



AUDIT PROCEDURE

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1. Purpose

- 1.1. This procedure sets forth the method for periodically and randomly examining practices, records, and operations to determine the effectiveness of the quality systems.
- 1.2. Besides, this procedure ensures that internal audits are properly planned, and conducted regularly and when problems have identified that need to be investigated in accordance with the Business Continuity Plan and 21 CFR Part 820 requirements.

2. Scope

- 2.1. This procedure applies to the practices employed as well as records and systems produced by CIQA company with regards to the development, modification, implementation, and testing of its operational activities and processes.
- 2.2. In addition, it explains how to plan and carry out internal audits. Internal audit provides reasonable assurance regarding the achievement of the following:
 - effectiveness and efficiency of procedures or implementation
 - compliance with the quality policy or business continuity policy
 - quality assurance improvement.

3. Definitions

- 3.1. Quality Assurance Audit - an official examination of practices employed as well as records and systems produced by a division, taking place on a periodic but random, unannounced basis, to verify the effectiveness of the company's quality program and business contingency efforts.

4. Responsibilities

The Audit Group is responsible for the following internal audit procedures:

- Working with the Laboratory Director to:
 - develop appropriate methodologies and objectives;
 - coordinate the preparation of annual and long-range internal audit plans;
 - establish documented standards for the conduct, documentation and reporting of audit, consultation and investigation activities.