giles	**GILES CHEMICAL ~ PREMIER MAGNESIA** **Company Form**	PREMIER MAGNESIA, LLC
	Title: Internal Audit Checklist – Quality System Number: Q12-PR-100-F008c	
	Owner: Katherine Cash Revision: 0	
	Effective Date: 01/14/13 Page: 1 of 2	

Audit #: _____ Auditor(s): _____ Date: _____

Quality System – ICH Q10	**Document(s) Reviewed/Person(s) Interviewed/Objective Evidence/Comments:**	**Conforms to Requirements**
Management has established a quality policy and has been signed by upper management.		☐ Yes ☐ No
Quality objectives are established at all relevant levels to reflect the principals of ICH-10 and performance against these objectives is measured and reviewed.		☐ Yes ☐ No
Adequate resources (human, financial, materials, facilities and equipment) are provided to implement, maintain and improve the quality system.		☐ Yes ☐ No
Internal communications assure the flow of appropriate information (in both directions) between all levels of the company.		☐ Yes ☐ No
Periodic reviews of the quality system, process performance and product quality are conducted, with documented completion of any identified follow-up actions.		☐ Yes ☐ No
Use of outsources activities and/or purchase materials includes: appropriate use of quality risk management; defined and documented evaluation and selection process; documented quality agreement defining respective responsibilities; and monitoring and review of supplier/subcontractor performance.		☐ Yes ☐ No
A process for managing the life cycle for products (development, technology transfer, commercial production, product discontinuation) is defined and implemented.		☐ Yes ☐ No
There is a defined control strategy for both process performance and product quality, and this strategy incorporates appropriate quality risk management principals		☐ Yes ☐ No

and techniques.		
Appropriate data management and statistical tools have been provided to implement the control strategy. These tools are implemented and results are evaluated to improve process and product performance.		☐ Yes ☐ No
There is a formal corrective and preventive action (CAPA) system to capture input from various sources (e.g. complaints, product rejections, process deviations, recalls, audits, process/product data trends, OOS, management reviews, etc.) and assure follow-up CAPA actions (including measuring the effectiveness of completed actions).		☐ Yes ☐ No
There is a defined and documented focus on continual improvement of the quality management system.		☐ Yes ☐ No