



ISO 9001:2008 & ISO 14001:2004 Integrated System Audit Template

**ARC Management Systems
Unit 4, IDA Industrial Estate,
Purcellsinch,
Kilkenny,
Ireland.**


www.arcmanagementsystems.com

info@arcmanagementsystems.com

This document has been formulated as a tool to help organizations conduct a System Audit or Gap Analysis on an existing or potential integrated ISO 9001 & ISO 14001 management systems. The audit tool is based on the requirements of both standards and simply turns each clause into a audit question.

We hope you find this document useful and please do not hesitate to contact us with any questions.

ISO 9001 & 14001 INTEGRATED SYSTEM AUDIT TEMPLATE

		AREA /LOCATION: AUDIT DATE:	AUDITOR NAME: AUDITEE NAME:	
9001	14001	REQUIREMENT	CONFORMANCE	COMMENTS / OBSERVATIONS
4.1		<p>Has the organisation defined the scope of its environmental management system?</p> <p>Has the organisation established, documented, implemented & maintained a QMS & EMS in accordance with ISO:9001 & ISO:14001?</p> <p>Has the organisation:</p> <ul style="list-style-type: none"> - Identified the processes needed for the QMS including their applications throughout the org. - Determined the sequence and interaction of these processes - Determined the criteria and methods needed to ensure that both the operation and control of these processes are effective. - Ensured the availability of resource and information necessary to support the operation and monitoring of the processes. - Measured, monitored and analyzed these processes. - Implemented actions needed to achieve planned results & continual improvement of these processes? <p>Does the organisation manage these processes in accordance with the requirements of ISO:9001?</p> <p>Where processes that affect product conformity with requirements are outsourced, are the controls for these processes identified within the QMS?</p>		



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5.3	4.2	<p>Have top management provided evidence of its commitment to the development and implementation of the QMS?</p> <p>Has the organisations top management defined the quality & environmental policy?</p> <p>Does the quality and environmental policies reflect the following:</p> <ul style="list-style-type: none"> - Appropriate to nature & scale. - Include commitment to comply with requirements of system - Commitment to improvement. - Prevention of pollution. - Legal requirements. - Objectives and targets. <p>Is the policy documented, implemented & maintained?</p> <p>Is the policy communicated to all persons working in the organisation?</p> <p>Is the policy available to the public?</p>		

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	4.3.1	<p>Has the organisation established procedures to identify the environmental aspects of its activities, products and services?</p> <p>Has the organisation taken into account planned or new developments or new or modified activities, products and services?</p> <p>Has the organisation determined those aspects that have a significant impact on the environment?</p> <p>Is this information documented and up to date?</p> <p>Have the significant aspects been taken into account within the EMS?</p>		

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	4.3.2	<p>Has the organisation established procedures to identify and have access to the applicable legal requirements to which the organisation subscribes?</p> <p>Has the organisation established procedures to determine how these requirements apply to its environmental aspects?</p> <p>Has the organisation reviewed international, national and local legal requirements within its review?</p>		

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5.4.1 5.4.2	4.3.3	<p>Has top management established , implemented and maintained documented environmental and quality objectives & targets?</p> <p>Are the objectives and targets aimed at relevant functions and levels within the organisations?</p> <p>Are the objectives and targets measureable?</p> <p>Are the objectives and targets consistent with the quality policy?</p> <p>Have quality objectives needed to meet the requirements of the product been established?</p> <p>Do they include commitments to</p> <ul style="list-style-type: none"> - Prevention of pollution? - Compliance with legal requirements? - For continual improvements? <p>Has the organisation taken into account technological, financial, operational, business requirements & views of interested parties when establishing its objectives and targets?</p> <p>Has the organisation established a program for achieving its objectives & targets, including responsibility, means & time-frames?</p>		

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5.5.1 5.5.2 6.1 6.3	4.4.1	<p>Has management provided resources to establish, implement, maintain & improve the quality and environmental management system?</p> <p>Have roles, responsibilities and authorities been clearly defined, documented and communicated?</p> <p>Has a management representative been appointed who has responsibility & authority for?</p> <ul style="list-style-type: none"> - Ensuring that processes are established, implemented and maintained? - Reporting to top management on the performance of the EMS & QMS including needs for improvement? - Prompting awareness of customer requirements throughout the organisation? <p>If so, does the representative's role include reporting to top management?</p> <p>To achieve conformity of product, does the organisation identify, provide & maintain the facilities including:</p> <ul style="list-style-type: none"> - Buildings, workspace & associated utilities? - Process equipment, hardware & software? - Supporting Services? 		

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6.2 6.2.2	4.4.2	<p>Has the organisation ensured that persons performing tasks with a potential impact on product quality or the environment are competent on the basis of education, training or experience?</p> <p>Have records been maintained for the above?</p> <p>Has the organisation identified training needs associated with its product quality and environmental impacts?</p> <p>Has it provided training to meet the above and maintained records of education, training, skills & experience?</p> <p>Has the organisation evaluated the effectiveness of the actions taken?</p> <p>Has the organisation implemented procedures to make persons aware of the following:</p> <ul style="list-style-type: none"> - Quality & Environmental Policy? - Aspects & impacts related each individuals work? - Their roles & responsibilities in conforming to the QMS & EMS requirements? - The potential consequences of departure from specified procedures? 		

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5.5.3 7.2.3	4.4.3	<p>Has the organisation established procedures for the internal communication among the various levels of the organisation?</p> <p>Does communication take place regarding the effectiveness of the QMS?</p> <p>Has the organisation established procedures for the receiving, documenting and responding to relevant communication from external interested parties?</p> <p>Has the organisation decided and documented its decision whether to communicate externally about its significant environmental aspects?</p> <p>If yes, has the organisation established a method for external communication?</p> <p>Has the organisation determined & implemented effective arrangements for communicating with customers relating to:</p> <ul style="list-style-type: none"> - Product information. - Inquires, contracts, amendments or order handling. - Customer feedback, including customer complaints. 		

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4.2.1	4.4.4	<p>Does the QMS & EMS documentation system include:</p> <ul style="list-style-type: none"> - A quality & environmental policy? - A Quality Manual - Objectives & Targets? - Scope of the Environmental Management System? <p>Description of the main elements of the EMS and their interaction & reference to related documents?</p> <p>Documented procedures required by ISO:9001?</p> <p>Documents & Records required by ISO:9001 & 14001 such as:</p> <ul style="list-style-type: none"> - Management Review Records - Internal Audit Records - Emergency Response Plan <p>Documents required by the organisation such as:</p> <ul style="list-style-type: none"> - Monitoring & Measurement Schedule - M.S.D.S Sheets - Waste Permits 		

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4.2.3	4.4.5	<p>Are documents required for the QMS controlled?</p> <p>Has a procedure been established to approve documents for adequacy prior to use?</p> <p>Has a procedure been established to review and update as necessary and re-approve documents?</p> <p>Has a procedure been established to ensure that changes and the current revision status are identified?</p> <p>Has a procedure been established to ensure that relevant versions of applicable documents are available at the point of use?</p> <p>Has a procedure been established to ensure that documents remain legible and readily identifiable?</p> <p>Has a procedure been established to ensure that documents of external origin are identified and controlled?</p> <p>Has a procedure been established to prevent the unintended use of obsolete doc's and identification if they are retained?</p>		

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	4.4.6	<p>Have procedures been established to control to situations where there absence could lead to deviations from the environmental policy?</p> <p>Have the procedures issued stipulated the operating criteria?</p> <p>Have procedures been established relating to the goods and services used by the organisation?</p> <p>Has the organisation communicated applicable procedures to suppliers including contractors?</p>		

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	4.4.7	<p>Has a procedure been established to identify potential emergency situations and how it will respond to them?</p> <p>Do the procedures shall outline how to prevent or mitigate adverse environmental impacts?</p> <p>Does the organisation periodically review its emergency preparedness and response procedures?</p> <p>Does the organisation periodically test such procedures?</p>		

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7.6 8.1 8.2.3 8.2.4	4.5.1	<p>Has a procedure been established to monitor & measure key impacts, the procedure should include information on performance, controls and conformity?</p> <p>Is calibrated monitoring and measurement equipment used and maintained with associated records?</p> <p>Where necessary to ensure valid results is measuring equipment:</p> <ul style="list-style-type: none"> - Calibrated at specific intervals against measurement standards traceable to national or international standards. - Adjusted or Re-adjusted as necessary. - Identified to enable calibration status identified - Safeguarded from adjustments that would invalidate the measurement result. - Protected from damage & deterioration during handling, maintenance & storage. <p>Has the organisation assessed and recorded the validity of the previous measuring results when equipment is found not to conform to requirements and taken the appropriate action on the equipment and any product affected.</p> <p>Are records of calibration & verification maintained.</p> <p>Where computer software is used in the monitoring & measurement of specified requirements, is the ability of the software to satisfy the intended application confirmed prior to initial use.</p> <p>Have monitoring, measurement, analysis &</p>		

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	<p>improvement processes been implemented and planned and implemented to:</p> <ul style="list-style-type: none">- Demonstrate the conformity of the product.- Ensure the conformity of the quality system.- Continually improve the effectiveness of the quality management system. <p>Have the applicable methods including statistical techniques and their extent of use been determined.</p> <p>Process - Are suitable methods applied for the monitoring and where applicable measurement of the QMS processes necessary to meet customer requirements.</p> <p>Do these methods demonstrate the ability of the process to achieve planned results.</p> <p>Are correction & corrective actions taken when planned results are not achieved.</p> <p>Product - Are product characteristics monitored and measured to verify that product requirements are met.</p> <p>Is the monitoring and measurement of product characteristics carried out at appropriate stages of the product realisation process in accordance with the planned arrangements.</p> <p>Is evidence of conformity with the acceptance criteria documented and maintained.</p> <p>Are records maintained to indicate the person(s) authorizing release of product.</p> <p>Unless otherwise approved by a relevant authority or the customer, are all planned arrangements satisfactory completed prior to proceeding with release.</p>		
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	4.5.2 4.5.2 .1	<p>Has a procedure been developed for the period evaluation of compliance with applicable legal requirements?</p> <p>Have records been kept of the results of the periodic evaluations?</p>		
	4.5.5 .2	<p>Has a procedure been developed for the period evaluation of compliance with other requirements to which it subscribes?</p> <p>Have records been kept of the results of the periodic evaluations?</p>		

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8.3 8.5.2 8.5.3	4.5.3	<p>Has the organisation issued procedures for dealing with actual and potential non-conformities and taking corrective and preventive actions?</p> <p>Does the procedure include requirements for:</p> <ul style="list-style-type: none"> - Identifying & correcting non-conformities - Investigating & determining cause - Implementing appropriate actions - Recording results. - Reviewing effectiveness <p>Has the organisation made provision for ensuring that any necessary changes are made to the EMS documentation?</p> <p>Is non conforming product identified and controlled to prevent unintended use or delivery?</p> <p>Has a documented procedure been established to define controls and related responsibilities and authorities for dealing with non conforming product?</p> <p>Are non-conforming product dealt with by one or more of the following ways:</p> <ul style="list-style-type: none"> - Action taken to eliminate the detected non-conformity. - Authorized use, release or acceptance under concession by relevant authority and where applicable by the customer - Actions taken to preclude its original intended use or application <p>Are records maintained identifying the nature of non-</p>		

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	<p>conformities and any subsequent actions taken including any concessions?</p> <p>When non-conforming product is corrected, is it subject to re-verification to demonstrate conformity to the requirements?</p> <p>When non-conforming product is detected after delivery, or use has started, is appropriate action taken by the organisation to the effect or potential effect?</p> <p>Are corrective actions taken to eliminate the cause of non-conformities and to prevent re-occurrence?</p> <p>Are corrective actions appropriate to the effects of the non-conformity encountered?</p> <p>Has a documented procedure been established for:</p> <ul style="list-style-type: none">- Reviewing non-conformities including customer complaints.- Determining the cause of non-conformity.- Evaluating the need for action to ensure that nonconformities do not occur.- Determining & implementing action needed.- Recording & maintaining actions taken.- Reviewing corrective action taken. <p>Has the org determined actions to eliminate the cause of potential non-conformities in order to prevent occ.</p> <p>Are preventive actions appropriate to the effects?</p> <p>Has a procedure been established to define;</p> <ul style="list-style-type: none">- Determine potential N/C and their causes.- Evaluate need for action to prevent occ of N/C.- Determining & implementing action needed.- Recording & maintaining actions taken.- Reviewing of preventive action taken		
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4.2.4	4.5.4	<p>Has the organisation established records to demonstrate conformity to the standard and the results achieved?</p> <p>Has a procedure been established for the</p> <ul style="list-style-type: none"> - identification, - storage, - protection, - retrieval, - retention time - disposal of records. <p>Are records legible, identifiable and traceable?</p>		

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8.2.2	4.5.5	<p>Has the organisation ensured that internal audits are conducted at planned intervals?</p> <p>Do the audits ensure</p> <ul style="list-style-type: none"> - Conformance to ISO:9001 & ISO:14001? - Conformance to the QMS & EMS - Systems effectively implemented & maintained? <p>Have the audits been planned with consideration to previous audit results?</p> <p>Have the audits been planned with consideration to the quality & environmental importance of the operations?</p> <p>Has a procedure been established outlining the responsibilities, requirements, reporting and retaining of results?</p> <p>Does auditor selection ensure objectivity & impartiality to the audit process and that auditors do not audit their own work?</p> <p>Has a procedure been established to determine the criteria, scope, frequency and method?</p>		

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5.6.1 5.6.2 5.6.3	4.6	<p>Are reviews conducted by top management at regular intervals?</p> <p>Have records of the management reviews been maintained as QMS/EMS records?</p> <p>Have the reviews included the following:</p> <ul style="list-style-type: none"> - Results of Audits - Customer Feedback - Process & Product Performance/Conformity. - Compliance with legal requirements - Communication from external parties. - Environmental Performance. - Extent to which objectives & targets are met - Status of corrective & preventive actions - Follow up actions from previous mgt reviews - Changing circumstances - Recommendations for improvements <p>Have the outputs of the reviews included decisions and actions relating to the following:</p> <ul style="list-style-type: none"> - Quality & Environmental Policy suitability - Objectives & Targets - Quality & Environmental continual improvement 		

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4.2.2		<p>Has a Quality manual been established & maintained?</p> <p>Does the manual include:</p> <ul style="list-style-type: none"> - The scope of the Management System. - Details and justifications for any exclusions. - Documented procedures established for the quality management system or reference to them. - Description of the interaction between the processes of the QMS. 		


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5.2		Have top management ensured that customer requirements are determined and met with the aim of enhancing customer satisfaction.		


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6.4		Has the environment needed to achieve conformity of product requirements been determined and managed?		


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7.2.1 7.2.2		<p>Has the organisation determined:</p> <ul style="list-style-type: none"> - Requirements specified by the customer, including the requirements for delivery and post delivery activities. - Requirements not stated by the customer but necessary for specified or intended use, where known. - Statutory and regulatory requirements related to the product. - Any additional requirements determined by the organisation. <p>Prior to the commitment to the customer (e.g. submission of tenders, acceptance of contracts or orders or acceptance of change orders) are requirements reviewed to ensure that:</p> <ul style="list-style-type: none"> - Product requirements are defined. - Contract or order requirements differing from those previously expressed are resolved. - The organisation has the ability to meet defined requirements. 		


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7.3.1		<p>Are product design and development activities planned and controlled?</p> <p>During the design and development planning has the organisation determined:</p> <ul style="list-style-type: none"> - Stages of design & development. - Review, verification and validation that are appropriate to each design & development stage. - Responsibility and authorities for design & development <p>Are interfaces between different groups involved in design & development managed to ensure effective communication and clear assignment of responsibilities.</p> <p>Is planning output updated as design and development progresses.</p>		


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7.3.2		<p>Are inputs relating to product requirements defined, documented and maintained as a record.</p> <p>Does design and development input include:</p> <ul style="list-style-type: none"> - Functional and performance requirements? - Applicable statutory & regulatory requirements? - Applicable information derived from previous similar designs? - Other requirements essential for designs and development? <p>Are design and development inputs reviewed for adequacy?</p> <p>Are incomplete, unambiguous or conflicting requirements resolved?</p>		

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7.3.3		<p>Are outputs of the design and development provided in a form that enables verification against design and development inputs?</p> <p>Are design outputs approved prior to release?</p> <p>Does the design and development output:</p> <ul style="list-style-type: none"> - Meet the design and development input requirements? - Provide appropriate information for purchasing production and for service provision? - Contain or reference product acceptance criteria. - Specify the product characteristics that are essential to its safe and proper use. 		

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7.3.4		<p>Are systematic reviews performed in accordance with planned arrangements at suitable stages of the design & development?</p> <p>Do design & development reviews:</p> <ul style="list-style-type: none"> - Evaluate the ability of the results of design and development to meet requirements - Identify problems and propose necessary actions? <p>Do review participants include representatives of functions concerned with the design & development stages being reviewed?</p> <p>Are results of reviews and any actions necessary maintained as records?</p>		

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7.3.5		<p>Is the design and development verification performed in accordance with planned arrangements to ensure that the design outputs have met the design and development input requirements?</p> <p>Are results of verification and actions maintained as a record?</p>		


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7.3.6		<p>Is the design and development validation performed in accordance with planned arrangements?</p> <p>Is design and development validation performed to confirm that the product is capable of meeting requirements for the specified application or intended use, where known?</p> <p>Is validation completed prior to delivery or implementation of the product wherever applicable?</p> <p>Are results of validation and actions maintained as a record?</p>		


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7.3.7		<p>Are design and/or development changes identified and recorded?</p> <p>Do reviews of design and development changes include evaluation of the effect of the changes on constituent parts and product already delivered?</p> <p>Are design and development changes reviewed, verified, validated as appropriate and approved before implementation?</p> <p>Are results of the review of changes and necessary actions maintained as records?</p>		


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7.4.1 7.4.2 7.4.3		<p>Are the purchasing processes controlled to ensure purchased product/service conforms to requirements?</p> <p>Is the type and extent of control applied to the suppliers & purchased product dependent upon the effect of the purchased product on subsequent product realisation or the final product?</p> <p>Are suppliers selected and evaluated based on their ability to supply product in accordance with the organisations requirements?</p> <p>Has the organisation established criteria for selection, evaluation and re-evaluation of suppliers?</p> <p>Are results of the evaluations and the necessary actions maintained as records?</p> <p>Does the purchasing information describe the product to be purchased? Including:</p> <ul style="list-style-type: none"> - Requirements for approval of product, procedures, processes & equipment - Requirements for qualification of personnel - Quality Mgt System requirements? <p>Is the adequacy of specified purchased requirements ensured prior to their communication to supplier.</p> <p>Have the inspection activities necessary for ensuring that purchased product meets requirements been est. Are arrangements in place for insp at suppliers prem.</p>		


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7.5.1		Are the production and service provision planned and carried out under controlled conditions including: <ul style="list-style-type: none"> - Availability of information that describes the product characteristics? - Availability of work instructions, as necessary? - Use of suitable equipment? - Availability and use of monitoring & measuring devices? - Implementation of monitoring & measurement? - Implementation of release, delivery and post delivery activities? 		

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7.5.2		<p>Have processes where deficiencies may become apparent only after the product is in use or the service has been delivered been validated?</p> <p>Do the results of validation demonstrate the ability of the process to achieve planned results?</p> <p>Where applicable, have arrangements been established for:</p> <ul style="list-style-type: none"> - Defining criteria for review and approval of processes? - Approval of equipment and qualification of personnel? - Use of specific methods and procedures? - Requirements for records? - Re-validation? 		

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7.5.3		<p>Is the product identified by suitable means throughout the realisation process?</p> <p>Is the product status identified with respect to monitoring and measurement requirements?</p> <p>When traceability is a requirement, is the product uniquely identified and controlled?</p> <p>Is the unique identification maintained as a record?</p>		

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7.5.4		<p>Does the organisation exercise care with customer property while it is under the organisations control or being used by the organisation?</p> <p>Is customer property identified, verified, protected and safeguarded?</p> <p>If lost, damaged or otherwise found to be unsuitable for use, is the condition recorded, reported to the customer and maintained as a record?</p>		

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9001	14001	REQUIREMENT	CONFORMANCE	COMMENTS / OBSERVATIONS
7.5.5		<p>Is conformity of product preserved during the internal processing and delivery to the intended destination?</p> <p>Do the preservation activities include:</p> <ul style="list-style-type: none"> - Identification - Handling - Packaging - Storage - Protection <p>Are preservation activities applied to constituent parts of a product?</p>		

ISO 9001 & 14001 INTEGRATED SYSTEM AUDIT TEMPLATE



AREA /LOCATION:

AUDITOR NAME:

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9001	14001	REQUIREMENT	CONFORMANCE	COMMENTS / OBSERVATIONS
8.2.1		<p>Is the information relating to customer perception monitored by the organisation as to whether customer requirements have been met?</p> <p>Have the methodologies for obtaining and using information related to customer perception been determined?</p>		

ISO 9001 & 14001 INTEGRATED SYSTEM AUDIT TEMPLATE



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AUDIT DATE:

AUDITEE NAME:

9001	14001	REQUIREMENT	CONFORMANCE	COMMENTS / OBSERVATIONS
8.4		<p>Is appropriate data determined, collected & analysed to demonstrate the suitability and effectiveness of the QMS and to evaluate where continual improvement of the effectiveness of the QMS can be made?</p> <p>Does this data include data generated from monitoring and measurement and other relevant sources?</p> <p>Does the analysis of this data provide information related to:</p> <ul style="list-style-type: none"> - Customer Satisfaction? - Conformance of Product Requirement? - Characteristics and trends of processes and product including opportunity for preventive action? - Suppliers? 		