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Common Nonconformances

Written to the 14th Edition of Standards for Relationship Testing Laboratories

1.1.6 Executive management shall have responsibility and authority for: Ensuring adherence to quality and operational policies, processes, and procedures.

The facility is expected to have policies, processes, or procedures (PPP) for each element of the standard. Standard 1.1.6 is cited when there are no written PPP for a standard or when there is a written policy, but the assessor observed evidence that the policy is not being followed.

4.3.3 There shall be written agreements between laboratories and third party administrators that define the following:

- 1) Collection requirements.
- 2) Responsibility for testing process.
- 3) Reporting of test results.
- 4) Appropriate marketing materials and claims.
- 5) Use of laboratory's name and accreditation status.
- 6) Unless accredited for collection or verification activities by AABB, third party administrators are prohibited from initiating cases for United States of America immigration, visa, passport, and citizenship testing.

Facilities that accept cases from third-party administrators must have a written agreement that addresses elements 1) through 6). The agreement covers the requirements, expectations, and responsibilities of both parties. The intent of this standard is not to require an agreement for the occasional individual case, but to address situations where a facility is conducting ongoing testing for a third-party administrator, even at low levels or in trial or probationary periods. Regular monitoring to ensure that third-party administrators continue to meet the requirements of the agreement is also required, see Standard 4.4. If third-party administrators refuse to comply with the agreement, action must be taken, including ceasing to accept cases from that supplier and/or ceasing to schedule collections at its facility.

4.7.1 The facility shall have policies, processes, and procedures to evaluate and respond to possible altered or fabricated documents.

Facilities have occasionally seen final reports and other documents that are altered or fabricated. Facilities should have mechanisms in place to readily identify these altered or fabricated documents. A written policy is required even if the facility has never encountered a possible altered or fabricated document.

5.1.2 The laboratory shall participate in a proficiency testing program for each genetic system used for reporting test results.

Every locus used to test case samples, even those only used occasionally, must be included in proficiency testing 3 times per year.

5.1.2.6 Proficiency testing, whether graded or not graded, shall be representative of the cases the **laboratory performs, including standard trios, single parent and family studies (reconstruction cases).** Some calculations may not be routinely available from a proficiency provider. An example is single parent cases. One mechanism of checking the single parent studies is to recalculate tested trios and compare the results. Typically a lower combined paternity index is expected when a parent is missing. Hand calculating a single parent case to evaluate the laboratory's computer calculations would also be documentation of checking this single parent calculation.

5.2.2.2 The laboratory shall have policies, processes and procedures to ensure that collectors are trained.

If an accredited collection facility is not used, the laboratory shall provide training instructions to the collection facility to ensure that the samples are collected in accordance with these RT Standards. Both the trainer and the trainee should acknowledge in writing that the training for a particular task has occurred. Documentation should indicate that the trainee adequately understood the training prior to working on client samples.

5.2.4.8.1 For cases intended for United States of America immigration, visa, passport, and citizenship, both a photo suitable for positive ID and a legible copy of the government issued photo ID shall be submitted for each tested individual. If these documents are not available, the collector shall document the explanation.

The United States Citizenship and Immigration Services (USCIS) and Department of State (DOS) have requested that a photocopy of the ID used be provided. If a document is not available the collector must thoroughly document the reason no identification was available. When collecting for other countries' equivalent of USCIS or DOS activities, check to see if there are different requirements than in the United States of America.

6.3.3 The laboratory shall have a process to ensure that relationship testing services and test reports meet these RT Standards before distribution or delivery.

Final inspection is the last opportunity to confirm that the relationship testing report has met all requirements and is ready for issue. Prior to release, the laboratory is expected to confirm that all inprocess inspections and tests were performed and verify that customer requirements are satisfied. Only final reports that have met these requirements should be signed.

9.1.6 Corrective Action: The laboratory shall have a process for corrective action that includes the following elements: ... An assessment of risk.

9.2.1 Preventive Action: The laboratory shall have a process for preventive action that includes the following elements:... An assessment of risk.

An assessment of risk is integral to an effective preventive action process. An assessment of risk should include identification of risks in the laboratory, an evaluation of the impact and severity of the risks and potential for occurrence, and implementation of controls to mitigate potential adverse events.

Relationship Testing Tool Kit

Available in the AABB Store

Combining go-to reference documents on relationship calculations and practical templates, this digital toolkit will assist members with the evaluation of both standard and complex testing situations and the development of forms for operational conformance.

Access is provided to guidelines and references from various sources covering the following topics: mass fatality DNA identification operations, relationship testing calculations, likelihood ratios, twinship, chimeras, hydatidiform moles, and incestuous parentage.

In addition, customizable forms may be downloaded in Microsoft Word format to assist with record-keeping in compliance with the AABB *Standards for Relationship Testing Laboratories*: Competency Record, Continuing Education Record, Proficiency Test Results Review, Evaluation of Calculation Software Validation, and Evaluation of RT Laboratory Director Qualifications.

COVID19/SARS CoV2 and Relationship Testing

While it may not appear germane on the surface to the topic of Relationship Testing, laboratories engaged in providing RT service interact in close physical proximity to clients, usually obtaining mouth swab samples. In the present era of Covid-19, it bears reminding that precautions must always be taken to avoid exposure of either the lab staff or the clients to the virus. Dr. Harlan Krumholz, a professor of medicine at Yale, suggests that "we should assume that anyone could be carrying the virus." Stay safe and be on guard at all times.

USCIS UPDATES

USCIS stops scheduling and collection of samples due to COVID-19

The U. S. Citizenship and Immigration Services (USCIS) has notified AABB that, due to the COVID-19 pandemic, the Department of State has instructed posts to stop scheduling and collecting samples for all visa, citizenship, and USCIS cases until further notice that routine services have resumed.

USCIS Policy Update on Acceptance of DNA Evidence for Sibling Relationships

There have been significant changes to USCIS policies regarding the acceptance of DNA evidence supporting sibling relationships. The news release is available on the USCIS website: <u>https://www.uscis.gov/news/alerts/uscis-updates-policy-dna-evidence-support-sibling-relationships</u>

The complete policy memorandum is available on the USCIS website: <u>https://www.uscis.gov/sites/default/files/USCIS/Laws/Memoranda/2018/2018-</u>04-17-PM-DNA-Evidence-of-Sibling-Relationships.pdf



Earn a Certificate of Training from AABB and be included on the list of qualified collection suppliers given quarterly to AABB Accredited Relationship Testing Laboratories worldwide.

Registration Fees*

List Price: \$69.00

Member Price: \$69.00

Register online through the AABB Marketplace

Questions? Contact the AABB eLearning Department: Phone: +1.301.215.6482 Email: <u>eLearning@aabb.org</u>

AABB / A2LA Joint Assessment Program

AABB and the American Association for Laboratory Accreditation (A2LA) have joined forces to offer the AABB/A2LA Accreditation Program to the relationship testing and forensics communities.

- Two assessments in one, covering AABB Relationship Testing Standards and ISO 17025:2017, reducing laboratory staff time
- Internationally-recognized accreditation through ILAC (A2LA) and IEEA (AABB) For information on ISO 17025 accreditation contact:

Randy Querry A2LA Accreditation Manager 1-301-644-3221 or rquerry@A2LA.org

CALL FOR CONTENT

Articles of Interest

Do you have an interesting case or question you would like to share through this newsletter?

Repurpose your old talks or presentations

If you have given a talk or presentation in the last 2-3 years on a topic that you think may be of interest to the relationship testing community, share your content as part of AABB's RT Webinar Series. If you decide to submit your content, you can choose to moderate the audio conference or we can assign a speaker for you.

For more information or to submit your content, email us at nikkib@aabb.org

RT Accreditaion Committee

- Would you like to be involved in creating educational material for Relationship Testing Facilities?
- Are you interested in ensuring that assessment/audit procedures are in consistent with AABB policies established by the AABB Accreditation Program Committee?
- Are you interested in working with U.S. Citizenship and Immigration Service and/or the Dept. of State as it relates to RT?
- Are you currently an AABB Member?

RT Accreditation Committee Members

Charles Kelly, PhD Chair

Michelle Beckwith, BS Elizabeth Kopitke Harmeet Kaur, PhD Robert Bever, PhD Debra L. Davis, PHD

RT Standards Committee

- Would you like to be involved in creating and revising the Relationship Testing Standards?
- Are you interested in ensuring that assessment/audit procedures are in consistent with AABB policies established by the AABB Accreditation Program Committee?
- Are you interested in working with U.S. Citizenship and Immigration Service and/or the Dept. of State as it relates to RT?
- Are you currently an AABB Member?

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