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Revised: August 30, 2000

IMPLEMENTATION PHASES: An accelerated approach...clients usually extend phase durations to 8 weeks

- ❑ **Phase 1: 4-5 Weeks**
  - Document the Quality Management System (QMS); Quality Manual, Procedures, Work Instructions and Forms
  - Conduct employee Quality Management System orientation
  - Create training records of orientations and officially launch the QMS
- ❑ **Phase 2: 4-5 Weeks**
  - Train internal auditors
  - Conduct internal audits to confirm good behaviors
  - Conduct a full Management Review Meeting (MRM) to verify the effectiveness of the QMS
    NOTE: The Registrar's Pre-Assessment (document review) Audit comes at the end of this period
- ❑ **Phase 3: 4-5 Weeks**
  - Systematically correct any Pre-Assessment non-conformances
  - Continue to create quality records
  - Audit for conforming behavior prior to the Registration Audit

PHASE 1 DOCUMENTATION SEQUENCE: Use the LeanISO.com Visio 5.0 Flowchart Models for Gap Analysis Focus Groups

Section 5 - Management Responsibility

Quality Manual
P51 - Management Responsibility (text)
P55 - Quality Objectives
P56 - Internal Communications
P566 - Control of Documents
P567 - Control of Records

Section 6 - Resource Management

P6 - Resource Management
P601 - QMS Awareness
W601 - Training Effectiveness Reporting Instruction
P602 - Supplier Training, if applicable

Section 7 - Product Realization

P71 - Product Realization
P72 - Customer Requirements
P73 - Design and Development, if applicable
P74 - Purchasing
P75 - Production Operations
P752 - Identification and Traceability, if applicable
P753 - Customer Property, if applicable
P754 - Preservation of Product, if applicable
P755 - Validation of Process, if applicable
P76 - Control of Measuring and Monitoring Devices, if appl

Section 8 - Measurement, Analysis and Improvement

P801 - Measurement, analysis and improvement
W801 - Customer Satisfaction Index Reporting Instruction
P802 - Internal Audit
P803 - Control of Nonconformity
P804 - Data Analysis Reporting
P805 - Corrective and Preventive Action

This documentation model has 25 procedures and 31 quality records, all applicable sections are needed. Compare to self documented systems with 200 procedures and 300 records.

SENIOR MANAGEMENT ROLES AND RESPONSIBILITIES:

1. Review the Project Plan weekly for evidence of steady progress.
2. Have managers report on the status of procedure training in staff meetings.
3. Confirm there is an internal audit schedule and your managers are releasing auditors to test for QMS effectiveness.
4. Lead a Management Review Meeting (MRM) at the end of each audit round to confirm effectiveness of the Quality Management System. Provide resources to correct and prevent the known QMS problems.
5. Review the Corrective Action Log monthly for a bias to close known non-conformances. Target a Closure Rate at 75% or greater, in days, not weeks or months. This shows the Registrar you have committed resources for achieving quality assurance.
6. New hires need good orientations prior to release for unsupervised work. Especially important for the ISO Version 2000.
7. Confirm the organization's trend charts have a goal line that has a slope. These goal lines are used to measure and report on the required continual improvement. When performance is not at goal, enter a corrective action on the Corrective Action Log so a team gets involved.

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Registration Readiness Process Flow

NOTE:
The ISO/QS/TE applicable Standard drives the documentation. Level One is the Quality Manual. Level Two is the compliant procedures. Level Three is applicable work instructions. Level Four is the quality records.