**Lines of Inquiry for ISO 9001:2008**

**Introduction**

**0.1 General**

Has the system been developed around ISO 9001:2008?

**0.2 Process Model**

Has a process approach been adopted?

**4 Quality Management System (QMS)**

**4.1 General Requirements**

Has the system been documented, implemented, maintained and continually improved in accordance with ISO 9001:2008?

Has the organization:

1. determined the processes needed and their application?
2. determined the sequence and interaction of these processes?
3. determined criteria/methods to ensure effective operation and control of these processes?
4. ensured availability of information necessary to support the operation and monitoring of these processes?
5. monitored, measured where applicable, and analysed these processes?
6. implemented action necessary to achieve planned results and continual improvement?

Are these processes managed in accordance with the ISO 9001:2008?

Does the organization ensure control over processes that affects product conformity that are outsourced?

Is the type and extent of these controls defined in the QMS?

**4.2 Documentation Requirements**

**4.2.1 General**

Does the quality management system documentation include:

1. documented statements of quality policy and quality objectives?
2. a quality manual?
3. documented procedures and records required by ISO 9001:2008?
4. documents, including records, determined to be necessary to ensure effective planning, operation and control of its processes?

**4.2.2 Quality Manual**

Has a quality manual been established and maintained that includes:

1. scope of QMS including details and justification of any exclusion?
2. the documented procedures established for the QMS or reference to them?
3. a description of the interaction between the processes of the QMS?

**4.2.3 Control of Documents**

Are documents required by the QMS controlled?

Has a documented procedure been established to define controls needed to:

1. approve documents for adequacy prior to use?
2. review and update as necessary and re-approve?
3. ensure changes and current revision status of documents are identified?
4. ensure relevant versions of applicable documents are available at points of use?
5. ensure documents remain legible and readily identifiable?
6. ensure documents of external origin determined by the organization to be necessary for planning and operation of the QMS are identified and their distribution controlled?
7. prevent unintended use of obsolete documents and to apply suitable identification to them if retained for any purpose?

**4.2.4 Control of Records**

Are records established to provide evidence of conformity to requirements and of the effective operation of the QMS controlled?

Do records provide evidence of effective operation of the QMS?

Do records remain legible, readily identifiable and retrievable?

Has a documented procedure been established that defines the controls needed for the identification, storage, protection, retrieval, retention time and disposition of records?

**5 Management Responsibility**

**5.1 Management Commitment**

Is top management committed to the development and implementation of the QMS?

Does commitment include continually improving its effectiveness by:

1. communicating to the organization the importance of meeting customer, statutory and regulatory requirements?
2. establishing the quality policy? (see 5.3 below)
3. ensuring quality objectives are established? (see 5.4.1 below)
4. conducting management reviews? (see 5.6 below)
5. ensuring the availability of resources? (see 6 below)

**5.2 Customer Focus**

Does top management ensure that customer requirements are determined, and are met with the aim of achieving customer satisfaction? (see 7.2.1 and 8.2.1 below)

**5.3 Quality Policy**

Does top management ensure that the quality policy:

1. is appropriate to the purpose of the organization?
2. includes a commitment to comply with requirements and continually improve the effectiveness of the QMS?
3. provides a framework for establishing and reviewing quality objectives?
4. is communicated and understood at appropriate levels in the organization?
5. is reviewed for continuing suitability?

**5.4 Planning**

**5.4.1 Quality Objectives**

Does top management ensure that quality objectives are established at relevant functions and levels within the organization?

Does this include the objectives needed to meet requirements for product?

Are the quality objectives measurable and consistent with the quality policy?

**5.4.2 QMS Planning**

Does top management ensure:

1. the planning of the QMS is carried out in order to meet requirements in 4.1 above as well as the quality objectives?
2. the integrity of the QMS is maintained when changes to the system are planned and implemented?

**5.5 Responsibility, Authority and Communication**

**5.5.1 Responsibility and Authority**

Has top management ensured that responsibility and authority are defined and communicated within the organization?

**5.5.2 Management Representative**

Has top management appointed a member of the organization’s management who, irrespective of other responsibilities, has responsibility and authority for:

1. ensuring that processes needed for the QMS are established, implemented and maintained?
2. reporting to top management on the performance of the quality management system, including needs for improvement?
3. promoting awareness of customer requirements throughout the organization?

**Note - The responsibility of a management representative can include liaison with external**

**parties on matters relating to the quality management systems.**

**5.5.3 Internal Communication**

Does top management ensure that appropriate communication processes have been established within the organization and that communication takes place regarding effectiveness of the QMS?

**5.6 Management Review**

**5.6.1 General**

Does top management review the QMS, at planned intervals, to ensure its continuing suitability, adequacy and effectiveness?

Does the review include assessing opportunities for improvement and the need for changes to the QMS, including quality policy and quality objectives?

Are records of management reviews maintained (see 4.2.4 above)?

**5.6.2 Review Input**

Do inputs to management review include information on:

1. results of audits?
2. customer feedbacks?
3. process performance?
4. status of preventive and corrective actions?
5. follow-up actions from previous management reviews?
6. changes that could affect the QMS?
7. recommendations for improvement?

**5.6.3 Review Output**

Do management review outputs include actions related to:

1. improvement of the QMS and its processes?
2. improvement of product related to customer requirements?
3. resource needs?

**6 Resource Management**

**6.1 Provision of Resources**

Has the organization determined and provided resources needed to:

1. implement and maintain the QMS and continually improve its effectiveness?
2. to enhance customer satisfaction by meeting customer requirements?

**6.2 Human Resources**

**6.2.1 General**

Are personnel performing work-affecting conformity to product requirements competent on the basis of appropriate education, training, skills and experience?

**6.2.2 Competency, Training and Awareness**

Does the organization:

1. determine the necessary competency needs for personnel performing work affecting product requirements?
2. where applicable provide training or take other actions to achieve the necessary competence?
3. evaluate the effectiveness of the actions taken?
4. ensure personnel are aware of the relevance and importance of their activities and how they contribute to achievement of quality objectives?
5. maintain appropriate records of education, training, skills and experience (see 4.2.4 above)?

**6.3 Infrastructure**

Does the organization determine, provide and **maintain** the infrastructure needed to achieve conformity to product requirements?

Does the infrastructure include as applicable:

1. building, workspace and associated utilities?
2. supporting services (such as transport and communication or information systems)?

**6.4 Work Environment**

Does the organization determine and manage the work environment to achieve conformity to product requirements?

**7 Product Realization**

**7.1 Planning of Realization Process**

Does the organization plan and develop the processes needed for product realization?

Is planning of product realization consistent with requirements of other processes of the QMS?

(see 4.1 above)

In planning product realization does the organization determine the following, as applicable:

1. quality objectives and requirements for the product?
2. the need to establish processes, documents, and to provide resources specific to the product?
3. required verification, validation, monitoring, measurement, inspection and test activities specific to the product and the criteria for product acceptance?
4. records needed to provide evidence that the realization processes and resulting product meet requirements? (see 4.2.4 above)

Is the output of this planning in a form suitable for the organization’s method of operations?

**7.2 Customer-Related Processes**

**7.2.1 Determination of Requirements Related to the Product**

Does the organization determine:

1. the requirements specified by the customer, including requirements for delivery and post-deliveryactivities?
2. requirements not specified by the customer but necessary for specified or intended use, where known?
3. statutory and regulatory requirements applicable to the product?
4. any additional requirements considered necessary by the organization?

7.2.2 Review of requirements related to the product (continued)

1. contract or order requirements differing from those previously expressed are resolved?
2. the organization has the ability to meet the defined requirements?

Are records of the results of the review and actions arising from the review maintained?

Where the customer provides no documented statement of requirement, are the customer requirements confirmed by the organization before acceptance?

Where product requirements are changed, does the organization ensure that the relevant documentation is amended?

Does the organization ensure that the relevant personnel are made aware of the changed requirements?

**7.2.3 Customer Communication**

Does the organization determine and implement arrangements for communication with customers relating to:

1. product information?
2. inquiries, contracts or order handling, including amendments?
3. customer feedback, including customer complaints?

**7.3 Design and Development**

**7.3.1 Design and Development Planning**

Does the organization plan and control design and development of the product?

During design and development planning does the organization determine:

1. the design/development stages?
2. review, verification and validation that are appropriate to each design/development stage?
3. responsibilities and authorities for design/development?

Does the organization manage the interfaces between different groups involved in design and development to ensure effective communication and clear assignment of responsibilities?

Is planning output updated, as appropriate, as the design and development progresses?

**7.3.2 Design and Development Inputs**

Are inputs relating to product requirements determined and records maintained? (see 4.2.4 above)

Does this include:

1. functional and performance requirements?
2. applicable statutory and regulatory requirements?
3. where applicable, information derived from previous similar designs?
4. other requirements essential for design and development?

Are these inputs reviewed for adequacy?

Are these requirements complete, unambiguous and not in conflict with each other?

**7.3.3 Design and Development Outputs**

Are the outputs of the design and development in a form suitable for verification against the design and development inputs?

Are outputs approved prior to release?

Do design and development outputs:

1. meet the input requirements for design and development?
2. provide appropriate information for purchasing, production and service provision?
3. contain or reference product acceptance criteria?
4. specify the characteristics of the product that are essential to its safe and proper use?

**7.3.4 Design and Development Review**

At suitable stages, are systematic reviews of design and development performed in accordance with planned arrangements (see 7.3.1 above) to:

1. evaluate the ability of the results of design and development to meet requirements?
2. identify problems and proposed necessary actions?

In such reviews, are representatives of functions concerned with the design and development stage(s) being reviewed included?

Are the result of the reviews and any necessary actions maintained? (see 4.2.4 above)

**7.3.5 Design and Development Verification**

Is verification performed in accordance with planned arrangements to ensure the design and development outputs meet the design and development inputs requirements?

Are records of the results of the verification and any necessary actions maintained?

(see 4.2.4 above)

**7.3.6 Design and Development Validation**

Is design and development validation performed in accordance with planned arrangements (see 7.3.1 above) to ensure that resulting product is capable of meeting the requirements for the specified application or intended use, where known?

Wherever practicable, is validation completed prior to the delivery or implementation of the product?

Are records of the result of the validation and any necessary actions maintained? (see 4.2.4 above)

**7.3.7 Control of Design and Development Changes**

Are design and development changes identified and records maintained?

Are the changes reviewed, verified and validated, as appropriate, and approved before implementation?

Does this review include evaluation of the effect of the changes on constituent parts and products already delivered?

Are records of the result of the review of changes and any necessary actions maintained?

(see 4.2.4 above)

**7.4 Purchasing**

**7.4.1 Purchase Process**

Does the organization ensure that purchased product conforms to specified purchase requirements?

Is the type and extent of control applied to the supplier and the purchased product dependent upon the effect of the purchased product on subsequent product realization or the final product?

Does the organization evaluate and select suppliers based on their ability to supply product in accordance with the organization’s requirements?

Are the criteria for selection, evaluation and re-evaluation established?

Are records of the result of evaluations and any necessary actions arising from the evaluation maintained? (see 4.2.4 above)

**7.4.2 Purchasing Information**

Does purchasing information describe the product to be purchased, including where appropriate:

1. requirements for approval or qualification of product, procedures, process and equipment?
2. requirements for qualification of personnel?
3. QMS requirements?

Does the organization ensure adequacy of specified purchase requirements prior to communicating to supplier?

**7.4.3 Verification of Purchased Products**

Does the organization establish and implement inspection and other activities necessary for ensuring purchased product meets specified purchase requirements?

Where the organization or its customer proposes to perform verification activities at the supplier’s premises, does the organization state the intended verification arrangements and method of product release in the purchasing information?

**7.5 Production and Service Provision**

**7.5.1 Control of Production and Service Provision**

Does the organization plan and carry out production and service provision under controlled conditions including as applicable:

1. the availability of information that describes the characteristics of the product?
2. the availability of work instructions, as necessary?
3. the use of suitable equipment?
4. the availability and use of monitoring and measuring equipment?
5. the implementation of monitoring and measuring?
6. the implementation of product release, delivery and post-delivery activities?

**7.5.2 Validation of Processes for Production and Service Provision**

Does the organization validate 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?

Does validation demonstrate the ability of these processes to achieve planned results?

Does the organization establish arrangements for these processes including, as applicable:

1. defined criteria for review and approval of the processes?
2. approval of equipment and qualification of personnel?
3. use of specific methods and procedures?
4. requirements for records? (see 4.2.4 above)
5. revalidation?

**7.5.3 Identification and Traceability**

Where appropriate, does the organization identify the product by suitable means throughout product realization?

Does the organization identify the product status with respect to monitoring and measurement requirement throughout product realization?

Where traceability is a requirement, does the organization control the unique identification of the product and maintain records? (see 4.2.4 above)

**7.5.4 Customer Property**

Does the organization exercise care with customer property while it is under the organization’s control or being used by the organization?

Does the organization identify, verify, protect and safeguard customer property provided for use or incorporation into the product?

If customer property is lost, damaged or otherwise found to be unsuitable for use does the organization report this to the customer and maintain records? (see 4.2.4 above)

**Note - Customer property may include intellectual property and personal data**

**7.5.5 Preservation of Product**

Does the organization preserve product during internal processing and final delivery to the intended destination in order to maintain conformity to requirements?

Does this include as applicable:

1. identification
2. handling
3. packaging
4. storage and
5. protection?

Does preservation also apply to the constituent parts of a product?

**7.6 Control of Monitoring and Measuring Equipment**

Does the organization determine the monitoring and measurement to be undertaken and the monitoring and measuring equipment needed to provide evidence of conformity of the product to determined requirements?

Does the organization establish processes to ensure that monitoring and measurement can be carried out and are carried out in a manner consistent with the monitoring and measurement requirements?

Where necessary to ensure valid results, is measuring equipment:

1. calibrated/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, is the basis used for calibration or verification recorded?
2. adjusted or re-adjusted as necessary?
3. identified in order to determine its calibration status?
4. safeguarded from adjustments that would invalidate the measurement result?
5. protected from damage and deterioration during handling, maintenance and storage?

Does the organization assess the validity of previous measuring results when the equipment is found not to conform to requirements?

Does the organization take appropriate action on equipment and any product affected as referenced above?

Are records of the results of calibration and verification maintained? (see 4.2.4 above)

When used in the monitoring and measurement of specified requirements, is the ability of computer software to satisfy the intended application confirmed?

Is this undertaken prior to initial use and reconfirmed as necessary?

**Note - Confirmation of the ability of computer software to satisfy the intended application would typically include its verification and configuration management to maintain its suitability for use.**

**8** **Measurement, Analysis and Improvement**

**8.1 General**

Does the organization, plan and implement the monitoring, measurement analysis and improvement processes needed to:

1. demonstrate conformity of to product?
2. ensure conformity of the QMS?
3. continually improve the effectiveness of the QMS?

Does this include the determination of the need for applicable methods, including statistical techniques and extent of their use?

**8.2 Monitoring and Measurement**

**8.2.1 Customer Satisfaction**

As one of the measurements of the performance of the QMS, does the organization monitor information on customer perception as to whether the organization has met customer requirements? (see 5.2 above)

Are the methods for obtaining and using this information determined?

**8.2.2 Internal Audit**

Does the organization conduct internal audits at planned intervals to determine whether the QMS:

1. conforms to the planned arrangements (see 7.1 above), to requirements of ISO 9001:2008 and to the requirements of the organization’s QMS?
2. has been effectively implemented and maintained?

Does the organization plan the audit program taking into consideration the status and importance of the processes and areas to be audited as well as results of previous audits?

Are the audit criteria, scope, frequency and methods defined?

Do the selection of auditors and the conduct of audits ensure objectivity and impartiality of the audit process?

Are auditors independent of area being audited (e.g. do not audit their own work)?

Has a **documented procedure** been established to define the responsibilities and requirements for planning and conducting audits, establishing records and reporting results

Have records of the audits and their results been maintained? (see 4.2.4 above)

Do management responsible for the area being audited ensure that any necessary corrections and corrective actions are taken without undue delay to eliminate detected nonconformities and their cause?

Do follow-up actions include the verification of the actions taken and the reporting of verification results? (see 8.5.2 below)

**8.2.3 Monitoring and Measurement of Processes**

Does the organization apply suitable methods for monitoring and, where applicable, measurement of the QMS processes?

Do these methods demonstrate the ability of the processes to achieve planned results?

When planned results are not achieved, is correction and corrective action taken as appropriate?

**8.2.4 Monitoring and Measurement of Product**

Does the organization monitor and measure the characteristics of the product to verify that product requirements have been met?

Is this carried out at appropriate stages of the product realization process in accordance with planned arrangements? (see 7.1 above)

Is the evidence of conformity with the acceptance criteria maintained?

Do records indicate the person(s) authorising release of product for delivery to the customer?

(see 4.2.4 above)

Does release of product and service delivery to the customer not proceed until planned arrangements (see 7.1 above) have been satisfactorily completed, unless otherwise approved by a relevant authority and where applicable, by the customer?

**8.3 Control of Nonconforming Product**

Does the organization ensure that product which does not conform to product requirements is identified and controlled to prevent unintended use or delivery?

Has a **documented procedure** been established to define the controls and related responsibilities and authorities for dealing with nonconforming product?

Where applicable does the organization deal with nonconforming product by one or more of the following ways:

1. taking action to eliminate the detected nonconformity
2. authorising its use, release or acceptance under concession by a relevant authority and, where applicable, by the customer?
3. by taking action to preclude its original intended use or application?
4. by taking action appropriate to the effects, or potential effects, of the nonconformity when nonconforming product is detected after delivery?

When nonconforming product is corrected is it subject to re-verification to demonstrate conformity to the requirements?

Are records of the nature of the nonconformities and any subsequent actions taken, including concessions obtained maintained? (see 4.2.4 above)

**8.4 Analysis of Data**

Does the organization determine, collect and analyse appropriate data to demonstrate the suitability and effectiveness of the QMS and to evaluate continual improvement of the effectiveness of the QMS?

Does this include data generated as a result of monitoring and measurement and other relevant sources?

Does the analysis of data provide information relating to:

1. customer satisfaction? (see 8.2.4 above)
2. conformance to customer requirements? (see 7.2.1 above)
3. characteristics and trends of processes and products including opportunities for preventive action? (see 8.2.3and 8.2.4 above)
4. suppliers? (see 7.4 above)

**8.5 Improvement**

**8.5.1 Continual Improvement**

Does the organization continually improve the effectiveness of the QMS through its use of the quality policy, quality objectives, audit results, analysis of data, corrective and preventive actions and management review?

**8.5.2 Corrective Action**

Does the organization take action to eliminate the cause of nonconformities in order to prevent recurrence?

Is the corrective action appropriate to the effects of the nonconformities encountered?

Has a **documented procedure** been establishes and does it define the requirements for:

1. reviewing nonconformities (including customer complaints)?
2. determining the causes of nonconformities?
3. evaluating the need for action to ensure that nonconformities do not recur?
4. determining and implementing the action needed?
5. recording results of action taken? (see 4.2.4 above)
6. reviewing the effectiveness of corrective action taken?

**8.5.3 Preventive Action**

Does the organization determine action to eliminate the cause of potential nonconformities in order to prevent their occurrence?

Are the preventive actions taken appropriate to the effects of the potential problems?

Has a **documented procedure** been established and does it define requirements for:

1. determining potential nonconformities and their causes?
2. evaluating the need for action to prevent occurrence of nonconformities?
3. determining and implementation of action needed?
4. recording results of action taken? (see 4.2.4 above)
5. reviewing the effectiveness of preventive action taken?