






Operation/Task:	Internal Audit			Equipment:	None
Owner:	Quality Manager	Date Created:	6/2015	Department:	Quality
		Revision History:	See last page		

ALERTS (see below): Critical Step  Quality Check  Tip  Team Safety 

**Purpose:** This SOP/work instruction describes ISO Internal Auditing process

Step #	Alerts	Step Description - "What to Do"	"How to Do it"	"Why to Do it"
1		Set audit schedule annually  Group audit areas to incorporate "process approach"	Quality Manager will determine departments to incorporate into each audit.	To expose non-conformity that results from linkages between departments.
2		Prepare audit plan	Review past audits and determine what documents and practices will be audited.  Assemble questions to ask auditees prior to interviews	Some departments may have had issues that need to be addressed in the upcoming audit based on performance metrics or non-conformance data.
3		Recruit auditors	Determine who s available to perform internal audit duties and add them to the audit schedule.  Train auditors as necessary.	All internal auditors are required to have auditor training prior to performing audits.
4		Conduct opening meetings for each audit when it starts.	The department manager and/or department manager will be alerted to the timing and scope of an internal audit.	So that department managers are aware of what is going on in their department.
5		Conduct interviews, make observations and obtain objective evidence of non-conformances	Interview pre-determined employees with a set of pre-determined questions about their work requirements.  Note discrepancies between individual responses to questions.	To discover problems in the operation of the QMS and standard procedures.

6		Write audit report	<p>Compile results of audits.</p> <p>Determine non-conformances.</p> <p>Write report.</p> <p>Review with Quality Manager.</p> <p>Deliver report to interested parties.</p>	<p>Quality manager will determine which findings are included in the report</p> <p>Deliver report to managers and executive team.</p>
		Add information to the audit schedule	Update the audit schedule posted in the QS office	To track progress of annual audit program
9		Close audit	Conduct a closing meeting with department stakeholders	To keep them informed and explain the audit results.
10		Follow up on action items resulting from audit	Work with department manager to complete corrective actions that are determined necessary from audit findings.	

Notes:

Definitions:

Revision History	Description of Changes	Requested by	Date
Rev 1	Converted procedure over to new SOP format	Kathy Osterberg	6/25/15
Rev 2	Reviewed entire document and updated it with what is currently being done	Kathy Osterberg	7/26/17
Rev 3	Reviewed for potential updates for 9001:2015 requirements. Some clarifications to existing processes were made.	Kathy Osterberg	12/14/17

Rev 4	Converted to current SOP format; Changed GLS Companies to ENPOINTE; updated font to Arial; reviewed for changes – some grammar updates.	Kathy Osterberg	02/21
Rev 5	Overhaul of audit process; retire matrix document, replace with schedule, process-based approach, create individual audit plan for each audit, performed annually, narrow focus with deeper dive vs. wide and shallow approach.	Dean Milinkovich	9/23