

Document Control

Based on ISO 9001:2008 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
	Updated to conform to 9001:2015 standard	1 Nov 2017



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1 Purpose

- **1.1** This procedure is established to provide instructions to assign responsibilities for reviews, authorization, issue, and revisions of the quality system documentation.
- **1.2** Quality System Documentation will be retained and maintained in electronic form. Printed and electronically saved copies of QMS documentation and forms are uncontrolled and must be verified prior to use.

2 Scope

2.1 This procedure applies to quality documents that include quality manual, procedures, work instructions, and external documents.

3 Responsibilities

3.1 Process Owner - Quality Manager

The Quality Manager is responsible for the following activities:

- Overseeing the control of all internal quality system related documents.
- Maintaining and ensuring that all ISO 9001 procedures and the QMS manual are revised and approved, as required and reflects the needs of the company.
- Ensuring that the quality system related documents are technically correct and usable.

3.2 Management Representative

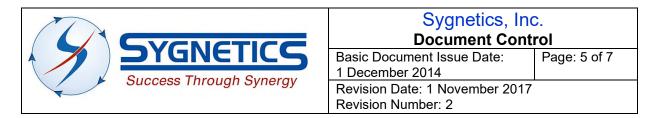
The Management Representative is responsible for approving newly released and revised corporate documents.

3.3 Program/Project Manager

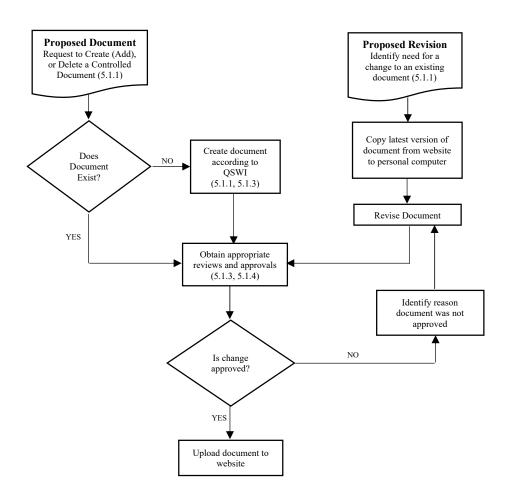
The Program/Project Managers are responsible for controlling project specific documents, including customer specifications, standards, and regulations. These documents are used to create project specific work instructions and procedures, if needed.

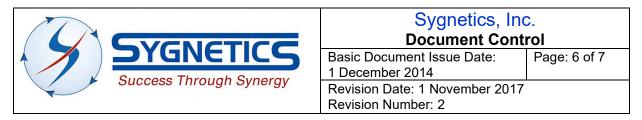
3.4 Human Resources

It is the responsibility of Human Resources and Program/Project Managers to ensure that all of the employees are made aware of the Sygnetics ISO documents, revisions to these documents, their on-line availability, and the necessity for them to read, understand, and comply with the requirements therein.



4 Flowchart





5 Procedure

5.1 Establishment of Initial Issues and Revisions

- **5.1.1** Any employee may identify and communicate the need for a new or revised Quality System Procedure (QSP), Quality System Work Instruction (QSWI), and Quality System Form (QSF) or external documentation. The employee should complete a Sygnetics Quality System Revision Form and submit it to the Program/Project Manager who is responsible for coordinating and reviewing the forms, making notes, and passing it on to the Quality Manager.
- **5.1.2** The Quality Manager will review the need for a new or revised quality system document and provide feedback to the originator through the respective Program/Project Manager.
- **5.1.3** If a new document is needed, the employee will follow Instructions for Developing Quality System Documentation to develop the documentation and submit the proposed new document to the Program/Project Manager. After review the Program/Project Manager will submit the proposed document to the Quality Manager for further review. The Program/Project Manager will provide input, as necessary, before modifications are made permanent.
- **5.1.4** If a revised QMS document is needed, the Quality Manager will make the modifications to the quality system documentation and forward the revised document to the Management Representative or the President for approval. If the revisions pertain only to a particular project, then the approval of that Program/Project Manager is required.
- **5.1.5** The nature of the change is identified using the Sygnetics Quality System Revision Form.
- **5.1.6** The Quality System Revision Form will be retained by the Quality Manager in the master quality system documentation file.

5.2 Distribution

- **5.2.1** The Quality Manager will electronically maintain the QMS documentation on a designated area.
- **5.2.2** When there is a change to the QMS documentation, an email will be sent to the President indicating the document has been revised and posted on the company website.
- **5.2.3** The IT department will establish and maintain the capability for all Sygnetics employees to have full time electronic access to the QMS documentation and forms on a "read only" and print on demand basis. Employees are expected to



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read, understand and comply with all provisions of said documentation that may be applicable.

5.3 Identification of Controlled Copy

5.3.1 The electronic files of QMS documentation and forms are the sole controlled copies of forms and documentation in the Sygnetics Quality Management System.

5.4 Uncontrolled Copy

- **5.4.1** All **printed and electronically saved copies** of Sygnetics Quality Management System forms and documentation **are uncontrolled** and must be verified prior to use.
- **4.4.2** There will be no restriction on employees printing any of the QMS documentation or forms, however, paper copies will be considered unofficial and will not be controlled. **Paper and electronically saved copies** of QMS documentation and forms **must be verified prior to use** by comparing the document or form, in question, with the controlled electronic version.

5.5 External Documentation

5.5.1 External documentation is defined as documents of external origin that are required in the performance of division tasks. The Program/Project Managers will identify, define, and control the distribution of required external documentation; and will maintain a Master List (as applicable) of all external documentation that they have defined as necessary for their project (i.e. project specifications, PWS, SOW, etc).

6 Quality Records

There are no quality records derived from this document.

7 Forms

Forms related to this documents are:

