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Title: Nonconformities and Corrective Actions		Control No. QM-008	Revision: 4
Approved by: Forensic Anthropology Director		Effective Date: 10 April 2023	

1. Policy

The FAU shall follow the specified procedures and requirements for addressing nonconformities and implementing corrective actions, when appropriate. This quality manual document fulfills the requirements of the ISO/IEC 17020 International Standards and ANCB AR 3120 Standards.

2. Scope

The procedures and requirements outlined apply to all FAU personnel who are involved in addressing nonconformities.

3. Addressing Nonconformities

3.1 **Nonconformity:** A nonconformity is a violation or non-compliance of a requirement outlined in the FAU SOPs. A nonconformity can be identified at any time and by anyone. The individual(s) who identifies a nonconformity must inform the Quality Assurance (QA) Specialist or the OCME Quality Assurance Director (QA Director) in a timely manner.

3.2 **Nonconformity Levels:** The QA Specialist or the QA Director is responsible for reviewing the nonconformity and assigning it to one of the two nonconformity types based on severity of the issue. The response taken shall vary depending on the nonconformity level assigned.

3.2.1 **Type 1:** Type 1 nonconformity refers to a non-compliance that can potentially undermine analytical conclusions, security and integrity of evidence and case records, negatively impact accreditation, and/or pose a safety hazard. Examples of Type 1 nonconformities include, but are not limited to:

- Faulty equipment.
- Failure to secure anthropology lab.
- Failure to wear appropriate personal protective equipment (PPE).
- Failure to conduct audit on time.

A Type 1 nonconformity should be corrected as soon as possible (e.g., fix faulty equipment). The nonconformity shall be appropriately documented (see section 3.4 documentation). If a Type 1 nonconformity requires more than a simple correction and an underlying cause needs to be identified and addressed, then the Corrective Action process should be followed (see section 3.3).

3.2.1 **Type 2:** Type 2 nonconformity refers to major non-compliances that directly undermine analytical conclusions, the security and integrity of evidence and case records, accreditation, and/or pose a safety hazard. Examples of Type 2 nonconformities include, but are not limited to:

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- Substandard analytical results
- Unauthorized access to evidence
- A direct compromise of the integrity of evidence.

All Type 2 nonconformities shall be subject to the corrective action process described below.

3.2.2 Evaluating the Nonconformity: After the Nonconformity type is identified, the QA Specialist or designee will evaluate whether a corrective action request needs to be initiated. When a corrective action request is initiated, the QA Specialist or designee will determine the appropriate action steps.

3.3 Corrective Action Procedures: A corrective action aims to identify the underlying systemic cause(s) of a “major” nonconformity (Type 2) or repetitive minor nonconformities (Type 1), and to implement steps to correct and to minimize the risk of recurrence.

When a corrective action is deemed necessary, a Corrective Action Request (CAR) form shall be used to record and track the corrective action taken to resolve the issue. The QA Specialist is typically responsible for managing corrective actions; however, any member of the FAU can be designated to implement a corrective action request by the Forensic Anthropology Director (Director). Additionally, the OCME QA Director can step in to manage a CAR if an external approver is needed.

3.3.1 Corrective Action Request (CAR) form: The CAR form records the non-compliant situation or condition under review, the requirement source(s) (e.g., describe the specific clauses in the FAU SOPs or Quality Manual that were violated), the name of the individual(s) responsible for implementing the corrective action, the cause(s) of the situation or condition under review, the action step(s), the expected date of completion, the completion date, and follow-up review.

3.3.2 Corrective Action Steps: Depending on the nature of the nonconformity, the appropriate action steps may include, but are not limited to:

- Halt casework and finalization of anthropology reports that may have been affected by the nonconformity
- Review of, and correction to, any relevant casework
- Inform clients, when necessary
- Issuing amendments to reports or analytical notes
- Remedial training
- Revision of policies, procedures, and/or forms
- Inclusion of additional quality measures.

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3.3.3 Approving a CAR: The designated CAR approver (i.e., QA Specialist, Director or OCME Quality Assurance Director) shall review the corrective action to confirm that the action steps are appropriate and effectively address the nonconformity and that the expected time frame is adequate.

If the designated CAR approver determines the corrective action plan is inadequate the CAR form shall be returned for revision. When the corrective action plan is accepted, the designated approver shall sign and date the form in the space labeled "Action Step(s) Accepted By" and return the form to the individual responsible for the CAR.

Note: The designated CAR approver shall not be the individual assigned to fill out the CAR form and implement the action step(s).

3.3.4 Completing Corrective Action: The action steps shall be implemented in a timely manner. Upon completion of the action step(s), the individual responsible for implementing the CAR shall sign and date the form in the space labeled "Action Step(s) Completed By".

3.3.5 Corrective Action Follow-up Review: The designated approver shall perform a follow-up review of the action step(s) to confirm the effectiveness of the corrective action in addressing the nonconformity. The corrective action is considered "closed out" once the approver signs and dates the CAR form in the space labeled "Follow-up Review Completed By". After the CAR is "closed out" the designated approver can allow previously halted casework and finalization of reports to resume. When necessary, the designated approver should notify the client when the CAR is completed.

3.3.5.1 If the approver determines the action step(s) were not sufficiently implemented or the action step(s) did not effectively address the nonconformity the CAR form shall be returned to the individual responsible for managing the CAR for further action.

3.4 Documentation: All Corrective Action Requests and associated records will be retained by the FAU for at least the duration of the current accreditation cycle. Additionally, nonconformities and their associated corrective actions shall be recorded and maintained on a digital document to track possible trends (see Findings and Nonconformity Log). At minimum, the following information shall be recorded for each nonconformity identified:

- Assigned nonconformity level
- Description of nonconformity

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- Requirement source
- Whether a corrective action was taken (if yes, then also the date of completion)
- Name of individual responsible for managing the CAR.

4. References

AKA 100: 2023 NAB Accreditation Requirements for Forensic Inspection (2023).

International Standard ISO/IEC 17020: 2012 (E) Conformity assessment - Requirements for the operation of various types of bodies performing inspection, 2nd edition, International Standards Organization (ISO)/International Electrotechnical Commission (IEC), 2012.

5. Revision History

REV.	DATE	SUMMARY OF CHANGES
0	29 January 2018	New document.
1	27 September 2018	<p>Added the following statement: “Halt casework and finalization of anthropology reports that may have been affected by the nonconformity” to the bullet points in section 3.3.2.</p> <p>Created sections 3.3.5 and 3.3.5.1</p> <p>3.3.5 Follow-up Review The designated approver shall perform a follow-up review of the action step(s) to confirm the effectiveness of the corrective action in addressing the nonconformity. The approver shall fill out the “Follow-up Review” section of the CAR form after confirmation is completed. The corrective action is considered closed out once the approver signs and dates the CAR form.</p> <p>3.3.5.1 If the approver determines the action step(s) were not sufficiently implemented or the action step(s) did not effectively address the nonconformity, the CAR form shall be returned to the individual responsible for managing the CAR for further action.</p>
2	19 November 2018	<p>Section 3.3.2: Added an additional bullet point stating that one of the corrective action steps will be to inform the client, when necessary.</p> <p>Section 3.3.5: Added the following statement “After the CAR is “closed out” the designated approver can allow previously halted casework and finalization of reports to resume. When</p>

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		necessary, the designated approver should notify the client when the CAR is completed.”
3	19 March 2021	Made minor edits to clauses 3.3.1, 3.3.4, and 3.3.5
	10 April 2023	Added new clause 3.2.2 Evaluating the Nonconformity: After the Nonconformity type is identified, the QA Specialist or designee will evaluate whether a corrective action request needs to be initiated. When a corrective action request is initiated, the QA Specialist or designee will determine the appropriate action steps. Updated language in clause 3.3.3 and added a statement regarding adequacy of the expected time frame. Added the following statement in 3.3.4: The action steps shall be implemented in a timely manner. Clause 3.4: corrected title of nonconformity log. Added reference to ANAB AR3120.