

**AGREEMENT UNDER HEALTH-GENERAL ARTICLE § 19-2302 AND COMAR 10.51
BETWEEN ANAB AND THE EXECUTIVE DIRECTOR OF THE MARYLAND DEPARTMENT
OF HEALTH**

Whereas, the ANSI-ASQ National Accreditation Board (ANAB) and the Executive Director of the Maryland Department of Health, Office of Health Care Quality (OHCQ) seek to ensure that Maryland forensic laboratories adhere to professional and legal standards and are subject to appropriate oversight;

Whereas, § 19-2302 of the Health-General Article of the Maryland code authorizes the Department to accept, as evidence in a licensure proceeding, a final report of an accreditation organization that has been approved by the Secretary;

Whereas, § 19-2302 of the Health-general Article of the Maryland Code authorizes the Secretary, prior to approval of an accreditation organization, to enter into a formal written agreement with the organization that may include, among other things, requirements for notice to the Department of surveys and inspections conducted by the accreditation organization, sharing of complaints and other relevant information, and participation by the Department in accreditation organization activities;

Now therefore, in furtherance of these joint objectives, the Secretary and ANAB agree to be bound by the conditions set forth below.

1. ANAB shall conduct surveys of Maryland licensed forensic laboratories accredited by ANAB that incorporate evaluation of the laboratories' compliance with Maryland State regulatory requirements set forth in Health-General §§ 17-2A-01 through 17-2A-12 and COMAR 10.51 and in accordance with the requirements imposed on accreditation organizations in Maryland law, including those set forth in health-general § 19-2302 and COMAR 10.51.02.02.
2. ANAB shall provide advance confidential notice to OHCQ of any routine or for-cause forensic laboratory assessment, audit, or investigation to be conducted in a Maryland licensed forensic laboratory accredited by ANAB.
3. After OHCQ receives notice of the ANAB assessment audit, or investigation and prior to an ANAB survey, OHCQ may provide ANAB with any information that raises concern about the operations of the subject laboratory. This may include descriptions of complaints or adverse events, the results of an OHCQ-initiated survey that might assist ANAB in identifying areas that need improvement, or other information that OHCQ wishes to provide. The transfer of information from OHCQ to ANAB may be via letter, e-mail, telephone call, or other communication methods.
4. ANAB shall notify accredited forensic laboratories licensed in Maryland through a signed agreement by ANAB that information from ANAB's assessment audits, or investigations will be shared with OHCQ. The information routinely, provided by ANAB to OHCQ without first being requested by OHCQ shall be provided by ANAB.
5. OHCQ and ANAB shall notify the other party when either learns of any high priority complaint (a complaint that is deemed Immediate Jeopardy or involves an employee safety issue) concerning forensic analyses in a Maryland licensed forensic laboratory and shall forward a copy of the complaint to the other party. In the investigation of any high priority

complaint, ANAB and OHCQ shall make reasonable attempts to coordinate their efforts and/or collaborate in the survey process. Although OHCQ and ANAB may share information in the course of such a survey, assessment, audit, or investigation, each entity is entitled to produce an independent report and draw independent conclusions. The confidentiality of documents in the possession of ANAB and OHCQ shall be governed by Health-General Article § 17-2A-03 which reads:

- a) Forensic laboratory deficiency statements and plans of correction are public documents.
 - b) A forensic laboratory shall make discrepancy logs, contamination records, and test results available to the public within 30 days of a written request.
 - c) Except as provided in subsection (a) of this section, the proceedings, records, and files of an organization or State agency responsible for assuring compliance with this subtitle shall be confidential and not discoverable or admissible in evidence in a civil or criminal action.
6. OHCQ shall require, prior to the issuance of a Maryland license to a forensic laboratory, that the forensic laboratory send to the OHCQ and an electronic copy of the ANAB Initial Assessment/Audit/ Investigation report that includes requirements for Improvements and Supplemental Findings, within 10 days of receiving such report.
7. If ANAB determines that a forensic laboratory is to be granted provisional or conditional accreditation, or is to be the subject of preliminary denial of accreditation or denial of accreditation, ANAB shall notify OHCQ within the time period required in COMAR 10.51.02.02 or, COMAR 10.51.02.02 is not applicable, within 10 days.
8. In the event that ANAB assessors, auditors, or investigators identify an immediate threat to forensic analyses results or personnel safety in a Maryland licensed forensic laboratory, ANAB shall notify OHCQ immediately.
9. OHCQ will notify ANAB if OHCQ sanctions a forensic laboratory pursuant to COMAR 10.51.07 for failure to report a deficiency; failure to successfully perform proficiency test(s); demonstrated incompetence; false statements made or fraudulent actions; misrepresentations; a violation of State law pertaining to a forensic laboratory; or failure to submit a timely root cause analysis in the case of an adverse event or an event that may affect the accuracy of the test results.
10. In the event that accreditation standards are revised or new standards are added, or upon specific OHCQ request for interpretation of a standard, ANAB will provide copies of the revision or change and, if required, provide training and training materials to OHCQ regarding interpretation of the accreditation standards in question.
11. In the event ANAB violates this Agreement, unless the Secretary determines that immediate withdrawal of the approval of ANAB under § 19-2302 of the Health-General Article is warranted, OHCQ shall issue written notice and provide an opportunity for ANAB to remedy said violation within 30 days.

12. This Agreement shall remain in effect for a period of 1 year and will renew automatically from year unless one party notifies the other of its intent to terminate this Agreement.

IN WITNESS WHEREOF, the parties agree to be bound by the foregoing Agreement.

Pamela L. Sale

Pamela Sale

VP, ANAB, Forensics

05/07/18

Date

Patricia Tomsco Nay

Patricia Tomsco Nay, M.D.

Maryland Department of Health, OHCQ

5/10/18

Date

Ang K. Chalk

Witness

5/7/2018

Date

Debra B. Webster

Witness

5/10/18

Date

