SOP Reference #: SOP-QS002

Operation/Task:	**Document Control**			Equipment:	**Employee Intranet, computer**
Owner:	Quality Manager	**Date Created:** **Revision History:**	6/20/15 See last page	**Department:**	Management

ALERTS (see below): Critical Step ◆ Quality Check ☑ Tip ☺ Team Safety ✚

Purpose: This SOP/work instruction describes the controls over the documents used as controlled forms or documents for the quality management system.

Step #	Alerts	Step Description - "What to Do"	"How to Do it"	"Why to Do it"
0		This procedure defines the controls needed for managing documentation required by the ENPOINTE quality management system • Where practical, all QMS required documentation will be controlled through the ENPOINTE employee Intranet • It is the responsibility of the Quality Manager to ensure that the activities described in this procedure are fully implemented • The Quality Manager, department managers, and the ISO administrative assistant are assigned the responsibility of establishing and performing these activities		
1		7.5.2 When **creating and updating** documented information, the organization shall ensure appropriate: a) identification and description (e.g. a title, date, author, or reference number); b) format (e.g. language, software version, graphics) and media (e.g. paper, electronic); c) review and approval for suitability and adequacy.	• Forms and documents are to contain titles and/or a form code and a revision number. Exceptions to this are documents that are generated from purchased software such as our ERP Print Stream system. • All documents will be in the English language and be stored electronically on the ENPOINTE intranet or secure network share. • Department managers and Quality manager are to provide approval prior to use and will perform periodic reviews.	We want to make sure that forms that are in use are the most updated and relevant to the QMS system.

2		7.5.3.1 Documented information required by the quality management system and by this International Standard shall be controlled to ensure: a) it is **available** and suitable for use, where and when it is needed; b) it is adequately **protected** (e.g. from loss of confidentiality, improper use, or loss of integrity).	• When applicable, documents are to be stored as controlled forms on the ENPOINTE intranet to be accessed by all employees or specific department network shares accessible by department staff. • Specific forms may be preprinted and stored as hardcopy in appropriate locations. • The ENPOINTE intranet and network shares are to be backed up to protect documents from loss. • Internal audits will occur to check for proper use	Documentation deemed important by QMS standards must be available for use when needed.
3		7.5.3.2 For the control of documented information, the organization shall address the following activities, as applicable: a) **distribution**, access, retrieval and use; b) **storage** and preservation, including preservation of legibility; c) **control** of changes (e.g. version control); d) **retention** and **disposition**.	• The ENPOINTE intranet or secure network share is to be used for controlled documentation that does not originate from other packaged systems (I.e.: ENPOINTE ERP system). • Revision status for documentation required by the QMS is identified using the current revision number (typically month / year) and can be found on the department's quality system documentation page under the title of each electronic document • Document updates (month / year) are located on the page for each electronic document • Users are to compare the form code and (month, year) of any printed document or form to the controlled form or document on the employee intranet to ensure they are using the most current version • The ISO Administrator Assistant is responsible for retaining the last and the most current revision of a controlled form.	Using old and outdated forms or documents are a quality concern. Users need to have a way to identify that the form they are using is the most current.
6		Documented information of external origin determined by the organization to be necessary for the planning and operation of the quality management system shall be identified as appropriate, and be controlled.	• Customer documents may take the form of a hard copy, an electronic file or both. It is the responsibility of sales and sales support representatives or IT services representatives (as appropriate) to ensure that all customer documents are identified and their distribution controlled • Electronic files will be controlled according to the appropriate department standard operating procedures. The applicable information for product manufacture will be indicated on the job ticket or statement or work (as appropriate) as defined by the customer • External documents that are not job or project specific, such as government or third party forms, are controlled in the same manner as internal documents described under the procedure for 7.5. Where electronic versions of these documents are not available, the document can be scanned and added to the intranet for visual comparison and verification purposes • External documents such as equipment manuals and general reference materials are identified and controlled, as ENPOINTE deems appropriate, according to department standard operating procedures	Some external documents can provide additional information and guidance and should be treated with the same importance as internal documents.

7		Documented information retained as evidence of conformity shall be protected from unintended alterations.	See SOP QS003 – Control of records	

Notes:

Definitions:

Revision History	Description of Changes	Requested by	Date
Rev 1	Converted to new SOP format, reviewed for accuracy and made a few alterations.	Troy / Kathy	6/23/15
Rev2	Updated clauses and verbiage to 9001:2015 standards. Processes/procedures remained the same.	Kathy Osterberg	12/17
Rev3	Converted to current SOP format; Changed GLS Companies to ENPOINTE; updated font to Arial; reviewed for changes – added verbiage which allows some controlled documents to be stored on secure network shares instead of the intranet. This was needed for some confidential forms within IT.	Kathy Osterberg	02/21