

ISO 9001 Lead Auditor Course

The following diagrams supplement the ISO 9001 Lead Auditor Course. Read these diagrams in conjunction with the relevant section (numbers) in the course.

Figure 1.3

Quality Management

The definition of **Quality Management** is "*coordinated activities to direct and control an organization with regard to quality*". The coordinated activities (quality management tools) identified in the ISO 9000:2000 standard are as depicted in the following diagram:

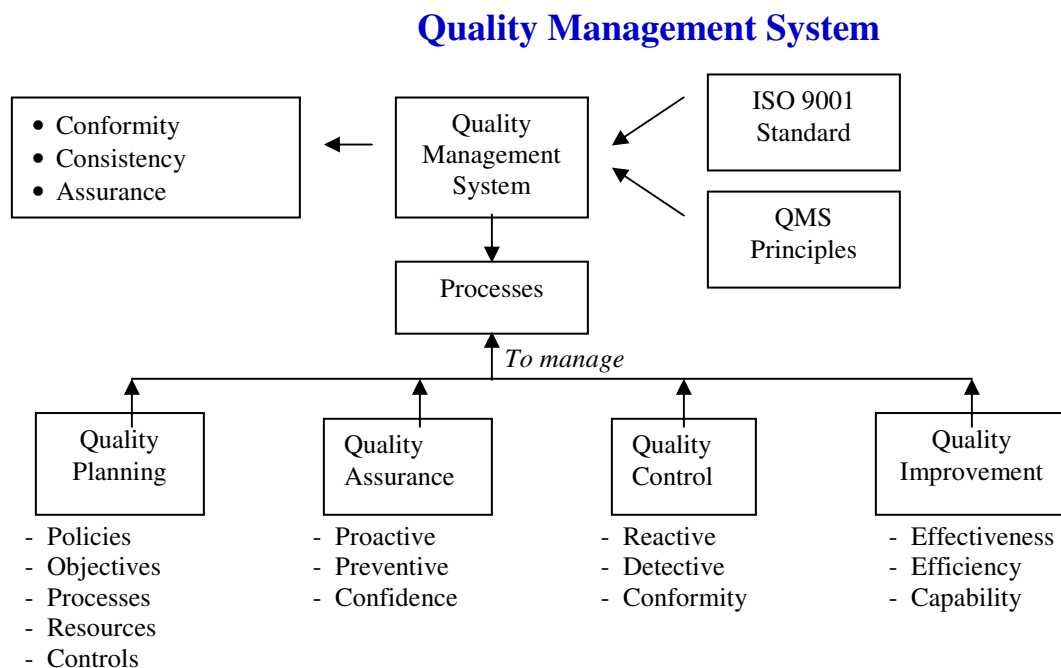


Figure 2.2

A typical documentation structure is depicted in the following pyramid diagram:

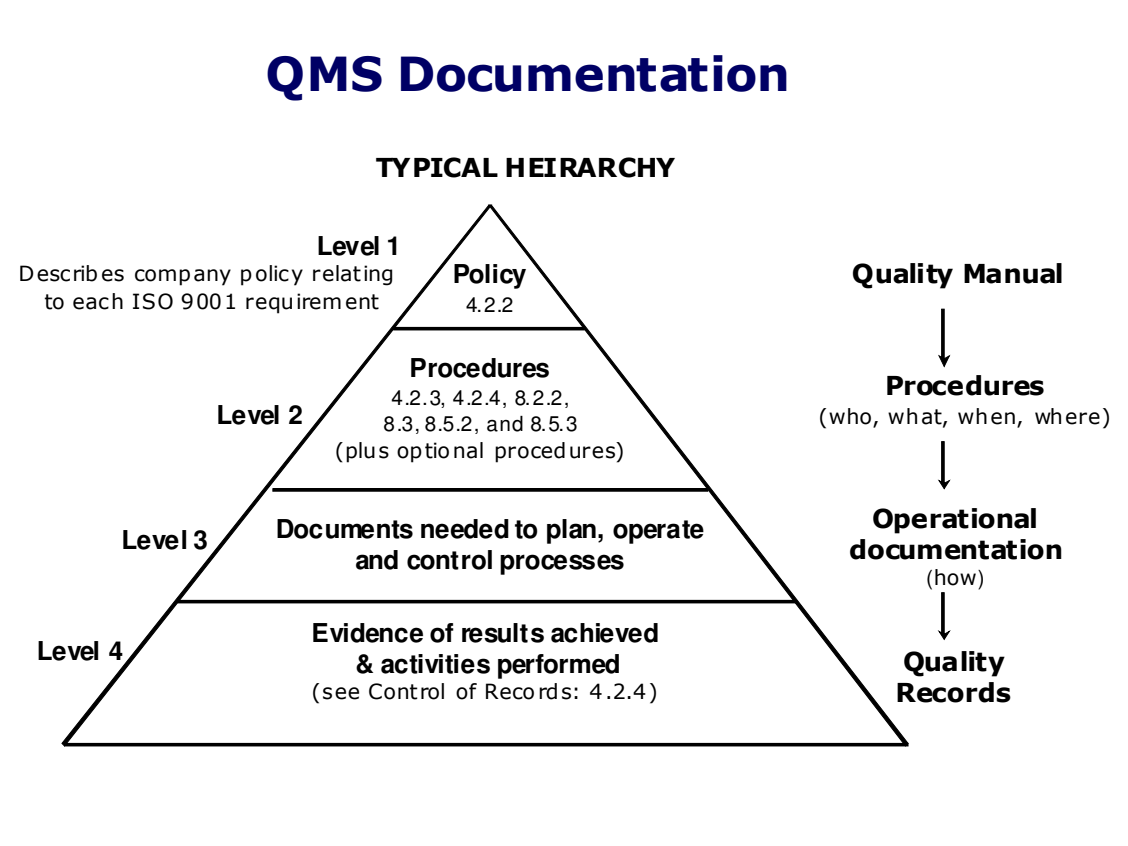


Figure 3.9

RAB/QSA ACCREDITATION PROGRAM

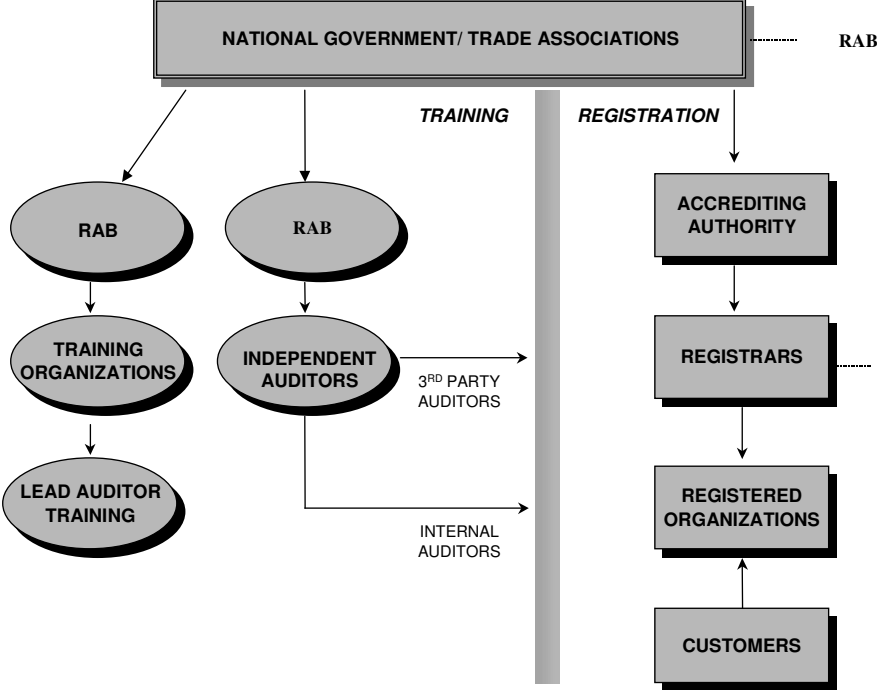


Figure 4.1

Managing an audit program

Managing an Audit Program – Process Flow

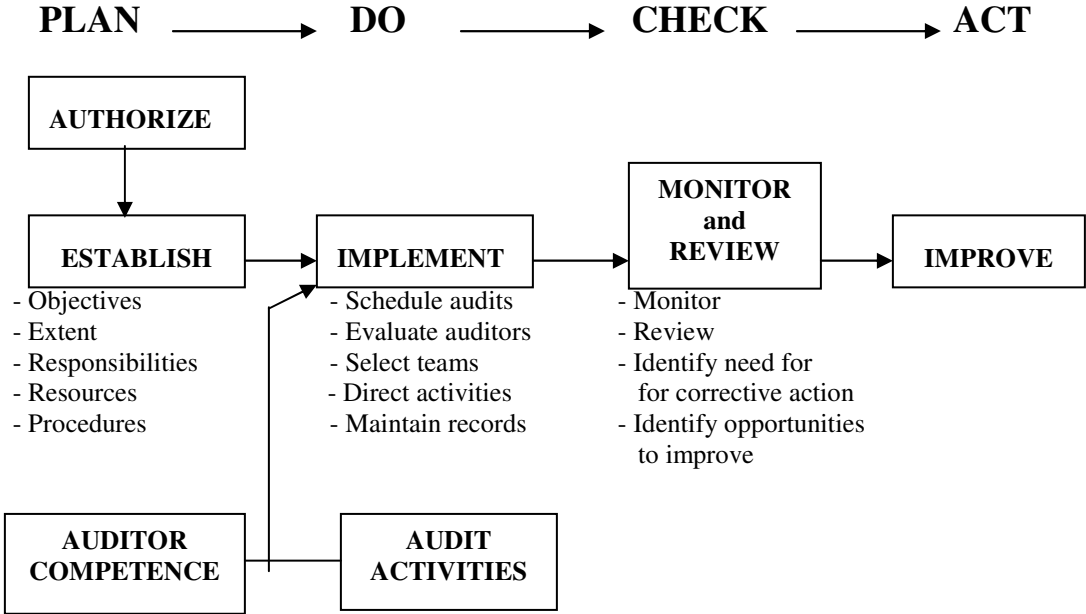


Figure 4.2.2.3

Internal Audit Planning and Preparation

| Departments | Jan | Feb | Mar | Apr | May | Jun | Jul | Aug | Sep | Oct | Nov | Dec |
|-------------|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|
| Sales | P | | | A | | | A | | | | | |
| Management | | P | | | | | | | | | | |
| Technical | | | P | | A | | A | | | | | |
| Planning | | | | P | | | | | A | | | |
| Logistics | A | | | | P | | | | A | | | |
| Purchasing | | | | A | | P | | | A | | | |
| Warehouse 1 | A | | | A | | | P | | | | | |
| Warehouse 2 | | A | | | | | | | P | | | |
| Process 1 | | | A | | | A | | | | P | | |
| Process 2 | | A | | | | A | | | | | P | |
| Calibration | | | | | A | | | | | | | P |

Key: P = Audits planned to be conducted once a year

A = Additional audits considering STATUS, IMPORTANCE, and prior AUDITS

Figure 5.3.2.1

Audit Plan - ABC, Inc.

Auditors: Group 1 - Mr. M. Damon (Team Leader); Mr. R. Moore
Group 2 - Ms. A. Jolie; Mr. R. Anderson

Audit Date: Month / Day(s) / Year

| DAY 1 | TIME | GROUP 1 | GROUP 2 |
|--------------|-------------|---------------------------|----------------------------|
| | 08.30-09.00 | <i>Opening Meeting</i> | <i>Opening Meeting</i> |
| | 09.00-09.30 | <i>Plant Tour</i> | <i>Plant Tour</i> |
| | 09.30-10.30 | <i>Quality Manual</i> | <i>Quality Manual</i> |
| | 10.30-12.00 | Contract Engineering | Warehouse |
| | 12.00-12.30 | <i>Audit Team Prep</i> | <i>Audit Team Prep</i> |
| | 12.30-13.00 | <i>Lunch</i> | <i>Lunch</i> |
| | 13.00-14.30 | Sales/Customer Support | Purchasing |
| | 14.30-16.00 | Design Engineering | Production Scheduling |
| | 16.00-18.00 | Product Development | Manufacturing Engineering |
| | 18.00-18.30 | <i>Review</i> | <i>Review</i> |
| DAY 2 | TIME | GROUP 1 | GROUP 2 |
| | 08.30-10.30 | Software Systems | Assembly |
| | 10.30-12.00 | Calibration - Lab | Assembly/Test |
| | 12.00-12.30 | <i>Audit Team Prep</i> | <i>Audit Team Prep</i> |
| | 12.30-13.00 | <i>Lunch</i> | <i>Lunch</i> |
| | 13.00-14.30 | Industrial Engineering | Test/Calibration - Mfg |
| | 14.30-16.00 | Quality Assurance | Final Inspection/Packaging |
| | 16.00-17.00 | <i>Audit Team Meeting</i> | <i>Audit Team Meeting</i> |
| | 17.00- | <i>Closing Meeting</i> | <i>Closing Meeting</i> |

Figure 5.6.1

Audit Checklist

Area audited: Document Control

Procedure DC-05

| | |
|-----------|--|
| Look at: | Procedure DC-05 |
| Look for: | <i>Conformity of procedure to policies and ISO 9001 standard Control of all document types, including external documents</i> |
| Look at: | Document Approvals |
| Look for: | <i>Approvals by authorized persons prior to document issue Evidence of approvals, e.g., signature or electronic proof</i> |
| Look at: | Document Changes |
| Look for: | <i>Documents reviewed, updated as necessary, and re-approved Current revision status identified along with nature of changes</i> |
| Look at: | Document Usage |
| Look for: | <i>Legible and identifiable versions available at points of use No obsolete documents in use; retained documents identified</i> |

Figure 6.1.4
Collecting and verifying information

Process for collecting information to reaching audit conclusions

