ISO9001: 2000 DOCUMENTATION
PROJECT IMPLEMENTATION GUIDELINES

Document Contents:

1. INTRODUCTION

Congratulations for your decision to build a customer-centric Quality Management System for your organisation. Best wishes for successful ISO9001: 2000 project implementation.

The purpose of this document is to give an overview of how to develop and implement an ISO9001:2000 compliant Quality Management System (QMS) in your organisation and get it certified to ISO9001: 2000 by an accredited certifying agency.

First of all, please believe that you can do it ! Be confident, have perseverance, learn to be patient. ISO9001: 2000 is a management system standard published by the International Organisation for Standardisation, which states the requirements for a quality management system. To be certified as an ISO9001: 2000 organisation, your firm needs to comply with the applicable requirements of the standard.

Kindly note that meeting the requirements of a standard (and getting the ISO9001: 2000 certificate) is like securing 60% marks in an examination. *You need to score 100% to become a truly world-class organisation, which can be done in phasesover a period of time, ideally after getting the ISO9001: 2000 accreditation. (What we mean by this is to restrict the scope of your ISO9001: 2000 implementation activities to the minimal requirements for certification in order to achieve the results in reasonable time.)*

2. PROJECT PLANNING

As the system development-implementation-certification is essentially a project, it is essential to identify the work elements and plan this project with a defined start date and end date.

The following lists out major work elements and the management level responsible.

1 Project Planning - To decide about the start date and end date for the ISO9001 project. Usually it takes between 3 to 6 months for QMS development, implementation and certification.

- To decide about the scope of ISO9001: 2000 certification (which offices / factories / warehouses and which products / services to be included)
- To nominate a senior member of the management as "Management Representative (MR)" who will have the authority to get things done, cutting across functional areas / departments. For small companies, one of the owners / directors can be the MR. In case of large companies, the head of Quality Assurance department would be the ideal candidate.
- To nominate a junior level manager / executive as the "QMS Co-ordinator" to assist the MR. This person can be from any department, but with computer skills.
- He/she should be hard working, good in paperwork and also acceptable to most of the departments.
- To convene a meeting of all Department Heads and briefing about the company's decision to go for ISO9001, nomination of MR and QMS Co-ordinator, and also about the project completion time frame.

2 Documentation - Understanding the present system of management.

- Comparing with the Sample Manuals and Formats.
- Customising the sample manuals and MR and QMS Co-ordinator formats and adding / dropping some documents if required.
- Issuing the manuals and formats for implementation

3 Training - To conduct an ISO9001: 2000 awareness training and familiarisation of QMS Documents (Procedure Manuals and Formats) for management personnel including supervisors. (4 to 8 hours duration)

- To conduct ISO9001: 2000 awareness training and familiarisation of QMS
- Documents (Work Instruction Manuals and Formats) for all workers. (2 to 4 hours duration)
- To conduct Internal Auditing Training for select group of Internal Auditors. (Four hours classroom lecture followed by hands-on training during 1st internal audit)

4 Implementation - Implementation of system procedures and work instructions and filling-up of quality system formats.

- Requesting changes in documents if required
- Document modification and issue of new versions.

5 Internal Audit - To conduct internal audits for assessment of system implementation.

- To take corrective actions on audit observations.
- To follow-up and verify the status of corrective actions.

6 Pre-assessment - To shortlist Certifying agencies, invite quotes and sign-up one agency.

- To schedule the pre-assessment dates with the Certifying Agency and communicate to HODs.
- To undergo Pre-Assessment and to take corrective actions on audit observations.
- To follow-up and verify the status of corrective actions and send a report to the certifying agency.

7 Final Assessment and Beyond

To schedule the final-assessment dates with the Certifying Agency and communicate to HODs.

- To undergo Final Assessment.
- If recommended for certification, to follow-up with the Certifying Agency and collect the certificate and logo etc.
- If not recommended for certification, to ensure that corrective actions are taken on the serious non-conformances observed by the certifying agency and to schedule a follow-up audit by the Certifying Agency. (This process will continue till Certification)
- To take corrective actions on audit observations.
- (Beyond certification) To follow-up and verify the status of corrective actions on minor observations by the Certifying Agency and to send a report to the Certifying Agency within the stipulated time.

Now let us make a week-by-week project schedule of the above activities spanning 15 weeks.

3. DOCUMENTATION

It is essentially a time consuming job to be done by the MR and QMS Co-ordinator. But it is very vital for the success of your ISO9001 project.
As a first step, go from one department to the other, talk to the Head of the department and others and …
- Understand the present system (what they do there).
- Construct an organisation chart for each department (with designations and the names of persons currently holding the designation).
- Make a flow chart of sequence of activities for better understanding.
- Identify the persons responsible for various job elements.
- Note down the authority (span of control) of the persons.
- List down the manuals / procedures (if any) that are already being followed. If possible, get a copy.
- Also list down the various activity records of internal / external origin and the purpose of keeping these records.

Second step is to compare the activities and activity records of the existing system with the sample procedures and formats given in the Documentation Kit. At this point, you MUST read the "Document Customisation Guidelines" given in the Kit and make your organisation's Quality Manual in the same sequence (reading sequence) recommended in this guideline document.
Regarding formats (forms), if an existing record resembles one of that is given in the Kit, merge the two and retain the format number of sample format. This way, implementation will be faster.
As a third step, present the applicable sections of the manual and formats to the Heads of each department and ask for suggestions for modifications. Modify the manual and formats on the basis of this input.
The fourth step would be to release the first version of manuals and formats for implementation.
Please read the quality system procedure for Document Control (QSP-04-02-A) in the Kit for details of document numbering, issuing etc.

You can expect people to send many document change requests during implementation. Please follow the system outlined in QSP-04-02-A.

4. TRAINING

Please note that ISO9001: 2000 (concept as well as the practical implications) WILL BE Greek and Latin to most of the people in your

organisation. As high calibre professionals excelling in their own functional area, they may not want to openly request any training.
You must conduct in-house training programmes for all levels of personnel (both employees and employers) in order to make them familiar with ISO9001: 2000 and the QMS documentation you have just released.

You can either use the Power Point Training Slides or prepare your own. Faculty may be from within the organisation or hired for the purpose. Records of training attendance, participant feedback and class tests must be kept.
(Please read QSP-06-02-A for better understanding of Training & HRD.)

5. IMPLEMENTATION

Once the quality manuals and formats are issued, it is the time for implementation.
Please understand this point clearly: By implementation what we mean is the implementation of system procedures and work instructions as per the issued manuals, NOT as per what people think it should be / existing practices.
There can be many queries from various quarters about form filling. Please refer the "Filled Formats" given in the Documentation Kit for help.
It is a good practice for the MR / QMS Co-ordinator to make weekly visits to all departments and help the people understand the procedures and forms. Sometimes you need to help the people to create computer files where form filling is electronic (in such cases, you need to give a softcopy of the formats along with the hard copies).
It is helpful if the top management convenes two or three review meetings and takes implementation feedback from Heads of Departments. Too many meetings to be avoided, as it is costly to the organisation.
The MR is authorised to ensure smooth implementation of the QMS. Use this power judiciously.

6. INTERNAL AUDITS

Internal audits are vital in QMS implementation.

Please read the procedure QSP-08-02-B for details.
At least one internal audit (and subsequent management review) must be completed before preassessment by the Certifying Agency.

7. SELECTION OF AUDITING (CERTIFICATION) AGENCY

There are more than 700 Certifying Agencies worldwide who are authorised to conduct assessments and issue the ISO9001: 2000 certificate. Many are fly-by-night operators without any credibility in the market. Be careful while selecting one.

After sign-up, the auditing agency would ask for your quality manual to review its adequacy. Also they need your manual for preparing their audit checklist.

8. PRE-ASSESSMENT BY CERTIFICATION AGENCY

The basic purpose of pre-assessment is to get a feel of what the auditing agency is looking for. Some agencies are very stringent, while others are very lenient. You need to implement almost all the suggestions made by the auditor. Corrective actions MUST be taken on the non-conformance notes and observations raised by the auditors.

9. PREPARING FOR FINAL ASSESSMENT (CERTIFICATION)

Please note that the auditors will first check whether suitable corrective actions have been taken on their observations during pre-assessment.
It is recommended to carry out the 2nd internal audit and complete corrective actions before the Final Assessment.

10. FINAL ASSESSMENT AND BEYOND.

Usually, final assessment would pass off as a peaceful day, though you may be the most anxious. In case the auditors find only minor non-conformances, your organisation will be recommended for certification. You need to take corrective actions which will be verified in the subsequent surveillance audit (after six / twelve months). Actual certificate and the artwork of Auditing Agency's Logo (with instructions for use) will reach you after 4 to 6 weeks of successful final assessment.
In the event of finding major non-conformances (very rare event) you need to take corrective action and undergo further audit (follow-up audit) before eventual certification.

Important Notes:

a. There is a tendency for many organisations to go slow on ISO9001 implementation after achieving certification. It is the job of the MR to monitor and detect such slackness and bring the system back to normal. The best way to achieve this is to conduct quarterly internal audits and follow-up the status of corrective actions.
b. After achieving the ISO9001 certification, you may plan for implementation of improvement tools such as Statistical Process Control (SPC), Engineering Process Control (EPC), Six Sigma Initiatives etc.

Example Procedure

ABC COMPANY LIMITED

QUALITY SYSTEM PROCEDURES MANUAL

PROCEDURE FOR MANAGEMENT REVIEW

1. PURPOSE:

To ensure the continuing suitability, adequacy and effectiveness of the company's quality management system.

2. SCOPE:

All elements of Quality Management System.

3. DEFINITIONS:

NIL

4. REFERENCES:

ISO9001 (Version 2000) Standard Clause 5.6 Management Review.

5. AUTHORITY AND RESPONSIBILITY:

Managing Director

He shall be responsible for convening management review meetings.

He shall have the authority to provide resources for implementing the corrective and preventive actions decided in the management reviews.

6. METHOD:

The top management shall conduct Management Reviews at regular intervals to ensure the continuing suitability, adequacy and effectiveness of the organization's quality management system. This shall include assessing opportunities for improvement and the need for changes to the quality management system, including the quality policy and quality objectives.

The Managing Director shall convene management review meeting every six months (or before that if necessary). Management Review meeting may be conducted after every Internal/External Quality Audit also. Participants of Management Review meeting includes the MR, Heads of Departments, and others if any, on invitation.

Review Input

The management shall collect information on the following things and review the same:

a) Results of audits
b) Customer feedback, including complaints
c) Process performance and product conformity
d) Status of corrective and preventive actions
e) Follow-up actions from previous management reviews
f) Changes that could affect the quality system, and
g) Recommendations for improvement.

Review Output

Each management review shall come up with definite action plans for quality system management till the next review meeting.

The output from management review shall include any decisions and actions related to…

a) Improvement of the effectiveness of the quality management system and its processes.
b) Improvement of product related to customer requirements and
c) Resource needs.

Minutes of Management Review meetings (FMT-05-06-01) shall be documented and kept by the MD.

7. QUALITY RECORDS:

The following quality record (s) shall be maintained.

Sl. No	Title	Retention Period	Custodian
1	Minutes of Management Review Meeting (FMT-05-06-01)	Min 3 Years	Managing Director

8. DOCUMENT AMENDMENT HISTORY:

Revision No. & Version No.	Summary of changes from previous version of the document	Changes sought by	Remarks of MR
R-00, V-01	First version issued for implementation.	N/A	Nil