

Maryland State OHCQ Forensic Survey Checklist- Discipline: Latent Prints

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<p>10.51.04.01 A Proficiency Testing. Each year a licensee shall participate in an external proficiency testing program for each forensic science discipline in which the laboratory performs forensic tests and examinations, including but not limited to:</p> <ul style="list-style-type: none"> (1) Firearms and toolmarks; (2) Questioned documents; (3) Latent prints; (4) Trace evidence; (5) Biology; (6) Controlled dangerous substances; and (7) Toxicology. 						
<p>10.51.04.01 B1 a-b Proficiency Testing Performance and Participation Requirements.</p> <p>(1) Annually, a forensic analyst shall:</p> <ul style="list-style-type: none"> (a) Participate in a proficiency test for each discipline for which the forensic analyst is qualified to perform tests or examinations for casework; and (b) Perform the proficiency testing analysis using the same methods and procedures routinely used for performing the forensic analysis of casework. 						
<p>10.51.04.01 B2 Proficiency Testing Performance and Participation Requirements.</p> <p>(2) For each subdiscipline for which a forensic analyst performs casework, the forensic analyst shall perform proficiency testing at least once in the 3-year license period or if applicable within the required time period outlined by the accreditation organization.</p>						
<p>10.51.04.01 C1 Proficiency Testing Performance, Participation Schedule, and Documentation. The quality assurance manager or technical leader, as designated by the director, shall:</p> <ul style="list-style-type: none"> (1) Establish a formal, written proficiency testing protocol covering both external and internal proficiency tests for each forensic science 						

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discipline and subdiscipline in which the laboratory performs tests and examinations;						
10.51.04.01 C2 Proficiency Testing Performance, Participation Schedule, and Documentation. The quality assurance manager or technical leader, as designated by the director, shall: (2) Document and maintain all records of proficiency testing and results for each individual forensic analyst required to participate in proficiency testing.						
10.51.05.01 A [. . . the forensic laboratory:] A. Establishes and follows policies and procedures for a comprehensive quality assurance program designed to monitor and evaluate the ongoing and overall quality and safety of the total examination and forensic analysis process;						
10.51.05.01 B1-4 [. . . the forensic laboratory:] B. Maintains a quality assurance program that: (1) Continually evaluates the effectiveness of the laboratory's policies and procedures; (2) Routinely revises policies and procedures based on the results of ongoing evaluation; (3) Identifies and corrects problems; (4) Assures: (a) Accurate, complete, and reliable reporting of results of examinations and analyses; (b) Technical procedures are validated and are accepted practice in the forensic discipline; and (c) Adequate and competent employees;						
10.51.05.01 B5-6 [. . . the forensic laboratory:] B. Maintains a quality assurance program that: (5) Requires documentation of all quality assurance and quality control activities; and (6) Includes policies and procedures for: (a) Handling and preservation of evidence;						

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(b) Calibration and maintenance of equipment; (c) Handling, maintaining, and securing laboratory records including case records and reports; (d) Evaluation and approval of employees; (e) Laboratory security; (f) Identifying and implementing corrective actions; (g) Documenting and investigating complaints; (h) The operation of individual characteristic databases, where appropriate; and (i) Data integrity and ethics;						
10.51.05.01 C1-3 [. . . the forensic laboratory:] C. Develops and maintains: (1) An organizational chart of all employees; (2) Job requirements and a job description for each contractor; and (3) Employee records that include, but are not limited to: (a) Job requirements and a job description for each employee; (b) Educational background and qualifications; (c) Curriculum vitae; (d) Court testimony evaluations and a record that the evaluations are reviewed with each examiner and analyst; (e) Documentation of successful completion of a training program set forth by the laboratory, including competency testing; (f) Authorization to perform independent casework; and (g) Performance evaluations;						
10.51.05.01 D [. . . the forensic laboratory:] D. Establishes and maintains a forensic laboratory safety program;						
10.51.05.01 E [. . . the forensic laboratory:] E. Employs appropriately trained employees and possesses equipment to conduct the scope of forensic services offered;						

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10.51.05.01 F [. . . the forensic laboratory:] F. Maintains reference literature in physical or electronic form that covers all disciplines and subdisciplines for which services are offered;						
10.51.05.01 G [. . . the forensic laboratory:] G. Designates an individual as the quality assurance manager ;						
10.51.05.01 H [. . . the forensic laboratory:] H. Defines and maintains a document retention policy ;						
10.51.05.01 I [. . . the forensic laboratory:] I. Maintains a facility that is designed to ensure the integrity of the forensic analyses and the evidence;						
10.51.05.01 J1-2 [. . . the forensic laboratory:] J. Conducts: (1) Administrative review of all cases and reports before issuing a report; and (2) Technical review , of no less than 5 percent of cases as determined by the laboratory director or designee, to ensure conclusions and supporting data are within the constraints of scientific knowledge; and						
10.51.05.01 K1-2 [. . . the forensic laboratory:] K. Establishes a mechanism to: (1) Address unresolved discrepant conclusions between an analyst and the technical reviewer; and (2) Require that unresolved discrepancies are documented in: (a) The case record; and (b) Any other laboratory document as determined by the director.						
10.51.05.02 A1 QA — Specific A. A licensee shall develop, establish, maintain, implement, and follow quality assurance policies and procedures that ensure that the laboratory’s quality system is maintained. (1) A licensee shall ensure that the laboratory has a clear procedure describing the process to:						

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(a) Uniquely identify evidence; (b) Determine and identify workflow; and (c) Assign and prioritize work.						
10.51.05.02 A2 QA — Specific (2) Chain of Custody. The licensee shall: (a) Maintain a record of chain of custody in written or electronic form in order to maintain accurate tracking of all evidence; and (b) Document each transfer of evidence with the date of transfer and the signature of the person receiving the evidence at the time of transfer.						
10.51.05.02 B1 B. Identifying and Handling Evidence. A licensee shall: (1) Ensure that each item of evidence received by the forensic laboratory: (a) Is permanently marked and includes a unique identifier either on the: (i) Evidence itself; or (ii) Proximal container of the evidence; and (b) Has a documented record that includes the: (i) Identity of the evidence submitter; (ii) Date the item of evidence was submitted; and (iii) Description of the item of evidence submitted;						
10.51.05.02 B2 [Licensee Handling Evidence] (2) Establish and follow a procedure to identify evidence that cannot be marked or identified as set forth in §B(1) of this regulation;						
10.51.05.02 B3 [Licensee Handling Evidence] (3) Ensure all items produced during a forensic analysis or examination are: (a) Marked with a unique identifier that can be traced back to the original evidence; (b) Appropriately packaged; (c) Documented in case notes, reports, and the evidence tracking						

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system; and (d) Packed with the original evidence when applicable or a disposition will be noted;						
10.51.05.02 B4 [Licensee Handling Evidence] (4) Ensure documentation of the date of receipt of each test item and evidence;						
10.51.05.02 B5 [Licensee Handling Evidence] (5) Establish, maintain , and follow a procedure to define proper packaging and sealing of evidence requiring that: (a) Evidentiary seals: (i) Are initialed or marked by the person sealing the evidence; and (ii) Prevent the evidence from being removed, lost, altered, or contaminated; and (b) Evidence is protected from: (i) Loss; (ii) Cross-contamination; and (iii) Any harmful change;						
10.51.05.02 B6 [Licensee Handling Evidence] (6) Consider evidence containers properly sealed only if: (a) The contents cannot readily escape; and (b) Entering the container results in obvious damage or alteration to the container or the container's seal; and						
10.51.05.02 B7 [Licensee Handling Evidence] (7) Clearly mark an item that is not evidence but is stored in an evidence storage area .						
10.51.05.02 C1 C. Deficiencies, Errors, and Corrective Actions. A licensee shall have: (1) A procedure for corrective actions to be taken when a deficiency or error is identified with: (a) A forensic analysis procedure or method; or (b) The casework or proficiency testing of a forensic analyst or examiner; and						

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<p>10.51.05.02 C2 [. . . Corrective Actions. . . A licensee shall] (2) The procedure and required documentation for the corrective actions include: (a) A determination of the cause of the deficiency or error; (b) An evaluation of the deficiency or error to determine if the deficiency or error causes or has caused an adverse effect on the quality of a forensic analysis; (c) An indication of the individual responsible for corrective action; (d) A timeline of corrective action or actions; and (e) Verification that the corrective action was: (i) Implemented; and (ii) Monitored effectiveness in correcting the deficiency or error.</p>						
<p>0.51.05.02 D D. A licensee shall designate a quality assurance manager to oversee and ensure that the quality assurance program is implemented, maintained, and routinely evaluated.</p>						
<p>10.51.05.02 E E. A licensee shall ensure that a change to an entry on an examination document, whether written or electronic, is: (1) Trackable to the person who made the change; and (2) Not erased, hidden, obscured, disguised, or obliterated.</p>						
<p>10.51.05.02 F F. A licensee shall establish and follow a procedure to document any: (1) Evidence discrepancies; (2) Compromise of evidence integrity; or (3) Lost or misplaced evidence.</p>						
<p>10.51.05.02 G G. A licensee shall document all quality assurance and quality control activities as set forth in this subtitle.</p>						

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<p>10.51.05.02 H H. A licensee shall establish a procedure to: (1) Investigate, resolve, and document a forensic analysis discrepancy; and (2) Allow for a request and approval from the director or designee for a deviation from standard operating procedures.</p>						
<p>10.51.05.02 I Public Record. (1) A licensee shall establish and follow a procedure to make discrepancy logs, contamination records, and test results available to the public within 30 days of a written request. (2) A contamination record shall include the following information: (a) Unique case identifier; (b) Encoded sample identification; (c) Description of results; and (d) Identifiers that led to an incident report.</p>						
<p>10.51.05.04 A1 Quality Control Program. A. A licensee shall: (1) Develop, establish, maintain, implement, and follow quality control policies and procedures that ensure accurate and reliable: (a) Forensic analysis results; and (b) Case reports;</p>						
<p>10.51.05.04 A2 QC Program. A. A licensee shall: (2) Ensure that all quality control activities set forth in this chapter are documented;</p>						
<p>10.51.05.04 A3 QC Program. A. A licensee shall: (3) Ensure that the quality control program is able to detect shifts and trends that could result in an adverse impact on the quality of forensic analysis results;</p>						

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<p>10.51.05.04 A4 QC Program. A. A licensee shall: (4) Ensure that quality control data are evaluated routinely and when found to be contaminated, out of range, incorrect, or otherwise unacceptable: (a) Corrective actions are taken; and (b) Incorrect results are not reported;</p>						
<p>10.51.05.04 A5 QC Program. A. A licensee shall: (5) Ensure that quality control material and reference standards are specified in the SOPM and the results of quality control testing are documented in the case record;</p>						
<p>10.51.05.04 A6 QC Program. A. A licensee shall: (6) Ensure that a reagent used for a forensic analysis: (a) Is tested for reliability before being put into use; (b) Is identified with the: (i) Name of the reagent; (ii) Lot number or date the reagent was prepared; and (iii) Expiration date; (c) Is checked for reliability on a cycle determined by the technical leader; (d) Has a record documenting: (i) Who prepared the reagent; and (ii) Completion of a reliability check before use; and (e) Has storage, safety, and handling requirements specified;</p>						
<p>10.51.05.04 A7 QC Program. A. A licensee shall: (7) Ensure that a reagent that is not used for a forensic analysis on a regular basis is tested for reliability before each use;</p>						

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<p>10.51.05.04 A8 QC Program. A. A licensee shall: (8) Discard a reagent, make a new reagent, and check the new reagent's reliability before any casework being performed, if the reagent reliability is found to be compromised;</p>						
<p>10.51.05.04 A9 QC Program. A. A licensee shall: (9) Use reagents that are suitable for the forensic analysis methods employed;</p>						
<p>10.51.05.04 A10-11 QC Program. A. A licensee shall: (10) Have procedures for tracking the receipt and use of commercial reagents; (11) Have procedures for the formulation of in-house reagents in the SOPM; and</p>						
<p>10.51.05.04 A12 QC Program. A. A licensee shall: (12) Test the forensic analysis method, before reporting a forensic analysis result, using: (a) A positive and negative external control for a qualitative forensic analysis; and (b) Known levels of external controls for each analyte in a quantitative forensic analysis.</p>						
<p>10.51.05.05 A SOPM A. Policies and Procedures. A licensee shall ensure that all policies and procedures affecting the scope of activities performed in the laboratory are: (1) Documented; and (2) Communicated to, understood by, available to, and implemented by employees performing the activities.</p>						

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<p>10.51.05.05 B1-7 SOPM Documents B. A licensee shall ensure that: (1) Documents issued to employees are reviewed and approved for use by authorized employees before issue; (2) The current revision status and distribution of documents is established to preclude use of archived documents; (3) Authorized documents are available at all locations where casework is performed; (4) Archived documents are promptly removed from access or otherwise identified to ensure against unintended use; (5) Documents are uniquely identified, including date of issue or version, page numbering, total number of pages or a mark to signify the end of the document, and the issuing authority; (6) Changes to documents are approved by the same authority that issued the document and altered or new text is clearly identified; and (7) Documents in computerized systems have equivalent procedures.</p>						
<p>10.51.05.05 C1 SOPM Procedures C. A licensee shall develop, establish, maintain, implement, and require that technical procedures meet the following: (1) The procedures included are: (a) Generally accepted in the appropriate forensic field or supported by data gathered and recorded in a scientific manner; (b) Available to all appropriate employees; (c) Able to produce valid and accurate results; and (d) Reviewed annually by the director or the director's designee and this review shall be documented;</p>						
<p>10.51.05.05 C2 SOPM Procedures (2) All procedures include, at a minimum: (a) Sample or specimen preparation, as needed for the method; (b) Required quality control, standard, and reference material;</p>						

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(c) Calibration requirements and instructions; (d) Interfering substances and potential sources of error ; (e) Literature references ; (f) Special analytical and safety precautions ; (g) Step-by-step instructions ; and (h) Calculations , if required;						
10.51.05.05 C3-6 SOPM Procedures (3) All discontinued technical procedures are signed by the laboratory director when the technical procedure is retired and include the date of discontinuance ; (4) A laboratory procedure identifies which documents are to be maintained in the case file; (5) All changes to a procedure are approved and signed by the director; (6) The SOPM is available to all forensic analysts and examiners;						
10.51.05.05 C7 SOPM Procedures (7) A departure from the SOPM is: (a) Approved by the laboratory director or qualified designee before implementation; (b) Scientifically validated before implementation; (c) Written ; and (d) Communicated to the quality assurance manager ;						
10.51.05.05 C8 SOPM Procedures (8) The laboratory has a procedure for determining the reasons, criteria, or conditions for when a report is not produced ;						
10.51.05.05 C9 SOPM Procedures (9) The laboratory has a procedure or policy for technical review of reports that: (a) Defines criteria for the technical review , for example, number or percent of case reports reviewed or corrective action protocol if discrepancies are found; (b) Ensures that a review cannot be performed by the examiner or						

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<p>analyst who prepared the report; and (c) Ensures that a technical review of a one-individual unit is performed at a review percentage determined by the laboratory director by an analyst or examiner of another licensed forensic laboratory, who is qualified within the same disciplines or subdisciplines; and</p>						
<p>10.51.05.05 C10 SOPM Procedures (10) The laboratory has a procedure for administrative review that: (a) Requires that reviews be performed on all case reports; (b) Specifies who may perform the administrative review; (c) Clearly defines how the administrative review is documented; and (d) Requires that reviews be performed before case reports are issued.</p>						
<p>10.51.05.05 D SOPM Procedures D. A licensee shall ensure that the laboratory has a policy and procedure for the handling of written or oral complaints received from customers, laboratory employees, or other parties.</p>						
<p>10.51.05.06 A1 Calibration—General. A. A licensee shall develop, establish, implement, maintain, and follow calibration procedures. (1) If computers or automated equipment are used for the processing, recording, reporting, storage, or retrieval of calibration data, the licensee shall ensure that: (a) Computer software is performance checked after updates occur or validated; (b) Procedures are established, maintained, and followed to protect and secure the data; and (c) Computers and automated equipment are maintained to ensure proper functioning.</p>						

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<p>10.51.05.06 A2 Calibration—General. (2) A licensee shall ensure that: (a) Reference standards are calibrated by an entity that can provide traceability; (b) Measuring devices including rulers, weights, pipettes, balances, thermometers, and other devices that affect a forensic analysis result are calibrated against a reference standard traceable to the International System of Units, if available, as required by the manufacturer or forensic laboratory’s quality assurance program; (c) Calibration, if applicable, is performed: (i) Before initial use and before the recalibrated item is returned to service; (ii) Following service or maintenance; and (iii) At intervals specified by the manufacturer or more frequently as determined by the technical leader or quality assurance manager; and (d) All calibration activities are documented.</p>						
<p>10.51.05.07 A1-3 Validation and Performance Checks. A. The licensee shall: (1) Separately perform a validation or conduct a performance check on standard methods before use; (2) Validate non-standard methods, laboratory designed methods, laboratory designed tests, and modifications of standard methods before use; and (3) Maintain documentation of all method validation and performance check activities.</p>						
<p>10.51.05.07 B1-7 Validation and Performance Checks. B. A licensee shall ensure that validation includes, but is not limited to: (1) Literature references; (2) Limitations of the method; (3) Sources of error; (4) Specificity;</p>						

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(5) Sensitivity ; (6) Accuracy ; and (7) Reproducibility .						
10.51.05.07 C1-4 Validation and Performance Checks. C. A licensee shall ensure that performance checks , if applicable, are performed: (1) Before: (a) Initial use of computers and automated equipment; and (b) Computers or automated equipment are returned to use for casework ; (2) Following servicing or maintenance; (3) At intervals specified by the manufacturer ; and (4) As needed as determined by the technical leader .						
10.51.05.07 D Validation and Performance Checks. D. A technical leader and a laboratory director shall approve all testing methods before the testing methods are put into use .						
10.51.05.07 E1-3 Validation and Performance Checks. E. A licensee shall ensure that: (1) Reference samples are used for method validation and performance checks ; (2) Validation and performance checks include a statement as to whether the method is fit for the intended use; and (3) All new procedures and modifications of current procedures are validated and documented before being used in case work.						
10.51.05.08 A Examination and Analysis. A. A licensee shall develop, establish, maintain, implement, and follow examination and analysis procedures .						
10.51.05.08 B1 Examination and Analysis. B. A licensee shall: (1) Ensure that all evidence is given a unique identifier ;						

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<p>10.51.05.08 B2 Examination and Analysis. (2) Ensure that, when computers or automated equipment are used for the processing, recording, reporting, storage, or retrieval of examination or analysis data: (a) Computer software is validated; (b) Procedures are established and maintained to protect and secure the data; and (c) Computers and automated equipment are maintained to ensure proper functioning;</p>						
<p>10.51.05.08 B3 Examination and Analysis. (3) Have a policy for securing short-term and long-term storage of documents, evidence, and reports, which includes: (a) Limited access; and (b) Environmental controls;</p>						
<p>10.51.05.08 B4 Examination and Analysis. (4) Ensure each individual sub-sample has a unique identifier, when evidentiary samples are subdivided;</p>						
<p>10.51.05.08 B5 Examination and Analysis. (5) Ensure that all positive comparative analyses are verified by a second independent qualified examiner or analyst who has documented expertise in the examination that was performed, and the verification is documented; and</p>						
<p>10.51.05.08 B6 Examination and Analysis. (6) Have a policy for securing evidence that is in the process of being examined or analyzed.</p>						
<p>10.51.05.08 C1-2 Examination and Analysis. C. Examinations and Analysis by Subcontractors. (1) All subcontractors shall be licensed as a forensic laboratory in the State, regardless of location, unless a waiver has been obtained for a rare or unique test as required by COMAR 10.51.03.01A(4). (2) A licensee shall ensure:</p>						

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(a) The customer who ordered the analyses is notified of the laboratory's intention to subcontract specific services for testing; (b) All subcontractors issue reports only to the forensic laboratory that ordered the testing ; and (c) All remaining evidence is returned to the forensic laboratory by the subcontractor.						
10.51.05.09 A1-12 Test Reports—General. A. A licensee shall ensure that a test report includes but is not limited to the following: (1) Name and physical address of the laboratory; (2) A unique identifier on each page of the report; (3) Identification of the forensic analysis method used ; (4) A clear identification of each item tested including a description of the item's condition ; (5) The date each forensic analysis was completed ; (6) Units of measurement , if applicable; (7) The name and written or electronic signature of the examiner or analyst responsible for : (a) Performance of the forensic analysis; (b) Interpretations of forensic analysis results; and (c) Opinions ; (8) Opinions and interpretations ; (9) When applicable, a statement of uncertainty of measurement if the uncertainty of measurement may affect the interpretation of the results of the forensic analysis; (10) The date report was generated ; (11) The indication of the end of the report on the report's last page ; and (12) If applicable, a statement that the analysis was performed by another laboratory and identifies the facility that actually performed the analysis.						

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<p>10.51.05.09 B Test Reports—General. B. A licensee shall ensure that any information from §A(1)—(12) of this regulation that is not included in the test report is documented in the case record.</p>						
<p>10.51.05.09 C1-4 Test Reports—General. C. A licensee shall ensure that test reports: (1) Are produced when analytical testing is performed on evidence; (2) Contain opinions and conclusions and the name of the report’s author; (3) Report results accurately, clearly, unambiguously, and objectively; and (4) Utilize a page numbering system that includes the total number of pages.</p>						
<p>10.51.05.09 D1-4 Test Reports—General. D. A licensee shall ensure that amended reports: (1) Clearly state that the report has been amended; (2) Reference the date of the original report; (3) Are placed or associated with the original report in the case file; and (4) Are provided to the customers.</p>						
<p>10.51.05.10 A Employee Training and Competency. A. A licensee shall develop, establish, maintain, implement, and follow a written training program for all technical skills in each discipline and subdiscipline for each new or untrained employee and employees who need remedial training.</p>						
<p>10.51.05.10 B1-7 Employee Training and Competency. B. A licensee shall ensure that available to all technical employees is a discipline-specific training program that includes: (1) All aspects of the work being performed by the laboratory for each discipline and subdiscipline in which the laboratory performs case work; (2) Ethics and data integrity;</p>						

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<p>(3) Criminal and civil law procedures; (4) Criteria or requirements to demonstrate competence; (5) Expectations of job performance; (6) Moot court training if court testimony may be required; and (7) Expert witness training if expert witness testimony may be required.</p>						
<p>10.51.05.10 C1-6 Employee Training and Competency. C. A licensee shall ensure that training records include at least: (1) Competency assessments; (2) Proficiency testing results; (3) Documentation of all training; (4) Documentation of training that occurred at a previous job, if applicable; (5) Written authorization by the laboratory director and technical leader to conduct independent casework in each type of testing assigned; and (6) Documentation of all continuing education.</p>						
<p>10.51.05.11 A Equipment Maintenance. A. General. The laboratory shall develop, establish, maintain, implement, and follow an equipment calibration and maintenance procedure and policy.</p>						
<p>10.51.05.11 B Equipment Maintenance. B. A licensee shall ensure that equipment, before being placed into use, is calibrated or checked to establish that the equipment meets either the laboratory's or manufacturer's specifications, or both, as determined by the director.</p>						
<p>10.51.05.11 C1-8 Equipment Maintenance. C. A licensee shall ensure that records are maintained on all items of equipment including at a minimum: (1) Identity of the item of equipment and the equipment's ancillary parts; (2) Manufacturer's name and serial number or other unique</p>						

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identifier; (3) Performance checks ensuring the equipment complies with the manufacturer's specifications; (4) Current location , if applicable; (5) Manufacturer's instructions or operating manual; (6) Dates and results of calibrations , adjustments, and service and date of next calibration ; (7) Documentation of all maintenance performed , including date and signature of the individual performing the maintenance ; and (8) Documentation of any damage , malfunction, modification, or repair to the equipment.						
10.51.05.11 D1-4 Equipment Maintenance. D. A licensee shall ensure that any equipment that gives questionable results or is not functioning properly is immediately taken out of use and the equipment: (1) Is clearly labeled as out of service ; (2) Is examined and repaired or retired; (3) Is calibrated or shown to perform correctly before being put back into service ; and (4) Has forensic analysis results on previously examined evidence evaluated for accuracy back to the previous calibration.						
10.51.05.11 E Equipment Maintenance. E. A licensee shall ensure that the equipment , including both hardware and software, is safeguarded from adjustments that invalidate or alter calibrations or test examinations and analyses.						
10.51.05.11 F Equipment Maintenance. F. A licensee shall ensure that operator's manuals for all equipment and instruments are available to all examiners and analysts who use the equipment or instruments.						
10.51.05.12 A1-4 Case Records. A. A licensee shall create and maintain a unique identifier system for all administrative and examination documents originating from						

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<p>or received by the laboratory for each case by:</p> <p>(1) Writing all documents in permanent ink and defining exceptions in the laboratory SOPM;</p> <p>(2) Using electronic signatures only if a security protocol is in place;</p> <p>(3) Having a tracking policy and system for electronic record changes, when the electronic document is complete; and</p> <p>(4) Identifying all administrative documents with a unique identifier and signing or initialing by the individual who prepared or received the document.</p>						
<p>10.51.05.12 B1 Case Records.</p> <p>B. In regard to examination documents, a licensee shall ensure that:</p> <p>(1) If information is recorded on both sides, each side of a page is considered a separate page;</p>						
<p>10.51.05.12 B2 Case Records.</p> <p>(2) If examination documents consist of multiple pages, a page numbering system that includes the total number of pages is used;</p>						
<p>10.51.05.12 B3 Case Records.</p> <p>(3) In the absence of the examiner or analyst, another competent examiner or analyst is able to evaluate and interpret the data;</p>						
<p>10.51.05.12 B4 Case Records.</p> <p>(4) An examination document:</p> <p>(a) Includes details to support the conclusions and opinions reported by each examiner or analyst;</p> <p>(b) Is free of erasures or obliterations;</p> <p>(c) Is marked with a unique identifier and the examiner's or analyst's handwritten initials or electronic signature; and</p> <p>(d) Includes each date casework or an analysis was performed;</p>						
<p>10.51.05.12 B5 Case Records.</p> <p>(5) If an individual in addition to the examiner or analyst interprets or reports the results, both individuals initial or electronically sign each page of the examination documents;</p>						

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10.51.05.12 B6 Case Records. (6) Abbreviations and symbols are defined in the SOPM ;						
10.51.05.12 B7 Case Records. (7) Erroneous results , corrections, and amendments: (a) Are crossed out with a single line , not erased, and not deleted or made illegible ; and (b) Have corrections entered beside the erroneous result ;						
10.51.05.12 B8 Case Records. (8) All corrections and amendments are initialed and dated;						
10.51.05.12 B9 Case Records. (9) If electronically signed , measures are taken to ensure the signature is secure ; and						
10.51.05.12 B10 Case Records. (10) There is no loss or change of the original documents .						
10.51.05.13 A Complaints. A. A licensee shall retain all complaint records and documentation of the investigations and corrective actions taken by the laboratory.						
10.51.05.13 B Complaints. B. A licensee shall ensure that complaint documents include at least the: (1) Name and organization of complainant , if applicable; (2) Date of complaint; (3) Details of complaint; (4) Corrective action and resolution ; and (5) Notification of the complainant as to the resolution of the complaint.						
10.51.05.13 C Complaints. C. A licensee shall forward all complaints to the laboratory director.						
10.51.05.14 A Subcontractors. A licensee shall: A. Maintain a list of all subcontractors to which forensic analyses						

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are referred;						
10.51.05.14 B Subcontractors. B. Be responsible for the subcontractor's forensic analysis or examination;						
10.51.05.14 C Subcontractors. C. Ensure that forensic analysis results from the subcontractor are written or in a secured electronic form;						
10.51.05.14 D Subcontractors. D. Ensure that if alternative methods are used, the customer is notified before performing the examination or analysis;						
10.51.05.14 E1-2 Subcontractors. E. Establish and use appropriate review procedures to ensure the integrity of: (1) Outsourced samples; and (2) Data received from the subcontractor; and						
10.51.05.14 F Subcontractors. F. Establish and use appropriate review procedures to verify compliance with applicable State regulations.						
10.51.05.15 A1-4 Facilities. A. Facility Administration. A licensee shall ensure that a laboratory: (1) Is adequate for the testing services offered; (2) Has lighting, plumbing, wiring, ventilation, heat, air conditioning, and humidity to meet the laboratory's requirements; (3) Has a fire detection system; and (4) Has the required safety equipment as defined by the laboratory SOPM.						
10.51.05.15 B1 Facilities. Security. B. Security. A licensee shall: (1) Control and limit access to areas of the laboratory to those persons who regularly work in an area or are designated by the laboratory director as having access to an area; and						

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<p>10.51.05.15 B2 Facilities. Security. (2) Ensure that: (a) Entrances and exits have adequate security measures; (b) Internal areas that are required to have controlled or limited access are protected by a locked system; (c) The distribution of all keys, magnetic cards, and entry devices is documented and authorized by the director; (d) The facility is secure; and (e) All short-term and long-term storage areas have controlled or limited access and have a lock system in place.</p>						
<p>10.51.05.15 C1-6 Facilities. Safety C. Safety. A licensee shall: (1) Have a safety policy and procedure, that is reviewed annually; (2) Designate an employee as the safety officer with responsibilities defined by the licensee; (3) Have safety devices and equipment, e.g., goggles, gloves, face protectors, ear protectors, and fire extinguishers, available and in close proximity to the appropriate areas; (4) Have a safety shower, eye washes, and exhaust hoods available in close proximity to the appropriate areas; (5) Have appropriate equipment and materials available for handling and storing hazardous and toxic substances and remediating spills of those substances; (6) Ensure first aid kits and employees trained in first aid are available;</p>						
<p>10.51.05.15 C1-6 Facilities. Safety (7) Ensure adequate space is provided for the safe storage of volatile, flammable, explosive, and otherwise hazardous materials; and (8) Be in compliance with all federal, State, and local regulations regarding the handling and disposal of infectious materials, chemicals, radioactive materials, sharps, and glassware.</p>						

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<p>10.51.05.16 A1-4 Ethics and Data Integrity Policy A. A licensee shall: (1) Establish and maintain a written ethics and data integrity policy to be followed by all forensic laboratory employees, which includes the items set forth in §B of this regulation; (2) Provide access to the information, training, and resources needed by all forensic laboratory employees to comply with applicable federal and State laws, including ethics laws and regulations and the ethics and data integrity policy required in §A(1) of this regulation; (3) Provide formal ethics and data integrity training: (a) As part of new employee orientation; and (b) On an annual basis for all current employees; (4) Develop and utilize an employee ethics and data integrity agreement, for each employee to sign annually after training, acknowledging, and certifying that the employee has read, understands, and will follow the forensic laboratory ethics and data integrity policy; and</p>						
<p>10.51.05.16 A5 Ethics and Data Integrity Policy A. A licensee shall: (5) Provide a working environment in the forensic laboratory that: (a) Prevents employees from being subject to inappropriate pressures, coercion, intimidation, unethical laboratory dilemmas, or bribery from internal or external sources; and (b) Promotes and maintains effective bilateral communication through the chain-of-command, regarding concerns, inquiries, and allegations pertaining to: (i) Suspected or actual unethical conduct; (ii) Data integrity issues; (iii) Questionable practices; or (iv) Questions concerning forensic analysis procedures or results.</p>						

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<p>10.51.05.16 B1-3 Ethics and Data Integrity Policy B. A licensee shall ensure that a licensee’s ethics and data integrity policy includes at least the following topics, requirements, and procedures: (1) An employee’s responsibility to report any activity or behavior by any other employee, subcontractor, or vendor that the employee has reason to believe violates applicable laws, rules, and regulations or the forensic laboratory’s ethics and data integrity policy; (2) The disciplinary action an employee will be subject to if the employee: (a) Makes or produces a report that the employee knows to be false or misleading; (b) Is found falsifying, short-cutting, camouflaging, or misrepresenting any information or facts about forensic analysis procedure, result, reports, or data management; or (c) Otherwise engages in conduct or behavior that violates the: (i) Forensic laboratory’s ethics and data integrity policy; or (ii) Established forensic laboratory practices; (3) Procedures for reporting, handling, and investigating complaints of unethical conduct and violations or suspected violations of the forensic laboratory’s ethics and data integrity policy;</p>						
<p>10.51.05.16 B4-5 Ethics and Data Integrity Policy B. A licensee shall ensure that a licensee’s ethics and data integrity policy... (4) Requiring employees to: (a) Act impartially and not give preferential treatment to any person; (b) Exhibit exemplary conduct and use honest efforts in the performance of duties and responsibilities; (c) Perform a forensic analysis in a manner that: (i) Is independent of internal and external influences; (ii) Is objective; and (iii) Assures that results are accurate, precise, and of known and documented quality; and</p>						

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<p>(d) Understand the:</p> <p>(i) Serious implications and consequences of unethical conduct, intent to defraud, or any impropriety in performing forensic analyses; and</p> <p>(ii) Zero tolerance policy regarding an employee who engages in any form of conduct or behavior that is a violation of the ethics and data integrity policy required in §A of this regulation or any forensic laboratory practice that is not authorized by a licensee’s established procedures; and</p> <p>(5) Prohibiting an employee from:</p> <p>(a) Soliciting or accepting any gift of goods or services or other benefit of value from a person or entity:</p> <p>(i) Seeking action from or doing business with the forensic laboratory; or</p> <p>(ii) Whose interests may be substantially affected by the performance or nonperformance of the employee’s duties and responsibilities;</p> <p>(b) Holding a financial or personal interest that conflicts with the conscientious and ethical performance of duties and responsibilities;</p> <p>(c) Engaging in a transaction allowing the improper use of confidential information to further a private interest;</p> <p>(d) Conducting an action that violates the standards and requirements set forth in this subtitle or the licensee’s ethics and data integrity policy; and</p> <p>(e) Engaging in outside employment or activities that conflict with the conscientious and ethical performance of duties and responsibilities.</p>						
<p>10.51.05.17 A-C Nonretaliation.</p> <p>A. A licensee shall establish, maintain, and follow a nonretaliation policy that ensures that an employee who in good faith reports to the Secretary or the Department an issue related to data integrity or unethical or fraudulent conduct will not be subject to any form of discrimination or retaliation.</p>						

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<p>B. An employee who works in a forensic laboratory may disclose information to the Secretary that the employee believes evidences a violation or possible violation of a standard or requirement set forth in this subtitle or Health-General Article, Title 17, Subtitle 2A, Annotated Code of Maryland, including a standard or requirement related to data integrity or unethical or fraudulent conduct.</p> <p>C. A licensee shall post the document developed by the Secretary and approved by the Department informing employees of a forensic laboratory of the procedures to report instances of noncompliance or other violations of the standards and requirements set forth in this subtitle or Health-General Article, Title 17, Subtitle 2A, Annotated Code of Maryland.</p>						
<p>10.51.05.17 F-H Nonretaliation.</p> <p>F. A licensee shall ensure that the document referenced in §C of this regulation is posted in a conspicuous place visible to all forensic laboratory employees.</p> <p>G. A licensee may not discriminate or retaliate against an employee of a forensic laboratory who:</p> <p>(1) In good faith makes a report to the Secretary as set forth in this regulation; or</p> <p>(2) Has agreed to cooperate with an investigation of the forensic laboratory.</p> <p>H. A licensee may be subject to the sanctions set forth in this subtitle and Health-General Article, Title 17, Subtitle 2A, Annotated Code of Maryland, if the licensee discriminates or retaliates against an employee who in good faith makes a report to the Secretary as set forth in this regulation, including:</p> <p>(1) Failing to promote the employee or provide an employment-related benefit for which the employee would otherwise be eligible;</p> <p>(2) Making an adverse evaluation or decision in relation to accreditation, certification, credentialing, or licensing of the employee; or</p> <p>(3) Taking a personnel action that is retaliatory to the employee.</p>						

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<p>10.51.06.01 A-B Employees Required</p> <p>A. A licensee operating a forensic laboratory shall employ or otherwise engage the services of qualified employees, including:</p> <ul style="list-style-type: none"> (1) A director; (2) A technical leader; (3) A quality assurance manager; and (4) Forensic analysts and examiners. <p>B. Based on the scope of forensic testing services or categories offered or performed by the forensic laboratory, a licensee:</p> <ul style="list-style-type: none"> (1) Shall employ a sufficient number of qualified forensic analysts and examiners to: <ul style="list-style-type: none"> (a) Accomplish the forensic laboratory’s mission and goals as determined by the director; (b) Meet the forensic laboratory’s established priority protocols for a forensic analysis; and (c) Ensure that the quality of forensic testing services is not jeopardized; and (2) May employ more than one technical leader. 						
<p>10.51.06.01 C-D Employees Required</p> <p>C. The laboratory director may identify or designate an individual in an equivalent role, position, or title for an employee required in §A of this regulation if the individual:</p> <ul style="list-style-type: none"> (1) Meets the qualifications for the position; and (2) Fulfills the responsibilities of the designated required employees as set forth in this subtitle. <p>D. An individual employed by a licensee may serve in one or more roles or positions of the employees required in §A of this regulation if the:</p> <ul style="list-style-type: none"> (1) Individual meets the qualifications for and fulfills the responsibilities of the required employees as set forth in this subtitle; and (2) Duties and responsibilities are delegated in writing to the assigned individual. 						

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<p>10.51.06.02 A-B Employees-Character and Education Verification.</p> <p>A. A licensee shall establish and follow written procedures for verifying the background and education of forensic laboratory employees.</p> <p>B. A licensee shall verify the background and education of an individual by a:</p> <p>(1) Background investigation;</p> <p>(2) Review of the individual's grade transcript from the college or university that the individual attended, that is:</p> <p>(a) The original record or transcript document; or</p> <p>(b) An official certified copy of the transcript;</p> <p>(3) Test for abuse of controlled dangerous substances; and</p> <p>(4) Polygraph examination, if available.</p>						
<p>10.51.06.03 A-D Employees-Qualification Effective Dates.</p> <p>A. Regardless of how an individual's role, position, or title is identified by a licensee, on or after January 1, 2012, an individual who begins employment with a licensee in a forensic laboratory shall meet the appropriate employee qualifications and requirements as set forth in this subtitle for a:</p> <p>(1) Director;</p> <p>(2) Technical leader;</p> <p>(3) Quality assurance manager;</p> <p>(4) Forensic analyst or examiner; and</p> <p>(5) Person in the chain of casework who could affect the forensic analysis results, including technicians.</p> <p>B. A licensee shall deem an individual who is performing the function of a forensic laboratory director, as set forth in this chapter, on or before December 31, 2011, as:</p> <p>(1) Meeting the qualifications of a forensic laboratory director; and</p> <p>(2) Fulfilling the duties and responsibilities of the director as set forth in this subtitle.</p> <p>C. A licensee shall deem an individual, other than the director, who</p>						

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<p>is performing the function of one or more of the required employees, as set forth in Regulation .01 of this chapter, on or before December 31, 2011, as:</p> <p>(1) Meeting the qualifications for the designated role, position, or title if the individual is authorized in writing by the director; and</p> <p>(2) Fulfilling the duties and responsibilities of the designated position as set forth in this subtitle.</p> <p>D. Deemed Qualification.</p> <p>(1) The deemed qualification for forensic laboratory employees as set forth in §§B and C of this regulation is limited to the specific role or function of an individual on or before December 31, 2011.</p> <p>(2) The deemed qualification of an individual in a specific role or function as set forth in §§B and C of this regulation is permanent and portable.</p> <p>(3) If the role of an individual employed by a licensee changes, the individual, before serving in the new role, shall:</p> <p>(a) Meet the appropriate qualifications for the role as set forth in this chapter; or</p> <p>(b) From January 1, 2012, through December 31, 2018, meet the employee qualifications established by the laboratory director for a forensic non-Biology-DNA:</p> <p>(i) Technical leader;</p> <p>(ii) Quality assurance manager; or</p> <p>(iii) Analyst or examiner.</p> <p>(4) Sunset of Deemed Qualifications. The deemed qualification of an individual in a specific role or function as set forth in §D(3)(b) of this regulation:</p> <p>(a) Is not permanent; and</p> <p>(b) Expires on December 31, 2018.</p>						
<p>10.51.06.04 A-B Director-Requirement.</p> <p>A licensee shall employ a forensic laboratory director who:</p> <p>A. Meets the qualifications set forth in this chapter; and</p> <p>B. Is responsible for the overall operation and administration of the</p>						

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laboratory.						
<p>10.51.06.05 A-B Director-Qualifications. A director of a forensic laboratory shall:</p> <p>A. Hold an earned master’s or doctoral degree from an accredited institution in:</p> <p>(1) Forensic science; (2) A natural science such as chemistry, physics, or biology; or (3) A subspecialty of a natural science such as organic chemistry, biochemistry, or molecular biology; and</p> <p>B. Have at least:</p> <p>(1) 3 years of documented forensic laboratory experience; and (2) 2 years of managerial or supervisory experience.</p>						
<p>10.51.06.06 A Director-General Duties and Responsibilities. A. A director of a forensic laboratory is responsible for the overall operation and administration of the forensic laboratory.</p>						
<p>10.51.06.06 B Director-General Duties and Responsibilities. B. A director of a forensic laboratory shall participate in and actively oversee the planning, organization, direction, and review of all laboratory operations, including but not limited to:</p> <p>(1) Employing individuals who are competent to:</p> <p>(a) Perform a forensic analysis; and (b) Record and report a forensic analysis:</p> <p>(i) Promptly within the priority protocols established by the director; (ii) Accurately; and (iii) Proficiently; and</p> <p>(2) Ensuring compliance with the requirements set forth in this subtitle.</p>						
<p>10.51.06.06 C Director-General Duties and Responsibilities. C. A forensic laboratory director may:</p> <p>(1) If qualified, perform the duties of a:</p> <p>(a) Technical leader; (b) Quality assurance manager; and</p>						

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(c) Forensic analysis employee ; and (2) Delegate a duty or responsibility set forth in this subtitle to an employee who is qualified to carry out the delegated duty or responsibility.						
10.51.06.06 D Director-General Duties and Responsibilities. D. If a forensic laboratory director delegates the performance of the director's duties or responsibilities as set forth in this subtitle, the forensic laboratory director shall ensure that the delegated duties and responsibilities are properly performed as required by this subtitle and Health-General Article, Title 17, Subtitle 2A, Annotated Code of Maryland.						
10.51.06.07 A Director-Specific Duties and Responsibilities. A forensic laboratory director shall : A. Be accessible to forensic laboratory employees to provide on-site, telephonic, or electronic consultation as needed;						
10.51.06.07 B1-6 Director-Specific Duties and Responsibilities. B. Ensure that: (1) Forensic testing and examination systems developed and used for each forensic analysis performed in the laboratory provide quality laboratory services for all aspects of test and examination performance including the pre-analytic, analytic, and post-analytic phases of the forensic analysis; (2) The physical plant and environmental conditions of the forensic laboratory are appropriate for the testing performed; (3) Forensic laboratory employees are provided a safe work environment and are protected from physical, chemical, and biological hazards; (4) A forensic analysis method selected for use in the laboratory has the capability of providing an accurate and reliable result with known or defined uncertainty; (5) Verification procedures used are adequate to determine the accuracy, precision, uncertainty, and other pertinent performance						

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characteristics of each forensic analysis method; (6) Forensic analysis employees perform the forensic analysis methods as required by the laboratory's established procedures to assure accurate and reliable results;						
10.51.06.07 B7-9 Director-Specific Duties and Responsibilities. B. Ensure that: (7) The forensic laboratory participates in and uses a Department-approved proficiency testing provider as set forth in this subtitle, for each forensic analysis the laboratory performs or offers to perform; (8) Received proficiency test reports are reviewed by the appropriate forensic analysis employees to: (a) Evaluate the laboratory's performance; and (b) Identify any problems which require corrective action; (9) A corrective action plan is followed when a proficiency test result is found to be unacceptable or unsatisfactory;						
10.51.06.07 B10 Director-Specific Duties and Responsibilities. B. Ensure that: (10) Quality control, quality assurance and assessment, and ethics and data integrity programs are established, maintained, and followed as set forth in this subtitle;						
10.51.06.07 B11 Director-Specific Duties and Responsibilities. B. Ensure that: (11) A case file is maintained for a minimum of 10 years after the case is officially closed;						
10.51.06.07 B12-14 Director-Specific Duties and Responsibilities. B. Ensure that: (12) Acceptable levels of analytical performance for each forensic analysis are established and maintained; (13) Remedial actions are taken and documented if a deviation from the forensic laboratory's established performance characteristics is identified; (14) Procedures and mechanisms are established, maintained, and						

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followed to preserve evidentiary sample and specimen integrity and identity throughout the forensic analysis process;						
10.51.06.07 B15-18 Director-Specific Duties and Responsibilities. B. Ensure that: (15) Forensic test and examination results are reported only when the forensic analysis system is functioning properly; (16) Reports of forensic analysis results include pertinent information required for correct interpretation; (17) Consultation is available to the forensic laboratory's clients on matters relating to the quality of the reported forensic analysis results and interpretation; (18) There is on-site supervision of forensic analyses and examinations being performed;						
10.51.06.07 B15-18 Director-Specific Duties and Responsibilities. B. Ensure that: (19) An employee has sufficient education and experience related to the forensic analyses and examinations being performed, has completed the training for the type and complexity of tests and examinations performed, and has demonstrated reliable test performance and examination operations to provide and report accurate results; (20) Before performing a forensic analysis on an evidentiary sample or specimen, an employee has demonstrated reliable and proficient analysis and the providing and reporting of accurate results; (21) Policies and procedures are established for monitoring the performance of employees who conduct pre-analytical, analytical, and post-analytical phases of the forensic analysis process to assure that: (a) Employees are competent and maintain competency to: (i) Process samples and specimens; (ii) Perform forensic tests and examinations; and (iii) Report forensic analysis results promptly and proficiently; and						

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(b) Employee needs for remedial training or continuing education to improve skills are identified, when necessary; and						
10.51.06.07 B22 Director-Specific Duties and Responsibilities. B. Ensure that: (22) A procedure manual is available to and followed by all employees responsible for any aspect of the forensic analysis process;						
10.51.06.07 C Director-Specific Duties and Responsibilities. C. Employ a sufficient number of forensic laboratory employees with the required education, experience, and training, and in accordance with the employee responsibilities set forth in this chapter to: (1) Provide consultation and court testimony; (2) Supervise the performance of forensic analyses; (3) Collect, process, and store evidentiary samples and specimens; (4) Perform forensic analysis procedures; and (5) Report forensic analysis results promptly and proficiently;						
10.51.06.07 D Director-Specific Duties and Responsibilities. D. Establish and specify, in writing, the duties and responsibilities of each: (1) Consultant; (2) Technical leader; and (3) Individual engaged in the performance of the pre-analytic, analytic, and post-analytic phases of a forensic analysis;						
10.51.06.07 E Director-Specific Duties and Responsibilities. E. Identify in the written duties and responsibilities required in §D of this regulation: (1) What forensic tests, examinations, and procedures each individual is authorized to perform; (2) The competencies required to perform each forensic test, examination, and procedure; (3) Whether supervision is required for specimen and sample						

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processing, forensic analysis performance, or result reporting; and (4) If review by a technical leader or director is required before reporting a forensic analysis result; and						
10.51.06.07 F Director-Specific Duties and Responsibilities. F. Have the authority to initiate, suspend, and resume forensic analysis operations for: (1) The laboratory; or (2) An individual analyst or examiner.						
10.51.06.08 A-B Quality Assurance Manager-Requirements. A. A director of a forensic laboratory shall designate a qualified individual as a quality assurance manager to be responsible for coordinating the activities required to ensure quality forensic analysis services. B. A quality assurance manager may be employed full-time or part-time as appropriate for the scope of forensic analysis services offered or performed.						
10.51.06.09 A-B Quality Assurance Manager-Qualifications. A quality assurance manager of a forensic laboratory shall: A. Hold an earned baccalaureate or advanced degree from an accredited institution in: (1) Forensic science; (2) A natural science such as: (a) Chemistry; (b) Physics; or (c) Biology; or (3) A subspecialty of a natural science such as: (a) Organic chemistry; (b) Biochemistry; or (c) Molecular biology; and B. Complete a training program as determined by the laboratory director.						

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<p>10.51.06.10 A Quality Assurance Manager-Duties and Responsibilities. A. Under the authority of the director, and operating independently of casework, a quality assurance manager shall be responsible for: (1) Establishing: (a) A comprehensive quality assessment system that includes quality control and quality assessment programs that cover the forensic analyses performed; and (b) Parameters for necessary levels of performance for forensic analyses; (2) The overall maintenance and operation of the laboratory's quality assurance program; and (3) Maintaining pertinent documentation and records of quality assurance activities.</p>						
<p>10.51.06.10 B1 & 12 Quality Assurance Manager-Duties and Responsibilities. B. The quality assurance manager shall: (1) Oversee the: (a) Participation and usage of an approved proficiency test provider commensurate with the licensed forensic analysis services; (b) Administration of proficiency testing; and (c) Evaluation of proficiency test results; (12) Maintain records that demonstrate that proficiency testing samples are analyzed in the same manner as any other evidentiary specimen or sample received by the forensic laboratory for forensic analysis.</p>						
<p>10.51.06.10 B2 Quality Assurance Manager-Duties and Responsibilities. B. The quality assurance manager shall: (2) Maintain the forensic laboratory's quality assurance: (a) Program; and (b) Program manual;</p>						

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<p>10.51.06.10 B3 Quality Assurance Manager-Duties and Responsibilities. B. The quality assurance manager shall: (3) Evaluate instrument records for: (a) Calibration; (b) Validation; and (c) Maintenance;</p>						
<p>10.51.06.10 B4-5 Quality Assurance Manager-Duties and Responsibilities. B. The quality assurance manager shall: (4) Review: (a) Standard operating procedures; (b) Internal audit records; (c) Training records; (d) Competency records; (e) Proficiency tests; (f) Management reviews; and (g) Quality assurance documentation; (5) Ensure all methods, including new methods and modifications to current methods, are validated;</p>						
<p>10.51.06.10 B6 Quality Assurance Manager-Duties and Responsibilities. B. The quality assurance manager shall: (6) Select, train, and evaluate internal auditors;</p>						
<p>10.51.06.10 B6 Quality Assurance Manager-Duties and Responsibilities. B. The quality assurance manager shall: (7) Investigate technical problems;</p>						
<p>10.51.06.10 B8-9,11 Quality Assurance Manager-Duties and Responsibilities. B. The quality assurance manager shall: (8) Propose corrective or remedial actions;</p>						

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<p>(9) Verify that corrective or remedial actions: (a) Are implemented; and (b) Correct the identified problem; (11) Document all corrective actions taken when forensic analysis systems and procedures deviate from the forensic laboratory's established performance specifications;</p>						
<p>10.51.06.10 B10 Quality Assurance Manager-Duties and Responsibilities. B. The quality assurance manager shall: (10) Assess the adequacy of record review activities, including but not limited to: (a) Reports; and (b) Case records;</p>						
<p>10.51.06.11 B Technical Leader-Requirements. B. Based on the scope of forensic analysis services, a licensee may employ one or more technical leaders who: (1) Meet the qualifications of this chapter; and (2) Are responsible for the technical and scientific oversight of: (a) The forensic laboratory; or (b) A specific section or forensic science discipline in a forensic laboratory.</p>						
<p>10.51.06.11 C Technical Leader-Requirements. C. A technical leader: (1) Is not required to be on-site in the forensic laboratory at all times forensic analyses are performed; and (2) Shall be: (a) Available to forensic laboratory employees as needed to provide technical and scientific oversight and assistance; and (b) Accessible to forensic laboratory employees to provide on-site, telephonic, or electronic consultation.</p>						
<p>10.51.06.12 A Technical Leader-Qualifications. A. General. Except for the discipline of Biology-DNA analysis, a</p>						

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<p>technical leader in a discipline or subdiscipline of a forensic laboratory shall:</p> <p>(1) Hold an earned baccalaureate or advanced degree from an accredited institution in:</p> <p>(a) Forensic science;</p> <p>(b) A natural science such as:</p> <p>(i) Chemistry;</p> <p>(ii) Physics; or</p> <p>(iii) Biology; or</p> <p>(c) A subspecialty of a natural science such as:</p> <p>(i) Organic chemistry;</p> <p>(ii) Biochemistry; or</p> <p>(iii) Molecular biology; and</p> <p>(2) Have documented post-degree experience in the forensic discipline or subdiscipline in which the individual will be a technical leader, as follows:</p> <p>(a) 4 years with a baccalaureate degree;</p> <p>(b) 3 years with a master's degree; or</p> <p>(c) 2 years with a doctoral degree.</p>						
<p>10.51.06.12 B Technical Leader-Qualifications.</p> <p>B. Except for Biology-DNA analysis and forensic toxicology, a director may establish alternate qualifications for a technical leader in a discipline or subdiscipline of a forensic laboratory if the individual:</p> <p>(1) Has 9 or more years of documented experience in the forensic discipline or subdiscipline in which the individual will be a technical leader; and</p> <p>(2) Is able to demonstrate competency under the laboratory's competency procedures in the forensic discipline or subdiscipline in which the individual will be a technical leader.</p>						

COMAR Reference Number and Maryland State Standard	C	N/C	I J	N/A	?	Comments
<p>10.51.06.13 A Technical Leader-Responsibilities. A. Authority. A licensee may authorize a technical leader to initiate, suspend, and resume a forensic analysis or forensic analyses operations for:</p> <p>(1) The laboratory, if assigned to the technical leader; (2) The forensic analysis section or unit of the laboratory assigned to the technical leader; or (3) An individual in the technical leader’s assigned forensic analysis section or unit of the laboratory.</p>						
<p>10.51.06.13 B1-2 Technical Leader-Responsibilities B. A technical leader shall be responsible for:</p> <p>(1) Selection of the test method, in concert with the laboratory director, that is appropriate, depending on the type of evidence, for forensic use and for reporting forensic analysis results; (2) Validation of each forensic analysis procedure performed;</p>						
<p>10.51.06.13 B3-4 Technical Leader-Responsibilities B. A technical leader shall be responsible for:</p> <p>(3) Establishing the forensic laboratory’s forensic analysis performance specifications, including:</p> <p>(a) Precision; (b) Accuracy; and (c) Uncertainty of measurement, where applicable; (4) Maintaining instrument records for:</p> <p>(a) Calibration; (b) Validation; and (c) Maintenance;</p>						
<p>10.51.06.13 B5 Technical Leader-Responsibilities B. A technical leader shall be responsible for:</p> <p>(5) Ensuring that:</p> <p>(a) The performance levels established in §B of this regulation are maintained throughout the entire forensic analysis process: (i) From initial receipt of the sample or specimen;</p>						

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(ii) Through testing and examination; and (iii) Through reporting of the forensic analysis results; and (b) Forensic analysis results are not reported until all corrective actions have been taken and the forensic analysis system is functioning properly;						
10.51.06.13 B6-7 Technical Leader-Responsibilities B. A technical leader shall be responsible for: (6) Resolving technical problems and ensuring that remedial actions are taken whenever a forensic analysis procedure or system deviates from the forensic laboratory's established performance specifications; and (7) Re-evaluating employee performance , before reporting forensic analysis results, to include the use of a new test method or instrumentation when a forensic analysis method or instrumentation changes.						
10.51.06.15 F Forensic Analysis Employees-Qualifications. F. Forensic Analysis Employees- Qualifications for Latent Examinations. An individual who classifies fingerprints or other friction-ridge prints or performs impression examinations shall: (1) Possess a high school diploma or equivalent ; and (2) Have successfully completed a training program, as determined by the laboratory director and technical leader , including: (a) 1 year performing duties related to: (i) Law enforcement activities ; or (ii) Forensic laboratory services ; and (b) 1 year performing : (i) Fingerprint classification ; or (ii) Latent examinations .						
10.51.06.16 Forensic Analysis Employee Responsibilities-General. A licensee shall ensure that: A. A forensic analysis employee is responsible for: (1) Specimen and sample processing ;						

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<p>(2) Performing forensic analyses; and (3) Reporting forensic analysis results; and B. An individual performs only those forensic analyses that: (1) Are authorized by the forensic laboratory director for the individual to perform; and (2) Require a degree of skill commensurate with the individual's education, training, experience, and technical abilities.</p>						
<p>10.51.06 .17 A-B Employee Responsibilities-Specific. Regardless of the forensic analysis category, an individual who performs a forensic analysis shall: A. Follow the forensic laboratory's approved procedures for: (1) Specimen and sample handling and processing; (2) Performing the forensic analysis; and (3) Reporting and maintaining records of forensic analysis results; B. Adhere to the forensic laboratory's policies and procedures for: (1) Quality control; (2) Quality assurance; and (3) Ethics and data integrity;</p>						
<p>10.51.06 .17 C Employee Responsibilities-Specific. C. Document all activities related to: (1) Quality assurance; (2) Quality control; (3) Ethics and data integrity; (4) Calibration of forensic analysis: (a) Equipment; (b) Instruments; and (c) Procedures; and (5) Performance of maintenance and repair of forensic: (a) Equipment; and (b) Instruments;</p>						
<p>10.51.06 .17 D-E Employee Responsibilities-Specific. D. Follow the forensic laboratory's established policies and</p>						

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<p>procedures if forensic analysis systems are not within the established specifications for acceptable performance; and</p> <p>E. Be capable of identifying a problem that may adversely affect performance of a forensic analysis or reporting of a forensic analysis result and either:</p> <p>(1) Correct the problem; or</p> <p>(2) Immediately notify the quality assurance manager and technical leader or the director that there is a problem.</p>						