State of Connecticut - Department of Emergency Services and Public Protection - Division of Scientific Services
ASCLD/LAB International Assessment Response

Clause	Source	Level	Finding	Laboratory Response (Note: all remediations will include a QAR as part of the remediation)	Lead Assessor Plan Accept	
4.1.5.I	ISO/IEC 17025:2005	1	The laboratory has not appointed one person to the position of Quality Manager. A number of staff have been appointed to the position of the same name.	1) One member of the QMT has been appointed as the DSS quality manager (Jane Ridley) 2) The Quality manager will report directly to the Division Laboratory Director 3) The responsibilities of the Division Quality Manager will be detailed in the Quality Manual GL-1	Accept	
4.1.8	ISO/IEC 17025:2005	1	The laboratory has defined top management with a different subset of individuals in two different quality documents.	1) Initiate a change order to update SOPs GL-1 and GL-8 to make the definition of Key and Top management consistent. 2) Re-issue SOPs 3) Hold a laboratory meeting to explain the changes to the SOPs 4) Update Document Control List	Accept	
4.2.1	ISO/IEC 17025:2005	1	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.	1) Initiate change order to update GL-1 section 4.1.5.h.1 (I) to add review all QARs to list of QM responsibilities 2) Initiate change order to update GL-9 to add a definition of QM responsibility to review all QARs 3) Re-issue SOPs 4) QM/QMT to meet with laboratory employees in small groups to review the QAR process	Accept	

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4.2.1 C.3.B	ISO/IEC 17025:2005 and SOP 10 Tox Method Validation		There was no documented validation plan developed for the volatiles method in toxicology. A thorough validation was conducted without a plan being developed.	1) Document the validation plan that represents the plan actually employed to validate the headspace instrument. 2) File this document with the validation documentation for the instrument.	Accept	
4.2.2.2	2011Supple-mental		Thirty-three percent of laboratory staff has not been briefed on the ASCLD/LAB "Guiding Principals of Professional Responsibility for Crime Laboratories and Forensic Scientists."	Issue the ASCLD/LAB "Guiding Principals of Professional Responsibility for Crime Laboratories and Forensic Science" as a read and sign to all laboratory personnel.	Not Accepted-Read does not mean reviewed	**Add: The Division Quality Manager will determine which employees were not in attendance for the meeting held on June 9, 2011 when the document was originally reviewed. The Quality Manager will have a meeting with these employees to review this document by the end of 2011. The QM will ensure that by the end 2011, at least 90% of the active employees will have attended a meeting to review this document.**

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4.3.2.1 GL-19	ISO/IEC 17025 (2005) GL-19	1	In the Digital Evidence discipline, the current version 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 in 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 presented on the document.	1) All current SOP's within the Computer Crimes section will be reviewed and compared to the Controlled Document list. The "Effective Date" on the controlled document list will be updated if necessary, to reflect the "Approved" date located on the corresponding SOP. 2) The "Date Issued" on the controlled document list will be updated , if necessary, to 04-01-2011 for all Rev. 0 SOPs. This date reflects the original issuance of those SOPs. Any SOP's that have a revision date will have a date issued on the controlled document list that reflects the date of the email sent to CCEEL personnel notifying them of the new revision. 3) SOP-CC-33 will be reviewed and re-issued (this was the document in question with one revision date with differing text).	Accept	

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4.3.2.2c, 4.3.2.2.c 5.(e)	ISO/IEC 17025 (2005) SOP GL-1 SOP GL-19	1	Over thirty-nine percent of the laboratory cases reviewed in the Digital Evidence discipline had obsolete forms in use. 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.	**Digital Evidence** 1) A computer crime staff meeting will be held and the following points will be discussed and documented: a. Any Quailty Record (QR) used for case work will be taken from the ISO exteranl storage device at the time the QR is needed. All the current section forms are maintained on the ISO external storage device (the section QM will assure that only the current QR forms are stored here). b. copies of the QR's are not to reside on the examiner's computers. If any are present they must be removed by the analyst. 2. At future staff meetings the QM will inquire to determine if any one is having issues accessing the ISO storage device. 3. Use of proper QR forms will be checked as part of case technical review. **Toxicology**: 1) Initiate change order form to remove SOP TX-22 from points of issue, explain removal to section members 2) add the SOP to the SOP Morgue 3) Update the Document Control list	Digital Evidence Not accepted- Audit required: Toxicology accepted if SOP to be discarded and GHB no longer analysed	**Toxicology: The questioned SOP has been permanently removed from service. GHB is currently not an analyte of this laboratory. The section is validating a new method for the analysis of GHB, based on GCMS analysis of GHB as a TMS derivative.**
4.8.1	2011 Supplemental -Testing	1	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.	1) Initiate a change order to update GL-10 to add a form for the documentation of internal complaints/issues with Quality Related Management System issues and verbiage on the use of the form. 2) Re-issue SOP 3) Hold a laboratory wide meeting to explain the changes 4) Update the Document control list 4) Add outdated SOP to the SOP Morgue.	Accept	

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4.11.1	ISO/IEC 17025 (2005)	1	The laboratory's policy for Quality Action Requests (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 non-conforming work 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. Not all section Supervisors knew the proper persons (laboratory director and quality manager) to notify when a QAR was to be instituted.	1) Initiate a change order to update GL-9 to include a list of items which may require a QAR to be initiated and to include a flow chart of the QAR process. 2) Re-issue the SOP 3) Explain the changes to the SOP as part of small group meetings as listed in response to 4.2.1 to explain the QAR process. 4) Place out of date version of the SOP in the SOP morgue. 5) Update the document control list.	Accept	

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4.13.2.1 4.13.2.5	ISO/IEC 17025 (2005) 2011 Supplemental-Testing	1	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. 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.	1) Update FBQR-02. FBQR-03, FBQR-05 to allow for section personnel to record the extraction solution and stain used during case analysis. 2) Re-issue forms 3) Section meeting to explain the changes	Not Accepted-Audit required	
4.13.2.1 4.12.2.5 2.3.3.5	ISO/IEC 17025 (2005) 2011 Supplemental Testing DNA SOP 2	1	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.	1) Per current procedures extraction volumes are measured and recorded on the extraction worksheet (see SOP-7 DNA analysis worksheets, QR-2 rev 3, dated 9/7/11 and DNA memo dated 3/17/11). 2) A meeting with all DNA personnel will be held to discuss this finding and re-training for documenting extraction volumes. 3) The documented values will be checked as part of the case technical review.	Not accepted-Audit required	

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4.13.2.2	ISO/IEC 17025 (2005)	1	Instances were noted where elution values were typed into the DNA extraction worksheet (DNA QR-2), including that these measurements were not recorded at the time they were made as there are no computers in the extraction area.	1) Initiate change order to amend SOP DNA-2 section 2.3.3.5 to specify that the reagent blank (RB) extraction volume shall be recorded manually on form QR-2. Original extraction volumes determined at the time they were made will be kept in the case file. 2) Re-issue SOP 3) A meeting for all DNA personnel will be held to discuss SOP changes and for re-training. 4) The Document Control list will be updated 5) The manual recording of the extraction volume will be reviewed as part of the case technical review. 6) The out of date SOP will be placed in the SOP morgue for the section.	Not acccepted-Audit required	
4.13.2.2.1	2011 Supplemental -Testing	2	throughout the laboratory, the examination record does not specify the ending date of testing.	1) Initiate a change order to update GL-11 to add a list of what constitutes the beginning and end of analysis for each section and add verbiage that these dates must be part of the case record, either documented in Justice Trax or in the case file. 2) Re-issue the SOP 3) Hold a Laboratory meeting to discuss the changes to the SOP. 4) Update the Document Control List 5) Add out of date copy of the SOP to the SOP morgue.	Not acccepted-Audit required	

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4.13.2.5	2011 Supplemental -Testing	1	In trace evidence, the laboratory does not maintain examination records to support conclusions in the analysis of the origin of animal hairs or human hairs. Only the conclusion is maintained in the examination records. The examination record in the Questioned Documents discipline contained individual writing characteristics which were not present in the questioned documents. The examination record did not support the conclusion.	**Trace**: 1) A change order will be initiated to update SOP TR-06 to include descriptive verbiage to support conclusions in the analysis of the orign of animal hairs or human hairs. 2) Re-Issue SOP 3) Hold section meeting to explain the changes to the SOP 4) Proper case documentation will be assessed as part of the technical review for each case. 4) Update the Document Control list 5) Add an out of date copy of the SOP to the SOP morgue. **Questioned Documents**: 1) Revise worksheet QR DOC-2 to properly identify individual charecteristics to the proper submissions and worksheets. 2) Issue worksheet 3) Section meeting to discuss change and use of form 4) Technical review of each case will include the proper use of the revised worksheet.	Not acccepted-Audit required	
4.13.2.5.2	2011 Supplemental -Testing GL-1	1	The instrument parameters for the Shimadzu gas chromatograph used for the analysis of blood alcohol concentrations in the toxicology discipline are not recorded.	1) Initiate a change order to update SOP TX-21 to include the instrument parameters for the volatiles method. 2) Re-issue the SOP 3) Section meeting to explain the changes to the SOP 4) Update the Document Control list 5) Add out of date copy of the SOP to the SOP morgue.	Not acccepted-Audit required	

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4.14.1	ISO/IEC 17025 (2005)	1	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 and ISO 17025 Quality Management System: therefore the Legacy Accreditation standards were not applicable at the time the internal audit was conducted. No internal audits have been conducted on 2011 and there is no predetermined schedule or requirement to complete an audit prior to the end of 2011.	1) Perform Internal audit using ASCLD/LAB International requirements 2) Follow-up on findings as appropriate Note: Predetermined schedule is part of the AUDIT SOP GL-7 "i. Schedule audits annually to assure that they are completed by the anniversary date of the ASCLD/LAB accreditation (no sooner than 10 months from prior audit unless deemed necessary)." 3) Division QM to assure use of proper ASCLD/LAB criteria/documents for future audits.	Accept	

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4.15.1	ISO/IEC 17025 (2005)	1	Not all of the lab top management was present at the management review conducted by the laboratory. The administrator of the laboratory was not present.	1) Perform Management System Review 2) Follow-up on findings as appropriate 3) File documentation as appropriate	Plan not clear-when will this mgmt review take place-in the next three months?	Add: The Management System Review will be performed in November of 2011 upon completion of the internal ASCLD/LAB International audit. This will be performed by Key management. Per SOP GL-1 Quality Manual defines Key Management as: "Key managerial personnel include the Laboratory Division Director and the Laboratory Directors. (At this time this is Ken Zercie and Dr Powers) Per GL-8 Management System Reviews section C. "a. A review of the Management System will be performed annually (no earlier than 10 months from the previous years review, no more than 12 months following) by the Laboratory's key management. When possible the review will be performed to include members of the QMT and section Supervisors (i.e. FSE 3 or Sgt) and other employees at the discretion of key management."

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5.1.3.1	2011 Supplemental Testing	1	Records for the acid phosphatase reagent do not indicate that the reagent worked as expected when its reliability was tested. Laboratory documentation does not define the performance expectations for the reagent during the reliability testing. A panel of know standards is used to test the reagent, some standards give a negative reaction when first tested, but gradually change to a positive over time. The acceptance criterion is not defined.	1) Initiate a change order to update SOP FB-25. Documentation to be added to the SOP to define the acceptable criteria for Acid Phosphatase. The reagent log sheet will include a check to demonstrate that the criteria was meet and that the reagent is acceptable for use. 2) Re-issue SOP 3) Have a section meeting to review the changes to the SOP 4) Update the Document Control list 5) Add a copy of the out of date SOP to the SOP morgue.	Not accepted-Audit required	
5.2.1.1	2011 Supplemental Testing	1	In Digital Evidence, there is no procedure for re-training, or standards for evaluation the knowledge, skills and abilities of the individuals who undergo training.	1) Initiate a change order to update the training SOP CC-25 to include guidance on when re-training may be appropriate and how to evaluate skills and abilities to those being trained. 2) Re-issue SOP 3) Section meeting to discuss the changes 4) Add out of date SOP to SOP morgue 5) Update document control list	Accepted	

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5.2.5 5.2.5 GL-15	ISO/IEC 17025 (2005) GL-1 LQM	1	SOP GL-1 states that Gl-15 addresses the requirements for authorizations. SOP GL-15 does not address the requirements for 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. For the Questioned Documents and Latent Prints disciplines the following records were not present in the Professional Development Files; competency testing records, statements of qualifications, or documents of educational background were not observed for all examiners.	1) Initiate change orders for updates to a) GL-15 to include authorization letters as part of the Professional Development File b) GL-1 to address how detailed Authorization letters should be and c) GL-1 what should be maintained by in the professional development files and how the files should be maintained. 2) Re-issue SOPs 3) Review changes to the SOPs with laboratory staff 4) Update the Document Control list 5) File copy of the out of date SOPs in the SOP morgue 6) Review all Professional Development Files to ensure that the items listed in GL-15 are included in the files for each analyst.	Accepted	

Clause	Source	Level	Finding	Laboratory Response (Note: all remediations will include a QAR as part of the remediation)	Lead Assessor Plan Accept	
5.2.6.2.1 5.2.6.2.1	2011 Supplemental Testing SOP Gl-1 LQM	1	Two examiners who are conducting examinations in Digital Evidence did not complete competency tests prior to assuming casework responsibility.	1) The 2 examiners in question will contact their former employers to obtain letters of qualification for the discipline. 2) These letters will be forwarded to the Laboratory Director for his review if acceptable the Laboratory Director will write authorization letters to continue casework in the area of Audio analysis.	Not accepted-Letters of authorization are not a substitute for a competency test in each category of testing	Previously analyzed proficiency case files will be reviewed for each of the two analysts in question. The Division Laboratory Director and the Division Quality Manager will review the files and use these as the basis for determining competency. The files will be reviewed to determine if laboratory procedures were followed, if the case file is properly documented and if the findings were acceptable per the test provider demonstrating that there was successful completion of the test.
5.4.1 9.6.4.a 9.6.4.b	Iso/IEC 17025 (2005) QAS Audit for Forensic DNA Testing Laboratories	1	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. Nerveless the laboratory does undertake a deconvolution process for the purpose of uploading DNA profiles and CODIS.	1) The laboratory will validate and implement as apropriate, a procedure for the statistical evaluation of DNA mixtures consistent with standard 5.4.1 2) The SOP will be issued to all section analysts 3) Training will occur as appropriate on the procedure 4) The Document Control List will be updated	Proposal unclear-what is meant by "as aporpriate"	In response 1) As appropriate means that the procedure will be performed for cases were the specification set forth in the SOP have been met, leading the examiner to perform this procedure. In response part number 3) as appropriate means that appropriate training procedures will be used to assure that all analysts are trained and competent in the procedure; this training will be documented.

Clause	Source	Level	Finding	Laboratory Response (Note: all remediations will include a QAR as part of the remediation)	Lead Assessor Plan Accept	
5.4.1 9.6.4.c	ISO/IEC 17025 (2005) QAS Audit for Forensic DNA Testing Laboratories	1	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.	1) Initiate a change order to include mixture interpretation guidlelines to SOP mtDNA-09, section 9.7 2) Re-issue the SOP 3) Review changes during a section meeting 4) Update the Document Control list 5) Add a copy of the out of date SOP to the SOP morgue.	Accept	
5.4.1	SO/IEC 17025 (2005)	1	The laboratory uses a method for the statistical evaluation of mixtures known as an unrestricted combined probability of inclusion (CPI). In applying this method, the lab does not account for the possibility that peaks in stutter position, which are below the laboratory's locus-specific stutter thresholds, may include contributions of DNA from contributors to the mixture. In addition the lab does not account for the possibility of allelic dropout in mixtures with peaks below a stochastic threshold.	1) The laboratory will validate and implement a procedure for the statistical evaluation of DNA mixtures consistent with standard 5.4.1 2) The SOP will be issued to all section analysts 3) Training will occur as appropriate on the procedure 4) The Document Control List will be updated	Proposal unclear-what is meant by "as appropriate"	As appropriate here is purely excessive wording and can be re-moved. Item 3 reworded to read, Training will occur for those section employees who will be responsible to perform statistical evaluation of DNA Mixtures. All training will be documented.

Clause	Source	Level	Finding	Laboratory Response (Note: all remediations will include a QAR as part of the remediation)	Lead Assessor Plan Accept	
5.4.1 5.4.5.1 5.4.5.3 7.3 7.7	ISO/IEC 17025 (2005) SOP-21 Tox Volatiles edited	1	The toxicology laboratory reports ethanol values in excess of 0.30% (both corrected and uncorrected urine values). There are no controls above the 0.3% calibrator and no validation data to indicate the procedure is acceptable above 0.30% for ethanol.	1) Perform linearity testing to 0.5g%, include this data as part of the validation of the method. 2) Initiate a change order to update the SOP to include the use of a 0.5g% control in each analytical batch 3) Re-issue the SOP 4) Have a section meeting to review the changes to the SOP 5) Update the Document Control list 6) Add a copy of the out of date SOP to the SOP morgue. 7) The use of the 0.5g% control will be documented as part of each volatile batch.	Not accepted-audit required	

Clause	Source	Level	Finding	Laboratory Response (Note: all remediations will include a QAR as part of the remediation)	Lead Assessor Plan Accept	
5.4.1	ISO/IEC 17025 (2005)		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.	1) Initiate a change order to update SOPs TX-23-28. The updates will include a statement on how/when to dilute samples when they are above the highest calibrator. 2) Re-issue SOP 3) Have a section meeting to review the SOP changes 4) Update the Document Control list 5) Add a copy of the out of date SOP to the SOP morgue.	Accept	

Clause	Source	Level	Finding	Laboratory Response (Note: all remediations will include a QAR as part of the remediation)	Lead Assessor Plan Accept	
			The practice in the toxicology discipline is to evaluate the response of blood samples run using EMIT procedure (TOX SOP20) 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.	1) Initiate a change order for SOP TX-20. This will be amended to add a statement on how to evaluate EMIT findings when the sample is a blood sample, identifying when specific follow up is needed. 2) Re-issue the SOP 3) Have a section meeting to explain the change to the SOP 4) Update the Document Control list 5) Add a copy of the out of date SOP to the SOP morgue. 6) Proper assessment of EMIT screen for blood samples will be reviewed as part of the final case review performed in general by the Laboratory Director or section Supervisor.	Not accepted-audit required	

Clause	Source	Level	Finding	Laboratory Response (Note: all remediations will include a QAR as part of the remediation)	Lead Assessor Plan Accept	
			The TOX SOP 21 Tox Volatiles was in use and relates to an older piece of equipment (Perkin Elmer Headspace Gas Chromatograph) no longer in use. There is no SOP issued or updated to reflect this new equipment. In addition, other volatile analytes, including acetone, isopranol 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.	1) Initiate a change order for SOP TX-21. This will include instructions on how to calculate volatiles other than ethanol with this method. 2) Re-issue the SOP 3) Have a section meeting to explain the change to the SOP 4) Update the Document Control list 5) Add a copy of the out of date SOP to the SOP morgue. 6) Quantitative results for volatiles other than ethanol are not reported in normal laboratory cases, they are reported only for proficiency cases. Proper calculations will be demonstrated in achieving accurate results on such proficiency cases.	Accept	
			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.	1) Initiate a change order to update SOPs TR-08 and TR-09 to include guidance on sample preparation and instruction on when the use of specific techniques are indicated. 2) Re-issue the SOPs 3) Have a section meeting to explain the changes to the SOPs 4) Update the Document Control list 5) Add a copy of the out of date SOP to the SOP morgue.	Accept	

Clause	Source	Level	Finding	Laboratory Response (Note: all remediations will include a QAR as part of the remediation)	Lead Assessor Plan Accept	
5.4.5.2	ISO/IEC 17025 (2005)	1	With the exception of the volatiles SOP there is no validation data available for the SOPs being used in Toxicology (SOP 23028). As it relates to the quantitation of specific 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.	1) Validation plans will be developed for the methods employed in SOPs TX 23-28 2) Perform the validations and create a validation book for the data 3) Update the SOPs if required based on the validation data 4) Re-issue the SOPs 5) Hold a section meeting to review any changes to the SOPs 6) Update the Document Control List 7) Add a copy of the out of date SOP to the SOP morgue.	Accept	

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4.9.1 (a,b) 5.5.7	ISO/IEC 17025 (2005)	1	The laboratory does not have a policy in place to cover the impact on previous tests regarding pipettes found to be out of tolerance when evaluated by an external calibration agency.	1) Determine what sections use pipettes in a manner where the true value of the pipette effects the validity of the testing. Note: This first step was adressed and it is found that only the Toxicology and Controlled Substances sections use pipettes for measurements that matter. Pipettes are used in the DNA and Forensic Biology sections for procedures where the pipette acuracy does not have a significant affect on the result. **Toxicology**: 1) Initiate a change order to update SOP TX-14 to add guidance on how to review calibration certificates and what to do if the "as found" condition is out of acceptable range. 2) Re-issue the SOP 3) Have a section meeting to explain the change to the SOP 4) Update the Document Control list 5) Add a copy of the out of date SOP to the SOP morgue. **Controlled Substances**: 1) Initiate a change order to update SOP CS-6 to add guidance on how to review calibration certificates and what to do if the "as found" condition is out of acceptable range 2) Re-issue the SOP 3) Have a section meeting to explain the change to the SOP 4) Update the Document Control list 5) Add a copy of the out of date SOP to the SOP morgue.	Not Accepted- I expect to see a CAR on situation as found additionally QAS 10.2.1.8 says mechanical pipettes are critical you need to review your response with that in mind.	Add: 1) A QAR will be performed to investigate any pipettes where the "as found" condition was not acceptable for all sections. The DNA section will review the QAS document and 1.Write a policy on mechanical pipettes including what to do if the "as found" condition of a pipette is out of acceptable range. 2. The SOP will be re-issued 3. A section meeting will be held to explain the change to the SOp 4. the document control list will be updated 5. A copy of the out of date SOP will be added to the SOP morgue.

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5.8.4.2.1 E.2.n	2011 Supplemental Testing SOP GL-13 LQM	1	There is unsealed evidence in Toxicology while being considered as "in process" has not been examined or analyzed for a year or more. The 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.	1) Meet with Toxicology section to remind them that cases will be sealed while waiting further analysis as per SOP GL-13, document the meeting 2) Note: All items in question have been sealed.	Not accepted unless audit was performed	Add: As part of the Internal Audit performed in October 2011 this evidence was reviewed and found to be sealed in the locked refrigerator of the Toxicology section. Quality Manager/ Audit Team member Jack Hubball performed this review. Also the QAR associated with this issue includes a check of the evidence to assure that all items are sealed.
5.9.1 7.7.1c	Iso/IEC 17025 (2005) QAS Audit for Forensic DNA Testing Laboratories	1	The laboratory does not have a procedure for uniquely identifying reagent blanks and therefore these cannot always be reliably associated to their test samples.	1) Initiate a change order to update SOP DNA-1 section 1.6.5 Labeling of controls to include "Each Reagent Blank and RKO (Positive Control) extraction tube will be labeled with a unique identifier that is documented on QR-2, DNA extraction worksheet - such as date and initials" 2) Re-issue the SOP 3) Have a section meeting to explain the change to the SOP 4) Update the document control list 5) Add a copy of the out of date SOP to the SOP morgue 6) Case technical reviews will include a review of the proper documentation of the reagent blank and positive	Not Accepted-Audit required	

Clause	Source	Level	Finding	Laboratory Response (Note: all remediations will include a QAR as part of the remediation)	Lead Assessor Plan Accept	
4.2.1 5.9.3.1 F3c	ISO/IEC 17025 (2005) 2011 Supplemental Testing SOP GI-16 LQM	2	There is no objective evidence that proficiency tests conducted in 2011 in Forensic Biology, Questioned Documents, portions of the Digital Evidence and Trace disciplines had a laboratory required technical review conducted.	1) Sections will be reminded that technical reviews are to be performed on proficiency cases, even in cases where each person in the section has been assigned the same proficiency. 2) When possible the proficiency tests will be purchased so that they are staggered so if there are only 2 analysts competent in the discipline they can technically review the proficiency without conflict. 3) 2011 proficiency cases that have been completed will be forwarded to the appropriate individuals for technical review. 4) The Quality Manager will assure that proficiency cases are technically reviewed. Note: this links to the remediation for 5.9.3.5	Accepted	
5.9.3.2	2011 Supplemental Testing	1	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. Documentation from the laboratory was received, but has not yet been reviewed.	1) Competent examiner's from Rhode Island reviewed case work performed by the two examiners in question. 2) Submitted a letter to the Proficiency Review Board with documentation on the remediation. Note: The laboratory has received a letter from Patti Williams of the PRC accepting the laboratories remediation of the proficiency.	Accepted as Completed	

Clause	Source	Level	Finding	Laboratory Response (Note: all remediations will include a QAR as part of the remediation)	Lead Assessor Plan Accept	
5.9.3.5 F4a and I	2011 Supplemental Testing SOP GL-16	1	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 are 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.	1) A laboratory meeting will be held to review what to do with completed proficiency files. (Upon completion of proficiency tests, primary examiner will deliver the case to the technical reviewer upon technical review the proficiency test will be delivered to the section Quality Manger) 2) The meeting will be documented and records maintained by QM.	Not Accepted-Audit required	
5.9.3.3	2011 Supplemental Testing	1	An analyst that works in both the Forensic Biology discipline and the Trace Evidence discipline did not complete a proficiency test in the Trace Discipline (hair analysis and comparison) in 2010 and 2011.	1) New proficiencies will be ordered for human hair/microscopic comparision for 2012. 2) An internal human hair/microscopic comparision proficiency test will be created by Trace section personnel, administered and reviewed prior to December 31, 2011.	Accept	

Clause	Source	Level	Finding	Laboratory Response (Note: all remediations will include a QAR as part of the remediation)	Lead Assessor Plan Accept	
5.9.4.2	ISO/IEC 17025 (2005)	1	The analyst, who performs technical reviews on fire debris cases, does not have fire debris casework experience.	1) The individual currently performing the duty of Technical Reviewer for fire debris cases will be fully trained in the section methods 2) The trainee will take a competency test and perform case work in the discipline.	Not accepted- who is performing the technical review during the present period?	The Laboratory has contacted an analyst proficient in Arson/Fire Debris case analysis from an ISO certified Laboratory to perform the technical reviews until the analyst in training is competency tested and approved by the Division Laboratory Director to perform case work in the discipline. This individual will look at all new arson/fire debris case files and those technically reviewed by the individual in question (these are cases in the date range of 2009 - 2011). The proficient analysts qualifications will be included as part of the QAR for this criteria remediation.
5.9.5 12.3 12.3.2	2011 Supplemental Testing QAS	1	The laboratory has not defined the requirements for administrative review of DNA cases to included a review of the chain of custody.	1) Initiate a change order to update SOP DNA-1 section 1.10 to add guidance on administrative reviews to include a review of the chain of custody. This review is documented on the DNA QA/QC casework checklist QR-4 2) Re-issue the SOP 3) Have a section meeting to review the changes to the SOP 4) Update the Document Control list 5) Add a copy of the out of date SOP to the SOP morgue.	Accept	

Clause	Source	Level	Finding	Laboratory Response (Note: all remediations will include a QAR as part of the remediation)	Lead Assessor Plan Accept	
5.9.6 SOP GL-17	2011 Supplemental Testing SOP GL-17 LQM	1	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 by the examiner. No documentation of testimony monitoring using one of the three acceptable methods was performed for the other three analysts. In Firearms for 2010 the two testifying examiners testified. No documentation of testimony monitoring using one of the three acceptable methods was present for there examiners. In DNA for 2010 there is no documentation that feedback of testimony monitoring was presented to two examiners. In digital evidence there is no documentation of testimony using any of the three acceptable metheds in two instances when court testimony was given. In Questioned Documents for 2010 there is no documentation of testimony monitoring using on of the three acceptable methods.	1)Review court records to determine who has not been reviewed 2) For individuals not reviewed find out if they testified and what court they testified in and on what case 3) Follow-up with courts and attorney's to see if a review can be obtained 4) Any reviews obtained will be reviewed with the analyst and documented per SOP GL-17 5) Court monitoring documents will be tracked and maintained by the division QM.	Accept	

Clause	Source	Level	Finding	Laboratory Response (Note: all remediations will include a QAR as part of the remediation)	Lead Assessor Plan Accept	
5.10.1	ISO/IEC 17025:2005	1	The controlled substance 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.	1) Initiate a change order to update SOP CS-1 to add verbiage on how to word reports to describe which items were tested to include from the total number of items submitted. 2) Re-issue the SOP 3) Have a section meeting to explain the change to the SOP 4) Update the Document Control list 5) Add a copy of the out of date SOP to the SOP morgue. 6) The technical review of each case will include the review of proper wording to describe which items were tested of the group of items.	Accepted if reporting mechanism is locked in place-if not audit required	Controlled Substance Report wording regarding the total number of items submitted is "free text." We understand that our use of the modified report wording will require evaluation.