



Quality Management Systems
 Operations Management
 Business Planning
 Training

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Quality Management System
 Implementation Process

| Task | Task Name |
|------|--|
| 1 | Perform Document Review of Quality Manual and Level II Procedures |
| 2 | Perform Gap Analysis |
| 3 | Conduct Management Briefing and Executive Overview Workshop |
| 4 | Conduct In-Depth Process Reviews and Fill in Gaps in Existing Processes |
| 5 | Develop Necessary Documentation and Media to provide Records of Activities |
| 6 | Assist with Registrar Selection |
| 7 | Conduct Supplemental Personnel Training |
| 8 | Monitor Progress Until Certification Audit |
| 9 | Conduct Internal Audits |
| 10 | Evaluate Management Review Records |
| 11 | Review Corrective Actions from Internal Audit |
| 12 | Provide Certification Audit Support |

1. Document Review of Quality Manual and Level II Procedures

The purpose of this review is to determine the overall compliance of any existing documentation to the relevant Standards. If possible, this will be done off-site using electronic or hard-copy supplied by the Client. Notes from this review will be used during the on-site Gap Analysis.

2. Perform Gap Analysis and Prepare Report

This will involve review of Client's current documents, records and practices to the requirements set forth in the Quality Management Systems Standard. Interviews with management and all relevant personnel will be required. At this time, a review of the company's scope of products and services, organizational structure and list of job responsibilities will be performed.

Deliverables:

Detailed report on current system status to Standard and/or requirements
Corrective Action Plan outlining recommendations to achieve compliance
Initial Project Plan (Gantt chart)

3. Management Briefing and Standard Overview – 2 - 4 hours

A meeting with Management is required in order to review the output of the Gap Analysis, discuss and determine specific objectives based on the output, define milestones, allocate resources and assign responsibilities to the Project Team to complete the required tasks.

The Overview will provide top management with the information necessary to initiate and actively support the implementation and maintenance of the Standard.

Deliverables:

Updated Project Plan
Task List and Project Team Assignment (consultant is part of project team)

4. Conduct Process Reviews

This step provides the information on how the processes already in place and new processes necessary for compliance to the Standard interact. Upon completion of these tasks, the Quality Manual and procedures can be finalized.

Deliverables:

Modified Quality System Process
General Improvement Opportunities throughout Organization

During the development of the Process Map and throughout the implementation effort, we will identify various opportunities for improvement to existing organizational structure and processes. These will be noted and discussed with the Project Team lead and/or Management.

Deliverables:

Verbal recommendations for improvement activities

5. Develop Required Procedures and Specs

Customized documentation will be developed as determined from Process Mapping and based on the requirements of the Standard. The extent of documentation will be sufficient to ensure the effective operation and control of the company's core processes.

Deliverables:

Quality Management System compliant Quality Manual (Level I), Required Procedures (Level II), customer required procedures and work instruction (Level III)

6. Provide Assistance with Registrar Selection

We will assist with the evaluation and selection of a new registrar as needed, determination of a suitable certification timetable and scheduling of the assessor.

Deliverables:

Provide list of applicable registrars and review final application. This is a complimentary service.

7. Provide Supplemental Training for Personnel

Review with relevant personnel the new requirements and interpretations of the Standard.

Deliverables:

Presentations, handouts, test of effectiveness of review

8. Monitor Progress

Check on the progress of the implementation activities and outputs and provide feedback and assistance as needed. Phone and e-mails are generated and answered as part of overall project scope.

Deliverables:

Verbal and e-mail reports to Management on current status of Quality Management System, recommendations for change/improvement

9. Conduct Internal Audits

Our personnel will perform the internal audits.

Deliverables:

All requirements completed as specified in Internal Audit procedure; agenda, summary report, findings, observations, etc.

10. Evaluate Management Review Records

We will review the Management Review meeting agenda and minutes to ensure all areas are covered and appropriate output is produced. Deficiencies and recommendations for improvement will be noted as needed.

Deliverables:

Written evaluation of Management Review activities

11. Review Implemented Corrective Actions from Internal Audits

At the end of the allocated time given to address the audit findings, follow-up will be conducted to review corrective action objective evidence. If the review indicates successful completion of all required activities and no other issues have arisen, recommendation will be made that the organization is ready to proceed with the certification audit.

Deliverables:

Follow-up and closure of findings and production of records for Internal Audit
Formal letter to Management of company's readiness to proceed with certification

12. Follow-up on Initial Certification Audit Findings

If the certification audit conducted by the registrar results in findings, we will provide assistance to develop a corrective action plan to address the findings. We will assist the Client in documenting the findings through the internal Corrective Action process, establishing a timeframe for completion, and providing adequate evidence for resolution.

Deliverables:

Recommendations for, review and approval of documented Corrective action plan(s) to address all findings