# HOW TO IMPLEMENT ISO 9001

# CHECKLISTS

# Overview of - Quality management systems

## What needs to be in place?

Before you start your 'quality journey' or your organization has decided to review what is currently in place, it is a good idea to take a planned approach. The following model is a very useful tool and is called the **PDCA model**:
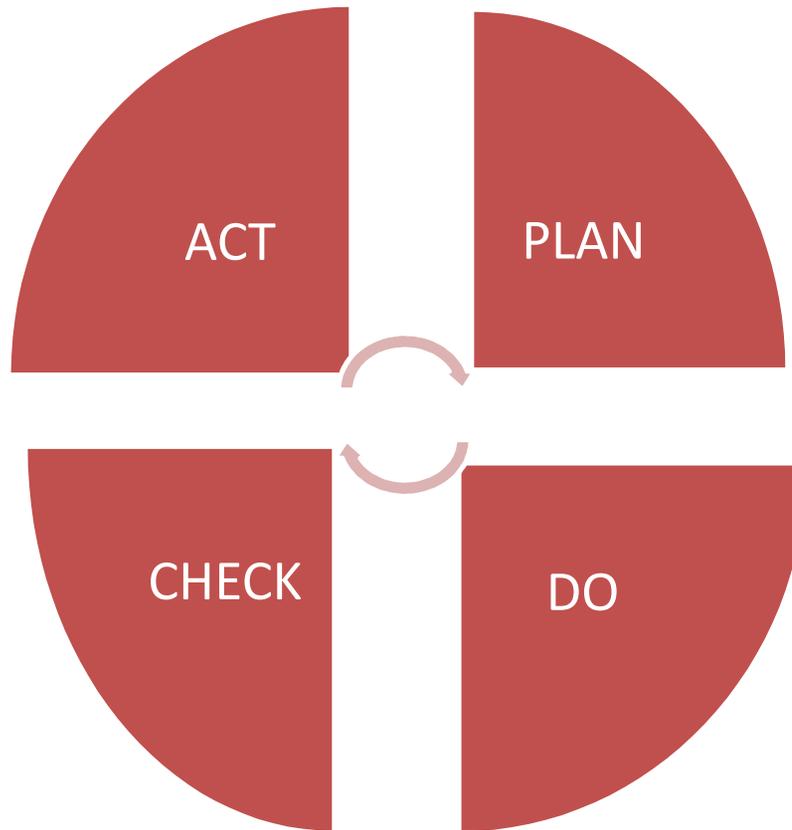
**P – Plan**
**D – Do**
**C – Check**
**A - Act**

## Determining operational processes, sequence & interaction

The following is an example of steps to be thought through when planning, developing and implementing a quality management system.

- Implement any system changes
- Refine the system
- Management Review
- Apply for ISO certification

**ACT**

**PLAN**

- Gain Top Management Commitment
- Appoint a quality representative
- Purchase ISO 9001 Standard
- Identify resources
- Conduct a gap analysis
- Management Review
- Establish an implementation team
- Identify key processes

**CHECK**

**DO**

- Audit the QMS
- Management Review

- Create awareness within the organization
- Appoint a quality consultant, if necessary
- Develop quality policy & objectives
- Establish roles & responsibilities
- Prepare documentation
- Provide training
- Communicate progress of the implementation of ISO 9001 within the organization & at Management Review
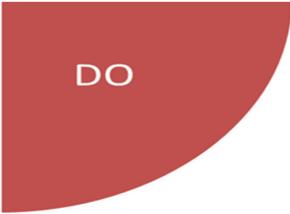
## PLAN

- Gain Top Management Commitment
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**PLAN** – Checklist

| ✓ / X | Action | Comments |
|---|---|---|
| | Top Management understands the 8 Quality Principles:<br>1. Customer Focus<br>2. Leadership<br>3. Involvement of People<br>4. Process Approach<br>5. System Approach to Management<br>6. Continual Improvement<br>7. Factual Approach to Decision making<br>8. Mutually Beneficial Supplier Relationships | |
| | Top Management committed to its organization developing, implementing, maintaining and supporting ISO 9001? | |
| | Top Management has appointed a quality representative (individual or team) and has communicated this to the organization?<br><br>Check that the quality representative has the necessary knowledge and authority to manage the development & implementation of ISO 9001.<br><br>The Quality representative / implementation team has clearly established goals. | |
| | Check that the scope of ISO 9001 quality management system has been agreed and all key processes identified. | |
| | Top Management has agreed to provide appropriate resources for the development, implementation and support of ISO 9001? | |
| | Check a gap analysis has been completed and any gaps identified and reported to management. | |
| | Management review is in place and effective. | |

## DO

- Create awareness within the organization
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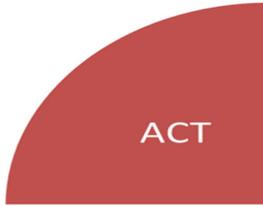
**DO** – Checklist

| ✓ / X | Action | Comments |
|---|---|---|
| | Check the implementation team has developed a communication plan for the implementation of the organizations QMS.<br><br>Check timelines have been communicated to the organization. | |
| | Check regular communication on the status of the development and implementation of the organizations QMS has been communicated to all relevant parties. | |
| | Check all staff is clear on their role in the development and implementation of the organizations QMS.<br><br>Check any training or upskilling has been identified and implemented.<br>• Document development<br>• Auditor<br>• Understanding ISO 9001<br><br>Check job descriptions include authority and responsibilities for quality. | |
| | Check an organization chart is in place which shows staff responsibility. | |
| | Check the quality representative / implementation team has worked with top management on the organizations quality policy and quality objectives. | |
| | Check the quality policy has been communicated to all staff. | |
| | Check documentation has been developed by the process owner and all requirements of the standard are satisfied. | |
| | Check management reviews are recorded and that Top Management is committed to the quality policy and objectives and provides support to the quality representative / implementation team. | |

**CHECK**

## CHECK – Checklist

| ✓ / X | Action | Comments |
|---|---|---|
| | Check all staff have awareness of their organizations QMS. | |
| | Confirm staffs know how to use their system. | |
| | Check internal audits have been planned and frequency based on the risk to the organization. Confirm that internal auditors do not audit their own work. | |
| | Verify that the results of the audits are presented to management for review and follow-up, if necessary. | |
| | Check the audits have assessed the organizations processes against ISO 9001 & the organizations requirements. | |
| | Verify the mandatory and organizational procedures written are in place, easily accessed, understood and used by the organization. | |
| | Check management reviews are recorded and that Top Management is committed to the organizations QMS and provides support to the organization. | |
| | | |

**ACT**

- Implement any system changes
- Refine the system
- Management Review
- Apply for ISO certification

## ACT - Checklist

| ✓ / X | Action | Comments |
|---|---|---|
|  | Check that the certification body has been engaged for the ISO 9001 initial assessment. |  |
|  | Confirm that any outstanding gaps found by staff or the auditors have been rectified.<br><br>Confirm any non-conformances raised have been investigated and actions put in place to remove the recurrence of the non-conformance. |  |
|  | Check any changes to the organizations QMS has been communicated to all staff |  |
|  | Check management reviews are recorded and that Top Management is committed to the organizations QMS and provides support to the organization continual improvement. |  |