GE Power & Water

ISO 9001:2008 Audit Checklist

Organization _____ **Auditor** _____

Date _____

Std. Para #	Requirement	Audit Finding
4.1	**General Requirements**	
	a. Are processes identified	
	b. Sequence & interaction of processes determined?	
	c. Criteria for operation of control of processes determined?	
	d. Availability of resources to support processes & monitoring?	
	e. Are processes monitored & measured?	
	f. Are actions implemented to achieve planned results with continual improvement?	
4.2.1	**Documentation Requirements General**	
	a. Are there documented statements for quality policy & objectives?	
	b. Is there a quality manual?	
	c. Required documented procedures? Implemented? Maintained?	
	d. Required documents for effective planning, operation & control of processes.	

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	e. Records required by this standard available?	
4.2.2	**Quality Manual**	
	a. Scope of QMS with exclusions and justifications defined?	
	b. Documented procedures established or referenced?	
	c. Interaction of processes described?	
4.2.3	**Control of Documents –** Is procedure established to insure:	
	a. Documents are approved for adequacy prior to issue?	
	b. Provision for review and update as necessary & re-approve?	
	c. Changes and current revision status of documents are identified?	
	d. Relevant version of applicable documents are available at points of use?	
	e. Documents are legible and readily identifiable?	
	f. Documents of external origin are identified and controlled?	
	g. Obsolete documents are controlled and identified?	
4.2.4	**Control of records** Is procedure established to insure:	
	Records maintained to provide evidence of conformity to requirements. Records are legible, identifiable and retrievable. Records are controlled for identification, storage, protection, retrieval, retention, and disposition.	
5	**Management responsibility**	
5.1	Is evidence of **management commitment** available to show:	

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	a. Communication to the organization the importance of meeting customer, statutory, and regulatory requirements.	
	b. Established quality policy.	
	c. Established quality objectives.	
	d. Management Reviews conducted.	
	e. Ensuring the availability of resources.	
5.2	**Customer Focus**	
	Are customer requirements determined and met with the aim of enhancing customer satisfaction?	
5.3	Insure **Quality Policy** is**:**	
	a. Appropriate to the purpose of the organization.	
	b. Commitment to comply with requirements & continuous improvement.	
	c. Provides a framework for establishing & reviewing quality objectives.	
	d. Is communicated and understood within the organization.	
	e. Is reviewed for continuing suitability.	
5.4	**Planning**	
5.4.1	Are **quality objectives** established at relevant levels, measurable, and consistent with the quality policy?	
5.4.2	Is **quality management system planning**	

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	a. Carried out to meet requirements in 4.1 as well as the quality objectives?	
	b. Implemented to maintain the integrity of the quality management system?	
5.5	**Responsibility, authority and communication**	
5.5.1	Is **responsibility & authority** defined & communicated**?**	
5.5.2	Does **management representative** have responsibility & authority that insures	
	a. Processes needed are established, implemented & maintained?	
	b. Reporting to top management on performance and improvements needed?	
	c. The promotion of customer requirements throughout organization.	
5.5.3	**Internal Communication**	
	Are communication processes established for effectiveness of quality system?	
5.6	**Management Review**	
5.6.1	**General** - Is frequency of management review at planned intervals with assessment of opportunities for improvement, need for changes to system, policy and objectives? Is this documented?	
5.6.2	**Management Review Input –** Does input include:	
	a. Results of audits?	
	b. Customer feedback?	
	c. Process performance and product conformity?	
	d. Status of preventive and corrective action?	
	e. Follow-up actions from previous management reviews?	

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	f. Changes that could affect the quality management system?	
	g. Recommendations for improvement?	
5.6.3	**Management Review Output –** Does output include decisions and actions on:	
	a. Improvement of the effectiveness of QMS and its processes?	
	b. Improvement of product related to customer requirements?	
	c. Resource needs?	
6	**Resource Management**	
6.1	**Provision of resources –** Have resource requirements been established and obtained to:	
	a. Implement, maintain and continually improve the effectiveness of the QMS	
	b. Enhance customer satisfaction by meeting customer requirements?	
6.2	**Human resources**	
6.2.1	**General –** Evidence that personnel performing work are competent based on education, training, skills & experience?	
6.2.2	**Competence, awareness and training –** The organization has**:**	
	a. determined the necessary competence for personnel performing work affecting product quality?	
	b. Provided training or taken action to satisfy (a.)?	
	c. Evaluated the effectiveness of actions taken?	
	d. Ensured that its personnel are aware of the relevance and importance of their activities and how they contribute to obtaining the quality objectives?	
	e. Maintained appropriate records of education, training, skills and experience?	

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6.3	**Infrastructure –** The organization has determined, provided and maintained the infrastructure to achieve conformity to product requirements including:	
	a. Buildings, workspace and associated utilities?	
	b. Process equipment (both hardware and software)?	
	c. Supporting services	
6.4	**Work environment –** has been managed to achieve conformity to product requirements?	
7	**Product Realization**	**Identify any areas of Section 7 with properly documented exclusions as NA (not applicable**).
7.1	**Planning of product realization –** Is planning & development of the processes evidenced, and are they consistent with requirements? Is the following determined as appropriate:	
	a. Quality objectives and requirements for the product?	
	b. The need to establish processes, documents and provide resources specific to the product?	
	c. Required verification, validation, monitoring, inspection and test activities specific to the product and the criteria for acceptance?	
	d. Records needed to provide evidence that the realization processes and resulting product meet requirements?	
7.2	**Customer related processes**	
7.2.1	**Determination of requirements related to the product –** Have the following been determined?	
	a. Requirements specified by the customer including delivery activities.	
	b. Requirements not specified by customer but necessary for specified or intended use.	

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	c. Statutory and regulatory requirements related to the product.	
	d. Additional requirements established by the organization.	
7.2.2	**Review of requirements related to the product –** Have requirements been reviewed prior to commitment to supply? Has the following been determined?	
	a. Product requirements are defined.	
	b. Contract or order requirements differing from those previously expressed are resolved.	
7.2.2	c. The organization has the ability to meet defined requirements.	
7.2.3	Effective **customer communication** evidenced for**:**	
	a. Product information	
	b. Inquiries, contracts or order handling, including amendments.	
	c. Customer feedback, including customer complaints	
7.3	**Design**	
7.3.1	**Design and development planning -** Has the organization determined:	
	a. The design and development stages including interfaces.	
	b. The review, verification and validation for each stage and design.	
	c. The responsibilities and authorities for design & development.	
7.3.2	**Design and development inputs** – Relating to product requirements including records and **:**	
	a. Functional and performance requirements.	
	b. Applicable statutory and regulatory requirements.	

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	c. Where applicable, information derived from previous similar designs.	
	d. Any other requirements essential for design and development.	
7.3.3	**Design and development outputs –** Are they in a format to facilitate verification against inputs and have they been verified? Have they been approved prior to release? Do design & development outputs:	
	a. Meet the input requirements for design and development.	
	b. Provide appropriate information for purchasing, production and for service provision.	
	c. Contain or reference product acceptance criteria.	
	d. Specify the characteristics of the product that are essential for its safe and proper use.	
7.3.4	**Design and development review** – Are reviews of design and development performed to planned arrangements to:	
	a. Evaluate the ability of the results of design and development to meet requirements?	
	b. Identify and problems and propose necessary actions?	
7.3.5	**Design and development verification** – Has verification been performed to ensure outputs equal requirements of inputs? Are there documented records?	
7.3.6	**Design and development validation** – Have validations been performed to insure products meet requirements and have they been documented?	
7.3.7	**Control of design and development changes** – Have they been identified, reviewed, documented, verified, validated and approved before implementation? Has effect of the changes on constituent parts and products been reviewed?	

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7.4	**Purchasing**	
7.4.1	**Purchasing Process** – Does Purchasing ensure purchased product meets specified requirements? Are suppliers evaluated & selected based on ability to support requirements? Are criteria established and records of results maintained?	
7.4.2	**Purchasing information** – Does purchasing describe the product to be purchased including:	
	a. Requirements for approval of product, procedures, processes and equipment?	
	b. Requirements for qualification of personnel?	
	c. Quality management system requirements?	
7.4.3	**Verification of purchased product** - Is receiving inspection or other suitable activities implemented to insure that purchased products meet requirements?	
7.5	**Production and service provision**	
7.5.1	**Control of production and service provision** – Are they carried out under controlled conditions including:	
	a. The availability of information that describes the characteristics of the product?	
	b. Work instructions available?	
	c. Suitable equipment in use?	
	d. Monitoring and measuring devices available and in use?	
	e. Monitoring and measurement implemented?	
	f. Release, delivery and post-delivery activities implemented?	
7.5.2	**Validation of processes for production and service provision –** Where output cannot be verified by subsequent monitoring and measurement evidence must be available to validate processes to demonstrate processes	

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	achieve planned results including:	
	a. Is criteria defined for review and approval of the processes?	
	b. Has there been approval of equipment and qualification of personnel?	
	c. Has there been use of specific methods and procedures?	
	d. Are there requirements for records?	
	e. Has there been revalidation?	
7.5.3	**Identification and traceability** – Has the product been identified by suitable means with status of product and control of identification evident?	
7.5.4	**Customer property** – Is customer property identified, verified, and protected?	
7.5.5	**Preservation of product** – Is there evidence that the product is protected during all phases of processing including delivery?	
7.6	**Control of monitoring and measuring devices** – Have requirements been determined and is monitoring and measurement equipment:	
	a. Calibrated or verified at specified intervals or prior to use to standards traceable to N.I.S.T. and recorded?	
	b. Adjusted or re-adjusted as necessary?	
	c. Identified to enable the calibration status to be determined?	
	d. Safeguarded from adjustments that would invalidate the measurement result?	
	e. Protected from damage and deterioration during handling, maintenance and storage?	
7.6	**General** – Are previous measuring results assessed for validity when equipment is found not to conform to requirements? Are records of results and assessment maintained?	
8	**Measurement, analysis and improvement**	
8.1	**General** – Are the planning and implementation of monitoring, measurement, analysis and improvement processes evident to:	

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	a. Demonstrate conformity of the product?	
	b. Ensure conformity of the quality management system?	
	c. Continually improve the effectiveness of the quality management system?	
8.2	**Monitoring and measurement**	
8.2.1	**Customer satisfaction** – Are there methods and metrics to measure the customers perception of requirements being met?	
8.2.2	**Internal audit** – Are internal audits performed at planned intervals based on status and importance of processes and area to be audited by independent auditors to determine if the quality management system:	
	a. Conforms to the ISO standard and quality system requirements?	
	b. Is effectively implemented and maintained?	
8.2.3	**Monitoring and measurement of processes** – Do monitoring and measurement methods show whether planned results are obtained? If not obtained are corrective actions taken to ensure conformity of product?	
8.2.4	**Monitoring and measurement of product** – Is there evidence to support monitoring and measurement at appropriate stages of the process has taken place? Conformance to requirements demonstrated? Product release in conformance to requirements?	
8.3	**Control of nonconforming product** – Is required procedure available and does it meet requirements? Is evidence available to show conformance to procedure and is one or more of the following in effect including records? Is corrected nonconforming product re-verified? Contained?	
	a. Taking action to eliminate detected nonconformity.	
	b. Authorizing its use, release or acceptance under concession by a relevant authority and customer where applicable?	
	c. Taking action to preclude its original intended use or application.	
8.4	**Analysis of data** – Is there data available to demonstrate the suitability and effectiveness of the quality management system and to evaluate continual improvement effectiveness? Does the analysis of data provide information	

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	relating to :	
	a. Customer satisfaction?	
	b. Conformity to product requirements?	
	c. Characteristics and trends of processes and products including opportunities for preventive action?	
	d. Suppliers?	
8.5	**Improvement**	
8.5.1	**Continual improvement** – Is there evidence to show the effectiveness of the quality management system is continually improved through use of quality policy, quality objectives, audit results, analysis of data, corrective and preventive actions and management review?	
8.5.2	**Corrective Action** – Is action to eliminate the cause of nonconformities and documented in a procedure for:	
	a. Reviewing nonconformities (including customer complaints)?	
	b. Determining the causes of nonconformities?	
	c. Evaluating the need for action to ensure that nonconformities do not recur?	
	d. Determining and implementing action needed?	
	e. Records of the results of action taken:	
	f. Reviewing corrective action taken?	
8.5.3	**Preventive Action** – Does procedure provide for and is evidence available to show action to eliminate the cause of potential nonconformities and does the procedure define requirements for:	

Std. Para #	Requirement	Audit Finding
	a. Determining potential nonconformities and their causes?	
	b. Evaluating the need for action to prevent occurrence of nonconformities?	
	c. Determining and implementing action needed?	
	d. Records of results of action taken?	
	e. Reviewing preventive action taken?	