A Harrington Group White Paper

HQMS Relationship to ISO Regulation 9001:2008

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Introduction

ISO 9001:2008 allows an organization flexibility in the way it chooses to document its quality management system (QMS). This enables each individual organization to develop the minimum amount of documentation needed in order to demonstrate the effective planning, operation and control of its processes and the implementation and continual improvement of the effectiveness of its QMS.

ISO standards are primarily technical in nature, but these also have important economic, social and environmental repercussions. ISO standards are useful to industrial and business organizations, to governments and other regulatory bodies, to trade officials, to conformity assessment professionals, to suppliers and customers of products and services in both public and private sectors, and ultimately, to people in general in their roles as consumers and end users.

This white paper has been produced to provide guidance on the fulfillment of the ISO Regulation when HQMS is the quality management solution of choice. The ISO Regulations are applied worldwide for all industries to leverage and define their quality processes and focus on continuous improvement. HQMS is built on best practices adhering to this ISO Regulation.

ISO 9001 Section Reference & HGI Solution		
Section No.	**Sub-Section No.**	**HGI Solution(s)**
4 **Quality Management System**	**4.1 General Requirements**: The organization shall establish, document, implement and maintain a quality management system and continually improve its effectiveness in accordance with the requirements of this International Standard. The organization shall a. determine the processes needed for the quality management system and their application throughout the organization (see 1.2), b. determine the sequence and interaction of these processes c. determine criteria and methods needed to ensure that both the operation and control of these processes are effective, d. ensure the availability of resources and information necessary to support the operation and monitoring of these processes, e. monitor, measure where applicable, and analyses these processes, and f. implement actions necessary to achieve planned results and continual improvement of these processes. These processes shall be managed by the organization in accordance with the requirements of this International Standard. Where an organization chooses to outsource any process that affects product conformity to requirements, the organization shall ensure control over such processes. The type and extent of control of such outsourced processes shall be defined within the quality management system.	HQMS Document Control Task Management Company Library
	4.2.1 Documentation Requirements: The quality management system documentation shall include: a. documented statements of a quality policy and quality objectives, b. a quality manual, c. documented procedures and records required by this International Standard, d. documents, including records determined by the organization to ensure the effective planning, operation and control of its processes.	Document Control
	4.2.2 Quality Manual: The organization shall establish and maintain a quality manual that includes a. the scope of the quality management system, including details of and justification for any exclusions (see 1.2), b. the documented procedures established for the quality management system, or reference to them, and c. a description of the interaction between the processes of the quality management system.	Document Control

	4.2.3 Control of Documents: Documents required by the quality management system shall be controlled. Records are a special type of document and shall be controlled according to the requirements given in 4.2.4. A documented procedure shall be established to define the controls needed: a. to approve documents for adequacy prior to issue, b. to review and update as necessary and re-approve documents, c. to ensure that changes and the current revision status of documents are identified, d. to ensure that relevant versions of applicable documents are available at points of use, e. to ensure that documents remain legible and readily identifiable, f. to ensure that documents of external origin determined by the organization to be necessary for the planning and operation of the quality management system are identified and their distribution controlled, and g. to prevent the unintended use of obsolete documents, and to apply suitable identification to them if they are retained for any purpose.	Document Control Business Rules to manage the review/approval cycle
	4.2.4 Control of Records: Records established to provide evidence of conformity to requirements and of the effective operation of the quality management system shall be controlled. Records shall remain legible, readily identifiable and retrievable. A documented procedure shall be established to define the controls needed for the identification, storage, protection, retrieval, retention time and disposition of records.	Document Control
5 **Management Responsibility**	**5.1 Management Commitment**: Top management shall provide evidence of its commitment to the development and implementation of the quality management system and continually improving its effectiveness by: a. communicating to the organization the importance of meeting customer as well as statutory and regulatory requirements, b. establishing the quality policy, c. ensuring that quality objectives are established, d. conducting management reviews, and e. ensuring the availability of resources.	Audit Management Reports Queries Analytics Risk Analysis Executive Dashboard
	5.2 Customer Focus: Top management shall ensure that customer requirements are determined and are met with the aim of enhancing customer satisfaction (see 7.2.1 and 8.2.1)	Customer Issue Opportunity for Improvement (OFI)

	5.3 Quality Policy: Top management shall ensure that the quality policy a. is appropriate to the purpose of the organization, b. includes a commitment to comply with requirements and to continually improve the effectiveness of the quality management system, c. provides a framework for establishing and reviewing quality objectives, d. is communicated and understood within the organization, and e. is reviewed for continuing suitability.	Document Control OFI Management Action
	5.4.2 Quality Management System Planning: Top management shall ensure that: a. the planning of the quality management system is carried out in order to meet the requirements given in 4.1, as well as the quality objectives, and b. the integrity of the quality management system is maintained when changes to the quality management system are planned and implemented.	Project Management
	5.5.1 Responsibility & Authority: Top management shall ensure that responsibilities and authorities are defined, and communicated within the organization.	Rights Management Security, Record Level Access Control, Level Security & Management Action
	5.5.3 Internal Communication: Top management shall ensure that appropriate communication processes are established within the organization and that communication takes place regarding the effectiveness of the quality management system.	Email notifications, Alerts, Newsletters, Collaboration, report Distribution & Management Action
	5.6.1 Management Review - General: Top management shall review the organization's quality management system, at planned intervals, to ensure its continuing suitability, adequacy and effectiveness. This review shall include assessing opportunities for improvement and the need for changes to the quality management system, including the quality policy and quality objectives. Records from management reviews shall be maintained (see 4.2.4).	Audit Management OFI

	5.6.2 Management Review - Input: The input to management review shall include information on: a. results of audits, b. customer feedback, c. process performance and product conformity, d. status of preventive and corrective actions, e. follow-up actions from previous management reviews, f. changes that could affect the quality management system, and g. recommendations for improvement.	HQMS Reports Queries Analytics Risk Analysis (All reports are configurable) Supplier Management Customer Issue Task Management
	5.6.3 Management Review - Output: The output from the management review shall include any decisions and actions related to: a. improvements of the effectiveness of the quality management system and its processes, b. improvement of product related to customer requirements, and c. resource needs.	Audit Management OFI Meeting Management
6 **Resource Management**	**6.2.1 Human Resources - General**: Personnel performing work affecting conformity to product requirements shall be competent on the basis of appropriate education, training, skills and experience.	Training Management
	6.2.2 Human Resources - Competence, Awareness, and Training: The organization shall a. determine the necessary competence for personnel performing work affecting conformity to product requirements, b. provide training or take other actions to achieve the necessary competence, c. evaluate the effectiveness of the actions taken, d. ensure that its personnel are aware of the relevance and importance of their activities and how they contribute to the achievement of the quality objectives, and e. maintain appropriate records of education, training, skills and experience (see 4.2.4).	Training Management
	6.3 Infrastructure: The organization shall determine, provide and maintain the infrastructure needed to achieve conformity to product requirements. Infrastructure includes, as applicable: a. buildings, workspace and associated utilities, b. process equipment (both hardware and software), and c. supporting services (such as transport or communication or information systems).	Audit Management Issue Management Asset Management
	6.4 Work Environment: The organization shall determine and manage the work environment needed to achieve conformity to product requirements	Document Control Non-Conformance

7 **Product Realization**	**7.1 Planning**: The organization shall plan and develop the processes needed for product realization. Planning of product realization shall be consistent with the requirements of the other processes of the quality management system (see 4.1). In planning product realization, the organization shall determine the following, as appropriate: a. quality objectives and requirements for the product; b. the need to establish processes and documents, and to provide resources specific to the product; c. required verification, validation, monitoring, measurement, inspection and test activities specific to the product and the criteria for product acceptance; d. records needed to provide evidence that the realization processes and resulting product meet requirements (see 4.2.4). The output of this planning shall be in a form suitable for the organization's method of operations.	Document Control First Article Inspection (AS9102) (PPAP)
	7.2.1 Customer-Related Processes - Determination of the Requirements Related to the Product: The organization shall determine: a. requirements specified by the customer, including the requirements for delivery and post-delivery activities, b. requirements not stated by the customer but necessary for specified or intended use, where known, c. statutory and regulatory requirements applicable to the product, and d. any additional requirements considered necessary by the organization.	Document Control
	7.2.2 Customer-Related Processes - Customer Communication: The organization shall determine and implement effective arrangements for communicating with customers in relation to: a. product information, b. inquiries, contracts or order handling, including amendments, and c. customer feedback, including customer complaints.	Document Control Customer Issues OFI Meeting Management
	7.3.1 Design & Development - Planning: The organization shall plan and control the design and development of product. During the design and development planning, the organization shall determine: a. the design and development stages, b. the review, verification and validation that are appropriate to each design and development stage, and c. the responsibilities and authorities for design and development. The organization shall manage the interfaces between different groups involved in design and development to	Document Control Project Management

	ensure effective communication and clear assignment of responsibility. Planning output shall be updated, as appropriate, as the design and development progresses.	
	7.3.2 Design & Development - Inputs: Inputs relating to product requirements shall be determined and records maintained (see 4.2.4). These inputs shall include: a. functional and performance requirements, b. applicable statutory and regulatory requirements, c. where applicable, information derived from previous similar designs, and d. other requirements essential for design and development. The inputs shall be reviewed for adequacy. Requirements shall be complete, unambiguous and not in conflict with each other.	Audit Management Issue Management Customer Issues Document Control Non-Conformance Supplier Issues
	7.3.3 Design & Development - Outputs: The outputs of design and development shall be in a form suitable for verification against the design and development input and shall be approved prior to release. Design and development outputs shall: a. meet the input requirements for design and development, b. provide appropriate information for purchasing, production and service provision, c. contain or reference product acceptance criteria, and d. specify the characteristics of the product that are essential for its safe and proper use.	Document Control Non-Conformance
	7.3.4 Design & Development - Review: At suitable stages, systematic reviews of design and development shall be performed in accordance with planned arrangements (see 7.3.1) a. to evaluate the ability of the results of design and development to meet requirements, and b. to identify any problems and propose necessary actions. Participants in such reviews shall include representatives of functions concerned with the design and development stage(s) being reviewed. Records of the results of the reviews and any necessary actions shall be maintained (see 4.2.4).	Issue Management Non-Conformance Customer Issues Document Control
	7.3.5 Design & Development - Verification: Verification shall be performed in accordance with planned arrangements (see 7.3.1) to ensure that the design and development outputs have met the design and development input requirements. Records of the	Document Control

	results of the verification and any necessary actions shall be maintained (see 4.2.4).	
	7.3.6 Design & Development - Validation: Design and development validation shall be performed in accordance with planned arrangements (see 7.3.1) to ensure that the resulting product is capable of meeting the requirements for the specified application or intended use, where known. Wherever practicable, validation shall be completed prior to the delivery or implementation of the product. Records of the results of validation and any necessary actions shall be maintained (see 4.2.4).	Document Control
	7.3.7 Design & Development - Control of Design/Development Changes: Design and development changes shall be identified and records maintained. The changes shall be reviewed, verified and validated, as appropriate, and approved before implementation. The review of design and development changes shall include evaluation of the effect of the changes on constituent parts and product already delivered. Records of the results of the review of changes and any necessary actions shall be maintained (see 4.2.4).	Document Control
	7.4.1 Purchasing Process: The organization shall ensure that purchased product conforms to specified purchase requirements. The type and extent of control applied to the supplier and the purchased product shall be dependent upon the effect of the purchased product on subsequent product realization or the final product. The organization shall evaluate and select suppliers based on their ability to supply product in accordance with the organization's requirements. Criteria for selection, evaluation and re-evaluation shall be established. Records of the results of evaluations and any necessary actions arising from the evaluation shall be maintained (see 4.2.4).	Supplier Issues Audit Management Non-Conformance
	7.4.2 Purchasing Information: Purchasing information shall describe the product to be purchased, including, where appropriate, a. requirements for approval of product, procedures, processes and equipment, b. requirements for qualification of personnel, and c. quality management system requirements. The organization shall ensure the adequacy of specified purchase requirements prior to their communication to the supplier.	Document Control

	7.4.3 Verification of Purchased Product: The organization shall establish and implement the inspection or other activities necessary for ensuring that purchased product meets specified purchase requirements. Where the organization or its customer intends to perform verification at the supplier's premises, the organization shall state the intended verification arrangements and method of product release in the purchasing information.	Supplier Issues Audit Management
	7.5.1 Production & Service Provision - Control: The organization shall plan and carry out production and service provision under controlled conditions. Controlled conditions shall include, as applicable: a. the availability of information that describes the characteristics of the product, b. the availability of work instructions, as necessary, c. the use of suitable equipment, d. the availability and use of monitoring and measuring equipment, e. the implementation of monitoring and measurement, and f. the implementation of product release, delivery and post-delivery activities.	Document Control Calibration Management Issue Management Corrective Actions Preventative Actions
	7.5.2 Production & Service Provision - Validation: The organization shall validate any processes for production and service provision where the resulting output cannot be verified by subsequent monitoring or measurement and, as a consequence, deficiencies become apparent only after the product is in use or the service has been delivered. Validation shall demonstrate the ability of these processes to achieve planned results. The organization shall establish arrangements for these processes including, as applicable: a. defined criteria for review and approval of the processes, b. approval of equipment and qualification of personnel, c. use of specific methods and procedures, d. requirements for records (see 4.2.4), and e. revalidation.	Document Control Supplier Quality Training Management
	7.5.3 Production & Service Provision - Identification and Traceability: Where appropriate, the organization shall identify the product by suitable means throughout product realization. The organization shall identify the product status with respect to monitoring and measurement requirements throughout product realization. Where traceability is a requirement, the organization shall control the unique identification of the product and maintain records (see 4.2.4).	Supplier Quality Non-Conformance

	7.5.5 Production & Service Provision - Preservation: The organization shall preserve the product during internal processing and delivery to the intended destination in order to maintain conformity to requirements. As applicable, preservation shall include identification, handling, packaging, storage and protection. Preservation shall also apply to the constituent parts of a product.	Document Control Non-Conformance Corrective Actions Preventative Actions
	7.6 Production & Service Provision - Control of Monitoring and Measuring Devices: The organization shall determine the monitoring and measurement to be undertaken and the monitoring and measuring equipment needed to provide evidence of conformity of product to determined requirements. The organization shall establish processes to ensure that monitoring and measurement can be carried out in a manner that is consistent with the monitoring and measurement requirements. Where necessary to ensure valid results, measuring equipment shall: a. be calibrated or verified, or both, at specified intervals, or prior to use, against measurement standards traceable to international or national measurement standards; where no such standards exist, the basis used for calibration or verification shall be recorded (see 4.2.4) b. be adjusted or re-adjusted as necessary; c. have identification in order to determine its calibration status; d. be safeguarded from adjustments that would invalidate the measurement result; e. be protected from damage and deterioration during handling, maintenance and storage. In addition, the organization shall assess and record the validity of the previous measuring results when the equipment is found not to conform to requirements. The organization shall take appropriate action on the equipment and any product affected. Records of the results of calibration and verification shall be maintained (see 4.2.4). When used in the monitoring and measurement of specified requirements, the ability of computer software to satisfy the intended application shall be confirmed. This shall be undertaken prior to initial use and reconfirmed as necessary.	Calibration Management Asset Management

8 **Measurement Analysis & Improvement**	**8.1 General**: The organization shall plan and implement the monitoring, measurement, analysis and improvement processes needed: a. to demonstrate conformity to product requirements, b. to ensure conformity of the quality management system, and c. to continually improve the effectiveness of the quality management system. This shall include determination of applicable methods, including statistical techniques, and the extent of their use.	HQMS
	8.2.1 Monitoring & Measurement - Customer Satisfaction: As one of the measurements of the performance of the quality management system, the organization shall monitor information relating to customer perception as to whether the organization has met customer requirements. The methods for obtaining and using this information shall be determined.	Customer Issues Audit Management Reporting
	8.2.2 Monitoring & Measurement - Internal Audits: The organization shall conduct internal audits at planned intervals to determine whether the quality management system: a. conforms to the planned arrangements (see 7.1), to the requirements of this International Standard and to the quality management system requirements established by the organization, and b. is effectively implemented and maintained. An audit program shall be planned, taking into consideration the status and importance of the processes and areas to be audited, as well as the results of previous audits. The audit criteria, scope, frequency and methods shall be defined. Selection of auditors and conduct of audits shall ensure objectivity and impartiality of the audit process. Auditors shall not audit their own work. A documented procedure shall be established to define the responsibilities and requirements for planning and conducting audits, establishing records and reporting results. Records of the audits and their results shall be maintained (see 4.2.4). The management responsible for the area being audited shall ensure that any necessary corrections and corrective actions are taken without undue delay to eliminate detected nonconformities and their causes. Follow-up activities shall include the verification of the	Audit Management Corrective Actions Preventative Actions Reporting

	actions taken and the reporting of verification results (see 8.5.2).	
	8.2.3 Monitoring & Measurement - Processes: The organization shall apply suitable methods for monitoring and, where applicable, measurement of the quality management system processes. These methods shall demonstrate the ability of the processes to achieve planned results. When planned results are not achieved, correction and corrective action shall be taken, as appropriate, to ensure conformity of the product.	Corrective Actions Preventative Actions Reporting Analytics
	8.2.4 Monitoring & Measurement - Product: The organization shall monitor and measure the characteristics of the product to verify that product requirements have been met. This shall be carried out at appropriate stages of the product realization process in accordance with the planned arrangements (see 7.1). Evidence of conformity with the acceptance criteria shall be maintained. Records shall indicate the person(s) authorizing release of product for delivery to the customer (see 4.2.4). The release of product and delivery of service to the customer shall not proceed until the planned arrangements (see 7.1) have been satisfactorily completed, unless otherwise approved by a relevant authority and, where applicable, by the customer.	Supplier Quality Non-Conformance Corrective Actions Preventative Actions
	8.3 Control of Non-Conforming Product: The organization shall ensure that product which does not conform to product requirements is identified and controlled to prevent its unintended use or delivery. A documented procedure shall be established to define the controls and related responsibilities and authorities for dealing with nonconforming product. Where applicable, the organization shall deal with nonconforming product by one or more of the following ways: a. by taking action to eliminate the detected nonconformity; b. by authorizing its use, release or acceptance under concession by a relevant authority and, where applicable, by the customer; c. by taking action to preclude its original intended use or application; d. by taking action appropriate to the effects, or potential effects, of the nonconformity when nonconforming product is detected after delivery or use has started. When nonconforming product is corrected it shall be	Corrective Actions Preventative Actions Document Control Reporting Analytics Non-Conformance

	subject to re-verification to demonstrate conformity to the requirements. Records of the nature of nonconformities and any subsequent actions taken, including concessions obtained, shall be maintained (see 4.2.4).	
	8.4 Analysis of Data: The organization determines, collect and analyze appropriate data to demonstrate the suitability and effectiveness of the quality management system and to evaluate where continual improvement of the effectiveness of the quality management system can be made. This shall include data generated as a result of monitoring and measurement and from other relevant sources. The analysis of data shall provide information relating to: a. customer satisfaction (see 8.2.1), b. conformity to product requirements (see 8.2.4), c. characteristics and trends of processes and products including opportunities for preventive action (see 8.2.3 and 8.2.4), and d. suppliers (see 7.4).	HQMS Reports Queries Analytics Risk Analysis (All reports are configurable)
	8.5.1 Improvement - Continual: The organization shall continually improve the effectiveness of the quality management system through the use of the quality policy, quality objectives, audit results, analysis of data, corrective and preventive actions and management review.	HQMS Document Control Corrective Actions Preventative Actions OFI Audit Management
	8.5.2 Corrective Action: The organization shall take action to eliminate the cause of nonconformities in order to prevent recurrence. Corrective actions shall be appropriate to the effects of the nonconformities encountered. A documented procedure shall be established to define requirements 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, and f. reviewing corrective action taken.	Corrective Actions Non-Conformance Preventive Actions Root Cause Analysis Reporting
	8.5.3 Preventative Action: The organization shall determine action to eliminate the causes of potential nonconformities in order to prevent their occurrence. Preventive actions shall be appropriate to the effects of the potential problems. A documented procedure shall be established to define requirements for:	Preventative Actions Reporting

	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 any action taken (see 4.2.4), and e. reviewing the effectiveness of the preventive action taken.	

About the Harrington Group: The Harrington Group was founded by quality software visionary Rick Harrington in 1991 after working for over 20 years with Pratt and Whitney, Lockheed Martin, Marietta and the United States government. Mr. Harrington's vision was to develop applications that would help organizations of any size realize their quality goals and achieve ISO certification.

Harrington Group software is designed to meet the quality management and business process improvement needs of both manufacturing and service organizations. Our software is based on a combination of Six Sigma standards for improvement and the quality management principles underlying the IS0 9001:2008 series. Using these standards, our products help our customers identify and remove defects while minimizing variability in manufacturing and business processes.

The Harrington Quality Management System

Core Applications of HQMS

CAPA	Equipment Calibration
Document Control	Training Management
Audit Management	Non-Conformance
Root Cause Analysis	Supplier/Customer Action

An All-In-One Software Solution

Corporate Benefits of an HQMS Implementation

- Increases top line revenues and bottom line profits through process improvement, minimization of production costs and waste reduction in your manufacturing processes.
- Improves customer satisfaction and increase customer loyalty by providing a high quality product at all times.
- Improves employee communications and creates greater levels of accountability within the organization.
- Assists your oganization in ISO and government regulatatory compliance

For additional Information visit our website at www.harrington-group.com , email info@harrington-group.com or call us at 1-800-ISO-9000.