SOP Reference #: SOP-QS003

Operation/Task:	**Control of Records**			Equipment:	**Employee Intranet, computer**
Owner:	Quality Manager	**Date Created:** **Revision History:**	6/2015 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 deemed as records 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	When controlled forms or business systems are used to 'record' activity about a task or job, these are deemed as 'records'. Certain 'records' that are deemed pertinent to the QMS are to be handled per this procedure.	
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.	• Pertinent records are to be documented using controlled forms or within ENPOINTE Business systems. • All records will be in the English language and be stored as hard copy or electronically on the ENPOINTE network. • Department managers and Quality manager determine which records are suitable and adequate.	We want to make sure that the records that we keep have the necessary information that was deemed necessary by the QMS.

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).	• Where applicable, records are to be stored electronically on ENPOINTE network, in storage cabinets, in binders, in job jackets or other areas that will protect the record from improper use. • The ENPOINTE network is to be backed up to protect records from loss. • Internal audits will occur to check for proper use	Records 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 matrix of quality records - CI030 defines these requirements for each record that ENPOINTE has deemed important to the QMS.	Records have various uses and purposes, this matrix documents the wide variety of distribution, storage, control, retention, and disposition.
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.	• The matrix of quality records - CI030 defines these requirements for each record that ENPOINTE has deemed important to the QMS.	Records have various uses and purposes, this matrix documents the wide variety of distribution, storage, control, retention, and disposition.
7		Documented information retained as evidence of conformity shall be protected from unintended alterations.	• The matrix of quality records - CI030 defines these requirements for each record that ENPOINTE has deemed important to the QMS.	Records have various uses and purposes, this matrix documents the wide variety of distribution, storage, control, retention, and disposition.

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 – updated the reason why for tasks 6 & 7.	Kathy Osterberg	02/21