prevent unauthorized access to or amendment of these records
4.14.1	conduct internal audits of its activities to verify that its operations
4.15.1	the agency's top management shall periodically conduct a review of the agency's management system
5.2.2	identifying training needs and providing training of personnel
5.3.5	measures shall be taken to ensure good housekeeping in the agency
5.4.1	The agency shall use appropriate methods and procedures for all tests and/or calibrations within its scope
5.4.5.2	The agency shall record the results obtained, the procedure used for the validation, and a statement as to whether the method is fit for the intended use
5.4.6.1	a calibration agency, or a testing agency performing its own calibrations, shall have and shall apply a procedure to estimate the uncertainty of measurement for all calibrations and types of calibrations
5.4.6.2	testing agencies shall have and shall apply procedures for estimating uncertainty of measurement.
5.4.7.2	computer software developed by the user is documented in sufficient detail and is suitably validated as being adequate for use;
5.5.6	safe handling, transport, storage, use and planned maintenance of measuring equipment to ensure proper functioning and in order to prevent contamination or deterioration
5.5.10	intermediate checks are needed to maintain confidence in the calibration status of the equipment
5.5.11	The agency shall have procedures to ensure that copies (e.g., maintained in computer software) are correctly updated
5.6.1	The agency shall have an established program and procedure for the calibration of its equipment.
5.6.3.1	The agency shall have a program and procedure for the calibration of its reference standards.
5.6.3.3	Checks needed to maintain confidence in the calibration status of reference, primary, transfer or working standards and reference materials shall be carried out according to defined procedures and schedules.
5.6.3.4	procedures for safe handling, transport, storage and use of reference standards and reference materials
5.7.1	a sampling plan and procedures for sampling when it carries out sampling of substances, materials or products for subsequent testing or calibration
5.7.3	have procedures for recording relevant data and operations relating to sampling

	that forms part of the testing or calibration that is undertaken
5.8.1	procedures for the transportation, receipt, handling, protection, storage, retention and/or disposal of test and/or calibration items
5.8.2	system for identifying test and/or calibration items
5.8.4	procedures and appropriate facilities for avoiding deterioration, loss or damage to the test or calibration item during storage, handling and preparation
5.9.1	quality control procedures for monitoring the validity of tests and calibrations undertaken

Preparation for ISO accreditation requires a careful reading of the applicable standards. Some Clauses require a policy, some a procedure, some both, as outlined above. In some instances, the International Standard employs terms such as “arrangements” which implies the need for policies, procedures, practices or other activity.

Specific detail enumerated in a single clause

Some clauses require specific detail in a policy or procedure. For example, **Control of Records** Clause 4.13.1.1 *The agency shall establish and maintain procedures for identification, collection, indexing, access, filing, storage, maintenance and disposal of quality and technical records*, (emphasis added) requires that procedures shall be maintained for all the activities from identification through disposal of controlled quality and technical records.

Requirements specified in separate subsections

In other instances, such as **Management Reviews**, specific items for review are individually named:

4.15.1 In accordance with a predetermined schedule and procedure, the agency's top management shall periodically conduct a review of the agency's management system and testing and/or calibration activities to ensure their continuing suitability and effectiveness, and to introduce necessary changes or improvements. The review shall take account of:

- the suitability of policies and procedures*
- reports from managerial and supervisory personnel*
- the outcome of recent internal audits*
- corrective and preventive actions*
- assessments by external bodies*
- the results of interagency comparisons or proficiency tests*
- changes in the volume and type of the work*
- client feedback*

complaints

recommendations for improvement

other relevant factors, such as quality control activities, resources and staff training

Procedures must address all of these elements, as well as occur on a predetermined schedule, that is, a specific timeframe during the year when this Management Review will take place.

3. Top-Ten Most Common Non-Conformities for Laboratories Seeking Initial ISO 17025 Accreditation

The complexities of preparing for the ISO accreditation process are reflected in the most common non-conformities found during on-site assessment. These were reviewed for VFL management staff.

As a part of the accreditation process, the consultants shared their experiences with the VFL on the most common non-conformities which have been observed in the Forensic Quality Services ISO 17025 program. These were memorialized in the July 2011, *FQS Newsletter*.

#1 5.4 Test and calibration methods and method validation. 5.4.1 was a problem for agencies seeking initial accreditation, in that they lacked procedures or had incomplete procedures, or simply were not in conformance with the procedures that they had. 5.4.2 and 5.4.5 were cited either in connection with lack of validation records for some tests that were being conducted, or when required aspects of validation were not addressed.

#2 4.3 Document Control. There were numerous findings throughout the clause. Chief among them were the failure to control all management system documents, most notably some forms or external manuals or standards; master lists of documents that were incomplete; lack of objective evidence for review of documents; and revision identifiers that were either obsolete or completely lacking.

#3 4.1.5 Organization and Management. Non-conformities were distributed throughout the sub-clauses. Examples are citations for lack of required policies/procedures, policies/procedures that did not adequately ensure freedom from undue pressures, and failure to adequately document the responsibilities and position of the Quality Manager and/or designate a deputy for that key managerial position.

#4 4.13 Control of Records. Non-conformities were clustered in three clauses: (1) 4.13.1.1—Either the laboratory's procedures did not cover all required elements, or the lab was not following its own procedures; (2) 4.13.2.1—agencies were not following their own procedures for recording data; and (3) 4.13.2.3—Corrections to data were not made properly, with numerous instances of obliterations and/or lack of identification of the person who made the correction(s).

#5 5.5 Equipment. The non-conformities were spread out fairly evenly over the clauses in this section, with no single predominant "problem" clause.

#6 5.2 Personnel. Non-conformities were evenly distributed between sub-clauses 5.2.1, 5.2.2, and 5.2.5. The lack of appropriate records—for training and educational background (5.2.1) and for competency testing and authorization to perform work (5.2.5)—were cited as non-conformities. Under 5.2.2, non-conformities were: (1) lack of training plans for areas of testing performed in the agency and (2) training/education/skills goals that either were not documented or were too narrow in scope to effectively anticipate future needs.

#7 4.14 Internal Audits. Most non-conformities were clustered in sub-clause 4.14.1. These included: no pre-determined schedule and/or audit procedures that did not address all elements of the management system. (Note to DNA labs: an audit with the FBI QAS will not address all elements of the ISO 17025 standard. Note to all agencies: Don't forget to audit the internal audit program.) The biggest issue in the remaining sub-clauses of 4.14 dealt with appropriate follow-up on problems that were identified during internal audits.

#8 4.15 Management Review. Non-conformities were evenly distributed between the two sub-clauses. Problems with 4.15.1 were incomplete procedures (all required elements not addressed) and the lack of pre-determined schedules for conducting management review. In 4.15.2, many laboratories failed to record "actions arising" from Management Review and/or did not establish timescales for dealing with the "actions arising" from the review.

#9 4.6 Purchasing Services and Supplies. At least half of the non-conformities were clustered in clause 4.6.1 and were due to incomplete procedures that did not contain all required elements. For example, a laboratory might have had a procedure that covered the purchase of critical supplies, but did not address the purchase of critical services, such as calibration.

#10 5.6 Measurement Traceability. The non-conformities were spread throughout the section. There were some citations for missing procedures and some citations for lack of documented traceability (to national standards) of reference standards used by the laboratories. There were also situations where laboratories were using non-ISO 17025 accredited calibration laboratories for calibration of critical measuring equipment, and the competence of these providers had not been otherwise established.

4. Specific ISO Requirements requiring extensive documentation, which need to be adopted for ISO 17025

a. Development of a Document Control System

ISO 17025 requires that there is a system of Document Control.

4.3.1 General

The laboratory shall establish and maintain procedures to control all documents that form part of its management system (internally generated or from external

sources), such as regulations, standards, other normative documents, test and/or calibration methods, as well as drawings, software, specifications, instructions and manuals.

The Purpose of Document Control

Document control provides a framework for deciding how information is created in the organization and how it is managed once created.

The goal of document control is not to create extra work or build a bureaucracy. Instead, established to protect the value of the content of documents and to enhance the usefulness of that content to the people in the organization who need to use it.

To be “under control” means that all aspects of the document from creation, through distribution and revision, use and archiving, is performed in accordance with procedures set down by the management of VFL.

Document control provides a framework for deciding how information is created in the organization and how it is managed once created. The purpose of a document control method is to ensure:

- Documents fulfill a useful purpose
- Resources are not wasted on the distribution of unimportant or useless information
- Only valid information is published
- Information is kept up to date
- Information is provided in a form that can be effectively used
- Classified, confidential, or proprietary information is restricted to the people who have a real need to access it
- Information is retained that could help solve a problem, improve opportunities, or avoid costly errors

Document Control Procedures

The document management process put in place to support the policy should include procedures that define the development of documents. While these procedures should not be cumbersome, they should be explicit and detailed enough to provide clear direction as to how documents should be prepared. The procedures may include essential topics such as:

- How to plan new documents; authorization, funding, establishing need
- How to prepare new documents; who prepares them, how they are drafted, how drafts are maintained
- Standards for the format and content of documents, forms, diagrams
- Document identification conventions
- Version control conventions

- Dating conventions; date of review, date of approval, date of issue, date of distribution, date of revision
- Document review procedures; who reviews, evidence of review
- Document approval; who approves, evidence of approval
- Publication; what constitutes “publishing” a document
- Printing; who prints a document, restrictions to printing
- Distribution; how is a document distributed, who does it, who checks it
- Use of documents; limitations, unauthorized copying, access to files, marking printed copy
- Revisions; identifying a need; who makes revisions, review and approval process, how changes are marked
- Amending issued documents; who creates amendments, reviews and approval process, identification of amendments
- Storing documents; determining location, security, access and prevention of unauthorized changes, indexing, retrieval by users, restrictions concerning paper documents vs. electronic document files, authorized and unauthorized external distribution and republishing.

b. Expansion of Corrective/Preventative Actions Policies and Procedures

ISO 17025 requires policies and procedures for corrective and preventative actions.

4.11 Corrective action

4.11.1 The laboratory shall establish a policy and procedure and shall designate appropriate authorities for implementing corrective action when nonconforming work or departures from the policies and procedures in the quality system or technical operations have been identified.

4.12 Preventive action

4.12.1 Opportunities for needed improvements and potential sources of nonconformities, either technical or concerning the quality system, shall be identified.

Corrective action and preventive action (CAPA, also called corrective action / preventive action) are improvements to an organization's processes taken to eliminate causes of non-conformities or other undesirable situations. CAPA is a concept within good laboratory practice (GLP). It focuses on the systematic investigation of the root causes of non-conformities in an attempt to prevent their recurrence (for corrective action) or to prevent occurrence (for preventive action).

Corrective actions are implemented in response to a problem or a non-conformance which can be identified internally through staff suggestions, management reviews, document reviews or internal audits, customer complaints, customer rejections, and non-conformities raised in external audits. Preventive actions are implemented in response to the identification of potential sources of non-conformity.

To ensure that corrective and preventive actions are effective, the systematic investigation of the root cause is required. Root cause analysis is to identify the cause of a discrepancy or deviation and suggest corrective actions to potentially prevent recurrence of a similar problem, or preventive action to ensure that discrepancies do not occur.

A common misconception is that the purpose of preventive action is to avert the occurrence of a similar potential problem. This process is all part of corrective action, because it is a process of determining such similarities that should take place in the event of a discrepancy.

Preventive action is any proactive methodology used to determine potential discrepancies before they occur and to ensure that they do not happen. Corrective and preventive actions both include investigation, action, review, and further action if so required.

All aspects of the investigation must be documented and form part of the laboratory's quality documents.

c. Management Reviews

ISO 17025 requires periodic management reviews

4.15.1 In accordance with a predetermined schedule and procedure, the agency's top management shall periodically conduct a review of the agency's management system and testing and/or calibration activities to ensure their continuing suitability and effectiveness, and to introduce necessary changes or improvements.

In ISO 17025, top management is crucial to the success of the quality assurance program by demonstrating their leadership and commitment to the accreditation process. Top management can be defined as a member of management within a chain of command including the laboratory function, and having substantial control over financial and personnel resources within the parent agency.

The management review is at least an annual event, on a predetermined schedule. It is perhaps best timed after the elements of the management reviews that are time-bound, e.g., internal audits, are completed.

The relevant Clause states that:

4.15.2 Findings from management reviews and the actions that arise from them shall be recorded. The management shall ensure that those actions are carried out within an appropriate and agreed timescale.

This would require that Top Management be engaged in the review process through some arrangement (staff meeting, email, presentation, etc.) and that, at least, the eleven elements required of a management review be included in that arrangement. If top management states that an action is to be taken as a part of this review, than that action

must be recorded and an action plan with a due date be established. In some instances, an action arising may be considered a non-conformity.

d. Uncertainty of Measurement

ISO 17025 introduces the concept of uncertainty of measurement (UM) as an integral part of the accreditation of testing laboratories. UM can be defined as a parameter characterizing the range of values within which the value of the measurement can be said to lie within a specified level of confidence. (From *G104 - A2LA Guide for Estimation of Measurement Uncertainty in Testing*)

Each accreditation body approaches UM slightly differently.

The FQS-I policy is reproduced below since it is not readily available from the FQS web site.

(FRAP-3 Uncertainty of Measurement)

Agencies are required to have and apply procedures for estimating the uncertainty of measurement (UM) for all quantitative testing reported to customers.

New quantitative test procedures developed or non-Standard methods implemented by the agency must include estimates of UM or define the procedure to be used to measure UM.

The estimation of UM can be made by direct or indirect methods, but all factors that could contribute more than 10% to total UM must be identified and taken into consideration in the estimate.

Where the reported quantitative test result will be used either alone or with other information to determine conformity to a specification such as a requirement in a law or regulation, the agency must be able to show that the UM is such that it will not contribute significantly to the reported value.

NOTE 1: Where there is a quantitative step in a test method that results in reporting of qualitative data, the laboratory must be able to show that the UM is such that it will not contribute significantly to the validity of the reported value.

NOTE 2: Where professional judgment is used to give an opinion that includes a quantity (for example, firing distance determination made by a firearms examiner) but where no measuring device that can be calibrated has been employed to determine the quantity, then UM is not required provided that:

- The report makes it clear that this is an opinion and not a measurement
- The competence of the examiner can be established by records of training, proficiency testing and history of supervised and/or peer-reviewed case work

- The quantity is expressed with an upper and lower limit that are within the ranges generally accepted in the field for the test conducted
- The quantity is not used to determine conformity to a specification

Where an agency conducts its own calibrations, it must be able to identify the UM of each stage in the traceability of reference standards used in the calibrations.

References

M H Ramsey and S L R Ellison (eds.) Eurachem/EUROLAB/ CITAC/Nordtest/AMC Guide: *Measurement Uncertainty Arising From Sampling: A Guide to Methods and Approaches* Eurachem (2007).

EURACHEM/CITAC Guide CG-4, *Quantifying Uncertainty in Analytical Measurement*, Second Edition, Editors S L R Ellison (LGC, UK) M Rosslein (EMPA, Switzerland) A Williams (UK)

ILAC G 17:2002. *Introducing the Concept of Uncertainty of Measurement in Testing in Association with the Application of the Standard ISO/IEC 17025*

NIST Technical Note 1297 "Guidelines for evaluating and expressing the uncertainty of NIST measurement results"

American Association of Laboratory Accreditation

The policy for the American Association of Laboratory Accreditation UM can be found here: http://www.a2la.org/guidance/est_mu_testing.pdf.

ASCLD/LAB

The policy for the ASCLD/LAB Estimation of Measurement Uncertainty can be found here: <http://asclcd-lab.org/documents/AL-PD-3055.pdf>.

WORK PRODUCTS DELIVERED TO DATE

The following documents have been prepared and delivered to the VFL (see attached):

- DOH-VFL-NFSTC Initial Meeting Agenda
- Current and Future Space Requirements
- Budget and Equipment Issues
- Ethanol Quantification Worksheet
- Transition Plan Working Document
- Status Report 4/30/12
- Final Report 8/22/12

CONCLUSIONS

During each of the three site visits the NFSTC Assessment Team observed significant effort and strides being made to successfully transition the alcohol testing program from DOH to VFL. Throughout the entire process the VFL staff were engaged and motivated to insure a quality alcohol testing program was implemented. It is the belief of the team members that the information exchange that occurred throughout the process will significantly aid the VFL in successfully achieving the goal of ISO 17025 accreditation for not only this program, but their entire laboratory. Although not an easy process, the willingness and attention to detail exhibited by staff throughout this engagement demonstrates their motivation to successfully achieve their goal.

Attachments

- DOH-VFL-NFSTC Initial Meeting Agenda
- Current and Future Space Requirements Report
- Budget and Equipment Issues
- Transition Plan Working Document
- Ethanol Quantification Worksheet

Vermont Alcohol Testing Program
Initial Site Visit Meeting Agenda
December 13, 2011 8:30 AM
Department of Health Laboratory
195 Colchester Ave. Burlington, VT.

- Opening Remarks

- Introduction of NFSTC Project Team Members/Responsibilities
 - DLS-Project Coordination
 - Frank Fitzpatrick-Project Manager/lab management activities
 - Albert Elian-onsite technical activities
 - Off-site SME(s)-document/material review and input

- Overview of NFSTC Proposal Activities
 - Analysis of current alcohol testing program processes as compared to the requirements of ISO17025 standards
 - Identify any need opportunities for improvement and specify additional resources required to affect the improvements
 - Evaluate the adequacy of equipment, personnel, and procedures for transfer to VFL
 - Evaluate current VFL space and program requirements projecting for growth over the next five years
 - Identify any potential program transition issue(s) and make recommendations
 - Participate in any identified procedures and processes revision as required

- Description of the NFSTC Needs Assessment Process
 - Off-site document analysis
 - On-site analysis and observation
 - Preparation of a preliminary draft findings document
 - Work plan development
 - Finalize findings document
 - Outcome(s) evaluation

- Goals and Outcomes
 - Preparation of a comprehensive report on the present state of the alcohol program operations
 - Work plan to bring alcohol testing program into ISO17025 compliance and the resources required
 - Work plan for seamless transition of program to VFL
 - Recommendations on space planning
 - Assistance with program procedures and protocol development to meet ISO 17025

- Schedule
 - Initial site visit 12/13/11-12/15/11
 - Presentation of draft report, work plans
 - On-going review of work plans, accomplishments
 - Final evaluation

- Questions and Answers

**Current and Future
Space Requirements for
Forensic Alcohol Program**

As a part of the study by the National Forensic Science Technology Center (NFSTC) to analyze the current program of the Department of Health (DOH) and make recommendations for transitioning the alcohol programs to the Vermont Forensic Laboratory, a site visit was conducted on December 13-14 to both the DOH and VFL facilities.

Given the need for providing some information ahead of the March 11, 2012 transition date, this preliminary report will provide observations for space needs.

Stakeholder: State of Vermont

Report Date: January 30, 2012

Report submitted by: Frank Fitzpatrick/National Forensic Science Technology Center

A portion of the contract between the State of Vermont and NFSTC obligates NFSTC to:

Provide an estimation of laboratory and administrative space, personnel and resources that would be required to perform the duties necessary to run a successful program to meet ISO 17025 requirements and provide space for 20% growth over 5 years

Provide an evaluation of current space(s) within the DPS VFL to determine if the program could be placed within the current lab or available space within the forensic facility. If the current spaces do not suffice, provide an estimate of space needs.

Space requirements were examined for five distinct forensic alcohol testing functions

1. Breath Alcohol testing
2. Blood Alcohol testing
3. Blood Drug NMS sample handling and storage
4. Legal Process Compliance
5. Blood Drug Testing

1. Space requirements for Breath Alcohol testing:

Requirements for the breath alcohol testing are similar to a repair depot in which space and adequate infrastructure is paramount.

Essential Elements

- Adequate Electrical
- LIMS access
- Storage space for Datamaster supplies, spare simulators and documents generated in the program
- Adequate bench space for instrument repair
- Sink with water for making simulator solutions

Desirable Elements

- Adjacency to deionized water supply
- Convenient access for police agencies
- Convenient exterior access when moving instruments

Room 164 would appear to be adequate in meeting all essential and most desirable elements. It could be used as a mixed use space with the current imaging function. This would also provide office space for the electronics technician.

2. Space requirements for Blood Alcohol testing:

Blood alcohol testing requires space for two different functions, the preparation of samples for analysis, and the space for the gas chromatograph.

Essential Elements for Sample Preparation Space

- Adequate Electrical, especially for a laboratory refrigerator
- Biological or fume hood
- LIMS access
- Sink with water
- Bench space with adequate support for an analytical balance

Desirable Elements for Sample Preparation Space

- Adjacency to deionized water supply
- Adjacency to gas chromatograph

Room 266 would appear to be adequate in meeting all essential and all desirable elements. It is currently an underutilized examination room space for the Biology program. Its use would require the purchase of a biological fume hood.

An alternative location could be Room 157D, currently being employed as a chemical preparation room. Use of this room would impact chemical preparation of the Latent Fingerprint section; however fume hoods exist in this room.

Office space for these positions could be carved out from existing underutilized office space.

Essential Elements for Instrumentation Space

- Adequate Electrical
- Compressed gas supply
- Stable bench top

Desirable Elements for Instrumentation Space

- Adjacency to sample preparation space

Room 265, which currently contains instrumentation for the Chemistry section, appears suitable to also house the forensic alcohol instrumentation. However, some of the current instrumentation will need to be moved so that the gas chromatograph has adequate electrical power. Not all the existing instrument benches have compressed gas plumbed to them. A hydrogen generator will need to be purchased before the gas chromatograph can be used.

3. Space requirements for Blood Drug NMS Sample Handling and Storage

Samples of blood are received from arresting agencies and forwarded to NMS, the toxicology service provider. The samples returned after analysis for eventual return to agencies or destruction.

Essential Elements for NMS Sample Processing Space

- Adequate Electrical
- Adequate counter space
- Refrigerated space

Space will be needed for samples that are received for eventual transmission to NMS for blood drug testing. Currently evidence is received and stored in Rooms 153-155. This area also contains a refrigerator that would be suitable for this function and the short-term storage of samples

4. Space requirements for Legal Process Compliance

The addition of an administrative analyst to be responsible for legal process compliance would require desk and storage space. The current administrative area is under-utilized. Documents related to forensic alcohol testing could be stored within the administrative space or in Room 164, which is adjacent. Adequate administrative space exists in the current Admin area.

5. Space requirements for Blood Drug Analysis:

While it is not anticipated that the VFL will not be involved in the analysis of samples for Blood Drug Testing, the following information was developed during the site visit.

Blood alcohol testing requires space for two different functions, the preparation of samples for analysis, and the space for the toxicological instrumentation, the LC/MS/MS.

Essential Elements for Blood Drug Sample Preparation Space

- Adequate Electrical
- Biological or fume hood
- LIMS access
- Sink with water
- Bench space
- Air and Vacuum

Desirable Elements for Blood Drug Sample Preparation Space

- Adjacency to deionized water supply
- Adjacency to LC/MS/MS

Given the small number of samples that will be analyzed if current practice continues, analytical space is found in 251A, the high copy DNA room. This would require extraordinary sanitation methods as the room changed function from blood sample preparation to DNA use.

An alternative location could be Room 157D, currently being employed as a chemical preparation room. Use of this room would impact chemical preparation of the Latent Fingerprint section; however fume hoods exist in this room. Also, if this room was used as an alcohol sample preparation area, it should not be used as a blood drug preparation room since organic chemicals should not share space with the alcohol function.

Essential Elements for Instrumentation Space

- Adequate Electrical
- Compressed gas supply
- Stable bench top

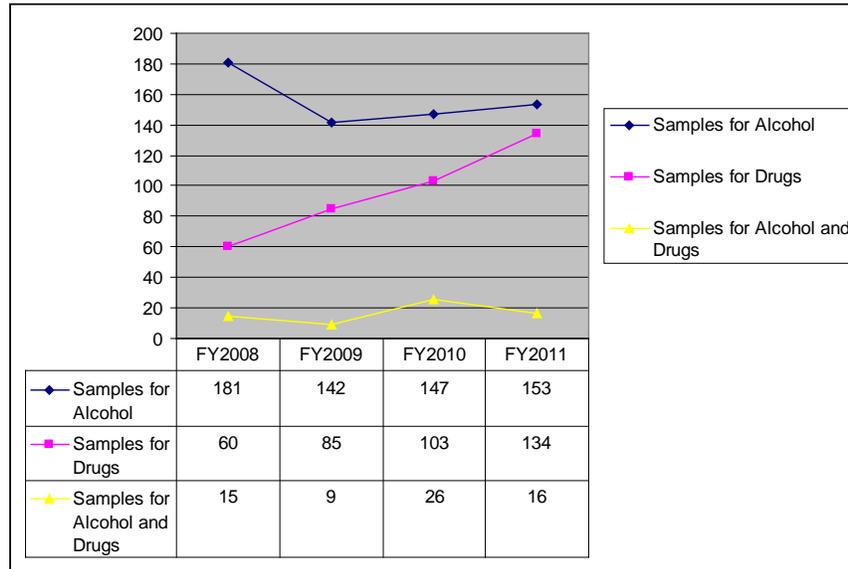
Desirable Elements for Instrumentation Space

- Adjacency to sample preparation space
- Room 265

Room 265, which currently houses instrumentation for the Chemistry section, appears inadequate to house the blood drug instrumentation. Room 265B, currently employed for the SEM/EDX instrument could be re-configured for an LC/MS/MS.

Estimated Future Growth

Statistics provided by DOH were analyzed for the last four years to project the growth of the program into the future.



The number of samples for alcohol analysis has not shown any increase in several years. Even if there is an increase, the supporting infrastructure of equipment and space has spare capacity so as not to impact space needs.

The number of samples for drug analysis has seen an increase which may be due to increased training of drug recognition experts. Since almost all of these samples are outsourced to NMS, any increase would not be expected to impact the space requirements over the next five years. If these samples were to be analyzed in-house, the spare capacity which would be present after the program is initially created would negate the need for additional space.

Increases in the number of Datamasters deployed in the field would not impact space requirements of this aspect of the forensic alcohol program.

**Budget Considerations for Transfer
of Alcohol Testing Program from
Department of Health to
Vermont Forensic Lab**

As a part of the study by the National Forensic Science Technology Center (NFSTC) to analyze the current program of the Department of Health (DOH) and make recommendations for transitioning the alcohol programs to the Vermont Forensic Laboratory, a site visit was conducted on December 13-14 to both the DOH and VFL facilities.

Given the need for providing some information ahead of the March 11, 2012 transition date, this preliminary report will provide observations for budgetary needs.

Stakeholder: State of Vermont

Report Date: January 30, 2012

Report submitted by: Frank Fitzpatrick/National Forensic Science Technology Center

Current Status:

The existing DOH program consists of a number of discrete divisions all working towards identification of the blood alcohol content (BAC) from an individual.

Breath Alcohol testing

The state employ DataMaster instruments which are located throughout the state to determine breath alcohol concentration. There are currently 67 sites for a total of 75 instruments. These instruments must be purchased, placed into appropriate locations, calibrated and be properly maintained by trained staff. Standard operating procedures must be detailed for processes involving the DataMaster and training provided to law enforcement officers certified to operate the instruments. Supplies and reference solutions are provided to the law enforcement agencies hosting these instruments. Some reference solutions are prepared and evaluated in-house. Documentation is maintained concerning the instrument- from purchase, calibration through routine operation.

Blood Alcohol testing The program performs blood alcohol testing. BAC kits are provided to law enforcement agencies and participating hospitals and clinics. Samples are stored for at least a year (although only 45 days is mandated and analyzed by gas chromatography/headspace instrument. Samples are delivered by courier or shipper.

Blood Drug NMS Sample Handling and Storage

The program includes the administrative and analytical functions of testing driver blood samples for commonly prescribed and abused drugs. The vast majority (estimated at greater than 95%) of these samples are packaged and transmitted to National Medical Services toxicology laboratory. This is a private forensic laboratory providing screening and confirmation drug analysis. The remainder of the samples is analyzed at the DOH laboratory. The enabling legislation did not assign this task to VFL.

Testimony and Consultation

This covers testimony in court or consultation concerning breath and blood alcohol testing technology and physiology. The staff provides training to law enforcement, prosecutors and defense concerning aspects of the program.

Legal Process Compliance

The staff must prepare affidavits and discovery packets. In addition, there are many administrative considerations to include documentation and tracking subpoenas, discovery requests, distribution of

information relevant to the program to State's Attorneys and others involved in the program. Files must be maintained and updated including instrument maintenance, performance and case files to include both breath and blood testing.

Staffing and Equipment Needs

The challenge with transitioning from the DOH to VFL is that most personnel and equipment currently in use by the DOH is not exclusively employed in alcohol testing. With the notable exception of a public health chemist, a public health electronics technician and a gas chromatograph with auto sampler, all other staffing and equipment is used on an ad hoc basis, or shared among several DOH programs.

Personnel Needs

NFSTC staff has identified the needs for a quality program which will meet the needs of the Vermont public safety community and its citizens. This is based upon current workloads, observation of the program at DOH and interviews with DOH and VFL staff and management.

Program Supervisor (1) Cost \$89,749

There is a need for a program supervisor to provide day to day supervision of the forensic alcohol testing program, as well as other roles of the supervisor including:

- Assign casework; monitor casework progress; review findings; coordinate, analyze, evaluates and critique casework activities, monitor testimony review.
- Participate in performance evaluation of Forensic Scientists; compose performance evaluations.
- Identify staff training needs; assist in design and presentation of training.
- Act as liaison with the courts, district attorney, police agencies, other laboratories, private attorneys and the public.
- Research literature to identify and assess new equipment and methodology; arrange for acquisition of equipment and implementation of new procedures;
- Performs chemical analyses and examinations; composes detailed reports of scientific analyses, new methods and research findings; documents chain of evidence
- Establish and monitor quality assurance guidelines for laboratory methodology consistent with goals of national laboratory accrediting bodies.
- Testify to work performed.

Forensic Chemist (2) Cost \$67,359 X 2 =\$134,718

It was reported that one of these positions would be transitioned from existing DOH staff.

The forensic chemists would be used for the analysis of blood for alcohol and drugs. These positions would also be responsible for the maintenance of analytical equipment within the forensic testing laboratory as well as the manufacture of quality control reference standards for in-house and breath alcohol machine use.

These positions would also be responsible for preparing detailed reports of forensic analyses and findings and testifies as an expert witness in court. They would also consult with and interprets results for law enforcement officers and attorneys.

Electronics Technician Cost \$57,516 see attachment

It was reported that one of these positions would be transitioned from existing DOH staff.

Currently these positions is responsible for providing maintenance and repair of the Datamaster breath alcohol testing machines, keeping detailed records, consulting with and interpreting results for law enforcement officers and attorneys, and testify as an expert witness. This position is responsible for travelling to the Datamaster locations to troubleshoot malfunctioning machines.

Supplies and Expendables

Item	Cost (\$)	Purpose
Volumetric flasks (2) each	260	Prepare simulator solutions
Carboys (2) each	150	Hold simulator solutions
autosampler tubes	300	For headspace alcohol analysis
caps, crimpers	800	For headspace alcohol analysis
Compressed Gases (increase)	N/A	To supply gas to instruments
NIST Thermometers	150	Check calibration of simulator solutions
Blood collection kits	TBD	Provided to law enforcements and citizens choosing independent sampling
Lab ethanol	500	Prepare simulator solutions
GC columns	600	For gas chromatographs
Pipettes	250	To prepare samples for analysis, prepare simulator solutions
DataMaster Supplies	TBD	Supplies to law enforcement for Datamaster operations
Biohood filters (2)	500	To replace filter in hood
DI water filters	N/A	For increased water use

Contractual

Item	Cost (\$)	Purpose
LIMS breath Add on	50,000	Provide LIMS access to Datamaster units. Units will require telecommunications support.
Maintenance of Add on	11,000	For above
LIMS modification for bloods	N/A	Provide for coding to track blood samples for alcohol and drug analysis
Additional NIST balance, pipette and thermometer certifications	1,200	Required by accreditation standards
Biohazard disposal	N/A	Increase biohazard generated from disposal of blood preparation supplies and blood samples
Alcohol Standards for blood and breath	\$1,200	Provide accurate standards for alcohol quality control, estimate
Proficiency tests	1,050	Provides for one proficiency test per analysts as required by accreditation standards

Training

Training	Cost (\$)	Purpose
National Patent breath training - each	1,400	Datamaster training from the manufacturer
Alcohol Physiology - Borkenstein - each	3,010	Training on behavioral effects of alcohol. Important for alcohol-related testimony

Blood Drug NMS Sample Handling and Storage

There does not appear to be a need to purchase additional equipment to perform this function.

Blood Drug Analysis

While it is not anticipated that the VFL will not be involved in the analysis of samples for Blood Drug Testing, the following information was developed during the site visit.

In FY2011, 150 samples were collected for drug analysis. While the vast majority of samples collected for blood drug analysis is outsourced to NMS. The current program at DOH analyzes a small number of samples in-house. This is less than 5% of the total number of samples requiring analysis.

DOH maintains instrumentation in their facilities which is applicable for toxicological analysis. VFL does not. In fact, any instrumentation associated with the VFL controlled substance analysis program must **NOT** be used for toxicological purposes since the chance of blood drug sample contamination is significant. The VFL would have to validate methods prior to use and establish a database of commonly found or tested drugs in blood samples. Existing space would need to be re-configured to house instrumentation for this equipment.

It would be difficult for the VFL to provide cost-effective analysis of blood drug samples. The volume of work produced by Vermont law enforcement is too small to justify expenditures to initiate a blood drug program.

However, one advantage of a locally run blood drug program is that the substantial cost of NMS-provided testimony is minimized.

Testimony in these cases would be limited to testimony as to the result of the drug being found, and not to the behavioral influence of the drug on driving behavior.

Equipment	Cost (\$)	Purpose
LC/MS/MS	125,000	Provides for the separation and identification of most drug samples
Evaporator	2,000	Evaporates chemical solvents from extracted drugs
SPE Equipment	25,000	Provides for the extraction of drugs from blood components
Vortex Mixer	600	Mixes samples
Nitrogen generator	15,000	Provides nitrogen gas for solvent evaporation

Supplies and Expendables

Item	Cost (\$)	Purpose
Increased solvent use	\$1,000	estimated
SPE (solid phase extraction) tubes	\$6/ea	Extracts drugs from blood

Drug Standards	\$20/drug	Provide accurate standards for quality control
Internal Standards	1,000	Provide accurate standards for quality control, estimate
Pipettes, test tube, caps	1,000	Disposable supplies for transferring and holding samples, estimate
LC column	300	For drug separation prior to identification

Training

DUID analysis (2)	6,000	Training for toxicological analysis, estimate
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Vermont Forensic Alcohol Program Transition Plan Working Document

In consultation with personnel from the Vermont Forensic Laboratory (VFL), NFSTC has advanced a transition plan to shift the alcohol analysis responsibilities from the Vermont Department of Health (DOH) on March 1, 2012 to VFL.

Activities are grouped together with suggested time lines (LT=long term, IT=intermediate term, ST=short term)

Past transition activities

VFL has been working on the transition of responsibilities since it was authorized by the State Legislature. To date the following activities have been accomplished.

- Identification of Program Space needs
- Identification of budget impacts
- Hands on training at DOH laboratory
- Scheduled to attend DMT class at National Patent Analytical Systems
- Arrange for the movement of gas chromatograph (GC) to VFL from DOH
- Order LIMS terminals
- Review enabling legislation to ensure compliance
- Review all DOH policy and procedure documents for transition

Transition Activities Going Forward

The following activities still need to be accomplished.

Policies and Procedures

Policies and procedure can be developed based upon the existing policies and procedures from DOH. VFL will need to ensure that the policies and procedures integrate into current policies, and are relevant to the VFL infrastructure and business practices. New or revised analytical should be adopted. Letterhead and or logo changes should be made on all documents which are created or adopted. The following should be considered:

- Determine that the policy and procedural content is relevant to VFL i.e. are references made to locations only found in DOH (ST)
- Put policies and procedures into VFL formatting (ST)
- Have approval of documents according to current VFL policies (ST)
- Modify existing evidence procedures to receive and store samples (ST)
- Update Organizational Chart (IT)
- Develop document control procedures (LT)
- Develop subcontracting policies and procedures (LT)
- Include Alcohol Program in internal audit schedule (LT)

Equipment and Supplies

Some equipment has been identified which will be transitioned from DOH; other supplies will need to be ordered from existing or new vendors. Additionally, ordering schedules will need to be updated to included Alcohol Program functions, including Independent sample kits.

- Make GC operational – Validate (ST)
- Obtain Standards and supplies (ST)
- Update ordering schedules for supplies (ST)
- Prepare new simulator solution (ST)
- Identify and move Biohood

Personnel

Using good laboratory practices, VFL should ensure the continuing competency of personnel transitioned from DOH to VFL. For the longer term, a robust training program should be developed for future new hires.

- Ensure academic background (ST)
- Typical new employee orientation (ST)
- Competency testing - Observe the DMT calibration and/or alcohol samples (ST)
- Equipment and Analytical Authorization of competence (ST)

- Adopt job description for new positions; develop task descriptions (IT)
- Include alcohol proficiency testing into VFL procedures (IT)
- Develop training manual (LT)

Breath Alcohol- Specific

VFL will assume responsibility for the 65 DataMaster instruments deployed in the field. This will require a transition of these assets from DOH to VFL, and a site visit to ensure continuing functionality of each instrument.

Equipment - Develop visit schedule

- DataMaster – Adopt a performance checklist for each DMT (ST)

- Develop change-over strategy to include: (IT)

- Inform agency of transition,

- Review machine's data packet

- Change password,

- Verify and document serial number and add asset tags,

- Leave new operator log sheet,

- Visit each DMT (IT)

Space

- Prepare Space for DMT repair depot (ST)

- Re-arrange current space

- Move in appropriate shelving

- Review electrical infrastructure

Blood Alcohol - Specific

Equipment

- GC Headspace

Space

- Prepare space for blood alcohol/ simulator solution preparation area (ST)

- Provide permanent gas plumbing for equipment

ETHANOL QUANTIFICATION

QA/QC & CALIBRATION WORKSHEET

Chemist Initials:

Date:

Name of Reagent	Lot No.	Expiration Date
Dichromate Reagent	PD-8	12-2013
Low Ethanol 0.015% Std	0.015ETOH-82	4/30/2012
Ethanol 0.158% Std	ETOH-82	4/30/2012
n-Propanol 0.161% Std	NPROPANOL-82	4/30/2012
(Cerilliant) Ethanol 0.08% Std	FN092407-01	09-2012

Calibration of GC-FID
instrument:

STANDARDS	RESULTS	PASS/FAIL	
Ethanol Std 1-0.016%		Pass	Fail
Ethanol Std 2-0.079%		Pass	Fail
Ethanol Std 3-0.158%		Pass	Fail
Ethanol Std 4-0.316%		Pass	Fail
Positive Control 0.08%		Pass	Fail
Negative Control		Pass	Fail

Tech. Rev.

Note: Attach results and blanks and store in the OUI file
Retain a copy of worksheet with each case
file.