

**ASCLD/LAB-*International***

**Final Assessment Report**

Vermont Department of Public Safety  
Vermont Forensic Laboratory  
Waterbury, Vermont

**PART 1 – GENERAL INFORMATION**

**INTRODUCTION**

This is the *ASCLD/LAB-International* Final Assessment Report of the Vermont Forensic Laboratory. The on-site assessment was conducted during the period May 19-21, 2015.

The *ASCLD/LAB-International* assessment team consisted of the following members:

**Lead Assessor:**

Melissa A. Smrz – Staff Assessor, ASCLD/LAB /Alexandria, VA

**Technical Assessors:**

Anthony S. DeMaria - San Diego Sheriff's Department / San Diego, CA  
Cyndi Hall - Idaho State Police Forensic Services / Meridian, ID  
Jennifer Lady - New York City Police Department / Jamaica, NY  
Heather E. LaSalle - Federal Bureau of Investigation / Quantico, VA  
Reta Newman - Pinellas County Forensic Laboratory / Largo, FL

**OBJECTIVES OF ASSESSMENT**

The assessment was conducted to evaluate the management and technical operations of the laboratory in accordance with the accreditation requirements specified below, and to report the findings of the assessment in a fair and impartial manner to the laboratory and to the ASCLD/LAB Board of Directors for the purpose of accreditation in accordance with the scope of the assessment.

**REQUIREMENTS**

The assessment was performed using the requirements of ISO/IEC 17025:2005; the *ASCLD/LAB-International* Supplemental Requirements for the Accreditation of Forensic Science Testing Laboratories (2011); the FBI Quality Assurance Standards Audit for Forensic DNA Testing Laboratories (2011); the FBI Quality Assurance Standards Audit for DNA Databasing Laboratories (2011) and the laboratory's own documented management system.

## LABORATORY OVERVIEW

The laboratory is located at 103 South Main Street, Waterbury, Vermont. Trisha L. Conti, Ph.D., is the laboratory director and, at the time of the assessment, the laboratory had a staff of 18 proficiency tested personnel and 4 non-proficiency tested personnel.

## SCOPE OF ASSESSMENT

The laboratory is seeking accreditation in and was assessed in the following areas:

<b>Field</b>	
Forensic Science Testing	
<b>Discipline(s)</b>	<b>Categories of Testing</b>
Drug Chemistry	Controlled Substances
Toxicology	Human Performance Forensic Toxicology (blood/alcohol only)
Biology	DNA – Nuclear Individual Characteristic Database Body Fluid Identification
Trace Evidence	Fire Debris
Firearms/Toolmarks	Firearms Toolmarks Serial Number Restoration

## SUMMARY OF ASSESSMENT TEAM FINDINGS

In general, the assessment team observed the overall operation of the laboratory to be as follows:

The laboratory works diligently to conform to accreditation requirements and its own management system requirements. There have been several management changes in the laboratory over the past two years, but the changes have not affected the laboratory's commitment to offering quality services for the criminal justice community it serves. Identified non-conformances are reviewed and acted on promptly and thoroughly, and taking preventive action and making improvements is a recurring theme in the laboratory's activities. Staff and management communicate well.

Management System: With the exceptions as noted in Part 2 of this report, the laboratory has established policies and procedures appropriate for the scope of its activities. The management team's commitment to quality was evident in their knowledge and understanding of accreditation requirements. Preventive actions and improvements to the quality system are a part of the laboratory's system and daily actions. Laboratory management involves the entire laboratory staff (when appropriate) to resolve problems and to improve laboratory activities. The laboratory has implemented a robust safety program that includes an electronic monitoring system that tracks employee presence in the laboratory, so that in the event of an emergency or at the end of the day, all employees are accounted for. The assessment team commends the entire staff for their professionalism and the open communication style displayed during interviews and witnessing activities.

Document Control: Management system documents are uniquely identified and include revision identification and page numbers. An electronic document control system is utilized to ensure that periodic review occurs and is documented, that changes to controlled documents are communicated to the appropriate personnel and that personnel have reviewed those changes.

Corrective Action: The laboratory takes appropriate corrective actions when needed. Root cause analyses conducted by laboratory management have identified causes for nonconforming work that were not obvious and have allowed the laboratory to effectively eliminate recurrence. In one instance, the laboratory exceeded accreditation requirements in its review of a toxicology non-conformance.

Technical Records: Technical records contain sufficient information to establish an audit trail and to support the conclusions of the analyst. Alterations made to technical records are appropriately tracked. Records are well maintained and easily understood by the assessment team.

Internal Audits: Annual internal audits are conducted by trained personnel. Appropriate actions are taken to resolve issues identified during the audits and the effectiveness of those actions is monitored. Preventive actions are identified through the audits. Audit records are detailed.

Management Reviews: Management reviews are conducted annually and include all required elements. Actions for improvement are completed quickly.

Personnel: Management staff, supervisory personnel and analysts are well-trained and are very knowledgeable in their disciplines of expertise. Administrative staff are also well-trained and extremely knowledgeable of their job duties. All staff are well-versed in laboratory procedures and practices and can explain and discuss them in detail and with enthusiasm.

Test Methods: The technical methods used by the laboratory are appropriate for the scope of testing conducted by the laboratory, and are reviewed periodically for effectiveness and suitability. Staff perform the test methods as written and understand the methods well.

Measurement Uncertainty: The laboratory has established measurement uncertainty for the disciplines of Drug Chemistry, Toxicology and Firearms. Uncertainty is reported in Toxicology and Firearms in conformance with the ASCLD/LAB Policy on Measurement Uncertainty. With one exception noted later in this report, the same is true for Drug Chemistry. No special customer

need for reporting measurement uncertainty information beyond that required in the Policy was noted.

Measurement Traceability: All measurements made in the laboratory have been reviewed for measurement traceability needs and requirements and are well documented. Measurement traceability has been established through the calibration of equipment using an appropriate supplier of external calibration services and the use of certified reference materials, as appropriate. Suppliers of calibration services are appropriately evaluated and reviewed for suitability, and the records of these evaluations and reviews are detailed.

Evidence Handling: Evidence is appropriately identified, sealed and secured in the laboratory. A complete chain of custody is maintained. Evidence handling and storage procedures are efficient and effective. The laboratory is commended for its electronic temperature monitoring system that is used to monitor temperatures for all evidence storage facilities and equipment.

Proficiency Testing: The laboratory's proficiency testing program is well-documented and meets all accreditation requirements. Records are well-maintained.

Reporting: The laboratory is accurately reporting results and identifying opinions and interpretations per accreditation requirements. Examination notes and records support the reported results and opinions. Report language is consistent within each discipline.

The laboratory was found to be in conformance with all ASCLD/LAB-*International* accreditation requirements, except for those requirements cited in Part 2 of this report, or the assessment team found that the requirement was not applicable to the operations of this laboratory.

Each requirement for which the assessment team found the laboratory to not be in total conformance was initially marked "No." For each requirement marked "No," the laboratory was provided with a Corrective Action Request (CAR) following the on-site assessment. A copy of each CAR provided to the laboratory is included in Part 2 of this report.

As reflected on the CAR documents in Part 2 of this report, the laboratory has now taken appropriate corrective actions for all CARs issued.

## COMMENTS

Comments include recommendations, suggestions, or other observations documented by the assessment team that are not supported by sufficient objective evidence of non-compliance. The laboratory is not required to respond to comments. The following comment(s) were documented by the assessment team during the on-site assessment:

- None

## OTHER CONSIDERATIONS

*Other Considerations* may include any topic, issue or information of which the ASCLD/LAB Board of Directors needs to be aware in order to make a more fully informed decision regarding the accreditation decision.

In accordance with ASCLD/LAB policy and procedures the following information was provided by the ASCLD/LAB headquarters office immediately prior to the accreditation decision:

### Proficiency Testing

On-site the assessment team found the laboratory to be in conformance with all applicable proficiency testing requirements. A follow-up check with the ASCLD/LAB Proficiency Program Manager immediately prior to this final report, reveals that the laboratory is currently in conformance with all applicable, ASCLD/LAB external proficiency testing requirements.

### Complaints against the Laboratory

None known to ASCLD/LAB

## REPORT AUTHORIZATION

This Final Assessment Report of the Vermont Forensic Laboratory is issued by Lead Assessor Melissa A. Smrz. As Lead Assessor, Ms. Smrz has reviewed the contents of this report and affirms that the report represents a true and accurate accounting of the findings of the ASCLD/LAB-*International* assessment team.

**Lead Assessor Melissa A. Smrz**

  
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Signature

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May 29, 2015  
Date

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## DISTRIBUTION LIST

- Trisha L. Conti, Ph.D., Laboratory Director
- Tara Tighe, Quality Manager
- John K. Neuner, ASCLD/LAB Executive Director
- Pamela L. Bordner, ASCLD/LAB Chief Operating Officer
- Laurel J. Farrell, ASCLD/LAB Senior Accreditation Program Manager
- Troy Hamlin, ASCLD/LAB Accreditation Program Manager-Testing



**CORRECTIVE ACTION**

Summary of Laboratory Response:	The laboratory had recently added this requirement to its procedures, but analysts were not aware of the change. The laboratory management will review the revised procedure with the staff, and will monitor conformance using the technical review process.
Supporting Documentation Provided by Laboratory:	The CAR is resolved and objective evidence of implementation will be reviewed during the next conformance monitoring activity.

**ACCEPTANCE**

Revisit required to verify effective implementation prior to surveillance:

No       Yes

Melissa Army  
 Assessor Signature

June 4, 2015  
 Date Accepted

**CORRECTIVE ACTION REQUEST (CAR) Number  2  of  11**

Laboratory Name:  Vermont Forensic Laboratory   
 Laboratory Location:  Waterbury, Vermont   
 Laboratory Contact Name:  Tara Tighe   
 Contact Number:  802-241-5403   
 Summation Conference Date:  May 21, 2015

**FINDING**

Clause No.:	4.2.1	Source:	ISO/IEC 17025:2005	Level:	2
	5.1		Firearms Technical Procedures Manual		
Requirement:	<p>4.2.1: The laboratory shall establish, implement and maintain a management system appropriate to the scope of its activities. The laboratory shall document its policies, systems, programmes, procedures and instructions to the extent necessary to assure the quality of the test and/or calibration results. The system’s documentation shall be communicated to, understood by, available to, and implemented by the appropriate personnel.</p> <p>Firearms Technical Procedures Manual:</p> <p>Section 5.1: “Prior to the restoration attempt, the firearm examiner shall test an area near the obliterated serial number for reactivity and note the reaction in the case notes. Such observations can include, “bubbling”, “vapors rising from the surface”, and/or “observed color change of surface”. This will ensure that this particular chemical is working with the metal surface to be restored.</p>				
Finding:	<p>In the Serial Number Restoration category of testing, there were no records of the chemical reactions in the case notes in two of three cases reviewed. Although the record documented that the test was performed, there was no record of the reaction/reactivity in the case notes.</p>				
Corrective Action Plan Due:	June 28, 2015				
Implementation of Corrective Action Due:	With submission of the next Performance Declaration or at the next on-site visit, whichever is scheduled to occur first.				

**CORRECTIVE ACTION**

Summary of Laboratory Response:	<p>The laboratory had recently added this requirement to its procedures, but analysts were not aware of the change. The laboratory management will review the revised procedure with the staff, and will monitor conformance using the technical review process.</p>
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Supporting Documentation Provided by Laboratory:	The CAR is resolved and objective evidence of implementation will be reviewed during the next conformance monitoring activity.
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**ACCEPTANCE**

Revisit required to verify effective implementation prior to surveillance:

No       Yes

*Melissa Long*  
Assessor Signature

June 4, 2015  
Date Accepted

**CORRECTIVE ACTION REQUEST (CAR) Number 3 of 11**

Laboratory Name: Vermont Forensic Laboratory  
 Laboratory Location: Waterbury, Vermont  
 Laboratory Contact Name: Tara Tighe  
 Contact Number: 802-241-5403  
 Summation Conference Date: May 21, 2015

**FINDING**

Clause No.:	5.10.2.h  7.1  DRG_P100_Ver 3 Section 16 (page 15 of 45)	Source:	ISO/IEC 17025:2005  ASCLD/LAB Policy on Sampling, Sampling Plans and Sample Selection in the Drug Chemistry Discipline  VFL Drug Chemistry Procedure Manual	Level:	1
Requirement:	<p>5.10.2: “Each test report or calibration certificate shall include at least the following information, unless the laboratory has valid reasons for not doing so:                  ...                  h) reference to the sampling plan and procedures used by the laboratory or other bodies where these are relevant to the validity or application of the results; ...”</p> <p>ASCLD/LAB Sampling Policy:</p> <p>7.1: For Drug Chemistry cases in which a sampling plan is used, information about the sampling plan, including the confidence levels and corresponding inferences of the population must be in the report, or an attachment to the report (e.g., 95% confidence that at least 90% of the baggies contain cocaine).</p> <p>Drug Chemistry Procedure Manual (For reporting of drug analyses that includes hypergeometric sampling):</p> <p>Reporting Guideline: Items XXX through XXX: Tested items were randomly selected from XXX bags. UNODC/ENFSI Guidelines on Representative Drug Sampling (2009) Table 1, pages 12-13 was used as a guideline for testing, with statistical sampling using hypergeometric distribution for a 95% confidence level that 90% of the population contains (a regulated drug).</p>				

Finding:	Three out of three drug analysis reports in which hypergeometric sampling was used did not include a statement of the confidence interval and associated percent population.
Corrective Action Plan Due:	June 28, 2015
Implementation of Corrective Action Due:	To avoid a lapse in accreditation, objective evidence of implementation must be provided to, reviewed by and accepted by the Lead Assessor no later than July 2, 2015.  If the laboratory's ASCLD/LAB Legacy accreditation expires, objective evidence of implementation must be provided to, reviewed by and accepted by the Lead Assessor no later than August 27, 2015, to complete the ASCLD/LAB- <i>International</i> accreditation process.

**CORRECTIVE ACTION**

Summary of Laboratory Response:	The laboratory will review its reporting requirements with the staff to ensure that there is understanding of the reporting requirement. The laboratory will review casework back to November 2014 (procedure implementation date) and amend reports as necessary to conform to the reporting requirements.
Supporting Documentation Provided by Laboratory:	The laboratory submitted the following records to demonstrate compliance: <ol style="list-style-type: none"> <li>1. A summary record of the casework review when procedure was implemented and the results of the review (two additional reports were identified);</li> <li>2. Five amended reports;</li> <li>3. Memo to analysts (signed) memorializing the laboratory; management's review of the CAR finding and procedure;</li> <li>4. The laboratory's corrective action records.</li> </ol> <p>Objective evidence of implementation has been reviewed and the CAR is resolved.</p>

**ACCEPTANCE**

Revisit required to verify effective implementation prior to surveillance:  No  Yes

  
 Assessor Signature

June 4, 2015  
 Date Accepted

**CORRECTIVE ACTION REQUEST (CAR) Number 4 of 11**

Laboratory Name: Vermont Forensic Laboratory  
 Laboratory Location: Waterbury, Vermont  
 Laboratory Contact Name: Tara Tighe  
 Contact Number: 802-241-5403  
 Summation Conference Date: May 21, 2015

**FINDING**

Clause No.:	5.4.6.3 4.1	Source:	ISO/IEC 17025:2005 ASCLD/LAB Policy on Measurement Uncertainty	Level:	1
Requirement:	<p>5.4.6.3: When estimating the uncertainty of measurement, all uncertainty components which are of importance in the given situation shall be taken into account using appropriate methods of analysis.</p> <p>ASCLD/LAB Policy on Measurement Uncertainty</p> <p>4.1: "ASCLD/LAB-<i>International</i> applicant and accredited testing and calibration laboratories shall record the following elements for each estimation of measurement uncertainty:</p> <p>(a) Statement defining the measurand,          (b) Statement of how traceability is established for the measurement,          (c) The equipment (e.g., measuring device[s] or instrument[s]) used,          (d) All uncertainty components considered,          (e) All uncertainty components of significance and how they were evaluated,          ..."</p>				
Finding:	<p>In Drug Chemistry, the uncertainty of measurement records associated with weighing of drug evidence do not include the following required elements: b) statement of how traceability is established for measurement; d) all uncertainty components considered and e) all uncertainty components of significance and how evaluated.</p>				
Corrective Action Plan Due:	June 28, 2015				
Implementation of Corrective Action Due:	<p>To avoid a lapse in accreditation, objective evidence of implementation must be provided to, reviewed by and accepted by the Lead Assessor no later than July 2, 2015.</p> <p>If the laboratory's ASCLD/LAB Legacy accreditation expires, objective evidence of implementation must be provided to, reviewed by and accepted by the Lead Assessor no later than August 27, 2015, to complete the ASCLD/LAB-<i>International</i> accreditation process.</p>				

**CORRECTIVE ACTION**

Summary of Laboratory Response:	The laboratory will provide records that include the missing elements cited in the finding.
Supporting Documentation Provided by Laboratory:	<p>The laboratory provided the following records to demonstrate compliance:</p> <ol style="list-style-type: none"> <li>1. Summary records that include the statement on how traceability is established for the balances and weights, on all uncertainty components considered by the laboratory, and on those uncertainty components determined by the laboratory to be significant and how the significance was determined;</li> <li>2. Memo to analysts (signed) memorializing the laboratory management’s review of the CAR finding and procedure;</li> <li>3. The laboratory’s corrective action records.</li> </ol> <p>Objective evidence of implementation has been reviewed and the CAR is resolved.</p>

**ACCEPTANCE**

Revisit required to verify effective implementation prior to surveillance:

No       Yes

  
 Assessor Signature

June 4, 2015  
 Date Accepted

**CORRECTIVE ACTION REQUEST (CAR) Number 5 of 11**

Laboratory Name: Vermont Forensic Laboratory  
 Laboratory Location: Waterbury, Vermont  
 Laboratory Contact Name: Tara Tighe  
 Contact Number: 802-241-5403  
 Summation Conference Date: May 21, 2015

**FINDING**

Clause No.:	4.2.1	Source:	ISO/IEC 17025:2005	Level:	1
Requirement:	The laboratory shall establish, implement and maintain a management system appropriate to the scope of its activities. The laboratory shall document its policies, systems, programmes, procedures and instructions to the extent necessary to assure the quality of the test and/or calibration results. ...”				
Finding:	The Drug Chemistry Training Manual and the Alcohol Training Manual both specify that the trainee analyze multiple casework samples under the direct supervision of an experienced analyst (Section 6 in training manuals) in the various drug test modules. These procedures allow a trainee to perform testing and to co-sign case reports before successfully completing a competency test. It is noted that the one Drug Chemistry analyst trained and authorized to perform testing since the laboratory’s application for accreditation did successfully complete a competency test prior to assuming any casework duties.				
Corrective Action Plan Due:	June 28, 2015				
Implementation of Corrective Action Due:	To avoid a lapse in accreditation, objective evidence of implementation must be provided to, reviewed by and accepted by the Lead Assessor no later than July 2, 2015.  If the laboratory’s ASCLD/LAB Legacy accreditation expires, objective evidence of implementation must be provided to, reviewed by and accepted by the Lead Assessor no later than August 27, 2015, to complete the ASCLD/LAB- <i>International</i> accreditation process.				

**CORRECTIVE ACTION**

Summary of Laboratory Response:	The laboratory will revise its Drug Chemistry and Alcohol Training Manuals to require that analyst trainees will complete a competency test (or tests) at prior to being authorized to perform bench analyses on evidence and to co-write reports while still in training, as part of the ‘supervised casework’ requirements of training and competency. A final competency test will still be used to qualify the analyst for independent casework duties.
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Supporting Documentation Provided by Laboratory:	<p>The laboratory provided the following documents and records to demonstrate compliance:</p> <ol style="list-style-type: none"> <li>1. The revised Drug Chemistry Training Manual (DRG_P200_DC, Training, Manual, Version 3) and the revised Alcohol Training Manual (ALC_P300_ Alcohol Training Manual, Version 2) which defines the requirements for analyst trainees to complete competency tests (practical, written and report writing) during various training modules before being authorized to perform bench work analysis and report co-writing functions for authorized independent analysts;</li> <li>2. Document revision records;</li> <li>3. Memos advising the staff of the document changes;</li> <li>4. Memos to analysts (signed) memorializing the laboratory; management’s review of the CAR finding and procedure;</li> <li>5. The laboratory’s corrective action records.</li> </ol> <p>Objective evidence of implementation has been reviewed and the CAR is resolved.</p>
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**ACCEPTANCE**

Revisit required to verify effective implementation prior to surveillance:

No       Yes

  
Assessor Signature

June 8, 2015  
Date Accepted

**CORRECTIVE ACTION REQUEST (CAR) Number 6 of 11**

Laboratory Name: Vermont Forensic Laboratory  
 Laboratory Location: Waterbury, Vermont  
 Laboratory Contact Name: Tara Tighe  
 Contact Number: 802-241-5403  
 Summation Conference Date: May 21, 2015

**FINDING**

Clause No.:	4.13.2.7	Source:	2011 Supplemental-Testing	Level:	1
Requirement:	When examination records are prepared by an individual(s) other than the analyst (however named) who interprets the findings, prepares the test report and/or testifies concerning the records, the handwritten initials (or secure electronic equivalent of initials or signature) of that individual(s) shall be on the page(s) of examination records representing his/her work.				
Finding:	In five of five Drug Chemistry cases reviewed in which a trainee and the reporting analyst performed work or issued reports, the initials of both analysts appear on all exam documentation. It is not clear from the examination record as to who performed the work in the various stages of the examination.				
Corrective Action Plan Due:	June 28, 2015				
Implementation of Corrective Action Due:	<p>To avoid a lapse in accreditation, objective evidence of implementation must be provided to, reviewed by and accepted by the Lead Assessor no later than July 2, 2015.</p> <p>If the laboratory's ASCLD/LAB Legacy accreditation expires, objective evidence of implementation must be provided to, reviewed by and accepted by the Lead Assessor no later than August 27, 2015, to complete the ASCLD/LAB-<i>International</i> accreditation process.</p>				

**CORRECTIVE ACTION**

Summary of Laboratory Response:	The laboratory will review all applicable cases in which the trainee analyzed casework and issue a memo memorializing what analyses were performed by the trainee. A copy of this memo will be placed into each applicable case file. The laboratory will instruct the staff that in such future instances, trainees will initial the specific records for the work/testing they performed.
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Supporting Documentation Provided by Laboratory:	<p>The laboratory provided the following records demonstrating compliance:</p> <ol style="list-style-type: none"><li>1. The above-cited memo memorializing the case review conducted and defining which analyses were performed by the analyst trainee/non-reporting analyst and which (if any) were performed by the reporting analyst;</li><li>2. Memos to analysts (signed) memorializing the laboratory; management's review of the CAR finding and procedure;</li><li>3. The laboratory's corrective action records.</li></ol> <p>Objective evidence of implementation has been reviewed and the CAR is resolved.</p>
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**ACCEPTANCE**

Revisit required to verify effective implementation prior to surveillance:

No       Yes

  
\_\_\_\_\_  
Assessor Signature

\_\_\_\_\_  
June 4, 2015  
Date Accepted

**CORRECTIVE ACTION REQUEST (CAR) Number 7 of 11**

Laboratory Name: Vermont Forensic Laboratory  
 Laboratory Location: Waterbury, Vermont  
 Laboratory Contact Name: Tara Tighe  
 Contact Number: 802-241-5403  
 Summation Conference Date: May 21, 2015

**FINDING**

Clause No.:	4.13.1.4, 5.4.7.2	Source:	ISO/IEC 17025:2005	Level:	2
Requirement:	<p>4.13.1.4: The laboratory shall have procedures to protect and back-up records stored electronically and to prevent unauthorized access to or amendment of these records.</p> <p>5.4.7.2: When computers or automated equipment are used for the acquisition, processing, recording, reporting, storage or retrieval of test or calibration data, the laboratory shall ensure that: ...</p> <p>b) procedures are established and implemented for protecting the data; such procedures shall include, but not be limited to, integrity and confidentiality of data entry or collection, data storage, data transmission and data processing; ...</p>				
Finding:	<p>The laboratory procedures for information technology (IT) security and access refer to the Vermont Department of Public Safety, Office of Technology Management (VDPS-OTM). The procedures do not describe how data backups are performed, the frequency of these backups, or how failures are communicated. The procedures also do not describe the steps taken to secure IT records and systems. Records from the other agency demonstrate that they are following appropriate practices to backup and secure IT records and systems.</p>				
Corrective Action Plan Due:	June 28, 2015				
Implementation of Corrective Action Due:	With submission of the next Performance Declaration or at the next on-site visit, whichever is scheduled to occur first.				

**CORRECTIVE ACTION**

Summary of Laboratory Response:	<p>The laboratory will update its procedure to define that top management will verify and document on a quarterly basis that the Department's Office of Technology Management is in compliance with the VFL's accreditation requirements regarding protection (back-up and restore) and communication (updates and system failures). The laboratory's top management will annually review the security (control of access) of the VFL's networked documents and LIMS database. The laboratory's top management will verify through objective</p>
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	evidence that the back-up and restore processes controlled by the Department's Office of Technology Management are being followed. The laboratory's top management will review IT and laboratory communications (document if there has been none) for the specified time period. The laboratory's top management will continue to review the security/control of access of its networked documents and LIMS database. Permissions are modified for lab staff on an as needed basis; reviewed and authorized by Top Management.
Supporting Documentation Provided by Laboratory:	The CAR is resolved and objective evidence of implementation will be reviewed during the next conformance monitoring activity.

**ACCEPTANCE**

Revisit required to verify effective implementation prior to surveillance:

No       Yes

  
Assessor Signature

June 9, 2015  
Date Accepted

**CORRECTIVE ACTION REQUEST (CAR)      Number   8   of   11**

Laboratory Name: Vermont Forensic Laboratory  
 Laboratory Location: Waterbury, Vermont  
 Laboratory Contact Name: Tara Tighe  
 Contact Number: 802-241-5403  
 Summation Conference Date: May 21, 2015

**FINDING**

Clause No.:	4.13.2.2, 5.4.7.1	Source:	ISO/IEC 17025:2005	Level:	1
Requirement:	<p>4.13.2.2: Observations, data and calculations shall be recorded at the time they are made and shall be identifiable to the specific task.</p> <p>5.4.7.1: Calculations and data transfers shall be subject to appropriate checks in a systematic manner.</p>				
Finding:	<p>Section 11 of Alcohol Analysis Manual describes specific quality control criteria for whole blood controls, ethanol controls and replicate analysis requirements that are expressed as calculations of percentages or acceptable range. However, there is no record of the calculations of the percentages or acceptable ranges to ensure that the criteria have been checked or met. This was observed in 7 out of 7 cases reviewed.</p>				
Corrective Action Plan Due:	June 28, 2015				
Implementation of Corrective Action Due:	<p>To avoid a lapse in accreditation, objective evidence of implementation must be provided to, reviewed by and accepted by the Lead Assessor no later than July 2, 2015.</p> <p>If the laboratory's ASCLD/LAB Legacy accreditation expires, objective evidence of implementation must be provided to, reviewed by and accepted by the Lead Assessor no later than August 27, 2015, to complete the ASCLD/LAB-<i>International</i> accreditation process.</p>				

**CORRECTIVE ACTION**

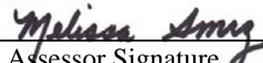
Summary of Laboratory Response:	<p>The laboratory will revise its practices and begin to record in the examination record the calculations of the percentages and acceptance ranges for the whole blood and ethanol controls and replicate samples, respectively. The laboratory will review the cited cases to ensure that the calculated values were within acceptable limits.</p>
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Supporting Documentation Provided by Laboratory:	<p>The laboratory provided the following records to demonstrate compliance:</p> <ol style="list-style-type: none"> <li>1. Memo to staff memorializing the review of the revised practice to record the cited calculations, and that the review of the calculations is recorded on the technical review form;</li> <li>2. A memo memorializing the review of the affected cases. It is noted that there were no inconsistencies or out of range values noted.</li> <li>3. Case records from four cases demonstrating the new practice of recording the calculations, as stated above;</li> <li>4. Case records from the same four cases demonstrating that the technical review of the calculations has been performed;</li> <li>5. The laboratory's corrective action records.</li> </ol> <p>Objective evidence of implementation has been reviewed and the CAR is resolved.</p>
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**ACCEPTANCE**

Revisit required to verify effective implementation prior to surveillance:

No       Yes

  
\_\_\_\_\_  
Assessor Signature

June 10, 2015  
Date Accepted

**CORRECTIVE ACTION REQUEST (CAR) Number 9 of 11**

Laboratory Name: Vermont Forensic Laboratory  
 Laboratory Location: Waterbury, Vermont  
 Laboratory Contact Name: Tara Tighe  
 Contact Number: 802-241-5403  
 Summation Conference Date: May 21, 2015

**FINDING**

Clause No.:	4.13.2.2, 5.4.7.1	Source:	ISO/IEC 17025:2005	Level:	1
Requirement:	<p>4.13.2.2: Observations, data and calculations shall be recorded at the time they are made and shall be identifiable to the specific task.</p> <p>5.4.7.1: Calculations and data transfers shall be subject to appropriate checks in a systematic manner.</p>				
Finding:	<p>In Drug Chemistry cases, the measurement uncertainty is only reported in samples or a combination of samples near legally defined weight thresholds. There is not a record of the measurement uncertainty being calculated in two cases containing multiple items to verify that the measurement uncertainty reporting was not required.</p>				
Corrective Action Plan Due:	June 28, 2015				
Implementation of Corrective Action Due:	<p>To avoid a lapse in accreditation, objective evidence of implementation must be provided to, reviewed by and accepted by the Lead Assessor no later than July 2, 2015.</p> <p>If the laboratory's ASCLD/LAB Legacy accreditation expires, objective evidence of implementation must be provided to, reviewed by and accepted by the Lead Assessor no later than August 27, 2015, to complete the ASCLD/LAB-<i>International</i> accreditation process.</p>				

**CORRECTIVE ACTION**

Summary of Laboratory Response:	<p>The laboratory will revise its practices and begin to record in the examination record the calculations of the measurement uncertainty in the cited circumstances. The laboratory will review the cited cases to ensure that the calculated values were within acceptable limits.</p>
Supporting Documentation Provided by Laboratory:	<p>The laboratory provided the following records to demonstrate compliance:</p> <ol style="list-style-type: none"> <li>1. Memo to staff memorializing the review of the revised practice to record the cited calculations (when applicable) and to make a note</li> </ol>

	<p>when the calculations are not applicable;</p> <ol style="list-style-type: none"> <li>2. The same memo to staff advising of the requirement for technical reviewers to evaluate/check the calculations and record this evaluation on the technical review form;</li> <li>3. A memo memorializing the review of the affected cases. It is noted that there were no cases in which a measurement uncertainty was not reported as required;</li> <li>4. Case records from one recently completed case demonstrating the new practice of recording the calculations, as stated above, and the technical review of these calculations;</li> <li>5. Case records from seven recently completed cases demonstrating that the measurement uncertainty evaluations had been performed and determined to be 'not applicable' and that the technical reviews of these evaluations had been performed;</li> <li>6. The laboratory's corrective action records.</li> </ol> <p>Objective evidence of implementation has been reviewed and the CAR is resolved.</p>
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**ACCEPTANCE**

Revisit required to verify effective implementation prior to surveillance:

No       Yes

  
Assessor Signature

June 10, 2015  
Date Accepted

**CORRECTIVE ACTION REQUEST (CAR) Number 10 of 11**

Laboratory Name: Vermont Forensic Laboratory  
 Laboratory Location: Waterbury, Vermont  
 Laboratory Contact Name: Tara Tighe  
 Contact Number: 802-241-5403  
 Summation Conference Date: May 21, 2015

**FINDING**

Clause No.:	5.2.5	Source:	ISO/IEC 17025:2005	Level:	2
Requirement:	The management shall authorize specific personnel to perform particular types of sampling, test and/or calibration, to issue test reports and calibration certificates, to give opinions and interpretations and to operate particular types of equipment. The laboratory shall maintain records of the relevant authorization(s), competence, educational and professional qualifications, training, skills and experience of all technical personnel, including contracted personnel. This information shall be readily available and shall include the date on which authorization and/or competence is confirmed.				
Finding:	In three of five cases reviewed for a recently trained Drug Chemistry analyst, supervised casework was performed and the analyst co-signed reports without written authorization to perform these casework activities.				
Corrective Action Plan Due:	June 28, 2015				
Implementation of Corrective Action Due:	With submission of the next Performance Declaration or at the next on-site visit, whichever is scheduled to occur first.				

**CORRECTIVE ACTION**

Summary of Laboratory Response:	The laboratory will review the analyst's training records and prepare a memo documenting the analyst's authorization to perform the work described in the finding.
Supporting Documentation Provided by Laboratory:	<p>The laboratory provided the following records to demonstrate compliance:</p> <ol style="list-style-type: none"> <li>1. Training records demonstrating that the analyst had been appropriately competency tested to perform the work cited in the finding;</li> <li>2. A memo from the laboratory director summarizing the analyst's authorizations, as a result of the cited finding;</li> <li>3. The laboratory's corrective action records.</li> </ol> <p>Objective evidence of implementation has been reviewed and the CAR is resolved.</p>

**ACCEPTANCE**

Revisit required to verify effective implementation prior to surveillance:

No

Yes

  
\_\_\_\_\_  
Assessor Signature

June 4, 2015  
\_\_\_\_\_  
Date Accepted

**CORRECTIVE ACTION REQUEST (CAR) Number 11 of 11**

Laboratory Name: Vermont Forensic Laboratory  
 Laboratory Location: Waterbury, Vermont  
 Laboratory Contact Name: Tara Tighe  
 Contact Number: 802-241-5403  
 Summation Conference Date: May 21, 2015

**FINDING**

Clause No.:	4.13.2.1	Source:	ISO/IEC 17025:2005	Level:	1
Requirement:	<p>The laboratory shall retain records of original observations, derived data and sufficient information to establish an audit trail, calibration records, staff records and a copy of each test report or calibration certificate issued, for a defined period. The records for each test or calibration shall contain sufficient information to facilitate, if possible, identification of factors affecting the uncertainty and to enable the test or calibration to be repeated under conditions as close as possible to the original. The records shall include the identity of personnel responsible for the sampling, performance of each test and/or calibration and checking of results</p>				
Finding:	<p>The Biology/DNA casework and database sections do not maintain sufficient records to establish an audit trail for the mechanical pipettes used during analysis. The laboratory maintains calibration records for pipettes and includes a list of serial numbers assigned to each discipline as well as the corresponding room number. However, in rooms containing multiple sets of pipettes, it is not possible to identify the specific set used through documentation in the case record.</p>				
Corrective Action Plan Due:	June 28, 2015				
Implementation of Corrective Action Due:	<p>To avoid a lapse in accreditation, objective evidence of implementation must be provided to, reviewed by and accepted by the Lead Assessor no later than July 2, 2015.</p> <p>If the laboratory's ASCLD/LAB Legacy accreditation expires, objective evidence of implementation must be provided to, reviewed by and accepted by the Lead Assessor no later than August 27, 2015, to complete the ASCLD/LAB-<i>International</i> accreditation process.</p>				

**CORRECTIVE ACTION**

Summary of Laboratory Response:	The laboratory will revise its records to include more specific designations and descriptions of applicable pipettes by sub-group in the laboratory room and the function in which the pipette is used. The laboratory will advise analysts to note in the examination record if a different set of pipettes is used for some reason (for example, when pipettes are out of service).
Supporting Documentation Provided by Laboratory:	<p>The laboratory provided the following documents and records to demonstrate compliance:</p> <ol style="list-style-type: none"> <li>1. The revised pipette inventory which now assigns each pipette to a specific room sub-group and function;</li> <li>2. Communication records advising staff on the revised pipette inventory and the requirement to record the pipette information in the examination records if different set is used for some reason;</li> <li>3. The laboratory's corrective action records.</li> </ol> <p>Objective evidence of implementation has been reviewed and the CAR is resolved.</p>

**ACCEPTANCE**

Revisit required to verify effective implementation prior to surveillance:

No       Yes

  
 Assessor Signature

June 4, 2015  
 Date Accepted