SOP Reference #: SOP-QS001

Operation/Task:	**PHI AND SPII Procedures**			Equipment:	**N/A**
Owner:	Quality Manager	**Date Created:** **Revision History:**	4/29/14 See last page	**Department:**	ALL

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

Purpose: To outline the controls necessary to process jobs containing [PHI] and [SPII] within the requirements of US Federal and State Law.

Step #	Alerts	Step Description - "What to Do"	"How to Do it"	"Why to Do it"
1	◆	It is the responsibility of all ENPOINTE Department Managers to ensure the details of this procedure are followed for jobs with [PHI] and [SPII] requirements.		
2	◆	Managers are responsible for choosing the correct employees and adequately train them before they are allowed to work on [PHI] and [SPII] jobs. This includes employees that meet any of the following conditions: Have access to [PHI] or [SPII] data files. Have access to storage locations where [PHI] or [SPII] personalized work-in-process materials are being stored. Perform personalization printing on [PHI] or [SPII] jobs, or perform subsequent processes up until the point that individual pieces are secured (e.g. trayed, sleeved and banded).	Employees and Temporary staffing that have access to [PHI] or [SPII] data or physical pieces are required to: Have a background check and be approved by Human Resources prior to gaining access. Be trained on company and department procedures for handling [PHI] and [SPII] jobs. Participate in annual Security Awareness training.	This process ensures we are compliant with Federal and State Law.

3		Transfer of Electronic [PHI] or [SPII] Files:	All [data files] and [artwork files] considered [PHI] or [SPII] will be transferred via an encrypted manner such as SFTP. Access to these [SFTP] sites are controlled via unique passwords. NOTE: [FTP] sites and E-mail attachments are not [encrypted] and are not an acceptable method for transferring [PHI] or [SPII] [data files]. Client Services Department is responsible for ensuring there is an active [SFTP] site established with the client before any [PHI] or [SPII] files are transferred.	
4		The Sales Department Account Executives or Client Services Department are responsible for conveying PHI or SPII requirements to organization.	Identifying and communicating jobs with [PHI] or [SPII] requirements via a ENPOINTE [job ticket] Communicating to Data Processing and PreMedia the location, method of access, and any programming or artwork requirements for [data files] and [artwork files] on the [SFTP] site Communicating any requirements regarding use 2D barcoding to Data Processing	The ENPOINTE [job ticket] is the main resource of information for production.

5		LETTER-SHOP Mail inserters with in-line detection systems require a 2D barcode.	The Mailing Department Machine Operator is responsible for the following: **SET-UP** Clearing the workstation of all materials not specifically associated with the next [PHI] or [SPII] job. Reviewing the [job ticket] to determine how many ways the personalization for the job is to be matched e.g., 2-way, 3-way, etc... Set up the cameras to the job type profile on the detection system e.g., folder to pocket match, folder to read-n-print, pocket to read-n-print, etc... Determining how each piece must be placed in the inserter pocket to meet the criteria of the insertion order and orientation. (2D placement dictates orientation) **RUNNING [Touch & Toss] Procedure** If a jam occurs, operator must inspect personalized components to get match back to last known correct position. All pieces physically handled during this process must be removed and moved to locked security shred bin. (They will be added to missing records file automatically) Pack processed pieces into a tray, box, bundle, or onto a skid as appropriate for the job. Before removing from work area use a sleeve, seal, or cover each container or skid as appropriate for the job Label or tag each skid **JOB COMPLETE OR END OF SHIFT** Supervisor must dispose of mail from the divert station in locked security shred bin. (They will be added to missing records file automatically) If job is not complete or not running on next shift: machine must be cleared of all material and strapped in mail trays. All work in progress material must be covered with secured and made inaccessible to anyone that has not had a background check and training.	Locked security bins are located through-out the organization.

6		LETTER-SHOP Inkjet or Laser	Missing or nonconforming pieces must be: Retained, Reprinted and Reinserted into the correct sequential order as appropriate for the job. After re-processing, all pieces determined to be scrap will be placed in a secure shred bin. **JOB COMPLETE OR END OF SHIFT** If job is not complete or not running on next shift: machine must be cleared of all material and strapped in mail trays. All work in progress material must be covered with secured and made inaccessible to anyone that has not had a background check and training.	Locked security bins are located through-out the organization.
7		DIGITAL PRINTING, FINISHING and DISTRIBUTION Production of jobs without in-line detection systems.	Pieces provided to a workstation will be securely contained, identified, and sequenced in either numeric or alphabetical order, or in reference to a client or third party provided list. Clear the workstation of all materials not specifically associated with the next [PHI] or [SPII] job Verify control information (product identification and visual reference used for sequencing) and how provided pieces are sequenced (lowest to highest e.g., 1-10 or A-Z, highest to lowest e.g., 10-1 or Z-A, etc…) Determine sequential order needed for next operation (lowest to highest e.g., 1-10 or A-Z, highest to lowest e.g., 10-1 or Z-A, etc…) Check for component pieces to ensure all sequence the same. Determine quality control methods for ensuring batch counts and sequence is maintained during processing. Missing or nonconforming pieces must be: Retained, Reprinted and Reinserted into the correct sequential order as appropriate for the job. After re-processing, all pieces determined to be scrap will be placed in a secure shred bin. Pack processed pieces in to a tray, box, bundle, or onto a skid as appropriate for the job. Before removing from work area use a sleeve, seal, or cover each container or skid as appropriate for the job. Label or tag each skid	Locked security bins are located through-out the organization.
8		Work in process and material handling	[PHI] and [SPII] personalized materials that are not being actively processed cannot be left unattended unless secured and made inaccessible to anyone that has not had a background check and training.	

9		Quality Controls	The following checks are required for each batch as appropriate for the job e.g., tray, box, bundle, or skid: 100% visual verification of sequencing; 100% verification of batch counts e.g., by hand or by scale as appropriate, and; 100% visual verification of component matching A record that the above checks have been completed for each batch that includes; job number, date, batch ID and the initials of the individual performing the checks	
10		Material Handling/Concealment	[PHI] and [SPII] personalized materials that are not being actively processed must be secured and be inaccessible to employees (or temps-visitors-vendors) that have not had background checks and training. Use a sleeve, seal or cover each container or skid as appropriate for the job.	We must secure and conceal [PHI] and [SPII] work as the information is confidential.

Notes:

At what point does a physical piece of material become PHI or SPII?

When PHI or SPII data stored in secure electronic form is transferred to a physical piece of material. An example of this is: name and address inkjetted onto a selfmailer, name or name and address lasered onto a letter or statement.

Definitions:

Artwork Files: An artwork file is an electronic file that represents the page layout components for a job. Components typically include; number of versions, number of pages, the colors to be used, page sizes, fonts, images, resolutions, and any overprint coatings or varnish.

Data Files: A data file is a computer file which stores data to use by a computer application or system. It generally refers to information used as input, such as names and mailing addresses.

Encryption: is the process of encoding information in such a way that eavesdroppers or hackers cannot read it, but that authorized parties can.

FTP: File Transfer Protocol is a network protocol that provides an unencrypted file transfer over a data stream, which is not an acceptable method for the transfer of [PHI] or [SPII] data.

PHI: Protected Health Information is linkage of actual or potential medical status to an individual.

SPII: Sensitive Personally Identifiable Information

Job Ticket: An electronic file or paper copy that contains all relevant information and requirements for processing a job, order, or project. The job ticket may be included with an envelop

Revision History	Description of Changes	Requested by	Date
Rev 1	Revised SOP to new format	Troy Bauer	4/29/14
Rev 2	Added Revision History table	Troy Bauer	8/1/16
Rev 3	Reviewed for 9001:2015 requirements.	Kathy Osterberg	12/15/17
Rev 4	Converted to current SOP format; Changed GLS Companies to ENPOINTE; updated font to Arial; reviewed for changes-none made.	Kathy Osterberg	02/21