

# ISO 9001 EXPECTATIONS

## Introduction

This document identifies AQA International's expectations for clients seeking registration to ISO 9001. It is organized into the following sections:

- I. Stage 1 Readiness Review Expectations
- II. Stage 2 Conformance Audit Expectations
- III. Surveillance Audit Expectations
- IV. Nonconformance Response Expectations

## I. Stage 1 Readiness Review Expectations

The Stage 1 Readiness Review is an audit usually performed on-site to determine if the organization is ready to proceed to the Stage 2 conformance audit. Prior to the Stage 1 Readiness Review clients are requested to complete AQA form F-019 to depict how the client's quality management system addresses ISO 9001 requirements and send it to the auditor along with the quality manual and procedures. The lead auditor will review documents and complete the F-019 during the audit. 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 all 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 organization's ability or 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 <b>cannot be excluded</b>
7.2	Determination of customer requirements must always take place and <b>cannot be excluded</b>
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 suppliers are involved, but this case is rare.
7.5.1	<b>Cannot be excluded</b> since controlled conditions will always be required.
7.5.2	<b>Should not be excluded</b> unless the nature of the business precludes special processes <u>from ever</u> being applicable. If they 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	<b>Should not be excluded</b> unless the nature of the business precludes customer property <u>from ever</u> 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 clients documented procedures. The following procedures are required to be documented:
  - Control of Documents

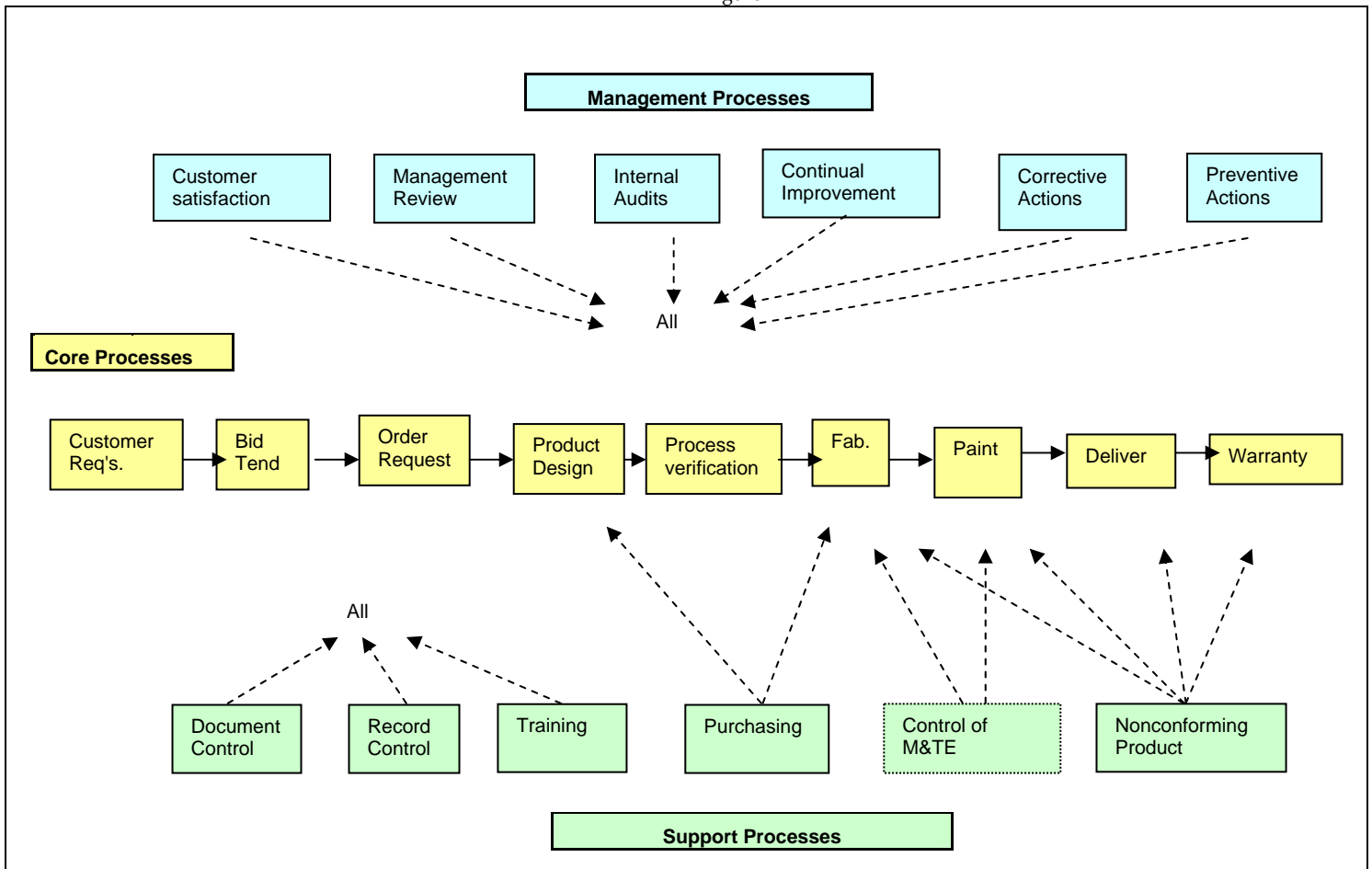
# ISO 9001 EXPECTATIONS

- Control of Quality Records
- Internal Audit
- Control of Nonconformity
- Corrective Action
- Preventive Action

Other procedures determined by the clients 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 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. The manual must include a description of the interaction between the specific processes of the client's quality management system. Core processes, support processes and management processes must be addressed. AQA strongly recommends linkage, or interaction, be shown pictorially, but any means to describe interactions between processes is acceptable as long 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 client processes. Figures 2 & 3 are examples of client completed portions of an F-019 form.

Figure 1



**Figure 1 is an example - it is essential that clients depict their specific processes**

Figure 2



## ISO 9001 EXPECTATIONS

An example of the filled out portion of the core processes section of the F-019(2K) matrix is below as Figure 2:

II PROCESS – REQUIREMENT MATRIX	A = addressed	4.1 General	4.2 Documentation	4.2.3 Document Control	4.2.4 Records control	5.1 Manage. Commit	5.2 Cust. Focus	5.3 Quality Policy	5.4 Planning	5.5 Res., Auth. & Comm	5.6 Manage. Review	6.1 Provision of Res.	6.2 Human Res.	6.2.2 Training	6.3 Infrastructure	6.4 Work Environment	7.1 Plan. Prod. Real.	7.2. Cust-Rel. Process	7.3 Design and Devel	7.4 Purchasing	7.4.3 Ver of Pur. Prod.	7.5 Prod. & Serv. Prov.	7.6 Cont. of Mon. & Mea.	8.1 Mea., Anal., & Improve	8.2.1 Cust. Sat.	8.2.2 Internal Audit	8.2.3 M&M-Process	8.2.4 M&M- Product	8.3 Cont. Nonconf.	8.4 Anal. Of Data	8.5 Improvement	8.5.1 Cont. Improve	8.5.2 Corrective Action	8.5.3 Preventive Action									
Elements requiring documented procedure																																											
Mandatory Assessment E=every audit; Y= yearly						E	E	E	E	E	E								Y						E	E											E	E	E	E			
<b>A. CORE PROCESSES:</b>																																											
<b>Bid/Tender</b> Owner Sales, Accounting & Engineering Procedure QSP A3																			A																								
<b>Order Request</b> Owner Sales & Accounting Procedure QSP A3 & S2																			A																								
<b>Product Design</b> Owner Engineering Procedure QSP E1, E4, E5,																			A																								
<b>Process Verification</b> Owner Manufacturing Engineering & Production Ctrl. Procedure QSP M3, M8& M9															A	A	A		A																								
<b>Fabrication</b> Owner Manufacturing Engineering Procedure QSP M5																			A			A				A	A	A	A														
<b>Paint</b> Owner Painting & Quality Depts. Procedure QSP M3, M7, M8,																			A			A				A	A	A	A														
<b>Deliver</b> Owner Service Dept. Procedure DQSP 19																			A			A			A																		

**Figure 2 is an example - it is essential that clients depict their specific core processes**

Client management and support processes will often have a one to one correlation with requirements of the standard. One example for each type of process completed on the F-019 matrix follows in Figure 3:



# ISO 9001 EXPECTATIONS

Figure 3

	4.1	4.2	4.2.3	4.2.4	5.1	5.2	5.3	5.4	5.5	5.6	6.1	6.2	6.2.2	6.3	6.4	7.1	7.2.	7.3	7.4	7.4.3	7.5	7.6	8.1	8.2.1	8.2.2	8.2.3	8.2.4	8.3	8.4	8.5	8.5.1	8.5.2	8.5.3
<b>B. SUPPORT PROCESSES:</b>																																	
<b>Document Control</b>		A																															
Owner All Depts.																																	
Procedure: DQSP-02, DQSP-05																																	
<b>C. MANAGEMENT PROCESSES:</b>																																	
<b>Management Review</b>																																	
Owner Management																																	
Procedure DQSP-03																																	

**Figure 3 is an example - it is essential that clients depict their management and support processes.**

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 must have been audited by qualified internal auditors. An AQA 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 client must contact the auditor or AQA Office to reschedule the conformance audit if any of these expectations cannot be fulfilled by the scheduled audit date.

## **II. Stage 2 Conformance Audit Expectations**

AQA 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.

## **III. Surveillance Audit Expectations**

The process audit approach will be utilized for surveillance audits. The first surveillance audit must occur within 12 months of the last day of the stage 2 audit. 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.

## **IV. Nonconformance Response Expectations**

AQA Clients are required to transfer each AQA identified nonconformance to their internal corrective action form and system. Failure to submit an acceptable response utilizing their corrective action form and system by the established due date may have a negative impact on new or existing registrations.

# ISO 9001 EXPECTATIONS

## Acceptable Client Corrective Action Responses Must Include:

### 1. The results of an investigation to determine the root cause or most basic cause(s) of the nonconformance.

If the root cause is not determined, it is unlikely the corrective actions will prevent recurrence of the nonconformance. In fact, a good test to determine if you have properly identified the root cause is to ask, “If we eliminate this cause, will the nonconformance happen again?” If the answer is no, then the root cause is properly identified. If the answer is yes or maybe, then the root cause needs to be further analyzed. It often takes asking “why did the potential root cause occur” several times to reach a root cause upon which corrective actions can be based to prevent recurrence

Below are some root causes that are usually inadequate and should be rarely used:

- “Operator error” or “Oversight on the part of the operator”,
- “Poor training” or “Training not effective ”,
- “Didn’t understand the requirement” or “Not aware of the requirement”
- “Isolated occurrence”

Use of these root causes may result in AQA asking for further clarification or investigation because they are not specific and lend themselves to narrow corrective actions that may not prevent recurrence of the nonconformance. When these are encountered, “why” should be asked at least once more to determine an underlying or more basic cause. For example, if asked why an operator error occurred, it may be determined to have been caused by the operator inadvertently selecting the wrong switch that looked similar and was close to the correct switch. This root cause would lend itself to mistake proofing that would separate or distinguish the switches to prevent recurrence.

Root causes must also be sought over which management has control. A root cause of “severe weather” does not support preventing recurrence of the nonconformance where-as root causes of inadequate contingency planning or leaking trucks do support preventing recurrence of the nonconformance.

### 2. Corrective actions including both:

- Corrective actions taken to determine the extent of, contain and correct (i.e. fix) the specific nonconformance
- Corrective actions taken in response to the root cause(s) to eliminate recurrence of the nonconformance. These corrective actions focus on changing a process to eliminate the root cause and thus eliminate recurrence of the nonconformance.

Often, corrective actions are submitted that fix the specific nonconformance but do not address the root cause to prevent recurrence of the nonconformance.

### 3. Verification that corrective actions have been implemented.

The client must verify corrective actions have been implemented and submit this verification, along with evidence of implementation (procedures, records, pictures, control plans, etc.) to AQA. Usually, corrective actions that have not been implemented are not acceptable. Corrective actions that, by nature, require more time to implement may be accepted for future verification if accompanied by specific target dates and adequate justification.

## Examples of Good Root Cause and Corrective Actions:

<b>Nonconformance, Root cause and corrective action</b>
<p><b>Nonconformance:</b> Nonconformance material was not identified.</p> <p><b>Root Cause:</b> Why? Inspector rejected the material but did not fill out reject tag Why? Inspector was waiting for supervisor to approve reject status before hanging tag Why? Work instruction says supervisor will make final rejection disposition</p> <p><b>Corrective Action:</b> (1) Work instruction was modified to place a reject tag on all suspect material without waiting for supervisor’s approval. The supervisor is required to sign the reject tag if he/she concurs with the reject status. If material is to be reworked, the supervisor will place a “to be re-worked” tag on the material. (2) All inspectors and supervisors have been trained on the new work instruction (3) Audit of area shows that the change was effective.</p>
<p><b>Nonconformance:</b> Preservation of product is not being maintained. Expired chemical being used in production.</p>

## ISO 9001 EXPECTATIONS

**Root Cause:** It was assumed that with the order levels and usage levels that no chemical would be in a position to be expired prior to usage. However, the chemical identified in the nonconformance, is used in such small quantities, that it passed its expiration date. Therefore the root cause is there is no system to monitor and control the expiration date.

**Corrective action:**

1. Containment: Chemical identified in the nonconformance has been removed from production
2. Correction: Order quantities have been reduced on this chemical to reflect low usage rates
3. Correction Action: Expiration dates are added to the supply room checklist. Also, chemicals that have expired will be removed from production by the supply room and dispositioned. Work instruction has been updated and audit of production and supply room show this change is implemented.

**Nonconformance:** Several new employees have no records showing that they are competent.

**Root Cause:** These employees were determined to be competent during on the job training. Human resource manager had been keeping these records but the procedure was recently changed for supervisors to keep these records. This change was not properly communicated to supervisors. No acknowledgement of procedural changes is required.

**Corrective action:**

Verified that on-the-job training records were on file with the Human Resource Manager for all new employees hired before the procedure was changed to have the supervisor keep these records. On-the-job training has been verified for all new employees hired after the procedure was changed and records are attached. The training procedure has been revised to require a procedure (new or revision) sign off for all affected people indicating that they are properly trained to the revision. Attached are the revised training procedure and the sign off sheet for all affected people. An audit has been scheduled for August 2005 to evaluate the effectiveness of training to new procedures and procedure revisions.

### Examples of Poor Root Cause and Corrective Actions:

Nonconformance, Root cause and corrective action	Reason for NOT being acceptable
<p><b>Nonconformance:</b> Annual audit plan does not provide objective evidence to support how the audits are planned according to status and importance of the activity</p> <p><b>Root Cause:</b> Not all the key points of internal auditing were grasped</p> <p><b>Corrective Action:</b> Retraining is to be held for the internal auditor whose qualifications shall be conferred with by the management. The internal auditing plan for the year 2005 is to be formulated to ensure that the planned arrangements are prioritized as per the quality activities of the company</p>	<p><b>Root Cause</b> does not identify the underlying cause of the nonconformance.</p> <p><b>Corrective action</b> fixes the 2005 audit plan, but needs to be verified as complete or have a target date established for completion.</p> <p><b>Corrective action</b> of retraining of internal auditor suggests that the initial training was not effective. This should be examined as part of the root cause.</p>
<p><b>Nonconformance:</b> Supplier evaluation of ABC company was not performed as required in procedure</p> <p><b>Root Cause:</b> The performance evaluation was missed</p> <p><b>Corrective action:</b> The evaluation of ABC company has been completed</p>	<p><b>Root Cause</b> is a restatement of the nonconformance, not the cause underlying why the procedure was not followed.</p> <p><b>Corrective Action</b> fixes ABC, but misses fixing any other evaluations not performed.</p> <p><b>Corrective Action</b> does not make any change to prevent it from recurring.</p>
<p><b>Nonconformance:</b> Monitoring equipment in use is found to be out of calibration.</p> <p><b>Root Cause:</b> Person responsible for calibration of equipment forgot to calibrate this equipment</p> <p><b>Corrective action:</b> Equipment is now calibrated.</p>	<p><b>Root Cause</b> doesn't address why the system allows equipment to go without calibration.</p> <p><b>Corrective Action</b> fixes "equipment", but is not clear if all out of calibrated equipment was identified and fixed.</p> <p><b>Corrective Action</b> the fix does not include an investigation to determine if any nonconforming product was delivered to customer because it was accepted with out of calibration equipment</p> <p><b>Corrective Action</b> does not make any change to prevent it from recurring.</p>

# ISO 9001 EXPECTATIONS

## Frequently Asked Questions

### **FAQ 1: Why are some ISO sections missing along the top row?**

Sub clauses, such as 4.2.3, are only listed where a special requirement, such as requiring a documented procedure, is identified.

### **FAQ 2: Is AQA insisting on procedures for each core process?**

No. Only 6 procedures are mandatory for ISO 9001, and some of those, such as 8.2.1, 8.2.3 and 8.4, may be addressed in one document. Mandatory procedures are shaded on the matrix.

### **FAQ 3: How is adequacy addressed in the F-019 matrix?**

The client initially indicates where requirements are addressed on the matrix with an “A”. The auditor will review the matrix and associated documentation. Any comments regarding adequacy are noted by “C1, C2, etc. on the matrix and explained in section VI.

### **FAQ 4: Why is Purchasing identified as a typical support process and not a core process?**

AQA borrowed these typical descriptions from automotive guidelines. AQA will accept purchasing as a core process.

### **FAQ 5: What should be filled in for “owner of process”?**

The position (Operations Manager, etc.) is preferred but the name of the person is acceptable

### **FAQ 6: What is meant on the F-019 matrix by “Mandatory Assessment - every audit”?**

Auditors are to address these elements each surveillance

### **FAQ 7: Will clients be requested to fill out an F-019 every surveillance?**

No, the AQA auditor will update it to reflect any changes prior to the re-registration audit.