R221a – Annex A: Specific Requirements for Forensic Facilities Licensed in Maryland

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Introduction

A1.0 Scope

This document describes additional accreditation requirements specifically applicable to organizations offering to perform forensic testing in the State of Maryland. The information contained in this Annex constitutes either additions to the A2LA forensic accreditation program general accreditation requirements or clarifications of the general requirements as they relate to the Code of Maryland Regulations (COMAR) Title 10, Subtitle 51 Forensic Laboratories.

Participation in this program is mandatory for all A2LA-accredited laboratories offering to perform or performing forensic analyses in the State of Maryland.

Licensure in the State of Maryland in accordance with COMAR 10.51 is overseen by the Maryland Office of Health Care Quality (OHCQ), Department of Health and Mental Hygiene. While gaining accreditation from an accreditation body approved by OHCQ is one method for obtaining licensure, laboratories seeking licensure must still apply and be approved by OHCQ to be licensed in the State of Maryland.

A2.0 Reporting to the Maryland Office of Health Care Quality (OHCQ), Department of Health and Mental Hygiene

A2.1 Each applicant laboratory shall complete and return a copy of A2LA form F233 - *A2LA Forensic Facility Consent Agreement* prior to their A2LA assessment. By signing this form, laboratories seeking and renewing accreditation to this standard agree to allow A2LA to provide information to Maryland OHCQ as outlined in sections A2.2 through A2.6.

A2.2 Within 30 days after each initial, surveillance and renewal assessment A2LA shall provide a copy of each assessment report to Maryland OHCQ.

A2.3 A2LA shall provide written notification to Maryland OHCQ within 30 days of:

a) Accrediting a forensic facility;

b) Initiating a complaint investigation of an accredited forensic facility; or

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1 A copy of the Code of Maryland Regulations (COMAR) Title 10, Subtitle 51 can be found on the COMAR website: [http://www.dsd.state.md.us/comar/searchall.aspx](http://www.dsd.state.md.us/comar/searchall.aspx)
c) Discovery of such situations that would cause serious jeopardy to individual rights or identifies a hazard to public safety.

A2.4 A2LA will provide written notification to Maryland OHCQ within 10 days of expiration of a forensic facility’s accreditation.

A2.5 A2LA will provide written notification to Maryland OHCQ within 24 hours of denying, withdrawing, suspending, revoking or otherwise limiting a forensic facility’s accreditation.

A2.6 On an annual basis, A2LA will provide OHCQ the name, address and accreditation expiry date of all A2LA Accredited forensic facilities in the State of Maryland.

A3.0 Definitions

A3.1 For the purposes of these requirements, the relevant terms and definitions given in ISO/IEC 17000, the VIM, ISO/IEC Guide 2 and R221 - Specific Requirements - Forensic Examination Accreditation Program-Testing apply. As used herein the following terms shall have the meanings specified:

A3.2 Administrative Document – A laboratory record including, but not limited to: case-related conversations and communications, evidence receipts, descriptions of evidence packaging and seals, incident reports, service request documentation, case-related correspondence including emails and letters, interim and preliminary reports and case-related database search documentation, where applicable.

A3.3 Analyte – A substance or constituent for which a forensic laboratory conducts testing.

A3.4 Case File – The part of the case record that is a file containing administrative and examination documentation generated or received by laboratory employees pertaining to a uniquely identified case.

A3.5 Contamination Record – A record of instances of unintentional introduction of exogenous DNA into a DNA sample or PCR reaction.

A3.6 Data Integrity – The conditions existing when data is unchanged from its source and has not been accidentally or maliciously modified, altered, or destroyed during any operation, such as transfer, storage, or retrieval.

2 The definitions provided are published in Code of Maryland Regulations (COMAR) 10.51.03
A3.7 Discrepancy Logs – A system used by a forensic laboratory to document administrative or processing errors related to evidence and tracked within a case record.

A3.8 External Control – A test or examination performed on an external test sample to demonstrate a procedure is working correctly.

A3.9 Incident Report – A record used by a forensic laboratory to document procedural or policy noncompliance or unexpected outcomes.

A3.10 Proficiency Test

A3.10.1 External Proficiency Test – An analysis performed on a proficiency testing sample provided to a forensic laboratory by an approved proficiency test provider external to the laboratory or laboratory system.

A3.10.2 Internal Proficiency Test – Samples or specimens developed by the laboratory director or the director’s designee and administered to an analyst or examiner for analysis or examination as unknown samples or specimens.

A4.0 Specific Requirements

Along with ISO/IEC 17025 and A2LA document R221 - Specific Requirements: Forensic Examination Accreditation Program-Testing, the specific requirements for the Maryland Forensic Examination program are found in C223a – Specific Checklist: Annex A – Forensic Facilities Licensed in Maryland.

Applicant laboratories must at a minimum, meet the requirements of ISO/IEC 17025, R221, and C223A.

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Approved proficiency test provider means an external proficiency test provider who has been approved by the Maryland Department of Health and Mental Hygiene as set forth in COMAR 10.51.04.03 or has been evaluated by A2LA and added to A2LA document I106 – Available Proficiency Testing Programs.
### REVISION HISTORY

<table>
<thead>
<tr>
<th>DATE</th>
<th>REVISION</th>
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<tbody>
<tr>
<td>June 27, 2012</td>
<td>▶ Initial document publication</td>
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<tr>
<td>December 4, 2012</td>
<td>▶ Added footnote 3 to page 5 clarifying what is meant by ‘approved’ proficiency test provider</td>
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