SYGNETICS

Success Through Synergy

QSP 9.2 Internal Quality Audit

Based on
ISO 9001:2015 Quality Management System

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Revision Status

REV #	DETAILS OF CHANGE	DATE
0	Initial Release	1 Dec 2014
1	Changes were caused from Stage 1 Audit findings. Major rewrite. Refer to Stage 1 Audit Forms – 0411 dated December 22, 2014	5 Jan 2015
2	Updated to conform to 9001:2015 standard	1 Nov 2017

1 Purpose

The purpose of this procedure is to define the necessary steps to prepare, perform, document, and follow up on internal audit activities.

Sygnetics conducts internal audits to verify that the QMS conforms to the requirements of ISO 9001 and has been effectively implemented and maintained.

2 Scope

This procedure applies to all personnel who are responsible for planning, developing, using, and maintaining the QMS at Sygnetics.

3 Responsibilities

3.1 Process Owner - Quality Manager

The Quality Manager is responsible for the following activities:

- Ensuring that the annual audit schedule is developed and updated,
- Ensuring that internal quality audits are performed in accordance with this procedure and the approved audit schedule
- Planning, scheduling, and initiating the audits in an efficient manner
- Coordinating the audit schedule with Program/Project Managers, Director of Operations, and the Sygnetics President
- Forming an internal audit team with the assistance and coordination of Sygnetics management
- Ensuring that all auditors have received the required training
- Reviewing audit reports and distributing to audited organizations

3.2 Director of Operations and President

The Director of Operations and President are responsible for ensuring that their employees are:

- Following the QMS procedures
- Available during the internal audit
- Correcting any nonconformity

3.3 Program/Project Manager

Program/Project Managers are responsible for:

- Following the QMS procedures
- Responding to audit findings and providing corrective actions

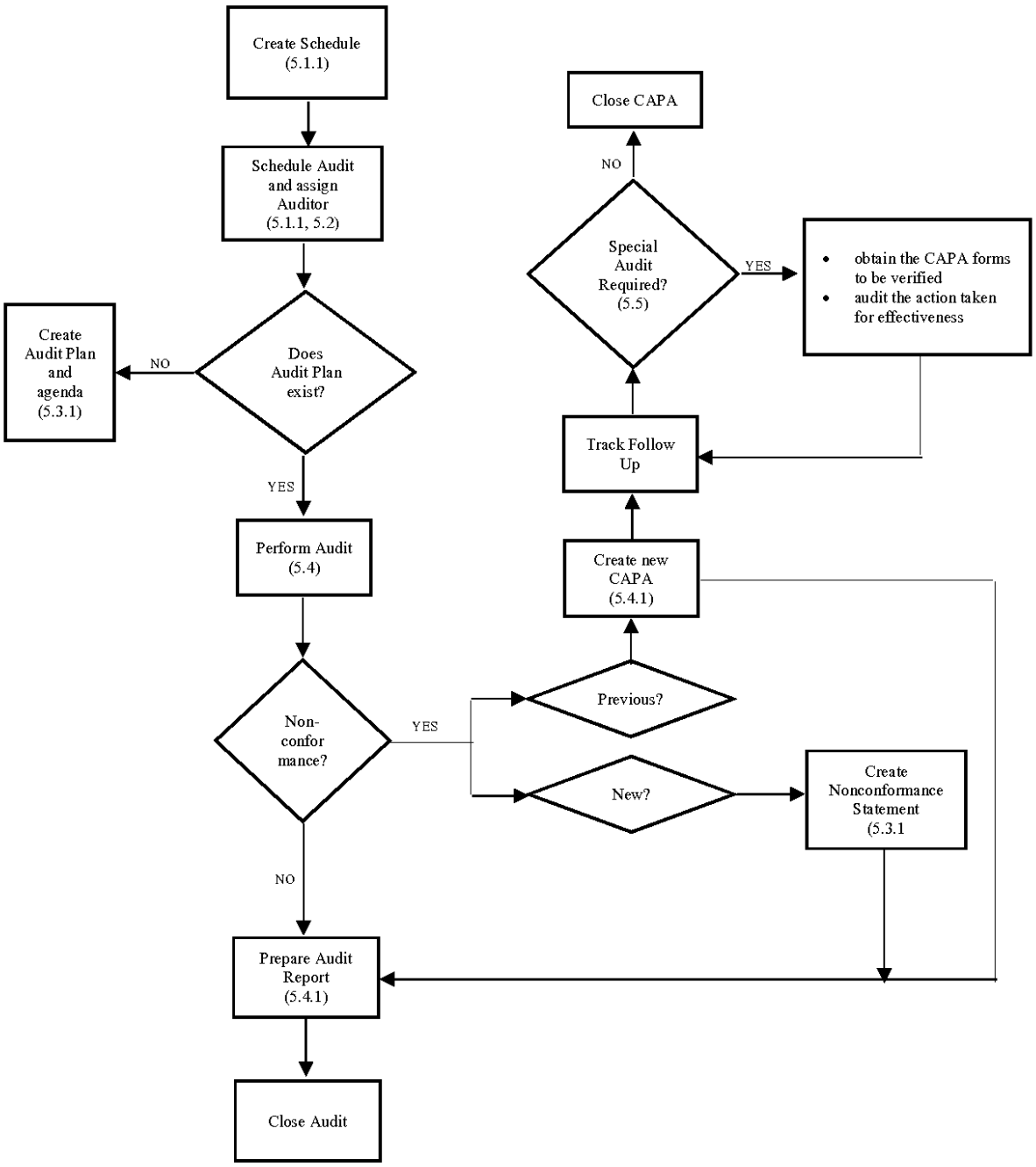
3.4 Lead Auditor

The Lead Auditor is defined as the internal or external auditor assigned to lead the audit team. Responsibilities include:

- Performing audit in accordance with approved audit schedule
- Conducting audit meetings

- Collecting objective evidence to support findings and CAR verifications
- Recording findings
- Preparing audit report and distributing to audited organizations

4 Flowchart


Create Schedule (5.1.1)
Schedule Audit and assign Auditor (5.1.1, 5.2)
Does Audit Plan exist?
NO
Create Audit Plan and agenda (5.3.1)
YES
Perform Audit (5.4)
Non-confor mance?
YES
Previous?
New?
Create Nonconformance Statement (5.3.1
Create new CAPA (5.4.1)
Track Follow Up
Special Audit Required? (5.5)
YES
obtain the CAPA forms to be verified
audit the action taken for effectiveness
NO
Close CAPA
NO
Prepare Audit Report (5.4.1)
Close Audit

5 Procedure

5.1 Internal Quality Audit Planning and Coordination

5.1.1 All elements in the QMS are audited annually. Selected activities may be audited more frequently if there is evidence of significant changes. (i.e., large number of new hires, high turnover of personnel, modified procedures or work instructions, etc.).

The audit schedule is created by the Quality Manager. The audit schedule will:

- address all elements of the Sygnetics Quality System during each 12-month period
- identify the area(s) to be audited

The Quality Manager is responsible for dissemination of the audit schedule through management to employees informing them of the internal audit dates.

5.1.2 The Quality Manager is responsible for definition of the specific objectives for the upcoming internal audit based on the status, maturity, and importance of specific elements in Sygnetics quality management system.

5.2 Establishment of an Audit Team

The Quality Manager recommends establishment of the audit team, if required. Audit Team Lead(s) and Team Members for each area to be audited cannot be directly responsible for the performance of the activity being audited.

The Lead Auditor must be trained in both the ISO 9001 requirements and effective auditing techniques.

5.3 Preparation for the Audit

5.3.1 The Lead Auditor will prepare an audit agenda that indicates specific audit dates, times, and team assignments.

5.3.2 The Audit Team shall:

- review previous audit reports and notes
- obtain corrective action requests (CARs) requiring verification of effective implementation from the Quality Manager

5.4 Internal Quality Audit Investigation

5.4.1 The Lead Auditor is responsible for performing the investigation according to the audit program and schedule.

For each activity being audited, the investigation proceeds as follows:

1. The Lead Auditor coordinates the investigation. He/she will:

- interview appropriate personnel and determine whether actual practices conform to the requirements of the documented policies, plans, procedures, and work instructions, and
- verify the effectiveness of CARs closed since the last audit. (If it is determined that the corrective action was not effective, see section 5.4.1 below.)

2. All findings are clearly documented referencing people interviewed as well as documents, materials, records, and other items reviewed as appropriate.
3. When a nonconformance is identified, the lead auditor or the Quality Manager presents the nature of the nonconformity as well as the evidence to the management spokesperson for verification. When and if the facts of the nonconformity are verified, the lead auditor or the Quality Manager drafts a nonconformance statement in his/her audit notes.
4. The nonconformance statement must include the following pieces of information. The nature of the nonconformity (i.e., the appropriate ISO 9001 standard clause number; the appropriate quality system document section/page/paragraph; what the management spokesperson says is the approved practice, contract requirements, statutory regulations, or national standards; and any other relevant requirements).
5. If time does not permit drafting of nonconformance statements during individual audits, the nonconformance must be documented within 3 days after finishing the full audit program.

5.3.2 The lead auditor and the Quality Manager are responsible for addressing any questions or concerns the management spokesperson may have.

5.4 Audit Closure

5.4.1 Prepare Audit Report

The lead auditor prepares a brief internal audit report which includes the audit scope and objectives; the names and titles of the audit team members; a summary of general observation (i.e. general degree of compliance and any significant problems encountered); and all statements of nonconformities, weaknesses, and /or opportunities for improvement.

In the event that a corrective or preventive action taken since the last audit was ineffective, a new CAPA is initiated. The new CAPA shall include the original CAR number, the original finding, the original action specified, and a statement as to the reason why the corrective action is ineffective.

5.4.2 Audit Report Review and Approval

The Quality Manager reviews and approves the internal audit report. Any additional comments or observations that the Quality Manager may have are attached to the report, but in no case are the lead auditor's observations deleted or modified. Copies of the report are then distributed to management.

The report is submitted to the Quality Manager, the Director of Operations, and the Sygnetics President within 1 week of completing the internal audit.

The Quality Manager issues Corrective/Preventive Action Requests (CAPAs), QSF 8.5.1–1, to the personnel responsible for any significant nonconformities identified in the Internal Audit Report. Corrective action and preventive action activities are performed, verified, and recorded according to QSP 8.5.1 Corrective and Preventive Action Procedure.

Corrective action on nonconformities is normally required within thirty days after the issuance of a CAPA. Additional time may be granted for cases which require extensive investigation and corrective action

5.5 Special Audits

When deemed necessary because of the nature, risk, scope, or prevalence of problems documented by corrective actions, the Quality Manager may schedule an audit to verify closed CAPA(s). During these audits, the auditor will only:

- obtain the CAPA forms to be verified
- audit the action taken for effectiveness
- issue CAPA(s) if it is determined that additional action is required to correct the problem resulting from the ineffectiveness of the original CAR.

6 Quality Records

Required Record	Custodian
Internal Audit Report	Quality Manager
Corrective/Preventive Action Request	Quality Manager

7 Forms

Forms related to this documents are:

Title
Sygnetics Internal Audit Summary