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Standard for a Quality Assurance Program in Forensic Anthropology

Forensic Anthropology Subcommittee
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OSAC Proposed Standard

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Standard for a Quality Assurance Program in Forensic Anthropology

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Foreword

This document was developed to provide forensic anthropology practitioners with the minimal components of a quality assurance system. Currently, there is no standardized guidance on quality assurance in forensic anthropology and this document provides the foundation for practitioners. This minimal approach to quality assurance creates a pathway to ensure that forensic evidence is handled in an appropriate manner by qualified individuals and can be followed by all laboratories, especially small laboratories performing infrequent analyses as well as sole practitioners. An associated document titled “*Guidelines for a Quality Assurance Program in Forensic Anthropology*” is provided to elaborate on these requirements and provide guidance on how to implement them.

Keywords: *quality assurance, laboratory management, accreditation requirements*

Table of Contents

1	Scope	6
2	Normative References	6
3	Terms and Definitions.....	6
4	Requirements	8

Standard for a Quality Assurance Program in Forensic Anthropology

1 Scope

A Quality Assurance (QA) program is necessary to ensure a consistent, transparent, and high-quality work product produced by a practitioner. This document specifies the minimum components of a QA program for forensic anthropology laboratories yet to be accredited. This standard is not a substitute for national or international accreditation standards, and adherence to this standard is not sufficient to satisfy such accreditation requirements. Rather, the components provided are intended to provide tangible steps toward laboratory accreditation. In instances where a laboratory has formal accreditation, those provisions supersede the requirements provided in this Standard.

2 Normative References

None.

3 Terms and Definitions

For the purposes of this document, the following definitions apply.

3.1

administrative review

An evaluation of a final report and supporting documentation for consistency with laboratory policies and for editorial correctness.

3.2

authorized personnel

Individuals approved by laboratory management, who meet the requirements needed to access the laboratory, access and/or handle evidence, perform tasks, etc.

3.3

calibration

The set of operations that establish, under specified conditions, the relationship between values indicated by a measuring instrument or measuring system, or values represented by a material, and the corresponding known values of a measurement.

3.4

case file

Compilation of all technical records, administrative material (e.g., submission, supporting, review, or tracking records), and a copy of the issued report for a specific case investigation.

3.5 competency test

Evaluation of a person's knowledge and ability to independently perform work.

3.6 controlled document

A document for which all changes, approvals and distribution are recorded, and the most recent revision is recognizable.

3.7 corrective action

Actions taken to address a nonconformance and to prevent its recurrence.

3.8 nonconformance

A failure to follow a laboratory standard operating procedure (SOP) or other controlled document in a process, design, documentation, or procedure.

3.9 performance check

A quality assurance measure to assess the functionality of laboratory instruments and equipment that affect the accuracy or validity of forensic sample analysis.

3.10 preventive action

Proactive measures that are taken to reduce or eliminate the opportunities for nonconformance or unexpected/undesirable events from occurring.

3.11 proficiency test

Evaluation of participant performance against pre-established criteria, typically by means of interlaboratory comparisons.

3.12 requesting agency

The entity that requests an analysis or service. Often it is a medicolegal authority (e.g., medical examiner or coroner), but it may be a law enforcement agency, prosecutor, defense counsel, or other legal professional.

3.13**risk assessment**

Assessment of potential issues that could create undesirable events.

3.14**standard operating procedure (SOP)**

A document which describes the regularly recurring operations in a workplace; the goal of such a document is to provide instructions for correct operations in the same manner each time they are performed.

3.15**task**

Any analysis, service, or other action that requires training prior to performing it independently. Often requires an SOP to ensure it is performed correctly and consistently.

3.16**technical review**

An authorized second party's evaluation of reports, notes, data, and other documentation to ensure there is appropriate and sufficient support for actions, results, conclusions, opinions, and interpretations.

3.17**uncontrolled document**

Electronic or printed copy of a document that is not formally managed (i.e., modifications, approvals, and distribution are not recorded) and may or may not be current with the latest version.

3.20**validation**

A process of evaluating a system, method, or component to determine that requirements for an intended use or application have been met.

4 Requirements**4.1 Scope of work**

The forensic anthropology laboratory shall have a list of analyses performed and services offered.

4.2 Organization

4.2.1 The forensic anthropology laboratory shall have a clear and unambiguous documented internal organization and chain of command.

4.2.2 The organizational structure shall clearly identify personnel who are responsible for the technical and administrative operations of the laboratory to ensure impartiality and consistent management.

4.2.3 When changes to the management and/or organization occur, the integrity of the work shall not be negatively impacted.

4.2.4 There shall be at least one person, however named, that has the responsibility for the monitoring, maintenance, and execution of the quality assurance program.

4.3 Safety

The forensic anthropology laboratory shall have a health and safety program to address personal safety while in the laboratory and during remote operations.

4.4 Security

A forensic anthropology laboratory shall have written policies and/or procedures to always ensure the security of evidence, including during evidence recovery, transportation, handling, and storage. The laboratory shall also have written policies and/or procedures to ensure the security of case files, including electronic and hard-copy documentation.

4.5 Document Control

The forensic anthropology laboratory shall have a system for identifying and maintaining all controlled documents (e.g., SOPs, forms). At a minimum, the system shall include a list of all controlled documents used by the laboratory, the history of each document's revisions and approvals, a procedure for clearly marking documents as either controlled or uncontrolled, and provisions for the archiving and disposition of obsolete documents.

4.6 Standard Operating Procedures (SOPs)

The forensic anthropology laboratory shall have written SOPs to ensure all operations are performed consistently and with high quality. Procedures and processes used to perform operations shall be clearly documented such that they can be repeated by another qualified person.

Laboratories shall develop and implement SOPs for all tasks they perform. These can include:

- scene search and recovery

- evidence handling and preservation
- case file creation and management
- case documentation (including evidence inventory, bench notes, and imaging)
- specimen processing/cleaning
- laboratory analyses
- sampling for other analytical tests (e.g., histology, DNA, isotopes)
- report writing
- administrative and technical reviews
- security of evidence and documents

Laboratory management (including sole practitioners) and personnel shall take actions to minimize deviations from SOPs. However, operations documented in SOPs may not encompass or be appropriate for all possible scenarios. Deviations from the SOP shall be documented, and documentation of deviations shall be available to customers and discovery/records requests. All deviations shall be documented by laboratory management and, when necessary, should be disclosed to the requesting agency prior to their implementation. Deviations that require destruction of the evidence shall be documented and disclosed to the requesting agency before samples are processed.

4.7 Method Development and Validation

The forensic anthropology laboratory shall have a written policy for developing and validating new or modified methods, equipment, and software.

4.8 Accuracy and Reliability of Measurements and Observations

To ensure accuracy and reliability of measurements (i.e., capturing the true measurement), the forensic anthropology laboratory shall have a policy and procedure that addresses the calibration and/or suitability (i.e., condition, completeness), performance, and maintenance of its equipment used during analyses.

NOTE: the generic term “equipment” is used in this context to encompass equipment, instruments, comparative materials, etc. Examples of equipment commonly used during forensic anthropological analyses include, but are not limited to calipers, osteometric boards, digitizers, digital microscopes, reference casts of pubic symphyses and sternal rib ends, and Fordisc.

The laboratory shall maintain a list of equipment that requires calibration, performance checking, and maintenance; the list shall include each item’s description/name, serial number or other unique identifier, and acceptable tolerances (when applicable). The laboratory policy and procedure addressing equipment shall provide the interval and frequency of calibrations, performance checks, and maintenance for all equipment that is in service. A log of calibration, performance checks and results, maintenance, and instrument repair shall be maintained.

Equipment failing to meet minimum acceptable criteria shall be removed from service, labeled as such, and documented in laboratory management records.

4.9 Personnel

Any forensic anthropology laboratory personnel authorized to perform tasks listed in the laboratory's scope of work shall hold the appropriate qualifications. The education and training of each of these individuals shall be documented and, when appropriate, should be made available upon request. A list of all authorized personnel and which tasks each are authorized to perform shall be maintained by the laboratory.

4.10 Training

The forensic anthropology laboratory shall identify the relevant competencies required to successfully perform tasks covered under the scope of the laboratory's work. Competency requirements may include a combination of knowledge, skills, and abilities evidenced through education and training, as well as internal laboratory training requirements. The laboratory shall maintain a training program to ensure personnel possess and retain the required knowledge, skills, and abilities. Training may be achieved internally from qualified personnel or externally via a continuing professional development program. The laboratory shall maintain documentation of the training and education each authorized personnel receives and the date it was completed.

4.11 Competency and Proficiency Testing

The forensic anthropology laboratory shall have a program and procedure(s) for competency testing, which shall include a practical component, and proficiency testing (internal and/or external) that evaluates participants' capabilities, performance, and overall laboratory practices.

4.12 Evidence Handling

Evidence transported by, received, and accessioned into a forensic anthropology laboratory shall be secured, conserved, examined, stored and otherwise treated in a manner that maintains its integrity. Evidence in the custody of the laboratory is protected against loss, commingling, contamination, deterioration, destruction, decomposition, and other changes at all times. The laboratory shall have a written policy addressing retention periods of evidence and records as well as final disposition of these items.

All evidence entering the custody of the laboratory shall have a unique identifier, whether previously assigned or assigned by the laboratory. This number is used on the chain-of-custody and remains associated with the evidence through its final disposition. If smaller samples are separated from the submitted evidence, these shall be provided with their own unique identifier and include associated documentation about the origin of the sample.

4.13 Case File

The forensic anthropology laboratory shall maintain documentation of all activities associated with an analysis or service provided, to include communication regarding the case. The documentation shall be trackable and retrievable (traceable) and shall carry the same unique identifier as that assigned to the evidence.

4.14 Technical and Administrative Review

The forensic anthropology laboratory shall have a written procedure for technical and administrative reviews of reports of analysis. The written procedure shall identify the qualifications for the technical and administrative reviewer(s). The laboratory shall maintain a list of personnel authorized to perform technical and administrative reviews, and for the former, specify the analyses each individual is authorized to review.

4.15 Risk Management

The forensic anthropology laboratory shall have a written policy and procedure to address continuous improvement that includes preventive actions and/or risk assessments and, in the event of nonconformance, ensure that corrective actions are taken.

The laboratory shall have a procedure on when and how to perform a risk assessment. The risk assessment shall identify how likely it is for the risk to occur and be identified, and if the impact is substantial enough to warrant a change in procedure.

The results of the risk assessment shall be used to develop associated preventive actions which can include staff training, changes to procedures, and/or resource allocation.

Corrective actions are implemented after a problem has occurred and shall be proportionate to the severity of the incident. These actions attempt to rectify the problem.

Additionally, the policy and procedure shall address the monitoring of corrective actions, preventive actions, and risk assessments to ensure that actions taken are effective.

4.16 Impartiality

The forensic anthropology laboratory shall have a policy and procedure for ensuring impartiality, which shall include a code of ethics and conduct and disclosure of conflicts of interest.