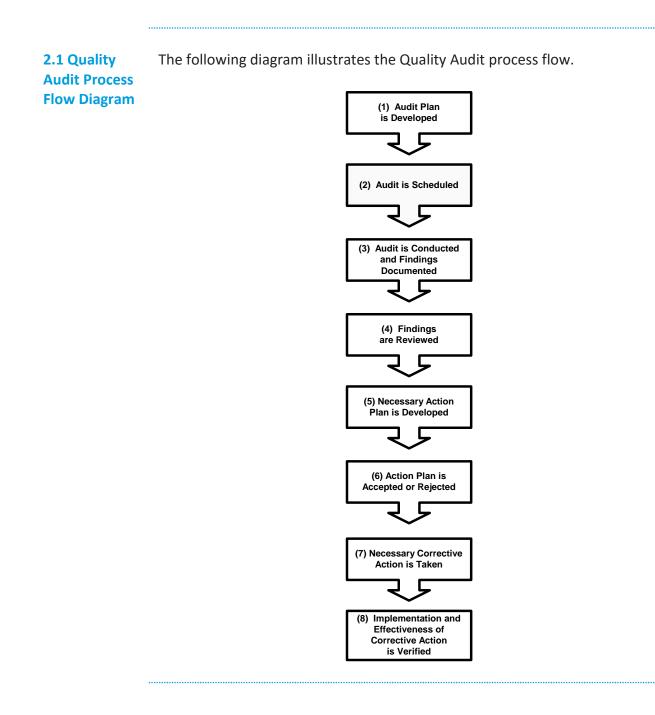| NUMBER	EFFECTIVE DATE	PAGE
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1.0 Overview

1.1 Purpose

This document describes the process for conducting and documenting quality audits.

1.2 Scope

This document applies to quality audits conducted by or on behalf of GPRD QA personnel.

1.3 Responsibilities

GPRD QA Management is responsible to establish an effective Quality Audit system.

1.4 Table of Contents

This document contains the following topics.

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2.0 The Quality Audit Process Flow

2.1 Quality Audit Process Flow Diagram

The following diagram illustrates the Quality Audit process flow.

```
        ┌─────────────────────┐
        │  (1)  Audit Plan    │
        │     is Developed    │
        └─────────┬───────────┘
                  ▼
        ┌─────────────────────┐
        │ (2) Audit is Scheduled │
        └─────────┬───────────┘
                  ▼
        ┌─────────────────────┐
        │ (3)  Audit is Conducted │
        │      and Findings   │
        │       Documented    │
        └─────────┬───────────┘
                  ▼
        ┌─────────────────────┐
        │   (4)  Findings     │
        │     are Reviewed    │
        └─────────┬───────────┘
                  ▼
        ┌─────────────────────┐
        │ (5) Necessary Action │
        │   Plan is Developed  │
        └─────────┬───────────┘
                  ▼
        ┌─────────────────────┐
        │  (6) Action Plan is  │
        │  Accepted or Rejected │
        └─────────┬───────────┘
                  ▼
        ┌─────────────────────┐
        │ (7) Necessary Corrective │
        │     Action is Taken  │
        └─────────┬───────────┘
                  ▼
        ┌─────────────────────┐
        │ (8)  Implementation and │
        │     Effectiveness of │
        │     Corrective Action │
        │       is Verified    │
        └─────────────────────┘
```

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3.0 Stages of the Quality Audit Process

3.1 The Quality Audit Process Description

The table below describes each stage in the quality audit process.

Stage	Who is Responsible	Description
1	GPRD QA Management	Develops an audit plan that addresses identified priorities.
2	GPRD QA Management	Defines the schedule.
3	Quality Auditor	• Conducts the audit, and • documents the findings.
4	GPRD QA Management	• Reviews the findings • identifies potential action items, and • assigns an overall rating.

5	• Functional Area Management, or
	• Vendor Management
		• Reviews the findings, and
		• responds with
		  − a corrective action plan, or
		  − justification for no action.

6	GPRD QA Management	Accepts or rejects the action plan in a timely manner.
7	• Functional Area Management, or • Vendor Management	Takes necessary corrective action according to the approved plan.
8	• GPRD QA Management, and • Functional Area Management	Verifies implementation and effectiveness of corrective action, if any.

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4.0 General Requirements

Introduction

This topic provides additional quality audit requirements.

4.1 Auditor Qualifications

A quality audit must be conducted by individuals who

- as a result of a combination of education, training, and experience, are qualified and have knowledge of applicable requirements, and
- do not have direct responsibility for the activity being audited.

4.2 Audit Findings and Action Plan

An audit report must be

- written and issued, including the dates and findings
- reviewed by management having responsibility for the activities audited.

Audit documentation must be controlled according to written procedures.

END OF DOCUMENT

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5.0 Document Information

Approvals

The personnel listed in the table below approved this document.

Title	Signature	Date

Description of Change

Issued new process document.

References

This process references the following documents and forms:

- Corporate Regulatory and Quality Science (CRQS) Policy A12-00, *Quality Audits*.
- (other)