Policy and Procedure Manual

Policy Title: Chapter 22 Internal Audit

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Effective: 1-29-2019

Revision History:

Revision Date	Revised by:	Reason for Change:	Authorized by:
1-29-2019	ACG	New Policy	ACG

Applicable Inspection Standards:

NAME:	
ISO 17020:	8.6

I PURPOSE

The purpose of this document is to provide the Quality Assurance staff with instructions for the planning, performance, and reporting of audit results. This document establishes the requirements for the performance of Internal Audits performed to ensure the requirements of ISO 17020 and NAME, are met.

II. APPLICABLE DOCUMENTS

The following documents of the latest issue are applicable to the extent specified herein:

NAME Inspection and Accreditation Checklist, Autopsy Facilities Accreditation First Version Adopted October 2013.

International Standard ISO/IEC 17020:2012; Conformity assessment- requirements for the operation of various types of bodies performing inspection.

Form(s): AF Internal Audit Checklist

III. RESPONSIBILITIES

Quality Assurance Manager is responsible for preparing and maintaining this document. In addition, shall ensure Internal Audits are scheduled and conducted as specified by this document. This includes scheduling the audits, assigning personnel to perform the audits, assigning corrective action as a result of the audit findings, and maintaining records of the systems audit results.

Quality Assurance is responsible for training and approving Auditors to the extent necessary to conduct effected audits defined in this document. Auditor may be Quality Assurance, other functional department(s) or subcontractor personnel.

Auditor(s) are responsible for performing the scheduled audits in a professional, impartial, objective and accurate manner in accordance with this procedure.

IV. GENERAL

Internal audits are conducted yearly at approximately 6 months after a formal external inspection by NAME or ANAB.

The internal audit shall be performed on accredited sections of American Forensics based on the Quality Manager's plan, in order to verify that the management system is implements and effective. The internal audit will also look for opportunities for improvement or preventive actions. The internal audit should include but is not limited to, document/record reviews, on-site direct observations and interviews of American Forensic Personnel in the following areas:

A. Quality system manual requirements
B. Quality assurance records such as proficiency tests, court monitoring records, preventive actions, non-conforming work, complaint and appeal reviews. Training programs, certifications, audit records ad documents, management system review documents, accreditation documents, and service
C. Evidence handling and chain of custody
D. Supplies
E. Security
F. Personnel records and personnel training records
G. Health and safety
H. Inspection activities
I. Case files
J. Policies, procedures and methods including calibration and service records

Audit Deficiencies and Opportunities for improvement

All audit deficiencies and opportunities for improvement identified shall be documented using the Internal Audit Checklist forms.

Training: Auditors shall receive basic training by the Quality Manager prior to Auditing. Previous auditing experience/training as determined by Quality Assurance management also documented. Auditor training and approval records are documented and retained in the Quality Manager's office.

V. PROCEDURE

All elements of the ISO 17020 and NAME standards shall be audited once per year, at no sooner than 6 months after a formal external inspection from ANAB or NAME.
A Formal Internal Audit Checklist is completed as a result of the audit.

The auditor will review results of previous audits, internal and external and ensure compliance with any previous nonconformities.

When conducting audits, the Auditor selects a random sample (i.e. three to four samples) of processes and verifies the process against the audit requirement. The audit observations, notes and comments are handwritten in the respective on the Internal Audit Checklist form. In order to give validity to the audit report, it is important for the auditor record information in this block citing what was examined and quantity, and other comments as necessary. It should also be noted if the issue discovered is a recurring problem. It is acceptable to attach support documentation that was examined during the audit to the Internal Audit Checklist.

The Auditor shall conduct the scheduled audit in a professional, impartial, objective and accurate manner. Auditors shall not audit their own work.

VI. ACCEPTANCE

Medical Director reviews the results of Internal Audits and will initiate corrective actions. Internal Audits shall be considered finished only after all corrective actions have been completed. Corrective actions should be completed within 7 days. Corrective Action is handled in accordance with Complaints and Appeals process (CH 19).

Personnel responsible for the area audited are informed of the outcome of the audit.

VII. RECORDS

Records of Internal Audits will be kept for 5 years in the Quality Managers Office