

1. Column 1 shows each of the elements of 9001
2. Column 2 input your experience of how the element fails to be effective because of a lack of 'People Involvement'
3. Column 3 is where you should record effective solutions you have experienced to the problem you just described

**These 'Notes' are in effect an ISO 9001 "Gap Analysis" from a 'People' perspective**

Typical Problems;	Typical Solutions with People Involvement;
<p>4.1</p> <ul style="list-style-type: none"> <li>a) process identification is a mechanistic process without an understanding of the systems approach to organizations.</li> <li>b) Interrelationship is a simplistic flowchart without dealing with interrelationships, internal politics and interface issues</li> <li>c) Often overlooked. Controls are results focused and do not consider controls exercised by people in their own work</li> <li>d) Processes often have to compete and scavenge for their resources</li> <li>e) Measures chosen for processes are not appropriate or analysis is superficial</li> <li>f) No effective corrective actions (8.5.2) taken when processes are not on track / improving</li> </ul> <p>Process management is given less importance than other internal and external measures (e.g. production volumes, share price)</p>	<p>Key involvement is people at all stages of identification of processes they work with and controls and resources necessary to ensure they are carried out effectively.</p> <p>Quality can be built into the business if people see it is about ways of working throughout the organization rather than documentation alone.</p>
<p>4.2.1 Documentation is produced for documents sake without an understanding of the need for a document and its application.</p> <p>Documents are produced by "documentation people" rather than the users.</p> <p>Implementation of documentation is poor. People are not aware of where the documents they need are. Documents are seldom referred to. Documentation becomes out of date as processes change and the documents are not revised.</p> <p>Documentation becomes a "one size fits all" no consideration of complexity or competence. Documentation loses its impact.</p>	<p>Guidance for staff on the purpose of documents and where they can contribute to performance and reduce risk.</p> <p>Users encouraged to develop their own procedures.</p> <p>Training and awareness on effective documentation.</p> <p>Guidance on amount of documentation required.</p>

<p>4.2.2 a) People do not understand the concept of “scope” and the principles underpinning clause 1.2.</p> <p>b) no significant people issues with this manual element</p> <p>c) process identification and description is conducted poorly (see 4.1.1). Interaction description is less than useful</p>	<p>Better guidance on manuals not “aping” ISO 9001</p>
<p>4.2.3</p> <p>a) the wrong people are assigned to approve documentation – authority can be set at too high a level or too central. People do not understand the role of “approver”.</p> <p>b) Documents aren’t periodically reviewed. Reapproval problems as above.</p> <p>c) Issue status not clearly identified or system is bureaucratic</p> <p>d) People don’t understand who need documents or ensure they have access to them. Users not aware of how to get access.</p> <p>e) No significant legibility issues. Identification of documents sometimes archaic / illogical</p> <p>f) Concept of “external document” not understood well</p> <p>Document retrieval systems are often poor. Plenty of old issues in the workplace.</p>	<p>Guidance on who is best to involve in document approval</p>
<p>4.2.4</p> <p>People don’t understand the concept of record retention and the purpose of records as evidence of satisfactory system performance.</p> <p>Responsibility for controlling records not adequately defined.</p>	<p>Guidance on need for records and how they can be used</p>
<p>5.1</p> <p>Top management is not committed to quality of the system. Lip service is paid.</p> <p>a) communication is not effective</p> <p>b) quality policy is produced to “tick a box”</p> <p>c) objectives are not relevant to quality or the business</p> <p>d) reviews are bureaucratic to meet certification requirements only</p> <p>e) quality is the “poor relation” when competing for resource</p>	<p>Guidance for top management on their role as leaders in the organization. Guidance on the following topics.</p> <ol style="list-style-type: none"> <li>a. Communication theory</li> <li>b. The role of mission statements</li> <li>c. Objective setting as a means of motivation</li> <li>d. Top management role in systems review</li> <li>e. Guidance on the importance of “real” quality systems</li> </ol> <p>McGregor Theory X / Theory Y</p>
<p>5.2 Top management abdicate responsibility and are not involved. Communication not effective.</p>	<p>Guidance for top management on leadership and on “the voice of the customer”</p>
<p>5.3 Policy is not heart felt. Often little top management involvement.</p> <p>a) generic quality policy</p> <p>b) commitments stated but not meant</p> <p>c) objectives unrelated to policy</p> <p>d) communication ineffective</p> <p>e) mechanistic review</p>	<p>As for 5.1 guidance on the role of mission type statements in providing focus / motivation.</p>

<p>5.4.1 Objectives are not relevant to quality or are not relevant to how the business wants to handle quality and improve quality performance.</p> <p>Lack of deployment of objectives. Little relevance to the workforce.</p> <p>Objectives are not “SMART”</p>	<p>Guidance on what constitute “quality” objectives and setting, deploying and monitoring objectives</p> <p>Deming’s policy deployment?</p>
<p>5.4.2 QMS is “bolted on” to the real management system.</p> <p>Changes to systems are not effectively planned and managed.</p>	<p>Guidance on integrating documented systems with real processes.</p> <p>Guidance of change management including cultural aspects of change and ensuring system robustness is maintained.</p>
<p>5.5.1 R &amp; A not effectively defined. People are made responsible without the authority to do the job.</p> <p>Communications ineffective</p>	<p>Guidance on ensuring authority levels are in balance with responsibilities assigned.</p> <p>Balance between quality and other areas of responsibility</p>
<p>5.5.2 Management representative has insufficient authority to carry out MR role.</p>	<p>Guidance on appropriate competence criteria for a management representative.</p>
<p>5.5.3 Communication processes are ineffective. No review of effectiveness of communications. Lack of interest in QMS.</p> <p>Top management not knowledgeable in motivation theory.</p>	<p>Guidance on communication theory and practical communication methods including review of effectiveness of methods chosen.</p>
<p>5.6.1 Management review is seen as a bureaucratic, tick-the-box activity. Top management does not buy in to the process.</p> <p>Little will to change the objectives, policy etc.</p>	<p>Guidance on effective reviewing of systems – how top management should review and what they should consider.</p> <p>Guidance on options for review:</p> <ul style="list-style-type: none"> <li>• tiers of review</li> <li>• reports</li> <li>• meetings</li> </ul> <p>Action centred reviews (PDCA model)</p>
<p>5.6.2 List of inputs to Management Review not seen as relevant to Top Management team.</p> <p>Little participation / discussion in the meeting of these key aspects of the QMS.</p>	<p>Build on guidance to objective setting and process measures (4.1 and 5.4.1 above) and the role of review in evaluating effectiveness.</p> <p>See 8.5.2 and 8.5.3 guidance for CA / PA</p> <p>Guidance on running effective meetings</p>

<p>5.6.3 Because of Top Management attitude little output form review – no drive for improvement.</p>	<p>Build on leadership guidance with role for review as being a new start each time for action plans.</p>
<p>6.1 Resources for QMS are difficult to obtain.</p>	<p>Guidance on resource allocation for quality and for different management structures.</p>
<p>6.2.1 Personnel competence not achieved</p>	<p>Guidance on identifying and specifying competence criteria</p>
<p>6.2.2</p> <ul style="list-style-type: none"> <li>a) organization does not understand what competence is needed for individual tasks affecting quality</li> <li>b) training is provided with no connection to need for competence</li> <li>c) evaluation of the effectiveness of training is not a meaningful process</li> <li>d) people are not aware of how their actions impact on quality</li> <li>e) See records</li> </ul>	<ul style="list-style-type: none"> <li>a) As for 6.2.1</li> <li>b) Guidance for training needs analysis identification</li> <li>c) Guidance for assessing the effectiveness of training provided</li> <li>d) Ensure communication covers people’s roles in satisfying quality objectives</li> <li>e) No specific guidance</li> </ul>
<p>6.3 Provision of resources does not take into account human factors –</p> <ul style="list-style-type: none"> <li>• Ergonomics</li> <li>• Social interaction</li> <li>• Hygiene factors (Herzberg)</li> </ul> <p>Little employee involvement in their workplace design / selection</p>	<p>Guidance on human aspects of the workplace. Reference motivational theories, Herzberg, Mintzberg</p> <p>Guidance on use of quality tools such as “Lean” for employee involvement in workplace design / redesign and in selection of machinery and equipment</p>
<p>6.4 Maintenance activity does not consider human factors (see 6.3)</p>	<p>As above</p>
<p>7.1 Process design does not consider people aspects:</p> <ul style="list-style-type: none"> <li>• Communication of requirements</li> <li>• Passing of work from one individual / function to another</li> <li>• Balance of resources between one stage of a process and the others (bottle necks, opportunity for stress)</li> <li>• Documentation need not effectively assessed (See 4.2.1)</li> <li>• Inappropriate quality objectives (see 5.4.1)</li> <li>• Product requirements not adequately specified at each stage of the process</li> <li>• Lack of consideration of developing robust processes</li> </ul> <p>Product realization not “designed” in the spirit of clause 7.3.</p> <p>Silo mentality to cross functional processes.</p>	<p>Guidance in designing processes around people’s needs and involvement of people in process design.</p> <p>Cross functional working and process ownership training.</p>

<p><b>7.2 Lack of attention to customer needs and wants</b></p> <p>Insufficient knowledge of application and use</p> <p>Legal obligations not known or understood</p> <p>Communication processes with customers ineffective.</p>	<p>Guidance on effectively capturing the “voice of the customer” – quality function deployment (QFD).</p> <p>Guidance on typical legal obligations for product safety, misselling of goods etc.</p> <p>Guidance on training in effective communications with external parties.</p>
<p><b>7.2.2 Process for understanding the needs of the product / service do not effectively understand what customer needs are and if there are any aspects of the requirements the organization cannot meet with existing products.</b></p> <p>Changes to customer requirements are not given the same attention as new orders.</p>	<p>Guidance on capturing customer needs and wants.</p> <p>Guidance on handling changes</p>
<p><b>7.2.3 Communication processes with customers are not clear and are not aimed at making clear the product requirements and order process.</b></p> <p>Communication processes are difficult and not focused on customer needs.</p>	<p>Guidance on effective communications with external parties.</p> <p>Reference ISO guidance on effective customer complaints</p>
<p><b>7.3.1 Design and development planning is not carried out effectively – stages are not clearly identified. Review verification and validation are put in place at inopportune stages.</b></p> <p>Responsibilities and authorities are not adequately defined. Interface issues are not addressed. Poor communication between stakeholders of the design process.</p> <p>Little review of design progress or tracking of issues – updating of plans.</p> <p>The “ivory tower” approach to design.</p>	<p>Guidance on effective project management and managing knowledge workers.</p> <p>Provide guidance on identification of project risk</p> <p>Communications again!</p> <p>Guidance on design focusing on benefits not features.</p>
<p><b>7.3.2 Design input mechanistic. Little attempt to understand product and its usage. Focus on features rather than benefits.</b></p> <p>Lack of buy in to design inputs from other parties in the organization.</p>	<p>As above, effective communication of needs and wants.</p> <p>Guidance on project management to focus on handover from design to users.</p>
<p><b>7.3.3 Lack of consideration of the users of the output from design process – what are their needs and how can designers best provide this information.</b></p> <p>Acceptance criteria often based on designer “standard” criteria rather than needs of the product / design output.</p>	<p>Guidance on control of design.</p>

<p>7.3.4 Design reviews are “bolted on” to the design process rather than key stages of evaluation of product suitability.</p> <p>Design review participants are not the most appropriate to evaluate suitability.</p>	<p>Guidance on effective reviews by independent parties. Link to plans and inputs vs. outputs.</p>
<p>7.3.5 Lack of understanding of design verification. Inappropriate verification tools chosen. Verification ineffective.</p> <p>Unwillingness to “interrupt” design process – focus on launch date before quality.</p>	<p>Guidance on role of design checks in ensuring product meets needs.</p>
<p>7.3.6 Lack of understanding of design validation. Inadequate understanding of “real world” usage.</p> <p>Unwillingness to “interrupt” design process – focus on launch date before quality.</p>	<p>Improve communication of needs and wants between customer and the organization – a tricky field in that it looks into the future.</p> <p>Guidance on effective project management</p>
<p>7.3.7 Design changes are treated as less important than new designs. Design process cut short for changes.</p>	<p>Provide guidance on identification of project risk for changes</p>
<p>7.4.1 People making purchasing decisions are not motivated by supplier quality but by price. Mix of objectives and targets they work to do not contain quality elements. Disconnect between their supplier selection role and the users of the purchased goods / services.</p> <p>Over reliance on the supplier questionnaire. Little continuing monitoring or re-evaluation of supplier capability.</p>	<p>As for R &amp; A (5.5.1 above) also effective leadership to monitor balance of responsibilities.</p>
<p>7.4.2 Information to suppliers inadequate leading to problems with purchased product.</p> <p>Little communication between the organization and its suppliers – arms length purchasing.</p>	<p>Guidance on communications with external parties again</p>
<p>7.4.3 Verification of purchased product is not planned to ensure it is effective and efficient. Either not enough or too much inspection / testing is carried out.</p>	<p>Link to guidance on effective process design and cross functional team working.</p>

<p>7.5.1 See 7.1 for planning of cross functional processes.</p> <p>Too much / too little control of processes. No involvement of workforce in process design.</p> <ul style="list-style-type: none"> <li>a) personnel assigning critical product characteristics do not communicate these effectively to the workforce</li> <li>b) work instructions are not understood by the workforce</li> <li>c) equipment selection not effective or doesn't take into account ergonomics</li> <li>d) monitoring measuring devices difficult to use effectively lack of training</li> <li>e) lack of ownership of inspection and testing</li> <li>f) customer needs not taken in to account for all product related activities. Too much focus on production.</li> </ul>	<p>Incorporate in guidance on effective process design.</p>
<p>7.5.2 Lack of understanding of the need to develop robust processes to ensure product quality.</p> <p>Validation ignored / not taken seriously.</p> <p>Lack of process ownership Lack of up front effort in rush to get into production – make do with what we have. procedures too prescriptive or too lax. Lack of involvement of workforce in development See 4.2.4 Processes rarely revisited</p>	<p>Incorporate in guidance on effective process design.</p>
<p>7.5.3 Need for identification and benefits of traceability not understood or evaluated.</p> <p>People don't understand the need for product identification at stages.</p>	<p>Incorporate in guidance on effective process design.</p>
<p>7.5.4 Systems for handling customer property separate from routine purchases is not understood. Communications with customers poor.</p>	<p>Incorporate in guidance on effective process design.</p>
<p>7.5.5 Importance of caring for product through stages of production not understood. Effect of defects on customers not understood.</p>	<p>Training and awareness of customer wants and needs</p>
<p>7.6 Monitoring and measuring is not developed from customer requirements but is carried out to a standard plan.</p> <p>Processes do not always consider capability. Often carried out by independent people – taking ownership from the workforce producing product.</p>	<p>Incorporate in guidance on effective process design.</p>

<p><b>8.1 Monitoring and measuring of product process and system does not consider the available data in the system. Data analysis and improvement processes are not robust.</b></p> <p>People do not have the necessary skills to be able to analyse processes and / or apply statistical techniques.</p>	<p>Training in quality tools and techniques – particularly the seven basic tools. Histograms Flow Charts Scatter Diagrams Pareto Charts Cause-and-effect Diagrams Check Sheets Control Charts</p>
<p><b>8.2.1 People within the system do not know how to evaluate customer satisfaction and revert to surveys – a tick box approach.</b></p>	<p>Guidance and need for training in understanding customer satisfaction</p>
<p><b>8.2.2 Internal audit operates ineffectively or inefficiently. Audits are too shallow to evaluate processes. Auditors do not have the necessary interpersonal skills to assess the effectiveness of processes.</b></p> <p>Audit programmes are not based on processes or organization need but on a rigid matrix (perhaps based on ISO 9001 clauses). No review of process status, importance, performance.</p> <p>Lack of ownership by management of the results of audits.</p>	<p>Guidance on people aspects of auditing and the role of auditing in communicating the effectiveness of the quality system to top management.</p> <p>Guidance on the importance of top management in owning audit results.</p>
<p><b>8.2.3 Process monitoring / process measures chosen not appropriate or relevant to process conformance.</b></p> <p>Lack of connect between process conformance and corrective action processes.</p>	<p>As for guidance on objective setting plus 7 core quality tools.</p> <p>Guidance on link from process measures to corrective action systems.</p>
<p><b>8.2.4 Disconnect between product monitoring and measuring and satisfying customer requirements.</b></p> <p>Lack of ownership of monitoring and measuring – conflict with production.</p> <p>Customer requirements overridden.</p>	<p>As for guidance on objective setting and on obtaining customer needs and wants (above).</p> <p>As for guidance on leadership and customer focus (5.2).</p>
<p><b>8.3 People unclear about nonconforming product status and suitability.</b></p> <p>Decision authority for dealing with nonconforming product not clear. Decision process does not lead to effective corrective action to prevent recurrence (see 8.5.2)).</p> <p>Data on nonconforming products not collected and analyzed (see 8.4).</p>	<p>Guidance on identifying types of non-conforming product and associated risks.</p> <p>Guidance on developing a process to identify NC product and dealing with it.</p> <p>Training in quality tools and techniques – particularly the seven basic tools.</p>

<p><b>8.4 Lack of analysis of data as a basis for improvement.</b>  <b>Lack of understanding of data analysis techniques.</b></p> <p><b>Data analysis seen as bureaucratic and time consuming instead of a source of improvement.</b></p>	<p><b>Training in quality tools and techniques – particularly the seven basic tools.</b></p> <p><b>Guidance on concept of variation and the work of the quality gurus Deming, Juran etc.</b></p>
<p><b>8.5.1 Lack of commitment to improvement.</b></p> <p><b>Improvement not built into the framework / culture of the organization.</b></p>	<p><b>Guidance for organization’s leaders in how to set up improvement programmes, particularly those involving people.</b></p>
<p><b>8.5.2</b></p> <ul style="list-style-type: none"> <li>• <b>Poor link to identification of non-conforming product (8.3).</b></li> <li>• <b>Data not gathered effectively (8.4)</b></li> <li>• <b>Root cause rarely identified</b></li> <li>• <b>Human factors in mistakes rarely assessed</b></li> <li>• <b>No robust review of corrective action</b></li> </ul>	<p><b>Guidance on effective corrective action systems dealing with levels of problems and investigating root cause. Disciplined problem solving processes.</b></p> <p><b>Understanding of human aspects of mistakes.</b></p> <p><b>Training in quality tools and techniques – particularly the seven basic tools.</b></p>
<p><b>8.5.3 Opportunities for identifying actions to prevent nonconformity rarely planned</b></p> <p><b>Lack of understanding of concept of preventive action</b></p>	<p><b>Guidance on effective assessment of potential problems. Quality tools such as FMEA, HAZOP etc.</b></p>