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.

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 labs.
- 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:

- 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.

3.3 **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 assigned 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), and the expected date of completion.

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

- Review of, and correction to, any relevant casework
- Issuing amendments to reports
- Remedial training
- Revision of policies, procedures, and/or forms
- Inclusion of additional quality measures.

3.3.3 **Approving a CAR:** The designated CAR approver (i.e., QA Specialist, Director or OCME Quality Assurance Director) shall review the CAR to determine if all the required sections of the CAR Form have been adequately filled out and that the action steps are acceptable and appropriate. If the CAR is determined inadequate it shall be returned for revision. Once the CAR action steps have been

reviewed and 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 implementing the CAR action steps.

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 Actions**: 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" before returning the form to the designated approver. The designated approver shall confirm that all the action steps have been sufficiently implemented before signing and dating the form in the space labeled "Closed Out By." Once this step has been taken the corrective action is considered completed.

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

- Assigned nonconformity level
- Description of nonconformity
- 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

International Standards ISO/IEC 17020: 2012 (E) Conformity assessment - Requirements for the operating 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.