

**ASCLD/LAB-*International***

**Full Assessment Report**

Connecticut Department of Public Safety  
Division of Scientific Services  
Forensic Science Laboratory  
Meriden, Connecticut

**PART 1 – GENERAL INFORMATION**

**INTRODUCTION**

This is the *ASCLD/LAB-International Full Assessment Report* of the Connecticut Department of Public Safety - Division of Scientific Services – Forensic Science Laboratory. The on-site assessment was conducted during the period September 13-16, 2011.

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

**Lead Assessor:**

Robert Gonsowski - Staff Inspector, ASCLD/LAB / Herrin, Illinois

**Technical Assessors:**

Jagjeet Bains - New York Police Laboratory / Jamaica, New York  
Thomas W. Barnes - Oregon State Police / Clackamas, Oregon  
John J. Bourke - Santa Clara County District Attorney's Office / San Jose, California  
Julie Doerr - California Department of Justice / Redding, California  
Chris Heartsill - Dallas County Southwestern Institute of Forensic Sciences / Dallas, Texas  
George W. Hertel Jr. - Miami-Dade Police Department Forensic Services Bureau / Doral, Florida  
Jack Laird - Wyndham Forensic Group Inc. / Guelph, Ontario, Canada  
Dale Gene Linden - FBI Digital Evidence Laboratory (Retired) / Manassas, Virginia  
Loren Mercer - Laboratory Management System Services, LLC / Pocatello, Idaho  
Robyn Ragsdale - Florida Department of Law Enforcement / Tampa, Florida  
Alyson E. Saadi - Louisiana State Police Crime Laboratory / Baton Rouge, Louisiana  
Karla K. Taylor - Los Angeles County Sheriff's Department / Los Angeles, California

**Discipline Expert:**

A. Dwayne Winston – LabCorp / Research Triangle Park, North Carolina

## OBJECTIVES OF ASSESSMENT

The assessment was conducted to assess 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.

## ACCREDITATION REQUIREMENTS

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

## 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 Quantitative Analysis General Chemical Testing
Toxicology	Human Performance Forensic Toxicology
Biology	DNA-Nuclear DNA-Mitochondrial Body Fluid Identification Individual Characteristic Database
Trace Evidence	Paint Fiber and Textiles Fire Debris Gunshot Residue (elemental analysis) Hair General Physical and Chemical Analysis

Latent Prints	Latent Print Processing Latent Print Comparisons
Firearms/Toolmarks	Firearms Toolmarks
Questioned Documents	Document Examination
Digital and Multimedia Evidence	Computer Forensics Video Analysis Audio Analysis Image Analysis
Other	Impression Evidence (Footwear/Tires) Considered a part of the Questioned Documents discipline

**Note:** The laboratory’s original application included the Explosives category of testing in the Trace Evidence discipline. However, the scope of the assessment was changed due to insufficient casework. Therefore, Explosives was not included as a category of testing during this assessment.

## LABORATORY OVERVIEW

The Connecticut Department of Public Safety - Division of Scientific Services – Forensic Science Laboratory is a state government laboratory that provides services and assistance to law enforcement agencies throughout Connecticut. The laboratory is located at 278 Colony Street, Meriden, Connecticut. Mr. Kenneth Zercie is the laboratory director and, at the time of the assessment, the laboratory had a staff of 58 proficiency tested personnel and 13 non-proficiency tested personnel.

## ASSESSMENT TEAM FINDINGS

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 program.

Each requirement for which the assessment team found the laboratory to not be in total conformance was marked “No.” A *Preliminary Assessment Report*, listing specific nonconformities cited by the assessment team, was provided at the on-site, closing meeting.

## 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:

- GL-14 specifically addresses the identification and documentation for re-training of analysts. GL-14 is not referenced in this section of the Quality Manual (SOP GL-1), nor is it referenced in the individual section SOPs referenced in section 5.2.1.1.
- FBQR-10 “Request for Examination” is prepared by the Forensic Biology examiners and forwarded to other sections. FBQR-10 summarizes the pertinent findings of the biological analysis. Interviews with biology analysts and section supervisors indicate that the general practice is to forward the original copy of the form to the appropriate section after their notes have been technically reviewed and a photocopy of the form is kept in the biology case record. The biology technical reviewer’s initials are not added to the original form that is forwarded to the other sections, but is added to the photocopy retained in the biology case record. Current practice does not document that the review of the data on the form occurs prior to submission of the form to another section.
- There were two examples noted where there was case information on both sides of pages of case documentation, but there were no unique identifiers or initials.

## RIGHT TO APPEAL

The laboratory director has the right to appeal at any time during the accreditation process. Further information about the appeals process may be obtained by contacting the ASCLD/LAB Executive Director at 919-773-2600.

## STATUS OF REPORT

This *Full Assessment Report* and the findings and corrective action requests are provided for pre-decisional purposes only.

## REPORT AUTHORIZATION

This *Full Assessment Report* of the Connecticut Department of Public Safety - Division of Scientific Services – Forensic Science Laboratory is issued by Lead Assessor Robert Gonsowski. As Lead Assessor, Mr. Gonsowski 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 Robert Gonsowski**

  
Signature

October 5, 2011  
Date

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## **DISTRIBUTION LIST**

Mr. Kenneth Zercie, Laboratory Director

Ms. Jane Ridley, Quality Manager

Mr. Ralph M. Keaton, ASCLD/LAB Executive Director

Mr. John K. Neuner, ASCLD/LAB-*International* Program Manager

Ms. Tracy Cheaney-Plummer, ASCLD/LAB Program Manager

## **PART 2 – CORRECTIVE ACTION REQUESTS**

A quality review of the nonconformities cited by the assessment team at the on-site closing meeting was conducted by an ASCLD/LAB Quality Review Panel. The purposes of the ASCLD/LAB quality review included considering consistency of interpretations, appropriate relationships between findings and the clause(s) to which those findings are assigned, and to consider the recommended level assigned to each finding by the assessment team.

Following the completion of the quality review, formal *Corrective Action Requests* were prepared by the Lead Assessor and are issued to the Connecticut Department of Public Safety - Division of Scientific Services – Forensic Science Laboratory in this *Full Assessment Report*.

Also, please be aware that in accordance with ASCLD/LAB-*International* policy, no specific *Corrective Action Request* (CAR) will be issued against 4.1.2 of ISO/IEC 17025:2005; however, the response to this clause will be marked “No” until appropriate corrective actions have been completed and accepted by the Lead Assessor for each Level 1 CAR.

The laboratory has thirty (30) calendar days from the date of release of this *Full Assessment Report* to provide the Lead Assessor with a proposed corrective action plan for each CAR issued with the report. The laboratory should refrain from implementing proposed corrective actions until the Lead Assessor’s acceptance of the proposed corrective actions.

For any Level 1 CAR contained in this *Full Assessment Report*, the laboratory will have 180 calendar days from the release date of the *Full Assessment Report* to complete corrective actions (including the initial 30 calendar days to submit a corrective action plan), provide the Lead Assessor with objective evidence of completed corrective actions, and to have the Lead Assessor accept the action as complete. The 180 calendar day completion date is April 2, 2012.

For any Level 2 CAR contained in this *Full Assessment Report*, the Connecticut Department of Public Safety - Division of Scientific Services – Forensic Science Laboratory may elect to complete corrective actions prior to the next surveillance visit. However, should the laboratory choose that option, the laboratory will still have thirty (30) calendar days from the release date of the *Full Assessment Report* to provide the Lead Assessor with a proposed corrective action plan for each Level 2 CAR issued with the report.

Alternatively, for any Level 2 CAR, the laboratory may elect to respond to the request in accordance with the provisions for a Level 1 CAR as indicated above.

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**CORRECTIVE ACTION REQUEST (CAR) Number 1 of 40**

Laboratory Name: Connecticut Forensic Science Laboratory  
 Laboratory Location: Meridan, Connecticut  
 Laboratory Contact Name: Kenneth Zercie  
 Contact Number: 203-639-6458  
 Summation Conference Date: September 16, 2011

**FINDING**

Clause No.:	4.1.5.i	Source:	ISO/IEC 17025:2005	Level:	1
Requirement:	The laboratory shall appoint a member of staff as quality manager (however named) who, irrespective of other duties and responsibilities, shall have defined responsibility and authority for ensuring that the management system related to quality is implemented and followed at all times; the quality manager shall have direct access to the highest level of management at which decisions are made on laboratory policy or resources.				
Finding:	The laboratory has not appointed one person to the position of Quality Manager. A number of staff have been appointed to the position at the same time.				
Corrective Action Due By:	On or before April 2, 2012				

**CORRECTIVE ACTION REQUEST (CAR) Number 2 of 40**

Laboratory Name: Connecticut Forensic Science Laboratory  
 Laboratory Location: Meridan, Connecticut  
 Laboratory Contact Name: Kenneth Zercie  
 Contact Number: 203-639-6458  
 Summation Conference Date: September 16, 2011

**FINDING**

Clause No.:	4.1.8	Source:	ISO/IEC 17025:2005	Level:	1
Requirement:	Key management and top management shall be defined by the laboratory.				
Finding:	The laboratory has defined top management with a different subset of individuals in two different quality documents.				
Corrective Action Due By:	On or before April 2, 2012				

**CORRECTIVE ACTION REQUEST (CAR) Number 3 of 40**

Laboratory Name: Connecticut Forensic Science Laboratory  
 Laboratory Location: Meridan, Connecticut  
 Laboratory Contact Name: Kenneth Zercie  
 Contact Number: 203-639-6458  
 Summation Conference Date: September 16, 2011

**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. The system's documentation shall be communicated to, understood by, available to, and implemented by the appropriate personnel.				
Finding:	Lab staff and top management were unclear about the mechanism for review of corrective actions. The mechanism cited by the lab director was a review of corrective actions by the quality management team (QMT). The policy and procedure for the duties of the QMT and the corrective action policy does not include that duty. The QMT does not perform that duty per interview with a QMT member.				
Corrective Action Due By:	On or before April 2, 2012				

**CORRECTIVE ACTION REQUEST (CAR) Number 4 of 40**

Laboratory Name: Connecticut Forensic Science Laboratory  
 Laboratory Location: Meridan, Connecticut  
 Laboratory Contact Name: Kenneth Zercie  
 Contact Number: 203-639-6458  
 Summation Conference Date: September 16, 2011

**FINDING**

Clause No.:	4.2.1 C 3 b	Source:	ISO/IEC 17025:2005 SOP10 Tox Method Validation	Level:	2
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>C 3 b - A validation plan will be developed by the Laboratory Director with the Quality Manger and/or the section Supervisor. In most cases a validation at this level will be minimal, it may include: ...</p>				
Finding:	<p>There was no documented validation plan developed for the volatiles method in toxicology. A thorough validation was conducted without a plan being developed.</p>				
Corrective Action Due By:	On or before first surveillance visit				

**CORRECTIVE ACTION REQUEST (CAR) Number 5 of 40**

Laboratory Name: Connecticut Forensic Science Laboratory  
 Laboratory Location: Meridan, Connecticut  
 Laboratory Contact Name: Kenneth Zercie  
 Contact Number: 203-639-6458  
 Summation Conference Date: September 16, 2011

**FINDING**

Clause No.:	4.2.2.2	Source:	2011 Supplemental-Testing	Level:	2
Requirement:	Has laboratory top management ensured that the <i>ASCLD/LAB Guiding Principles of Professional Responsibility for Crime Laboratories and Forensic Scientists</i> are reviewed annually with all laboratory personnel?				
Finding:	Thirty-three percent of laboratory staff has not been briefed on the <i>ASCLD/LAB Guiding Principles of Professional Responsibility for Crime Laboratories and Forensic Scientists.</i> "				
Corrective Action Due By:	On or before first surveillance visit				

**CORRECTIVE ACTION REQUEST (CAR) Number 6 of 40**

Laboratory Name: Connecticut Forensic Science Laboratory  
 Laboratory Location: Meridan, Connecticut  
 Laboratory Contact Name: Kenneth Zercie  
 Contact Number: 203-639-6458  
 Summation Conference Date: September 16, 2011

**FINDING**

Clause No.:	4.3.2.1 GL-19	Source:	ISO/IEC 17025:2005 Laboratory Quality Manual (LQM)	Level:	1
Requirement:	<p>4.3.2.1 - All documents issued to personnel in the laboratory as part of the management system shall be reviewed and approved for use by authorized personnel prior to issue. A master list or an equivalent document control procedure identifying the current revision status and distribution of documents in the management system shall be established and shall be readily available to preclude the use of invalid and/or obsolete documents.</p> <p>GL-19 - All MSD will be uniquely identified. When possible each page of the document will have a designator in the upper right hand corner which will include the Document ID, Version/Revision number and Revision date.</p>				
Finding:	<p>In the Digital Evidence discipline, the current version numbers of documents in use did not match the version number in the controlled document list. The date of approval was found to be after the issue date in thirty-nine out of forty documents listed. One document was not located although it was listed on the controlled document list. Two official copies of documents with the same revision do not contain the same text. One document did not have the required revision date present on the document.</p>				
Corrective Action Due By:	On or before April 2, 2012				

**CORRECTIVE ACTION REQUEST (CAR) Number 7 of 40**

Laboratory Name: Connecticut Forensic Science Laboratory  
 Laboratory Location: Meridan, Connecticut  
 Laboratory Contact Name: Kenneth Zercie  
 Contact Number: 203-639-6458  
 Summation Conference Date: September 16, 2011

**FINDING**

Clause No.:	4.3.2.2 c 4.3.2.2 c 5(e)	Source:	ISO/IEC 17025:2005 SOP GL1 LQM SOP-GL19 LQM	Level:	1
Requirement:	<p>4.3.2.2 c (ISO) - Invalid or obsolete documents are promptly removed from all points of issue or use, or otherwise assured against unintended use;</p> <p>4.3.2.2 c - Removal of expired, invalid, or obsolete documents. The SOP specifies that Laboratory Section quality managers ensure that expired, invalid, or obsolete documents are removed from points of issue or use when appropriate, or when superseded by new documents.</p> <p>5(e) - The section QM or QMT is responsible for removing the old version of the document and issuing the current version.</p>				
Finding:	<p>Over thirty percent of the laboratory cases reviewed in the Digital Evidence discipline had obsolete forms in use.</p> <p>The method SOP 22 Tox GHB in Toxicology is invalid due to instrumentation replacement. It has not been removed from the point of issue or use.</p>				
Corrective Action Due By:	On or before April 2, 2012				

**CORRECTIVE ACTION REQUEST (CAR) Number 8 of 40**

Laboratory Name: Connecticut Forensic Science Laboratory  
 Laboratory Location: Meridan, Connecticut  
 Laboratory Contact Name: Kenneth Zercie  
 Contact Number: 203-639-6458  
 Summation Conference Date: September 16, 2011

**FINDING**

Clause No.:	4.8.1	Source:	2011 Supplemental-Testing	Level:	1
Requirement:	The laboratory policy and procedure for the resolution of complaints shall cover complaints concerning quality related aspects of the management system submitted by laboratory personnel.				
Finding:	The laboratory policy/procedure regarding complaints (GL-10) does not specifically address a process for internal staff complaints pertaining to quality-related aspects of the management system.				
Corrective Action Due By:	On or before April 2, 2012				

**CORRECTIVE ACTION REQUEST (CAR) Number 9 of 40**

Laboratory Name: Connecticut Forensic Science Laboratory  
 Laboratory Location: Meridan, Connecticut  
 Laboratory Contact Name: Kenneth Zercie  
 Contact Number: 203-639-6458  
 Summation Conference Date: September 16, 2011

**FINDING**

Clause No.:	4.11.1	Source:	ISO/IEC 17025:2005	Level:	1
Requirement:	<p>The laboratory shall establish a policy and a procedure and shall designate appropriate authorities for implementing corrective action when nonconforming work or departures from the policies and procedures in the management system or technical operations have been identified.</p>				
Finding:	<p>The laboratory's policy for its Quality Action Request (QAR) does not give clear direction for what non-conforming work must be entered into the QAR system. Non conforming work which are believed to not be the fault of the laboratory are entered as incidents, but nonconforming work in which laboratory error may have played a part are not always entered into the system. Examples of nonconforming work which were not entered into the system include incorrect proficiency test results or amended reports in which the original conclusion was flawed in some fashion.</p> <p>Not all section supervisors knew the proper persons (laboratory director and quality manager) to notify when a QAR was to be instituted.</p>				
Corrective Action Due By:	On or before April 2, 2012				

**CORRECTIVE ACTION REQUEST (CAR) Number 10 of 40**

Laboratory Name: Connecticut Forensic Science Laboratory  
 Laboratory Location: Meridan, Connecticut  
 Laboratory Contact Name: Kenneth Zercie  
 Contact Number: 203-639-6458  
 Summation Conference Date: September 16, 2011

**FINDING**

Clause No.:	4.13.2.1 4.13.2.5	Source:	ISO/IEC 17025:2005 2011 Supplemental-Testing	Level:	1
Requirement:	<p>4.13.2.1 - The laboratory shall retain records of original observations, derived data and sufficient information to establish an audit trail,</p> <p>4.13.2.5 - Records to support conclusions shall be such that in the absence of the analyst (however named), another competent reviewer could evaluate what was done and interpret the data.</p>				
Finding:	<p>In Forensic Biology, SOP-FB-12 identifies three solutions that can be used for extraction of samples to examine for semen. Review of the examination records does not show documentation of which solution was used for the extractions.</p> <p>SOP-FB-13 identifies two different staining/examination methods for spermatozoa identification. Review of the examination records does not show consistent documentation of which (if any) staining method was used for the examinations.</p>				
Corrective Action Due By:	On or before April 2, 2012				

**CORRECTIVE ACTION REQUEST (CAR)      Number   11   of   40**

Laboratory Name: Connecticut Forensic Science Laboratory  
 Laboratory Location: Meridan, Connecticut  
 Laboratory Contact Name: Kenneth Zercie  
 Contact Number: 203-639-6458  
 Summation Conference Date: September 16, 2011

**FINDING**

Clause No.:	4.13.2.1 4.13.2.5 2.3.3.5	Source:	ISO/IEC 17025:2005 2011 Supplemental-Testing DNA SOP 2	Level:	1
Requirement:	<p>4.13.2.1 - 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.</p> <p>4.13.2.5 - Records to support conclusions shall be such that in the absence of the analyst (however named), another competent reviewer could evaluate what was done and interpret the data.</p> <p>2.3.3.5 - Using a sterile pipette tip, determine the volume of the DNA solution. Document the extract volume on the extraction worksheet. The volume of the RB must not exceed the volume of any sample.</p>				
Finding:	<p>Instances were noted reviewing DNA examination records where elution volumes were not documented in the extraction records to establish an audit trail for the volume conditions of the extraction set.</p>				
Corrective Action Due By:	On or before April 2, 2012				

**CORRECTIVE ACTION REQUEST (CAR) Number 12 of 40**

Laboratory Name: Connecticut Forensic Science Laboratory  
 Laboratory Location: Meridan, Connecticut  
 Laboratory Contact Name: Kenneth Zercie  
 Contact Number: 203-639-6458  
 Summation Conference Date: September 16, 2011

**FINDING**

Clause No.:	4.13.2.2	Source:	ISO/IEC 17025:2005	Level:	1
Requirement:	Observations, data and calculations shall be recorded at the time they are made and shall be identifiable to the specific task.				
Finding:	Instances were noted where elution volumes were typed into the DNA extraction worksheet (DNA QR-2), indicating that these measurements were not recorded at the time they were made as there are no computers in the extraction area.				
Corrective Action Due By:	On or before April 2, 2012				







**CORRECTIVE ACTION REQUEST (CAR)      Number 16 of 40**

Laboratory Name: Connecticut Forensic Science Laboratory  
 Laboratory Location: Meridan, Connecticut  
 Laboratory Contact Name: Kenneth Zercie  
 Contact Number: 203-639-6458  
 Summation Conference Date: September 16, 2011

**FINDING**

Clause No.:	4.14.1	Source:	ISO/IEC 17025:2005	Level:	1
Requirement:	<p>The laboratory shall periodically, and in accordance with a predetermined schedule and procedure, conduct internal audits of its activities to verify that its operations continue to comply with the requirements of the management system and this International Standard. ... Such audits shall be carried out by trained and qualified personnel who are, wherever resources permit, independent of the activity to be audited.</p>				
Finding:	<p>The internal audit for the Identification Laboratory was conducted on December 30, 2010, using the ASCLD/LAB Legacy standards. The Laboratory application for accreditation, under this ISO 17025 standard, was submitted on December 17, 2010. By submitting their application for accreditation, the laboratory was certifying that it was operating under an ISO 17025 Quality Management System; therefore, the Legacy accreditation standards were not applicable at the time the internal audit was conducted.</p> <p>No internal audits have been conducted in 2011 and there is no predetermined schedule or requirement to complete an audit prior to the end of 2011.</p>				
Corrective Action Due By:	On or before April 2, 2012				





**CORRECTIVE ACTION REQUEST (CAR) Number 19 of 40**

Laboratory Name: Connecticut Forensic Science Laboratory  
 Laboratory Location: Meridan, Connecticut  
 Laboratory Contact Name: Kenneth Zercie  
 Contact Number: 203-639-6458  
 Summation Conference Date: September 16, 2011

**FINDING**

Clause No.:	5.2.1.1	Source:	2011 Supplemental-Testing	Level:	1
Requirement:	The laboratory shall have a documented training program that shall be used to train the individual in the knowledge, skills, and abilities needed to perform the testing. The laboratory's management system shall include procedures for retraining and maintenance of skills and expertise.				
Finding:	In Digital Evidence, there is no procedure for re-training, or standards for evaluating the knowledge, skills and abilities of the individuals who undergo training.				
Corrective Action Due By:	On or before April 2, 2012				

**CORRECTIVE ACTION REQUEST (CAR) Number 20 of 40**

Laboratory Name: Connecticut Forensic Science Laboratory  
 Laboratory Location: Meridan, Connecticut  
 Laboratory Contact Name: Kenneth Zercie  
 Contact Number: 203-639-6458  
 Summation Conference Date: September 16, 2011

**FINDING**

Clause No.:	5.2.5 5.2.5 SOP GL15	Source:	ISO/IEC 17025:2005 SOP GL1 LQM LQM	Level:	1
Requirement:	<p>5.2.5 - 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.</p> <p>5.2.5-SOP GL1 - “Professional Development” specifies that the documentation of management authorization to perform specific procedures is maintained in each analysts Professional Development file.</p> <p>SOP GL15</p> <p>A. <u>Professional Development Files:</u></p> <ol style="list-style-type: none"> <li>1. Professional Development files are maintained for all analytical personnel. These files are maintained by the QMT and consist of, at a minimum:                     <ol style="list-style-type: none"> <li>i. Employee’s Statement of Qualifications and CV</li> <li>ii. Documentation of Educational Background</li> <li>iii. Training and Competency testing records (this may be a memo from the section supervisor stating the date training was complete and what the individual was deemed competent in. The full records of the training and competency testing being maintained by the section Quality Manager. Note: DNA section records will be maintained by the DNA Technical Leader.).</li> <li>iv. Training Certificates for courses attended</li> <li>v. Note: A copy of current job descriptions are maintained by the QMT with the professional development files.</li> </ol> </li> </ol>				

Finding:	<p>SOP GL1 states that SOP GL-15 addresses the requirements for authorizations. SOP GL-15 does not address the requirements for authorizations.</p> <p>Authorizations to perform work are not in the Professional Development Files of staff for the following disciplines: Latent Prints, Questioned Documents, Firearms/Toolmarks, Forensic Biology, Trace Evidence, and Digital Evidence. Competency letters were found in a binder not associated with that file.</p> <p>For the Questioned Documents and Latent Prints disciplines the following required records were not present in the Professional Development Files: competency testing records, statements of qualifications, or documentation of educational background were not observed for all examiners.</p>
Corrective Action Due By:	On or before April 2, 2012



**CORRECTIVE ACTION REQUEST (CAR) Number 22 of 40**

Laboratory Name: Connecticut Forensic Science Laboratory  
 Laboratory Location: Meridan, Connecticut  
 Laboratory Contact Name: Kenneth Zercie  
 Contact Number: 203-639-6458  
 Summation Conference Date: September 16, 2011

**FINDING**

Clause No.:	5.4.1 9.6.4.a 9.6.4.b	Source:	ISO/IEC 17025:2005 Quality Assurance Standards Audit for Forensic DNA Testing Laboratories (QAS)	Level:	1
Requirement:	<p>5.4.1 - The laboratory shall use appropriate methods and procedures for all tests and/or calibrations within its scope. These include sampling, handling, transport, storage and preparation of items to be tested and/or calibrated, and, where appropriate, an estimation of the measurement uncertainty as well as statistical techniques for analysis of test and/or calibration data.</p> <p>9.6.4 - Does the laboratory have and follow documented procedures for mixture interpretation to include the following:                      a - Major and minor contributors                      b - Inclusions and exclusions</p>				
Finding:	<p>The laboratory does not have a procedure for distinguishing major and minor contributors of DNA in mixtures and instead relies solely on the calculation of a combined probability of inclusion. Nevertheless, the laboratory does undertake a deconvolution process for the purposes of uploading DNA profiles to CODIS.</p>				
Corrective Action Due By:	On or before April 2, 2012				

**CORRECTIVE ACTION REQUEST (CAR)      Number   23   of   40**

Laboratory Name: Connecticut Forensic Science Laboratory  
 Laboratory Location: Meridan, Connecticut  
 Laboratory Contact Name: Kenneth Zercie  
 Contact Number: 203-639-6458  
 Summation Conference Date: September 16, 2011

**FINDING**

Clause No.:	5.4.1 9.6.4.c	Source:	ISO/IEC 17025:2005 QAS	Level:	1
Requirement:	<p>5.4.1 - The laboratory shall use appropriate methods and procedures for all tests and/or calibrations within its scope. These include sampling, handling, transport, storage and preparation of items to be tested and/or calibrated, and, where appropriate, an estimation of the measurement uncertainty as well as statistical techniques for analysis of test and/or calibration data.</p> <p>9.6.4.c - Policies for reporting results and statistics</p>				
Finding:	<p>There are no directions for interpreting mtDNA mixture results. The mtDNA SOP gives one example for reporting a mixed mtDNA sequence result, but there are no directions for what constitutes a mtDNA mixture or how to interpret such a mixture.</p>				
Corrective Action Due By:	On or before April 2, 2012				



**CORRECTIVE ACTION REQUEST (CAR) Number 25 of 40**

Laboratory Name: Connecticut Forensic Science Laboratory  
 Laboratory Location: Meridan, Connecticut  
 Laboratory Contact Name: Kenneth Zercie  
 Contact Number: 203-639-6458  
 Summation Conference Date: September 16, 2011

**FINDING**

Clause No.:	5.4.1, 5.4.5.1, 5.4.5.3 7.3 7.7	Source:	ISO/IEC 17025:2005  SOP 21-Tox-Volatiles edited	Level:	1
Requirement:	<p>5.4.1 - ....Deviation from test and calibration methods shall occur only if the deviation has been documented, technically justified, authorized, and accepted by the customer.</p> <p>5.4.5.1 - Validation is the confirmation by examination and the provision of objective evidence that the particular requirements for a specific intended use are fulfilled.</p> <p>5.4.5.3 - The range and accuracy of the values obtainable from validated methods (e.g. the uncertainty of the results, detection limit, selectivity of the method, linearity, limit of repeatability and/or reproducibility, robustness against external influences and/or cross-sensitivity against interference from the matrix of the sample/test object), as assessed for the intended use, shall be relevant to the customers' needs.</p> <p>7.3 - Sensitivity: Sensitivity of the method has been documented by performance on the external PT program (CAP, NHTSA, ODOH) between the ranges of 0.02 g/% - 0.30 g/%.</p> <p>7.7 - Linearity: Linearity of the Calibration Curve for the range of 0.0 - 0.3 g/100 ml is evaluated on each instrument run, and is required to be &gt; 0.99 (r**2).</p>				
Finding:	<p>The toxicology laboratory reports ethanol values in excess of 0.30% (both corrected and uncorrected urine values). There are no controls above the 0.30% calibrator and no validation data to indicate the procedure is acceptable above 0.30% for ethanol.</p>				
Corrective Action Due By:	On or before April 2, 2012				

**CORRECTIVE ACTION REQUEST (CAR) Number 26 of 40**

Laboratory Name: Connecticut Forensic Science Laboratory  
 Laboratory Location: Meridan, Connecticut  
 Laboratory Contact Name: Kenneth Zercie  
 Contact Number: 203-639-6458  
 Summation Conference Date: September 16, 2011

**FINDING**

Clause No.:	5.4.1	Source:	ISO/IEC 17025:2005	Level:	1
Requirement:	<p>...The laboratory shall have instructions on the use and operation of all relevant equipment, and on the handling and preparation of items for testing and/or calibration, or both, where the absence of such instructions could jeopardize the results of tests and/or calibrations. All instructions, standards, manuals and reference data relevant to the work of the laboratory shall be kept up to date and shall be made readily available to personnel...</p>				
Finding:	<p>The toxicology discipline does not have sufficient instructions in the SOPs (TOX SOP 23-28). Specifically, the laboratory practice is to dilute blood specimen if the concentration exceeds the value of the calibrator. There are no instructions relating to the dilution of blood samples, when to do it, or what to do if this occurs.</p> <p>The practice in the toxicology discipline is to evaluate the response of blood samples run using the EMIT procedure (TOX SOP 20) that fall below the set cutoff. Blood drug concentrations are typically lower than urine drug concentrations and this evaluation is done due to the higher EMIT cutoff values used for urine specimen. More work may be done based on this evaluation, such as extracting the blood for drug quantitation if the response is elevated above the baseline or negative control. There are no instructions related to this practice in the SOP.</p> <p>The TOX SOP21-Tox-Volatiles was in use and relates to an older piece of equipment (Perkin Elmer Headspace Gas Chromatograph) no longer in use. There was no SOP issued or updated to reflect this new equipment. In addition, other volatile analytes, including acetone, isopropanol, and methanol are reported and quantitated in proficiency cases. These analytes are not reported in casework and there are insufficient instructions in the SOP regarding quantitation of these analytes.</p> <p>SOP-TR-08 (fibers) and SOP-TR-09(paint) in Trace Evidence do not provide instructions on the preparation of samples for instrumental analysis (rolling, diamond cell, on KBr etc). Additionally these procedures do not provide instructions as to when a test should be utilized. A general scheme is provided but the examiner is given discretion to use all or some without instructions of when they should be utilized.</p>				
Corrective Action Due By:	On or before April 2, 2012				

**CORRECTIVE ACTION REQUEST (CAR)      Number   27   of   40**

Laboratory Name: Connecticut Forensic Science Laboratory  
 Laboratory Location: Meridan, Connecticut  
 Laboratory Contact Name: Kenneth Zercie  
 Contact Number: 203-639-6458  
 Summation Conference Date: September 16, 2011

**FINDING**

Clause No.:	5.4.5.2	Source:	ISO/IEC 17025:2005	Level:	1
Requirement:	The laboratory shall validate non-standard methods, laboratory-designed / developed methods, standard methods used outside their intended scope, and amplifications and modifications of standard methods to confirm that the methods are fit for the intended use. The validation shall be as extensive as is necessary to meet the needs of the given application or field of application. The laboratory 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.				
Finding:	With the exception of the volatiles SOP, there is no validation data available for the SOPs being used in toxicology (SOP 23-28). As it relates to the quantitation of specific drugs and drug classes, these SOPs incorporate a single point calibration with two controls. The controls do not bracket the calibrator but fall below it. There is no verification of linearity, sensitivity, or method performance without documented validation of these non-standard methods.				
Corrective Action Due By:	On or before April 2, 2012				

**CORRECTIVE ACTION REQUEST (CAR) Number 28 of 40**

Laboratory Name: Connecticut Forensic Science Laboratory  
 Laboratory Location: Meridan, Connecticut  
 Laboratory Contact Name: Kenneth Zercie  
 Contact Number: 203-639-6458  
 Summation Conference Date: September 16, 2011

**FINDING**

Clause No.:	4.9.1 (a, b) 5.5.7	Source:	ISO/IEC 17025:2005	Level:	1
Requirement:	<p>4.9.1 - The laboratory shall have a policy and procedures that shall be implemented when any aspect of its testing and/or calibration work, or the results of this work, do not conform to its own procedures or the agreed requirements of the customer. The policy and procedures shall ensure that:</p> <p>a) the responsibilities and authorities for the management of nonconforming work are designated and actions (including halting of work and withholding of test reports and calibration certificates, as necessary) are defined and taken when nonconforming work is identified;</p> <p>b) an evaluation of the significance of the nonconforming work is made;</p> <p>5.5.7 - ...The laboratory shall examine the effect of the defect or departure from specified limits on previous tests and/or calibrations and shall institute the "Control of nonconforming work" procedure (see 4.9).</p>				
Finding:	<p>The laboratory does not have a policy in place to cover the investigation of the impact on previous tests regarding pipettes found to be out of tolerance when evaluated by an external calibration agency.</p>				
Corrective Action Due By:	On or before April 2, 2012				

**CORRECTIVE ACTION REQUEST (CAR) Number 29 of 40**

Laboratory Name: Connecticut Forensic Science Laboratory  
 Laboratory Location: Meridan, Connecticut  
 Laboratory Contact Name: Kenneth Zercie  
 Contact Number: 203-639-6458  
 Summation Conference Date: September 16, 2011

**FINDING**

Clause No.:	5.8.4.2.1 E.2.n	Source:	2011 Supplemental-Testing SOP GL13 LQM	Level:	1
Requirement:	<p>5.8.4.2.1 - Laboratory policy concerning evidence in the process of examination/analysis cannot be open-ended and shall be based upon a justifiable expectation of frequent examination/analysis.</p> <p>E.2.n - Active cases are defined as cases assigned or pending assignment for analysis. Case examinations cannot be “open-ended”; meaning they are assigned, have been opened and work has begun on the case. There must be a defined end to the analysis; in general this will be no longer than 6 months from the date of assignment to an analyst supplemental request may follow for re-examinations. There may be exceptions to this, such as the need to have a standard produced for a specific case; this is acceptable as long as the reason is annotated in the case file. Specific time lines for active analysis are designated in section SOPs as required.</p>				
Finding:	<p>There is unsealed evidence in toxicology while being considered as “in process” has not been examined or analyzed for a year or more. This evidence consists of urine or blood specimen waiting for the analysis of GHB. The GHB assay is not currently valid, needs to be validated on a new instrument, and no definite time frame for this procedure has been given; therefore, is open-ended.</p>				
Corrective Action Due By:	On or before April 2, 2012				

**CORRECTIVE ACTION REQUEST (CAR) Number 30 of 40**

Laboratory Name: Connecticut Forensic Science Laboratory  
 Laboratory Location: Meridan, Connecticut  
 Laboratory Contact Name: Kenneth Zercie  
 Contact Number: 203-639-6458  
 Summation Conference Date: September 16, 2011

**FINDING**

Clause No.:	5.9.1 7.1.1.c	Source:	ISO/IEC 17025:2005 QAS	Level:	1
Requirement:	5.9.1 - The laboratory shall have quality control procedures for monitoring the validity of tests and calibrations undertaken.  7.1.1.c - Does the laboratory have and follow a method to distinguish each sample throughout processing?				
Finding:	The laboratory does not have a procedure for uniquely identifying reagent blanks and therefore these cannot always be reliably associated to their test samples.				
Corrective Action Due By:	On or before April 2, 2012				

**CORRECTIVE ACTION REQUEST (CAR) Number 31 of 40**

Laboratory Name: Connecticut Forensic Science Laboratory  
 Laboratory Location: Meridan, Connecticut  
 Laboratory Contact Name: Kenneth Zercie  
 Contact Number: 203-639-6458  
 Summation Conference Date: September 16, 2011

**FINDING**

Clause No.:	4.2.1 5.9.3.1 F3c	Source:	ISO/IEC 17025:2005 2011 Supplemental-Testing SOP GL-16 LQM	Level:	2
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>5.9.3.1 - When participating in proficiency testing programs, the laboratory's own approved test methods shall be used.</p> <p>F3c - dealing with proficiency testing states that "Upon completion of the test and the accompanying report, all worksheets, data, photographs, digital images, electronic files, other documentation and the report from each individual tested must be forwarded to the Supervisor or designee for a final technical review to determine that appropriate examinations and tests were conducted."</p>				
Finding:	<p>There is no objective evidence that proficiency tests conducted in 2011 in Forensic Biology, Questioned Documents, portions of Digital Evidence and Trace Evidence disciplines had a laboratory required technical review conducted.</p>				
Corrective Action Due By:	On or before first surveillance visit				

**CORRECTIVE ACTION REQUEST (CAR)      Number   32   of   40**

Laboratory Name: Connecticut Forensic Science Laboratory  
 Laboratory Location: Meridan, Connecticut  
 Laboratory Contact Name: Kenneth Zercie  
 Contact Number: 203-639-6458  
 Summation Conference Date: September 16, 2011

**FINDING**

Clause No.:	5.9.3.2	Source:	2011 Supplemental-Testing	Level:	1
Requirement:	The laboratory proficiency testing program shall comply with the <i>ASCLD/LAB Proficiency Review Program</i> .				
Finding:	<p>The laboratory has a latent print proficiency test from 2010 that is not in compliance with the Proficiency Review Program. Required remediation has not been submitted to the ASCLD/LAB Proficiency Review Program Manager.</p> <p>Documentation from the laboratory was received, but has not yet been reviewed.</p>				
Corrective Action Due By:	On or before April 2, 2012				

**CORRECTIVE ACTION REQUEST (CAR) Number 33 of 40**

Laboratory Name: Connecticut Forensic Science Laboratory  
 Laboratory Location: Meridan, Connecticut  
 Laboratory Contact Name: Kenneth Zercie  
 Contact Number: 203-639-6458  
 Summation Conference Date: September 16, 2011

**FINDING**

Clause No.:	5.9.3.5 F4 a and I	Source:	2011 Supplemental-Testing SOP GL-16 LQM	Level:	1
Requirement:	<p>5.9.3.5 - The laboratory shall maintain records of proficiency testing...</p> <p>F4 a - The TL, QM or designee shall keep and maintain records as to who analyzed each (proficiency) test; copies of the reports and all supplemental materials.</p> <p>I.</p> <p><b>A. RECORDS:</b></p> <ol style="list-style-type: none"> <li>1. The section Quality Manager shall maintain records of proficiency testing for each DSS Laboratory section, including as a minimum:                             <ol style="list-style-type: none"> <li>a. Test set identifier</li> <li>b. Sample source</li> <li>c. Analyst</li> <li>d. Analysis and completion dates</li> <li>e. All analytical and associated data</li> <li>f. Findings</li> <li>g. Any discrepancies noted</li> <li>h. Documentation of review and feedback for analyst</li> <li>i. Corrective and/or remedial action (if appropriate)</li> </ol> </li> <li>2. Records of Proficiency testing will be maintained for a period of no less than 10 years.</li> </ol>				
Finding:	<p>Completed proficiency test forms and records are not always maintained by the Quality Manager or designee. In the questioned document discipline, proficiency test logs indicate that a series of proficiency tests were given, but these tests were not in the Quality Manager's proficiency test file. There was no designee assigned to keep the tests. Some of the tests were eventually located in questioned documents analyst's office.</p>				
Corrective Action Due By:	On or before April 2, 2012				





**CORRECTIVE ACTION REQUEST (CAR) Number 36 of 40**

Laboratory Name: Connecticut Forensic Science Laboratory  
 Laboratory Location: Meridan, Connecticut  
 Laboratory Contact Name: Kenneth Zercie  
 Contact Number: 203-639-6458  
 Summation Conference Date: September 16, 2011

**FINDING**

Clause No.:	5.9.5 12.3, 12.3.2	Source:	2011 Supplemental-Testing QAS	Level:	1
Requirement:	<p>5.9.5 - The laboratory shall establish a procedure which requires administrative review of the case record prior to the release of each test report. Laboratory policy shall define the scope of the review...</p> <p>12.3 - Does the administrative review include the following elements (any or all of which may be included within the technical-review process):</p> <p>12.3.2 - A review of the chain of custody and disposition of evidence</p>				
Finding:	The laboratory has not defined the requirements for administrative review of DNA cases to include a review of the chain of custody.				
Corrective Action Due By:	On or before April 2, 2012				

**CORRECTIVE ACTION REQUEST (CAR) Number 37 of 40**

Laboratory Name: Connecticut Forensic Science Laboratory  
 Laboratory Location: Meridan, Connecticut  
 Laboratory Contact Name: Kenneth Zercie  
 Contact Number: 203-639-6458  
 Summation Conference Date: September 16, 2011

**FINDING**

Clause No.:	5.9.6 SOP GL-17	Source:	2011 Supplemental-Testing SOP GL-17 LQM	Level:	1
Requirement:	<p>5.9.6 - The laboratory shall have and follow a procedure whereby the testimony of all testifying personnel is monitored on an annual basis. Each individual shall be given feedback, both positive and in any area needing improvement, and the monitoring procedure shall prescribe the remedial action that is to be taken should the evaluation be less than satisfactory.</p> <p>SOP GL-17 - Court monitoring will be performed for each employee during each calendar year in which they testify on a laboratory case....There are three ways in which court monitoring can be performed: a) Witness Evaluation Form... b) Telephone Contact with the attorney... c) Direct Observation.</p> <p>All reviews, whether obtained through direct monitoring, feedback from the courts or interview with the courts, will be reviewed minimally by the section Supervisor and the testifying analyst.</p>				
Finding:	<p>In Latent Prints for 2010, four of the five examiners testified. One examiner who testified, had his testimony monitored via method (b) as listed in GL-17, but the monitoring was not reviewed with the examiner. No documentation of testimony monitoring using one of the three acceptable methods was present for the other three examiners.</p> <p>In Firearms for 2010, the two testifying examiners testified. No documentation of testimony monitoring using one of the three acceptable methods was present for these examiners.</p> <p>In DNA for 2010, there is no documentation that feedback of testimony monitoring was presented to two examiners.</p> <p>In Digital Evidence there is no documentation of testimony monitoring using any of the three acceptable methods in two instances when court testimony was given.</p> <p>In Questioned Documents for 2010, there is no documentation of testimony monitoring using one of the three acceptable methods.</p>				
Corrective Action Due By:	On or before April 2, 2012				

**CORRECTIVE ACTION REQUEST (CAR)      Number   38   of   40**

Laboratory Name: Connecticut Forensic Science Laboratory  
 Laboratory Location: Meridan, Connecticut  
 Laboratory Contact Name: Kenneth Zercie  
 Contact Number: 203-639-6458  
 Summation Conference Date: September 16, 2011

**FINDING**

Clause No.:	5.10.1	Source:	ISO/IEC 17025:2005	Level:	1
Requirement:	The results of each test, calibration, or series of tests or calibrations carried out by the laboratory shall be reported accurately, clearly, unambiguously and objectively, and in accordance with any specific instructions in the test or calibration methods.				
Finding:	The controlled substances discipline conducts an analysis of sub-exhibits such as two bindles out of sixty-two. The results of individual sub-exhibits in controlled substances are reported as “analyzed.” The exhibit of which the sub-exhibits are part are reported as containing controlled substances. The laboratory report is ambiguous and does not clearly indicate that all items were not examined.				
Corrective Action Due By:	On or before April 2, 2012				

**CORRECTIVE ACTION REQUEST (CAR)      Number   39   of   40**

Laboratory Name: Connecticut Forensic Science Laboratory  
 Laboratory Location: Meridan, Connecticut  
 Laboratory Contact Name: Kenneth Zercie  
 Contact Number: 203-639-6458  
 Summation Conference Date: September 16, 2011

**FINDING**

Clause No.:	5.10.1 9.1	Source:	ISO/IEC 17025:2005 QAS	Level:	1
Requirement:	<p>5.10.1 - The results of each test, calibration, or series of tests or calibrations carried out by the laboratory shall be reported accurately, clearly, unambiguously and objectively, and in accordance with any specific instructions in the test or calibration methods.</p> <p>9.1 - Does the laboratory have a documented standard operating procedure for each analytical method used?</p>				
Finding:	<p>There is no laboratory procedure which defines the criteria required to report a DNA profile as insufficient for comparison.</p>				
Corrective Action Due By:	On or before April 2, 2012				

