OSAC 2024-S-0001 Guidance Document for Understanding and Implementing the Minimal Components of a Quality Assurance Program in Forensic Anthropology

Forensic Anthropology Subcommittee
Medicine Scientific Area Committee
Organization of Scientific Area Committees (OSAC) for Forensic Science

Draft OSAC Proposed Standard

OSAC 2024-S-0001 Guidance Document for Understanding and Implementing the Minimal Components of a Quality Assurance Program in Forensic Anthropology

Prepared by
Forensic Anthropology Subcommittee
Version: 1.0
November 2023

Disclaimer:

This OSAC Proposed Standard was written by the Organization of Scientific Area Committees (OSAC) for Forensic Science following a process that includes an open comment period. This Proposed Standard will be submitted to a standards developing organization and is subject to change.

There may be references in an OSAC Proposed Standard to other publications under development by OSAC. The information in the Proposed Standard, and underlying concepts and methodologies, may be used by the forensic-science community before the completion of such companion publications.

Any identification of commercial equipment, instruments, or materials in the Proposed Standard is not a recommendation or endorsement by the U.S. Government and does not imply that the equipment, instruments, or materials are necessarily the best available for the purpose.

Guidance Document for Understanding and Implementing the Minimal Components of a Quality Assurance Program in Forensic Anthropology

Foreword

This guidance document was developed to provide forensic anthropology practitioners with fundamental information on the minimal components of a quality assurance system. All forensic science service providers, including forensic anthropology laboratories, should seek accreditation from an accrediting body following an international standard such as ISO/IEC 17020:2012; however, some laboratories may not have sufficient financial means or necessary administrative support to pursue accreditation. In these cases, the laboratory staff are expected to implement, at a minimum, the components of a quality assurance system identified in this document. 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 both small laboratories performing infrequent analyses as well as sole practitioners. The document is organized into succinctly stated quality assurance components followed by note sections that explain the components in plain language, often with examples.

Keywords: *quality assurance, laboratory management, accreditation*

Table of Contents (*to be updated when the document is finalized*)

1 Scope

A Quality Assurance (QA) program is necessary to ensure a consistent, trustworthy, and high quality work product produced by an analyst. This document outlines the basic components of a QA program and serves as guidance to forensic anthropology laboratories that have not yet pursued accreditation through an accrediting body. In instances where a laboratory has formal accreditation, those provisions supersede the guidance provided in this document.

Note: This document is intended to identify the minimal components of a QA program for forensic anthropology laboratories and provide instructional information to define and implement these components. The target audience is anthropologists performing forensic casework within a larger entity that provides little to no administrative support for establishing a full quality assurance system that meets an accrediting body's requirements or international standards such as ISO 17020. For example, a forensic anthropologist who works within an academic department that does not recognize forensic casework as a significant aspect of its mission or scope, and which handles a limited number of cases each year. Also, it is intended for a sole practitioner who does not have the necessary infrastructure to meet an accrediting body's requirements or international standards. Laboratories that perform forensic casework on a regular basis, especially those with contracts from medicolegal authorities, are expected to seek formal accreditation through a certified accrediting body.

Appendix A is a diagram to assist with understanding the relationship between standards, accreditation, and QA programs.

2 Normative References

None

3 Terms and Definitions

For purposes of this document, the following definitions apply.

3.1
administrative review
An evaluation of the report and supporting documentation for consistency with laboratory policies and for editorial correctness.

3.2
authorized personnel
Individuals who meet the requirements needed to access the laboratory, access and/or handle evidence, perform tasks, etc.

3.3
calibration

The process of configuring an instrument to provide a result for a sample within an acceptable range defined by the specific instrument technical data.

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
chain of custody
Chronological record of the handling and storage of an item from its point of collection to its final return or disposal.

3.6
competency test
Evaluation of a person's knowledge and ability to perform work before authorization to do so independently.

3.7
controlled document
A document for which all changes, approvals and distribution are recorded, and the most recent revision is recognizable.

3.8
laboratory manager
Individual responsible for technical and administrative aspects of laboratory casework and operations.

3.9
nonconforming work
A failure to follow a laboratory standard operating procedure (SOP) or controlled document in a process, design, documentation, or procedure.

3.10
performance checks
Checking equipment (e.g., instruments and reference materials) against a known source, quantity, or substance to ensure proper functioning.

3.11
preventive actions
Actions taken to reduce or eliminate the opportunities for nonconforming work or unexpected/undesirable events from occurring.

3.12
proficiency test
A recurring assessment to ensure that a practitioner maintains basic skills needed to perform a test independently and accurately, and that they understand the laboratory's policies and procedures.

3.13
requesting agency
The entity that requests the forensic analysis or service. Often it is a medicolegal authority (e.g., medical examiner or coroner), but may be a law enforcement agency, prosecutor, defense counsel, or other legal professional.

3.14
retention schedule
A set period of time an item (e.g., document, case file, specimen) is maintained in a secure environment. The retention schedule may be indefinite for some items.

3.15
risk assessment
Evaluations of potential issues that could create undesirable events.

3.16
root cause analysis
Steps taken to understand the nature and extent of a nonconformity and its impact on the laboratory's function.

3.17
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.

3.18
task
Any analysis, service, or other action that requires training prior to performing it independently. Often requires an SOP to ensure it is performed consistently.

3.19
technical review
A qualified 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.

3.20
uncontrolled documents
A document that does not meet the requirements of a controlled document. Often these are copies of controlled documents that may not be the most recent revision or have been otherwise altered from their approved form.

3.21
validation
A process of evaluating a system, method, or component, to determine that requirements for an intended use or application have been fulfilled.

4 Recommendations

4.1 Scope of Work

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

Note: A forensic anthropology laboratory should identify and document what analyses and services (i.e., tasks) it provides. Examples of analyses are generating a biological profile, skeletal trauma analysis, histological examinations, and antemortem/postmortem radiograph comparison. Services may include search and recovery of evidence from a scene. The scope of work is the foundation of the QA program. All standard operating procedures, training modules, and competency and proficiency testing should focus on tasks provided. A laboratory can expand the list of tasks with an appropriate expansion of the QA program. Laboratories should not perform ad hoc tasks without appropriate standard operating procedures, training, and competency testing.

4.2 Organization

The forensic anthropology laboratory should have a clear and unambiguous internal organization and chain of command. The organizational structure should clearly identify personnel who are responsible for the technical and administrative operations of the laboratory to ensure impartiality and consistent management. When changes to the management and/or organization occur, the integrity of the work shall not be negatively impacted.

Note: The internal organization and chain of command may be highly variable depending on the setting of the laboratory, but must include all individuals (e.g., staff, students, volunteers) that perform tasks. For example, in an academic setting, the organization of the laboratory may be for an undergraduate intern to report to an attending graduate student who reports to the faculty laboratory director. A sole practitioner may document that they report facility concerns to the facilities manager and case concerns to the requesting agency which may be a law enforcement agency, medicolegal authority, district attorney, defense counsel, etc.

4.3 Safety

The forensic anthropology laboratory should have a health and safety program to address personal safety while in the laboratory and at the scene.

Note: An appropriate health and safety program can be as simple or elaborate as needed, depending on the tasks performed by the forensic anthropology laboratory. The purpose of the program is to reduce and mitigate any potential hazards encountered during casework, whether in-house or at the scene. For example, this program should address the use of appropriate personal protective equipment (PPE) to prevent transmission of bloodborne and airborne pathogens during examinations, including how to appropriately don and doff the PPE. This program should also address safety in the use of autopsy/scene tools, handling of biohazard chemicals and biological tissues, and establishing safety procedures.

4.4 Security

A forensic anthropology laboratory should have measures to ensure the security of evidence to include evidence recovery, transportation, handling, and storage, as well as the security of case files (electronic and hard copy documentation).

Note: The laboratory's security policy should address physical evidence, case files (hard copies and electronic), and building/facility access. The security of physical evidence should be ensured at all stages of the process including receipt, transportation, transfer, analysis, storage, and disposition. Transport of human remains should be secured so that only authorized individuals have access to the transporting vehicle. Consider if written permission is needed to transport human remains from a scene to a laboratory; if so, written procedures should address appropriate documentation and necessary signatures.

Access to the laboratory should be limited to authorized personnel and the laboratory manager should maintain documentation of individuals who have authorized access. Access may be restricted by key card, physical key, or other security device. Doors to the laboratory should remain secured at all times. Some laboratories also utilize surveillance cameras in/around the facility. Controlled access may be granted to visitors. A visitor log should be used to document who has entered the laboratory, the date and time of the visit, and which authorized person was escorting the visitor or providing access. The security policy should address when photographs may be taken inside the laboratory and by whom.

Access to electronic case files should be controlled through a password protected computer system wherein only authorized personnel have access. Any paper documentation should be contained in a secure area such as a locking cabinet or in a locked and secured room accessible only to authorized personnel. Individuals accessing the secure documents should be documented in a log.

4.5 Document Control

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

Note: Documents that dictate how the laboratory performs tasks (e.g., SOPs) as well as standardized forms used to collect information (e.g., bench notes, chain of custody, etc.) should be controlled. Current versions of a document should be clearly marked and readily available to staff; obsolete versions of a document should be clearly marked and may not be available to staff. The current version of a document should be kept in a controlled location (e.g., a properly labeled binder or electronic file). When copies are made of the controlled document (e.g., photocopy of a document held within the controlled binder or printed copy of the document from the controlled electronic file) it should be marked as 'uncontrolled'.

There are several ways to create a document control system through properly labeled and secured files. Commercial software is available as well. Several accredited forensic anthropology

laboratories post their SOPs on the internet and have them marked with their effective dates. This allows laboratory personnel to access the documents and easily recognize the most current version. A list of offices that post their documents on the internet is included in Appendix B.

4.6 Standard Operating Procedures

The forensic anthropology laboratory should have written Standard Operating Procedures (SOPs) to ensure all tasks are performed consistently and with high quality. Procedures and processes used to perform tasks should be clearly documented such that they can be repeated by another competent and qualified forensic anthropologist.

Laboratories should develop and implement SOPs for all tasks they perform, for example:

- scene search and recovery,
- evidence handling and preservation,
- case file creation and management,
- case documentation (including evidence inventory, bench notes, and imaging),
- remains 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.

When feasible, tasks should be performed in compliance with the recommendations in these documents to ensure quality assurance. This may include tasks that are performed at locations away from the laboratory. When tasks are performed at locations away from the laboratory (i.e., fieldwork), the location should be documented.

Steps documented in SOPs may not encompass or be appropriate for all possible casework scenarios. Occasionally, deviations from a SOP are needed. When possible (and if appropriate), a planned departure from a procedure or process should be pre-approved and documented by laboratory management. Additionally (when possible), the requesting agency should be notified of potential deviations prior to their occurrence. The laboratory should foster open discussion with the requesting agency regarding potential deviations. The laboratory should clearly explain the reasoning for the departure from the SOP and the justification for the proposed alternative procedure or process. Prior to conducting the alternative procedure or process, the laboratory should obtain consent/authorization from the requesting agency for deviating from laboratory SOPs, and whenever possible other downstream stakeholders (especially if the evidentiary material/remains will be entirely consumed or chemically, thermally, or structurally altered). When the laboratory deviates from its SOPs, the deviation(s), the reasoning for the deviation(s), and the authorization(s) should be documented in the case file.

Note: A SOP is a document designed to inform practitioners how to perform a specific task in a specific laboratory. The goal of the documents is to ensure consistency among laboratory staff that perform each task. These documents should cover the full range of the laboratory's operations including receiving evidence, accessioning evidence, analyzing evidence, writing analytical reports, technical and administrative review, transferring evidence, disposition of

evidence, and so forth. Some accredited forensic anthropology laboratories publish their SOPs online (see Appendix B); these may serve as helpful resources as a laboratory develops its own SOPs.

Standards published by accredited Standard Development Organizations (SDOs) such as the Academy Standards Board (ASB) can serve as a basis or component of an SOP. For example, a SOP for skeletal analysis may reference the American National Standards Institute (ANSI)/ASB standards for age, sex, and stature estimation.

4.7 Method Development and Validation

The forensic anthropology laboratory should have a written policy for developing and validating new or modified methods.

NOTE: Most forensic anthropologists use methods that have been validated and published in peer reviewed journals. The majority of these methods are not sensitive to laboratory conditions such as temperature and humidity and do not need to be internally validated prior to use.

In some situations, methods may need to be modified or developed by the laboratory. In these situations, the method development or modification must be done with a documented plan and the experiment/study must be carried out with known samples by personnel who are competent to perform the method development. All records associated with method development and validation should be retained to show the scientific validity and reliability of the method.

At minimum, method validation should demonstrate validity and reliability of the method prior to implementation. Some elements to be considered, as applicable, when performing method validation include accuracy, uncertainty of measured results, limit of detection, repeatability, reproducibility, bias, and precision. Methods need to be validated when they have not been peer-reviewed/published, have been modified, or are being used outside of the intended purpose. If the modification(s) are significant enough to depart from the original validated method and/or the end result, the method should be re-validated. For example, a new method for estimating sex was developed and validated on the Hamann-Todd skeletal collection and is published in a peer reviewed journal. A forensic anthropologist who regularly analyzes skeletal material found along the US/Mexico border would like to use the method on a case. Prior to using the method, the anthropologist needs to validate the method on known skeletal material that is representative of their casework. Since the casework population is significantly different than the population used to develop and validate the method, using it can be considered a modification of the method.

4.8 Calibration and Performance Checking

The forensic anthropology laboratory should have a policy and procedure that addresses the calibration, performance, and maintenance of its instruments (e.g., calipers, mandibulometer, osteometric board), equipment (e.g., digitizer, digital microscopes), and reference materials (e.g., pubic symphysis casts) used during testing that includes the interval/frequency of these actions.

The laboratory should maintain a list of equipment that requires calibration, performance checking, and maintenance, including each instrument's serial number or other unique identifier, and the type or name of the instrument. A log of calibration, performance checking, maintenance, and instrument repair should be maintained. Instruments or equipment shall not be used for casework if satisfactory calibration, performance, and maintenance cannot be achieved.

Note: Instruments, equipment, and reference materials may be damaged during routine handling and become unreliable. Calibration and performance checking ensures that instruments, equipment, and reference materials are functioning properly and in good repair.

An instrument is calibrated when it is checked against a National Institute of Standards and Technology (NIST) traceable standard. Typically, the instrument is sent to a calibration service provider that is certified to ISO 17025 and a certificate of calibration is received following a calibration test. Performance checking is done in-house by measuring an item of known dimension and is done at regularly scheduled intervals.

Calibration and maintenance of equipment may require regular service by a certified technician, such is the case with microscopes and medical imaging equipment. More specialized equipment such as a digitizer may require the forensic anthropology laboratory staff to work directly with the manufacturer.

Reference material, such as pubic symphysis casts, should be inspected for damage or wear and tear. This may be done by comparing the material to photographs of the material taken before it was used.

Calibration and performance checking of instruments, equipment and reference materials should be done at established regular intervals. An example would be scheduled calibration annually and performance checks quarterly. The calibration certificates and performance checks (i.e., logbook and associated records) should be maintained. Each instrument, equipment, and reference material should be given a unique identifier so that it can be properly identified in calibration certificates and logbooks.

4.9 Personnel

All forensic anthropology personnel should be qualified to perform the tasks outlined in the laboratory's scope of work. The education and training of each individual authorized to perform tasks should be documented and available upon request. A list of all authorized personnel should be maintained.

Note: All individuals (i.e., staff, students, interns, volunteers) handling evidence and/or performing tasks need to be adequately trained before working independently, regardless of the tasks being performed. Furthermore, the required education and training needed to perform a task must be identified and documented. A record of education and training should be created and maintained for each individual authorized to perform each task. The record should be

updated when an individual receives additional education and training. Some jurisdictions may require laboratories to provide access to these records. Having a list of authorized individuals may help manage records of individuals who have left the laboratory.

4.10 Training

The forensic anthropology laboratory should identify its core function(s) (i.e., tasks) and identify the relevant competencies required to achieve successful performance of the stated functions (See section 4.1). Competency requirements may include a combination of knowledge, skills, and abilities evidenced through education and training. The laboratory should identify or create a training program to ensure personnel have the required knowledge, skills, and abilities to perform the stated functions. Training may be achieved through internal sources from qualified personnel or external training via a continuing professional development program. The laboratory should maintain documentation of the training and education each staff member receives to include the date the education or training was completed.

Note: The laboratory should have a training program for staff that meets its own QA program requirements. The laboratory should be able to demonstrate staff/analyst-level competency and proficiency through a training and testing program. Staff should have knowledge, skills, and abilities tied to laboratory security and safety, evidence handling, cognitive bias and human factors (see Appendix B for resources to facilitate human factors training), in addition to the core scientific disciplines practiced (i.e., determine non-human from human bone, sort commingled remains, estimate the biological profile from a skeleton, etc.).

4.11 Competency and Proficiency Testing

The forensic anthropology laboratory should have a program and procedure(s) for competency testing as well as external and/or internal proficiency testing, that evaluates practitioners' capabilities and performance.

Note: Competency tests provide a means to gauge an individual's ability to function independently in a laboratory. Any new laboratory personnel who has the potential to handle casework or perform analyses should be competency tested prior to beginning casework. The laboratory should have a defined list of areas (e.g., sex estimation, age estimation, population affinity estimation, human/non-human differentiation, etc.) that require testing and all new personnel should be administered tests related to their duties.

Proficiency testing occurs at regular intervals to ensure that the personnel are familiar with the SOPs and equipment as well as maintaining their skill level of routine analyses. To be most effective, blind proficiency tests should be implemented, if possible. See Appendix B for resources on proficiency test implementation strategies. External vendors are available to provide proficiency testing for forensic anthropology laboratories for a fee. Each proficiency test typically addresses one examination area (e.g., sex estimation) per test. A laboratory can choose how many proficiency tests it requires in one year. A documented plan/schedule of what tasks are proficiency-tested and when is strongly recommended to reduce chances of missing proficiency-testing of specific tasks. When the result of a proficiency test does not match the expected result and is not scientifically justifiable, an analysis of the source of the error should

be done. When necessary, the analyst should be retrained and retested before returning to performing independent analysis.

Results of the competency and proficiency tests and any follow-up action such as retraining should be archived.

4.12 Evidence Handling

Evidence should be received and accessioned into a forensic anthropology laboratory and handled within the laboratory in a manner that maintains the integrity of the evidence and protects evidence against commingling, contamination, deterioration, inadvertent loss, or destruction. Evidence should be transported, secured, conserved, and stored to minimize loss, contamination, decomposition, and other changes. The laboratory should have a written policy addressing retention periods of evidence and records as well as final disposition of these items.

Note: Evidence handling procedures should include how evidence is received and accessioned. All human remains are treated as evidentiary material. Accessioning should include assigning a unique identifier (e.g., case number) to each case. At times, additional remains may be received for a case already accessioned into the laboratory. When this occurs, the original unique identifier can be assigned to the additional remains, but the secondary accessioning should be documented in the case file.

The written procedure should address steps to protect against commingling and contamination. These steps can be as simple as allowing only one case to be placed on a table or tray at a time. A laboratory may choose to write the unique identifier on each bone of a case or may choose to label the container holding the remains with the unique identifier. The system that a laboratory employs to label a case with the unique identifier should be included in the written procedure.

The written procedure should include documentation of evidence transfer (i.e., appropriately signed chain of custody). The documentation should be initiated when evidence is first received–whether as a recovery from the scene or through transfer from the requesting agency–and should continue until final disposition of the evidence. Evidence transfer is typically documented on a form and the form (or copy of it) should be stored in the case file.

The written procedure should include the final disposition of the evidence. Final disposition may be to return the evidence to the requesting agency, to archive evidence for a specific period of time then destroy it, or to archive evidence indefinitely. Regardless of the final disposition chosen, it should be communicated to the requesting agency and documented.

4.13 Case File

The forensic anthropology laboratory should maintain written documentation of all activities associated with an analysis or service provided, to include communications regarding the case.

The documentation should be traceable and carry the same unique identifier as that assigned to the evidence, and it should be tracked and retrievable.

Note: The laboratory should have a written policy or SOP identifying which documents pertaining to a task must be retained; these documents constitute the case file. The case file and all documents held within it should be labeled with the unique identifier assigned to the evidence. The case file should include all forms used to track evidence (receipt, transfer, release, or final disposition), documents pertaining to the task (e.g., police report, medical examiner report, etc.), documents created during the task (e.g., site map, bench notes, analysis printouts, final report, etc.), all communications regarding the case (e.g., copy of emails, written documentation of phone calls, expert witness testimony documents, etc.), and so forth. Items such as radiographs and photographs may be kept in a separate location (e.g., designated server), but must be associated with the case file (typically accomplished by labeling each item with the unique identifier) and retrievable. If items are stored separately from the case file, there should be written documentation of the storage location in the policy or SOP.

4.14 Technical and Administrative Review

The forensic anthropology laboratory should have a written procedure for technical and administrative reviews of reports of analysis. Technical review is an evaluation by a qualified second party of reports, notes, data, and other documentation to ensure there is appropriate and sufficient support for the actions, results, conclusions, opinions, and interpretations. Administrative review is intended to confirm that the laboratory's standard report format is followed and to ensure editorial correctness. The written procedure should identify the qualifications of the technical and administrative reviewer(s).

Note: Technical review is an independent evaluation by a qualified forensic anthropologist. The goal of the technical review is to ensure the methods used during the analysis are appropriate and followed correctly, the results are accurate, the bench notes are clear and complete, the evidence is adequately documented (e.g., photographs, radiographs, etc.), all items are properly marked with the unique case identifier, and the final report is clearly written. The technical review may be done internally or externally. Technical review is not required for 100% of cases produced by a laboratory, but a laboratory should define parameters for cases that require technical review if 100% is not met. The technical review should be documented (typically on a form) and that documentation should be retained in the case file. A formal agreement between agencies may be required prior to providing technical review. The agreement may include an expected turnaround time for a review and how to handle discordance. When a discordance occurs and cannot be settled between the analyst and reviewer, another expert should be consulted. Note that a reviewer may be subpoenaed to discuss their role in the case and their opinion of the analysis.

Administrative review is usually conducted by an individual familiar with the laboratory's reporting format. During the administrative review, the final report is checked for the laboratory's standard report format and accuracy of basic case information such as case number, spelling of decedent's name, dates, initials, page number, presence of signature, etc. The technical and administrative reviews may be conducted by the same individual.

4.15 Preventive and Corrective Actions

The forensic anthropology laboratory should have a written policy and procedure to address continuous improvement which includes preventive actions and/or risk assessments and, in the event of nonconforming work, ensure that corrective actions are taken. Corrective action plans should be proportionate to the severity of the incident.

Note: Preventive actions are actions taken to reduce the opportunities for nonconforming work or unexpected/undesirable events from occurring. Risk assessments are evaluations of potential issues that could create undesirable events. Risk assessments can result in preventive actions being taken to reduce the risk and/or prevent an event from occurring. These are typically documented using the following: identified risk, evaluation of risk, preventive actions to address risk, and monitoring of effectiveness of actions taken. Together, these processes allow for improvement in the quality of work in a laboratory while reducing any negative impacts.

For example, the laboratory manager notices that only the lids of specimen jars are labeled with the case number. The manager is concerned that if the lids are switched (which is easy to do), then the cases would be incorrectly labeled (identification of risk). The manager performs a risk assessment by reviewing the Evidence Management SOP. The SOP states to "label the jar" and is not specific as to what part of the jar should be labeled (evaluation of risk). The manager revises the SOP to state that the jar itself should be labeled, regardless of whether the lid is labeled. The manager distributes the updated SOP to all staff and provides training (preventive action to address risk). The manager monitors the labeling of the specimen jars for a period of time to ensure that all staff are following the revised procedure (monitoring of effectiveness).

Nonconforming work is work performed which does not follow the laboratory's own policies/procedures, good laboratory practices, or this document. When nonconforming work is discovered, a corrective action is taken. The procedures for handling nonconforming work should include the following:

a) identify affected case(s) and sample(s),
b) identify potential impact on the case(s) and sample(s),
d) perform a root cause analysis,
e) investigate to determine if incident is systemic,
f) create a corrective action plan,
g) monitor for effectiveness of the corrective action,
h) notify relevant stakeholders, if applicable.

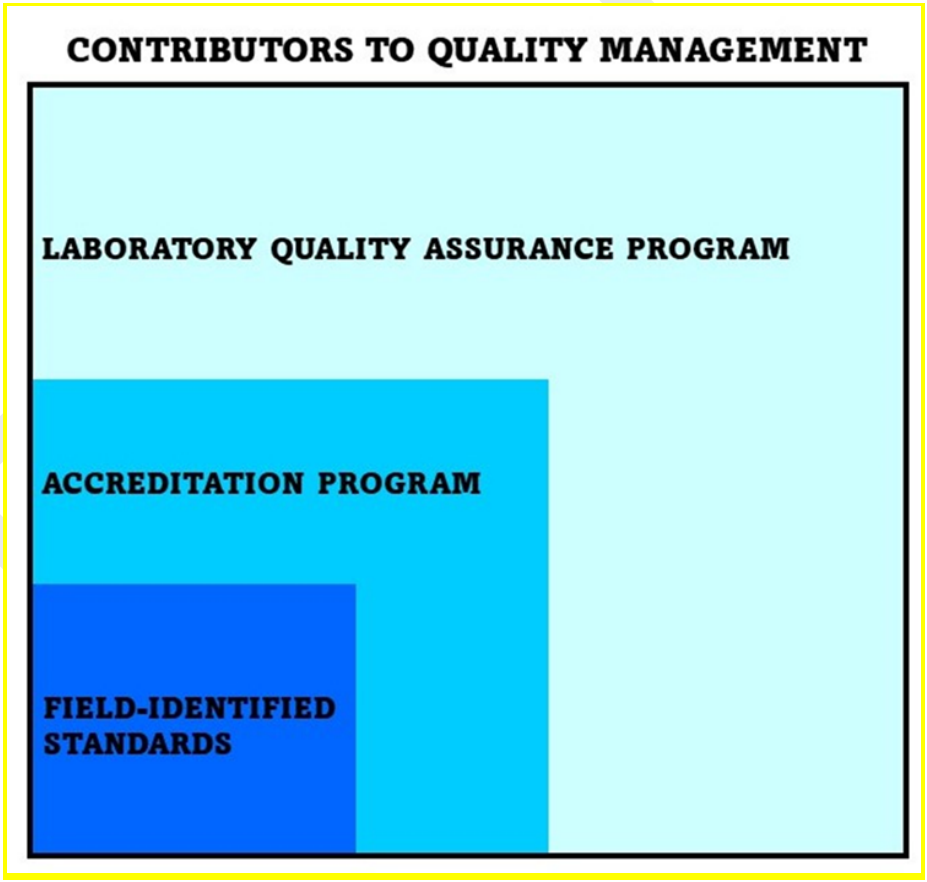
Building on the previous example, an analyst at the laboratory has labeled the lids of specimen jars and not the jars themselves. A colleague notices this and notifies the laboratory manager about the nonconformance as this is in violation of the newly revised Evidence Management SOP. The laboratory manager performs a root cause analysis by interviewing the analyst, reviewing the analyst's training record, re-reviewing the SOP to see if there are any deficiencies, examining other specimen jars handled by the analyst as well as specimen jars handled by other analysts. The manager determines that the analyst received the original training, the SOP is clearly written, and other analysts are properly labeling specimen jars. The manager determines that this is a problem affecting one analyst and not a systemic problem. The manager also determines that the analyst has not been following the revised SOP, but it is unlikely that

they have switched labeled lids and no casework has been negatively affected. The manager creates a corrective action plan for the analyst which involves re-reading the SOP and taking a short quiz. Then, the analyst's specimen jars are monitored for a specific period of time to ensure the SOP is followed correctly.

All events of the nonconformance and corrective action should be documented to include a description of the nonconformity, list of specimens/cases affected, outcome of the root cause analysis, necessary corrective actions, and monitoring period and results. A laboratory may consider adding this documentation to the case files of affected cases. This record should be retained for a defined period of time based on the documented retention schedule. Some corrective actions may be minor like the above example; some may be major, requiring work to be suspended, retracted, or re-done as necessary.

Some accredited laboratories post their corrective action SOP on their website and these can serve as resources (See Appendix B).

Appendix A



This diagram demonstrates the relationship between field-identified standards (i.e., OSAC and ANSI/ASB), accreditation program requirements (i.e., ISO 17020, etc.), and the laboratory

Quality Assurance program. Field-identified standards are narrowly focused, typically on a single task (e.g., estimating sex from skeletal remains; determination of medicolegal significance). They tend to be very general and provide the most basic consensus-based requirements. Practitioners should be able to follow them with current resources. Accreditation program requirements are broader in scope and provide guidance on what elements are needed for a laboratory to create an efficient and rigorous Quality Assurance program. Being accredited encourages public trust in the quality of products produced by a laboratory. The laboratory Quality Assurance program is the broadest component and dictates how a laboratory operates. This includes everything from types of analyses performed, evidence handling, case record management, and so on. These procedures are typically guided by the standards and accreditation requirements. Although these three levels are not contingent on each other, they can help inform the other levels.

Appendix B

Informative References

The New York City Office of the Chief Medical Anthropology Unit's Technical Manuals can be accessed at https://www.nyc.gov/site/ocme/services/forensic-anthropology-unit-technical-manuals.page.

The New York City Office of the Chief Medical Anthropology Unit's Laboratory Analysis Manual can be accessed at https://www.nyc.gov/site/ocme/services/fau-anthropological-laboratory-analysis-manual.page

Arkansas State Crime Laboratory Quality Manual can be accessed at https://www.dps.arkansas.gov/wp-content/uploads/2020/07/ASCL-DOC-01-Quality-Manual-1709-22.pdf

Hundl C, Neuman M, Rairden A, Rearden P, Stout P. 2020. Implementation of a blind quality control program in a forensic laboratory. *Journal of Forensic Sciences*, 65(3):815-822. https://doi.org/10.1111/1556-4029.14259

Kassin SM, Dror IE, Kukucka J. 2013. The forensic confirmation bias: Problems, perspectives, and proposed solutions. *Journal of Applied Research in Memory and Cognition*, 2(1): 42-52. https://doi.org/10.1016/j.jarmac.2013.01.001

Meija R, Cuellar M, Salyards, J. 2020. Implementing blind proficiency testing in forensic laboratories: Motivation, obstacles, and recommendations. *Forensic Science International: Synergy*, 2:293-298. https://doi.org/10.1016/j.fsisyn.2020.09.002

Quigley-McBride A, Dror IE, Roy T, Garrett BL, Kukucka J. 2022. A practical tool for information management in forensic decisions: Using Linear Sequential Unmasking - Expanded

(LSU-E) in casework. *Forensic Science International: Synergy*, 4:1-6. https://doi.org/10.1016/j.fsisyn.2022.100216

Spellman BA, Eldridge H, Bieber P. 2022. Challenges to reasoning in forensic science discussions. *Forensic Science International: Synergy*, 4:1-16. https://doi.org/10.1016/j.fsisyn.2021.100200