AUDIT AND DOCUMENTATION EXPECTATIONS FOR QUALITY MANAGEMENT SYSTEMS BASED ON ISO 9001-2008

Introduction

ISO 9001:2008 introduced giving more clarifications from its predecessor, ISO 9001- 2000 as follows:

Top Management
More emphasis has been placed on the role of top management, which includes its commitment to the development and improvement of the quality management system, with a customer focus, consideration of statutory and regulatory requirements, and establishment of measurable objectives at relevant functions and levels.

Continual Improvement
An enhanced requirement for "continual improvement" has been introduced into ISO 9001, defining a complete cycle to improve the effectiveness of the quality management system.

Application
The concept of exclusions to requirements has been introduced as a way to cope with the wide spectrum of organizations and activities that will be using the standard.

Customer Satisfaction
Another new item that has been introduced into ISO 9001-2008 is the requirement for the organization to monitor information on customer satisfaction as a measure of system performance.

Resources
Attention has been placed on top management to provide and make available the necessary resources. Requirements now include evaluation of the effectiveness of training, provision of relevant information, internal and external communication, facility needs, and human and physical factors of the work environment.

Documentation

The number of requirements for documented procedures has been reduced in ISO 9001-2008, and the emphasis placed on the organization demonstrating effective operation.

Pre-Audit Expectations

The quality management system, including the quality manual and procedures must be reviewed by the auditor prior to the audit to establish ISO 9001-2008 requirements are addressed. The customer will complete AQA-India form F-014 to depict how the organization's quality management system addresses ISO 9001-2008 requirements and send it to the auditor along with the quality manual and procedures. Guidance to the significant requirements that must be addressed includes:

1. The quality manual must include the scope of the quality management system, including justification for any exclusions to the requirements of the standard. Exclusions are only permitted to requirements in clause 7. All exclusions must be justified in the manual and will be verified by the auditor that they do not affect the organizations ability nor responsibility in providing a product or service. Guidance to permissible exclusions is as follows:

Clause 7.1	Planning of product realization must always be addressed and **cannot be excluded**
7.2	Determination of customer requirements must always take place and **cannot be excluded**
7.3	Product design may be excluded if it is not performed. Product design is defined as transforming requirements (need or expectation) into specific characteristics (distinguishing features). A test for manufacturing operations is often "whoever creates and controls the drawing has design

	responsibility". A test for a provider of courses or training would be "whoever creates and controls the curriculum has design responsibility"
7.4	May be excluded if no customers are involved, but this case is rare.
7.5.1	**Cannot be excluded** since controlled conditions will always be required.
7.5.2	**Should not be excluded** unless the nature of the business precludes special processes from ever being applicable. If they are currently are not required but may be required in the future, the QMS should imply it will address the requirement should it become applicable.
7.5.3	Identification is usually applicable even if product is intangible, such as a service
7.5.4	**Should not be excluded** unless the nature of the business precludes customer property from ever being applicable. If currently are not required but may be required in the future, the QMS should imply it will address the requirement should it become applicable.
7.5.5	May be excluded if product or constituent parts do not require physical preservation. Care must be exercised since a service such as healthcare may still require preservation of medicines.
7.6	May be excluded if no monitoring and measuring devices are involved.

2. The manual must include or reference the customers documented procedures. The following procedures are required to be documented:
    - Control of Documents
    - Control of Quality Records
    - Internal Audit
    - Control of Nonconformity
    - Corrective Action
    - Preventive Action

    Other procedures determined by the customers to be necessary to ensure effective implementation of the quality management system must also be included or referenced in the quality manual.

3. ISO 9001-2008 promotes the adoption of a quality management system based on a process management approach. This approach identifies and manages those linked activities that together address the requirements ISO 9001-2008. The manual must include a description of the interaction between the specific processes of the customer's quality management system. Core processes, support processes and management processes must be addressed. (AQA-India references typical core processes, management processes and support processes.) AQA-India strongly recommends linkage, or interaction, be shown pictorially, but any means to describe interactions between processes is acceptable as along as analysis of the interactions to ensure all processes operate as a network may be performed by the auditor. Figure 1 is an example of a pictorial representation of interaction between customer processes.

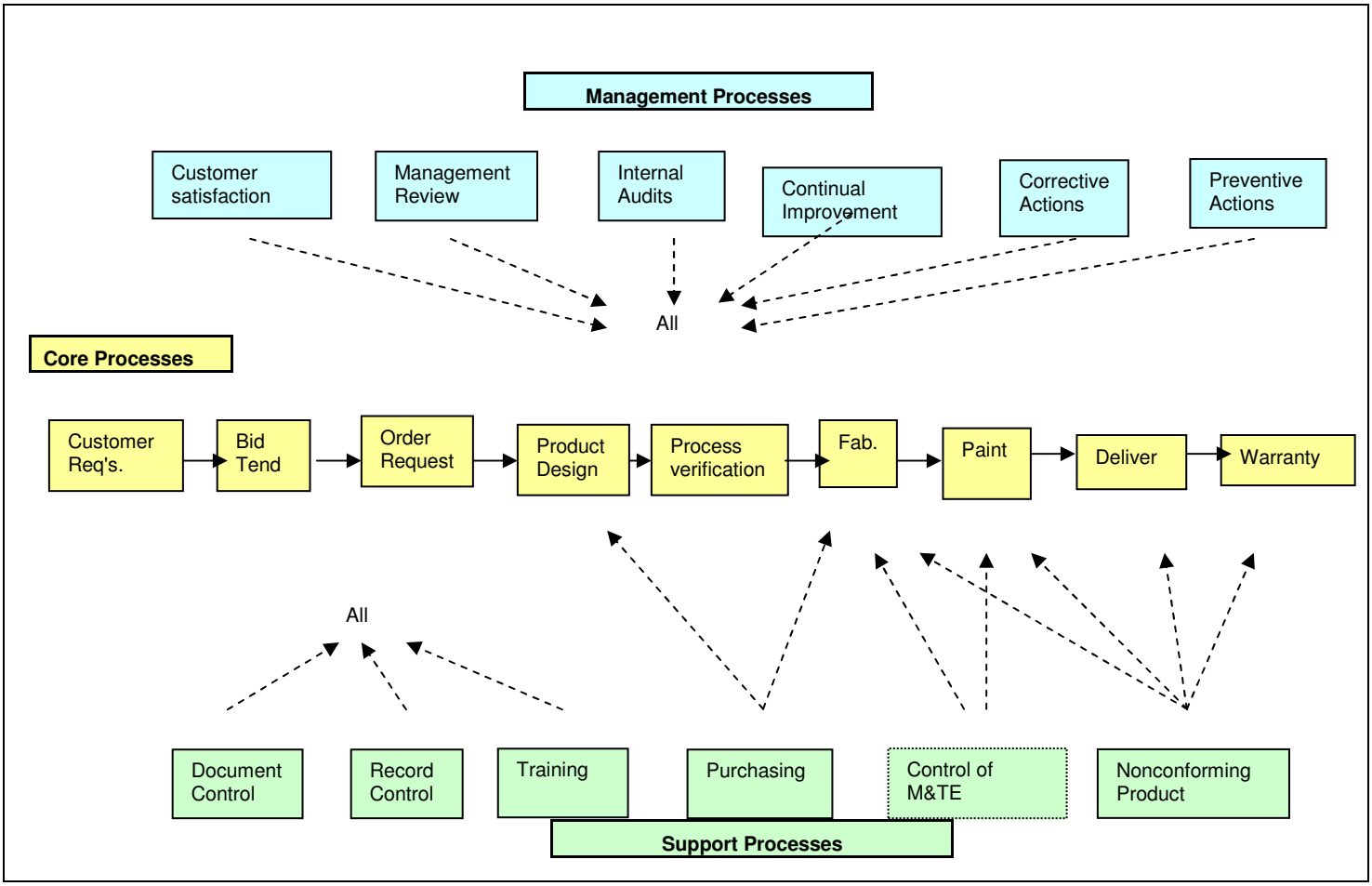

Figure 1

The above is an example - it is essential that customer depict their processes (especially core processes) and not necessarily the ones in the example.

4. **At least one (1) management review,** which includes an assessment of the quality systems suitability and effectiveness must be completed and recorded prior to the conformance audit.

5. **At least one (1) full internal audit cycle** must be completed and recorded prior to the conformance audit. All clauses of ISO 9001-2008 must have been audited by qualified **internal** auditors. An AQA-India pre-assessment audit does not qualify as evidence of meeting this requirement.
6. At least three (3) months of records required by the quality management system must have been generated.

The customer must contact the auditor or client relation manager to reschedule the conformance audit if any of these expectations cannot be fulfilled by the scheduled audit date.

Conformance Audit Expectations

AQA-India will utilize a process audit approach for the conformance audit. The audit plan will focus on management processes and core processes. Support processes will be audited as audit trails develop during management process and core process audit activities. The auditor will expect process owners to be identified and that processes be monitored, measured and analyzed to determine their effectiveness.

Surveillance Audit Expectations

The process audit approach will be utilized for surveillance audits. The auditor will also expect:

1. Effective implementation of corrective actions in response to previous nonconformances

2. Evidence of efforts made toward ***continuous improvement***.

3. A comprehensive list, or equivalent control system, identifying the nature of all revisions to the quality manual and procedures.

Nonconformance Response Expectations

Customers are expected to use their own internal corrective action system and forms to identify root cause, establish corrective action and verify implementation of corrective actions for all AQA-India identified non-conformances.

The customer corrective action forms must reference the AQA-India nonconformance number and be submitted by the auditor established due date. Expectations and guidance for customer corrective action forms includes:

1. Root Cause is the results of an investigation to determine the most basic cause(s) of the nonconformance. "Isolated occurrence" should be infrequent and accompanied with the basis for that conclusion.

2. Corrective action should include:
   - Actions taken to determine the extent of and contain the specific nonconformance
   - Actions taken in response to the root cause to eliminate recurrence of the nonconformance

3. Ideally, customer verification of corrective action implementation should be completed prior to submittal to AQA-India. Longer range plans that cannot be verified by the due date must have a target date for completion

4. Copies of objective evidence (revised procedures, training records, etc. should be included wherever possible.

AQA-India recognizes that the customer must put the extent and cost of corrective actions into perspective by the severity of and risk associated with the nonconformance.

Rev.01 Revised in line with ISO/IEC I7021:2006 requirements.
Rev.02 Customer contact with AQA linked up to Client relation Manager