

Quality Manager,

Introduce Your New ISO Quality Manuals Program.

Attached find a copy of ***“Overview of Our New Quality Documentation”***.

This outline may be used to introduce the quality program documented in your new manuals to your organizations personnel.

We have provided the notes below to help guide you through your first meeting and give you a fast start.

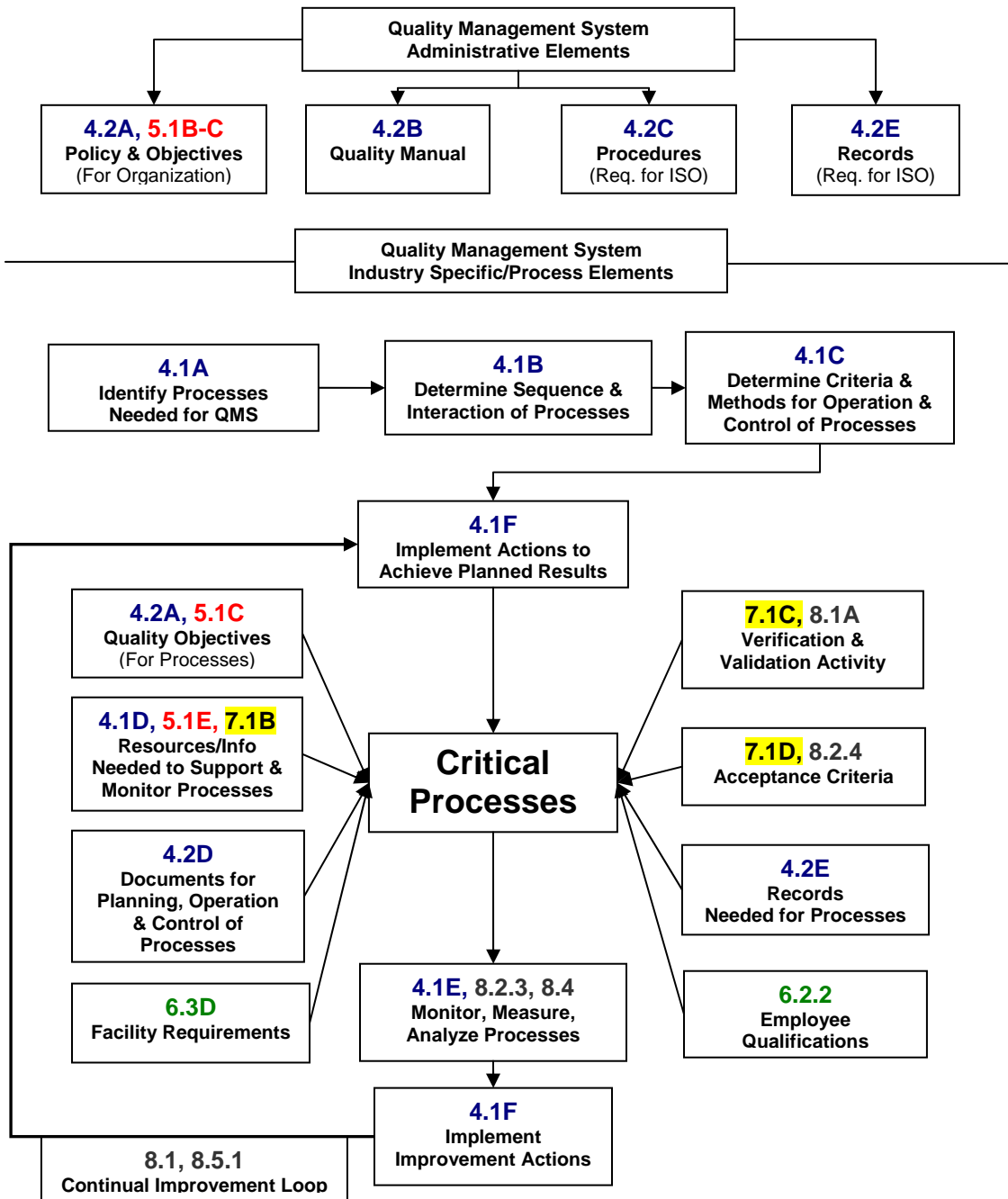
This format may be used as a benchmark for future implementation meetings.

Every organization is different therefore you will need to develop an implementation plan based on the unique characteristics of your organization. The complexity of your operations, resources available, employees involved, etc. are all factors that are relevant to your implementation plan.

The following activity is recommended for your first meeting with manual holders and/or management personnel:

1. Call a meeting to distribute the new manuals
2. Explain the transmission and review form F-4.2.3
(Located in the QSM)
3. Review the documentation.
4. Explain to the team, this is a preliminary review and you will research any questions that the team asks.
(Record research questions below.)
5. Assign the following action items:
 - a. Read the QCM and QSM for content
 - b. Make revision notes on F-4.2.3
 - c. Record individual responsibilities and action items on the last page of this overview.
(Have the individuals list immediate responsibilities and action items required to begin, example is the assignment below. Encourage them to also record responsibilities and action items they identify as they review the Manuals.)
 - d. Locate any procedures, forms, or records that are currently used that may be applicable to the quality program. Have for the next meeting.
6. Determine the return date for the form F-4.2.3
(This will be your next meeting date.)

**Diagram 2
The Process Approach**



Overview of Our Quality Documentation

Getting to Know Your New Manuals

Our QMS documentation includes two (2) levels or tiers of documentation as outlined below:

1st Level - Quality Control Manual (QCM)

The QCM includes the companies' policies regarding our new Quality Management System. It is designed to include the basic elements of ISO 9001:2000. As the top-level policy manual this document will:

1. Satisfy desktop review requirements for future audits and ISO assessment,
2. Provide the primary quality document issued to customers and employees.
3. Convey the companies' quality goals and objectives.

Policies - Policies document what the company will do. Highest-level document.

“Fast Track Tip” Our QCM includes 11 sections (0.0 through 10.0). Sections 4-8 follow the format of ISO 9001:2000, and include the elements needed for the Quality Management System. The section numbering follows through to all supporting documentation including procedures and forms.

4.0	Quality Management System	Everyone on the distribution list will receive his or her individual copy of the QCM. They can use this copy for review activity and should feel free to make notes in the text.
5.0	Management Responsibility	
6.0	Resource Management	
7.0	Product Realization	
8.0	Measurement, Analysis & Improvement	

2nd Level - Quality Systems Manual (QSM)

The QSM is divided into 5 sections called Record Groups. A Record Group (RG) contains all documentation required to support the policies of the QCM and the requirements of ISO 9001:2000. Sections 4-8 each include a RG in your new QSM.

QUALITY SYSTEMS MANUAL					The record group contains what is needed to support the policy, including; procedures, forms, tags, labels, etc.
QSM					
Record Group 4	Record Group 5	Record Group 6	Record Group 7	Record Group 8	

2nd Level - Quality Systems Manual (QSM) – Continued

Procedures – While policies document what the company will do, the procedures document how the company will do it. Instructions for accomplishing the policy, procedures should always support the intent of the policy. If there is ever a question, the policy overrides the procedure.

In addition to the 6 procedures required by ISO, our QSM also includes many of the major records and forms required to support the QMS. Our organizations existing procedures and records will be integrated into this manual.

Procedures included with the new QMS:

- | | |
|--|--|
| <ol style="list-style-type: none"> 1. Document Control 2. Control of Quality Records 3. Internal Quality Audits | <ol style="list-style-type: none"> 4. Control of Nonconforming Product 5. Improvement – Includes: 6. Preventive & Corrective Action |
|--|--|

“Fast Track Tip” The QSM includes an Index & Overview that provides Quick Tips for identifying Documents. Behind each procedure you will find the forms that are required for that procedure. Forms in the QSM are considered “For Reference Only”, and shall not be reproduced for use. The “Master Reproducible” will be retained by the Quality Manager. This will prevent the necessity of updating and re-issuing the QSM when a small change is made to a form.

Records

The system includes the forms our company needs to satisfy minimum record requirements and verify activity as required by ISO 9001:2000.

You will be responsible for:

- Reviewing and revising the records included with this system, and
- Locating/creating records not included and integrating them into the appropriate Record Group.
- Completing the forms required for your work activity.

Records - Records document an activity. This is the proof or verification that an activity considered critical to the QMS has been performed. Types of records include; forms, logs, schedules, tags, etc.

“Fast Track Tip” You will be asked to review, revise and complete the forms included with this package.

QMS Records Binder

Maintaining a QMS Binder provides a simple way to keep track of the records required for our program. If you need a copy of an original form it may be found in the binder kept in the Quality Managers office.

Notes:

Overview of Record Types – This is summary information. Complete details are found in your QSM - Record Group 4. **Procedure P-4.2.4 Control of Quality Records**

Types of Records

Records are divided into two (2) classifications.

Type 1 - Records generated as a result of activities involved in the management and maintenance of the Quality Management System. These records generally fall into:

- Section 4**
- Section 5**
- Section 6**

