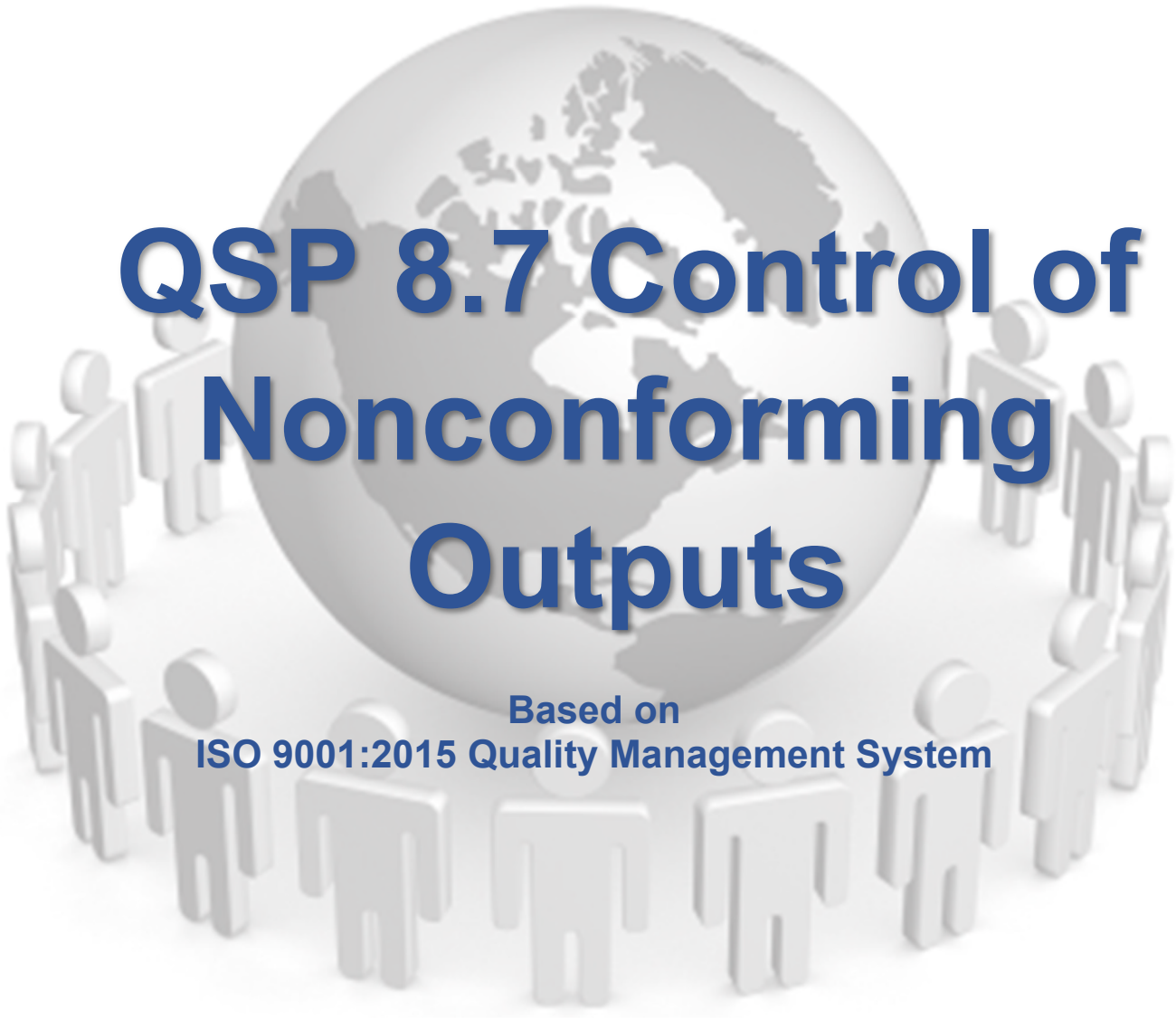
SYGNETICS

Success Through Synergy



QSP 8.7 Control of Nonconforming Outputs

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
3	Updated to include step for PM review evidence (Section 4 Flowchart, page 5 and Section 5 Procedure, page 6)	4 Mar 2021

1 Purpose

1.1 This procedure establishes the process to correct the cause(s) of nonconformances or potential nonconformances in products, processes, the Quality System, and/or services at Sygnetics, Inc. in accordance with the Quality Manual.

It provides for a system and instructions, and assigns responsibilities for:

- Identifying, documenting, and evaluating a nonconforming product
- Determining disposition for a nonconforming product or deliverable
- Creating a permanent solution that prevents recurrence of problems

Processes, services, and/or products that are considered to be nonconforming may be identified in any one of the following ways:

- services provided to customer (i.e. deliverables)
- services provided by external sources (e.g., subcontractors)
- producing negative results, internal quality audits, and external audits

Nonconforming services can be identified by the customer or by any employee. All nonconforming services will be brought to the attention of the program/project manager who will record this service nonconformance.

2 Scope

2.1 This procedure applies to any process, product, or service that falls within the scope of the Sygnetics Quality System.

3 Responsibilities

3.1 Process Owner - Program/Project Manager

The Program/Project Managers are responsible for the following activities:

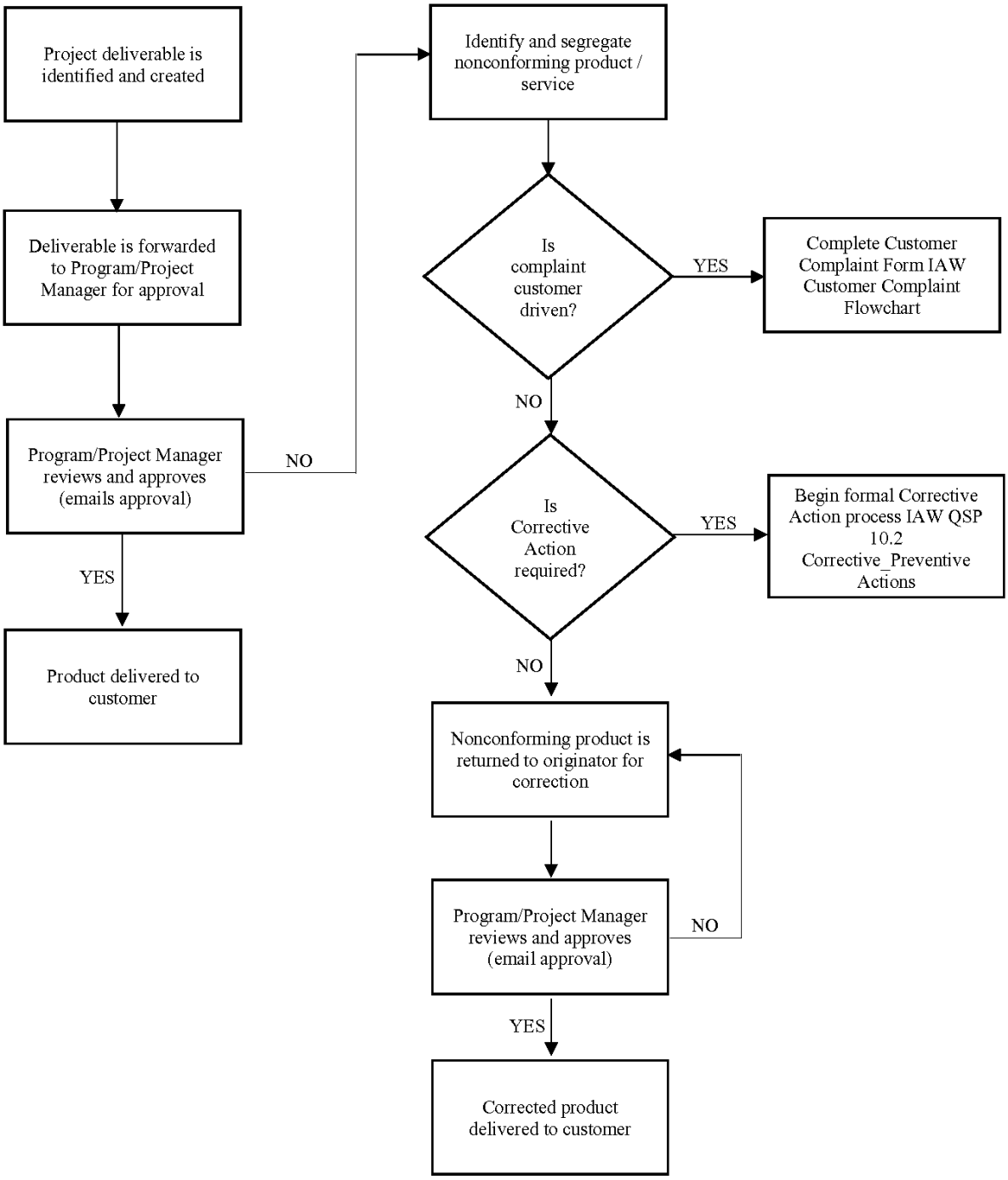
- ensuring nonconforming products and services are controlled as defined in documented procedures
- determining if the magnitude of the nonconformance and its associated risk warrants corrective action in accordance with Corrective & Preventive Actions
- ensuring nonconformance data is analyzed and improvement opportunities are identified
- recommending appropriate dispositions of nonconforming products and services
- defining required rework and re-inspection criteria

3.2 Quality Manager

The Quality Manager is responsible for the following activities:

- initiating CAPA if a need for corrective or preventive action is identified
- filing completed CAPAs and update log

4 Flowchart


Project deliverable is identified and created
Deliverable is forwarded to Program/Project Manager for approval
Program/Project Manager reviews and approves (emails approval)
NO
YES
Product delivered to customer
Identify and segregate nonconforming product / service
Is complaint customer driven?
YES
Complete Customer Complaint Form IAW Customer Complaint Flowchart
NO
Is Corrective Action required?
YES
Begin formal Corrective Action process IAW QSP 10.2 Corrective_Preventive Actions
NO
Nonconforming product is returned to originator for correction
Program/Project Manager reviews and approves (email approval)
NO
YES
Corrected product delivered to customer

5 Procedure

Processes, services, and/or project deliverables (i.e. monthly report) called out in the project contract are identified.

The deliverable is forwarded to the program/project manager for review.

The program/project manager will review the deliverable and forward an email with approval of the information or a nonconformance.

If a nonconformance is found, the program/project manager will review the nonconformance issue and discuss that issue with the responsible individual(s).

The nonconforming product will be returned to the product originator who will correct the problem.

The program/project manager will make a decision to determine if a formal corrective action is required. If the decision is yes, the formal corrective action is handled in accordance with QSP 10.2 Corrective & Preventive Actions.

Once the nonconforming product has been corrected, the product is returned to the program/project manager for final review and approval prior to being sent to the customer.

Program/project Manager emails approval after final review and product is delivered to the customer.

The program/project manager will determine a course of action to ensure the problem does not reoccur.

6 Metrics

To assess product quality levels and identify opportunities for improvement, the patterns and trends in nonconformance data shall be analyzed, reported and reviewed by appropriate levels of management.

Analyses could include, but should not be limited to, current performance levels and depictions of trends over time in:

- Nonconformance type – e.g. nonconformities per deliverable
- Nonconformance rate - e.g. percentage beyond suspense

7 Quality Records

The following Quality Records shall be generated and managed in accordance with QSP Record Control.

Required Record	Custodian
CAPA	Quality Manager
CAPA Log	Quality Manager
Customer Complaint Form	
Customer Complaint Log	

8 Forms

Forms related to this document are:

Title
CAPA Request Form
Sygnetics Customer Complaint Form