Process Mapping
ISO 9000 Documents

ISO 9000-1
Guidelines

ISO 9000-2
Guidelines for implementation of ISO 9001/2/3

ISO 9000-3
Guidelines for Application of ISO 9001 to Development, Supply and Maintenance of Software

ISO 9000-4
Application for Dependability Management

ISO 9001:2000

ISO 10011-1
Auditing

ISO 10011-2
Qualification Criteria for Quality System Auditors

ISO 10011-3
Management of Auditing Programmes

ISO 10012-1
Measurement Confirmation System for Measuring Equipment

ISO 10012-2
Quality Assurance

ISO 10013
Guidelines for Developing Quality Manuals

ISO 9004-1
Guidelines

ISO 9004-2
Guidelines for Services

ISO 9004-3
Guidelines for Processed Material

ISO 9004-4
Guidelines for Quality Improvement

ISO 9004-5
Guidelines for Quality Plans

ISO 9004-6
Guidelines for Project Management

ISO 9004-7
Guidelines for Configuration Management

Courtesy of:
Cayman Business Systems
www.16949.com
513 777-3394

Process Mapping
Liability

- The ISO 9000 series is a vehicle to address liability issues
- Driver was the European Common Market
- Is relevant locally and world wide
Base ISO9001:2000 DIS Structure

Section 4: Quality Management Systems Requirements

Section 5: Management Responsibility
- General Requirement 4.1
- Customer Requirement 4.3
- Policy 4.1
- Planning Objectives 4.1, 4.2
- Quality Management System 4.1, 4.2, 4.5, 4.16
- Management Review 4.1

Section 6: Resource Management
- General Requirement 4.1
- Human Resources 4.18
- Information New
- Infrastructure New
- Work Environment New

Section 8: Measurement, Analysis, Improvement
- General Requirement 4.1o, 4.14, 4.20
- Measuring / Monitoring 4.9, 4.10, 4.17
- Control Of Nonconformity 4.13
- Analysis of Data For Improvement New
- Improvement 4.14

Section 7: Product and / or Service Realization
- General Requirement 4.9, 4.19
- Customer-related Processes 4.3
- Design & Development 4.4
- Purchasing 4.6
- Production and Service Operation 4.7, 4.8, 4.9, 4.10, 4.12, 4.15, 4.19
- Control of Measuring Devices 4.11

Process Mapping
ISO9000:2000 ‘Process Model’

- Quality Management System
  - Continual Improvement
- Customer Requirements
- Resource Management
- Measurement, Analysis, Improvement
- Input
- Product Realization
- Product
  - Output
- Customer Satisfaction

Process Mapping
Business as a Process

Process Mapping
<table>
<thead>
<tr>
<th>Requirement</th>
<th>QS 9000</th>
<th>SPEC PHX</th>
<th>Level II</th>
<th>PIO</th>
<th>GDL SPC</th>
<th>Levels</th>
<th>GUALAJARA SPEC TITLE 2ND AND 3RD LEVELS</th>
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<tr>
<td>Supplier Development</td>
<td>4.6.2</td>
<td></td>
<td></td>
<td>X</td>
<td>CM-305</td>
<td>CM-306</td>
<td>CM-308 Supplier manufacturing effectiveness survey</td>
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<td>Scheduling Subcontractors</td>
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<td>CM-310</td>
<td>CM-309 New supplier qualification procedure</td>
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<td>CM-307</td>
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<tr>
<td>Verification of Purchased Product</td>
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<td>CM-306</td>
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<td>Government Safety and Environmental Regulations</td>
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<td>SE-105</td>
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<td>12MRE96619A</td>
<td>CC-175</td>
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<td>12MSW00389A, 12MSW00345A</td>
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<td>CM-314 Supplier manufacturing effectiveness survey</td>
</tr>
</tbody>
</table>

(See the Document Mapping Herein)
Agenda

Company X Documentation Hierarchy Review

Why Process Maps?

Company X Process Map Elements

Sample Map Review

7 Steps to Process Mapping
Initial Expectations

- I suggest you make and use a ‘history’ binder.
- Make a list of your departmental ‘responsibilities’.

  Think **INPUTS** and **OUTPUTS**

- Prioritize each into ‘Tiers’ or ‘Levels’ in accordance with the Document Pyramid herein. Please categorization is approximate.
- Make a **Plan** or **Schedule** for each.
- I will want to meet with each of you to discuss your list within 2 weeks (the week of the 8th to the 12th).
- **Always ask**, as the auditor will:

  “Does this affect the quality of your product(s)?”
Documentation Tiers

Requirements flow from the top down.

Tier 1: Quality Manual
- Defines Policy, Objectives, & Approach

Tier 2: Company X Process Maps
- Define Who, What, and When of our Business Processes.

Tier 3: Process Operating Documents
- Define the ‘How’ of Process Tasks.

Tier 4: Product Specific Documents (Routings, Prints, Etc.)
- Results / Evidence of Process Activities

Tier 5: Forms and Tags

- Process Records

Tier 5: Ad Hoc / Temporary Documentation
- (Data Collection Sheets made for special investigations, Temp Material Tags)

Process Mapping
Typical Documentation Tiers

We ensure flow down of requirements from the top down

Tier 1: Quality Assurance Manual
- Defines Policy, Objective and Approach (Non-Specific)

Tier 2: Policies & Procedures
- Defines Who, What and When
- Answers How
- The Results

Tier 3: Department Specific Instructions
- Product & Process Documents & Instructions

Tier 4: Forms & Tags
- Objective Evidence Records

Tier 5: Ad Hoc, Temporary Documents
- E.g.: Data collection sheets made for special investigations and temporary material identity tags.

Process Mapping
Mapping - Two Aspects

1. Pick a document to map.
2. Verify all internal references are valid and that they ‘make sense’ and that the requirements flow is always down.
3. Enter the document number (the one being mapped) in the appropriate column and row of the QS 9000 Line Item Matrix.
4. Examine matrix for redundancy.

Process Mapping
After verifying internal links for existence and continuity, one maps the document to the requirements matrix while checking for redundancy.

### ISO 9000 Line Item Matrix Mapping

Matrix Class (Document Type) Listing is Descending Tier Hierarchy

<table>
<thead>
<tr>
<th>Requirement</th>
<th>QS 9000</th>
<th>QA Man.</th>
<th>AIAG Ref.</th>
<th>Corp. SOP</th>
<th>PIO</th>
<th>12MRM-</th>
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<tbody>
<tr>
<td>Analysis and Use of Company-Level Data</td>
<td>4.1.5</td>
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<td>SOP 4-15, SOP 8-13</td>
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</tr>
<tr>
<td>Customer Satisfaction &amp; Customer Complaints</td>
<td>4.1.6</td>
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<tr>
<td>Quality Planning (per APQP &amp; CP)</td>
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<td>APQP</td>
<td>SOP 4-15</td>
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</table>

**Process Mapping**

Elsmar.com
Mapping Aspects

- Mapping starts at the top with the QA Systems Manual. This may be a sector manual or it may be a local manual.
- **Verification** - When you map documents, you ‘verify’ links between documents (where one document cites another within it). The first thing to verify is that the cited document exists.
- A second aspect of mapping is to verify that the content of the citation is relative. This is to say that the links should ‘make sense’. If a citation in one document says something like “The audit will be performed in accordance with procedure ABC-1234” and procedure ABC-1234 is titled ‘Calibration of Pressure Gages’, it is evident that the link is NOT Valid! It does not make sense!
- After verifying that the linked document both exists and that the links are ‘relative’ and make sense, the document is mapped to the matrix relative to the mapping project. In our case the matrix is QS 9000 line items against the document ‘class’.

Process Mapping
After You Map...

After you map your documentation (Verification), you have to Validate your documentation. You Validate your document(s) by stepping through the actual process in step with the associated document. Each step must exist and must be in the order of the documents’ procession.
Business As A System
(A Series Of Processes)

- Design Product
- Purchase Materials
- Receive Materials
- Mfg Processes
- Wafer Fab
- Assembly
- Ship
- MOS
- Die (Wafer) Test
- Device Test
- FDMO
- Process Validations

Process Mapping
Use a Process Flow Chart!

Because:

• You want to understand your current process
• You are looking for opportunities to improve
• You want to illustrate a potential solution
• You have improved a process and want to document the new process

Let’s Try A Process Flow Chart
Creating a Process Flow Chart

1. **Identify the process or task** you want to analyze. Defining the scope of the process is important because it will keep the improvement effort from becoming unmanageable.

2. **Ask the people** most familiar with the process to help construct the chart.

3. **Agree on the starting point and ending point.** Defining the scope of the process to be charted is very important, otherwise the task can become unwieldy.

4. **Agree on the level of detail** you will use. It’s better to start out with less detail, increasing the detail only as needed to accomplish your purpose.
Creating a Process Flow Chart

5. Look for areas for improvement
   • Is the process standardized, or are the people doing the work in different ways?
   • Are steps repeated or out of sequence?
   • Are there steps that do not add value to the output?
   • Are there steps where errors occur frequently?
   • Are there rework loops?

6. Identify the sequence and the steps taken to carry out the process.

7. Construct the process flow chart either from left to right or from top to bottom, using the standard symbols and connecting the steps with arrows.

8. Analyze the results.
   • Where are the rework loops?
   • Are there process steps that don’t add value to the output?
   • Where are the differences between the current and the desired situation?
Early Process Flow Diagram

- Inspection Points
- Inspection Frequency
- Instrument
- Measurement Scale
- Sample Preparation
- Inspection/Test Method
- Inspector
- Method of Analysis
Basic Flow Chart Example

Start

Manufactured Parts
- Receive Raw Materials
  - Inspect
    - Bad
  - Move to Production
    - Process Material
      - Inspect
        - Bad

Purchased Parts
- Receive Parts
  - Inspect
    - Bad
  - Move to Production

Disposition
- Bad
Basic Flow Chart Example

Assemble → Functional Test

Bad → Disposition

Package → Ship
Why Process Maps?

Maps draw a picture that allows the reader to ‘visualize’ the process flow. “A picture is worth a thousand words”

These Process ‘pictures’ allow the reader to see the process inputs and outputs as well as links to other processes.

By ‘linking’ all the process maps together, we can verify that all the individual processes flow appropriately and that references from one Map to another make sense.

This makes its easier for auditors as well!

Process Mapping
There are 8 elements / sections to a Company X Process Map

They are:

1) Purpose Statement
2) Scope Statement
3) Main Process Inputs
4) Main Process Outputs
5) Process Responsibilities Listing
6) Process Flow Chart
7) Essential Controls Listing
8) Quality Measure
## Process Map Elements

1) **Purpose Statement**

This should be a single sentence stating what process the procedure is describing.

Example: The purpose of this procedure is to describe the process by which Company X will approve suppliers.

2) **Scope Statement**

This should be 1 or 2 sentence describing the boundaries of the process described in the procedure. Also use this section for defining abbreviations and jargon as well as referencing other documents.

Example: This procedure applies to the approval of all suppliers of materials that make up the final products shipped to Company X’ customers.

3) **Main Process Inputs**

A list of the Main Process Inputs and where they *come from*.

Example:
Request for new Supplier from the Purchasing Process

4) **Main Process Outputs**

A list of the Main Process Outputs and where they *go to*.

Example:
Approved Supplier to the Approved Supplier List
Company X Process Map Elements

5) Process Responsibilities

A list of the major / critical responsibilities associated with the process. This list is typically 3 - 5 items long.

Example: It is the responsibility of the Purchasing Agent to ensure that they are purchasing production material from Approved Suppliers.

7) Essential Controls

A list of elements that must happen or be in place for the process to be successful. This list is typically 3 - 5 items long.

Example: An Approved Supplier List is generated and maintained. Disqualified suppliers are maintained on a Disqualified Supplier List.

6) Process Flow Chart

A flow chart showing the process inputs & outputs as well as the process sequence with defined functional responsibilities.

See Flow Chart examples.

8) Quality Measure

A statement describing the 1-2 (maximum) measures that will be used to monitor the successful execution of the process. Remember: If we say we do it we have to!

Example: The number of number supplier caused defects found at Incoming Inspection.
Company X Process Map
Sample Review
7 Steps to Process Mapping

1) Gather and Review all existing documentation

2) Identify Weaknesses of the current documentation / process

3) Identify Inputs and Outputs of the Process

4) Generate a Draft Procedure

5) Review Draft Procedure with XXXX

6) Develop an Implementation Plan

7) Release the Document, Implement the Process and Audit
Company X Process Mapping Worksheets

The following sheets have been designed to help your team organize your thoughts and actions as you work through the mapping of your process. Please fill out all sections as completely as possible. If you have any questions feel free to give me a call at 777-3394.

Thank you.

Team Members:

_____________________________________________________

_____________________________________________________

_____________________________________________________

_____________________________________________________

_____________________________________________________

_____________________________________________________

_____________________________________________________

_____________________________________________________

Process Name:

_____________________________________________________

Date Started

_____________________________________________________

Projected Step Completion Dates

Step 1: ___________  Step 5: ___________

Step 2: ___________  Step 6: ___________

Step 3: ___________  Step 7: ___________

Step 4: ___________
Step 1: Gather (sweepes) and **review** all existing Process Documentation.

Step 2: Identify current **weaknesses** of each Document.

<table>
<thead>
<tr>
<th>Doc No.</th>
<th>Document Name</th>
<th>Weaknesses</th>
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### Identify Main Process Inputs and Outputs

**Step 3:** Identify the Main Process Inputs and the Outputs.

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</tbody>
</table>

<table>
<thead>
<tr>
<th>Output</th>
<th>To</th>
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</tbody>
</table>
Generate a Draft of the Process Steps

6.0 Process Flowchart As a team, flowchart the process before writing the rest of the document’s sections. Attach a copy of the flowchart to the back of this sheet.

After you have completed your flow chart, fill in the rest of the sections of the Map.

1.0 Purpose: ________________________________

_________________________________________________________________________________

_________________________________________________________________________________

_________________________________________________________________________________

_________________________________________________________________________________
Generate a Draft of the Process Map

2.0 Scope: ____________________________________________________________
                                                                
                                                                
                                                                
                                                                

Definitions:                                               Abbreviations:                                               References:
                                                                
                                                                
                                                                
                                                                

3.0 Main Process Inputs  See Step 3 of this package

4.0 Main Process Outputs  See step 3 of this package
Steps in Generating a Process map

5.0 Process Responsibilities

7.0 Essential Controls

8.0 Quality Measure
Review the Draft Process Map with the Taem

Review Results:  
☐ OK to Implement  ☐ Changes Recommended

Record Of Recommended Changes:

Date of Next Review:
### Implementation Plan for the Process and Documentation

**Step 6: Create an Implementation Plan for the Process and Documentation.**

<table>
<thead>
<tr>
<th>What</th>
<th>Who</th>
<th>When</th>
<th>How</th>
<th>Status</th>
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<tr>
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<tr>
<td>Training</td>
<td></td>
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<td>Communicating</td>
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<td>Quality Measure Implementation</td>
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<tr>
<td>Get on Audit Schedule</td>
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