

ISO 9001

Getting The Results You Need and Anticipated?

Evaluate Your Organization's Performance Measurement and CI approach on your ISO 9001 journey.

**Session facilitated by: ISO 9001 Consultant Karen Zanetti (IMSM, Inc.)
Contributions by Kevin Gilson (Orion Auditor) and Alan Lane (APL Auditor).**

ISO 9001-Includes A Continuous Process Improvement System That Requires

- Defined objectives
- That are put in place
- With method for collecting, analyzing data
- Application of data analysis to Continuous Improvement

But How Do We Do It?

- How simple has it been?
- How effective?
- Let's take a short survey

4.1 General Requirements of Quality Management Systems

- Organization shall establish, document, implement and maintain a QMS & continually improve its effectiveness in accordance with this International Standard
 - ID processes needed for QMS and their application throughout the organization
 - Determine sequence and interaction of these processes
 - Determine criteria & methods needed to ensure that both operation & control of processes are effective
 - Ensure availability of resources and information necessary to support operation and monitoring of these processes
 - Monitor, measure and analyze these processes
 - Implement actions necessary to achieve planned results and continual improvement of these processes.

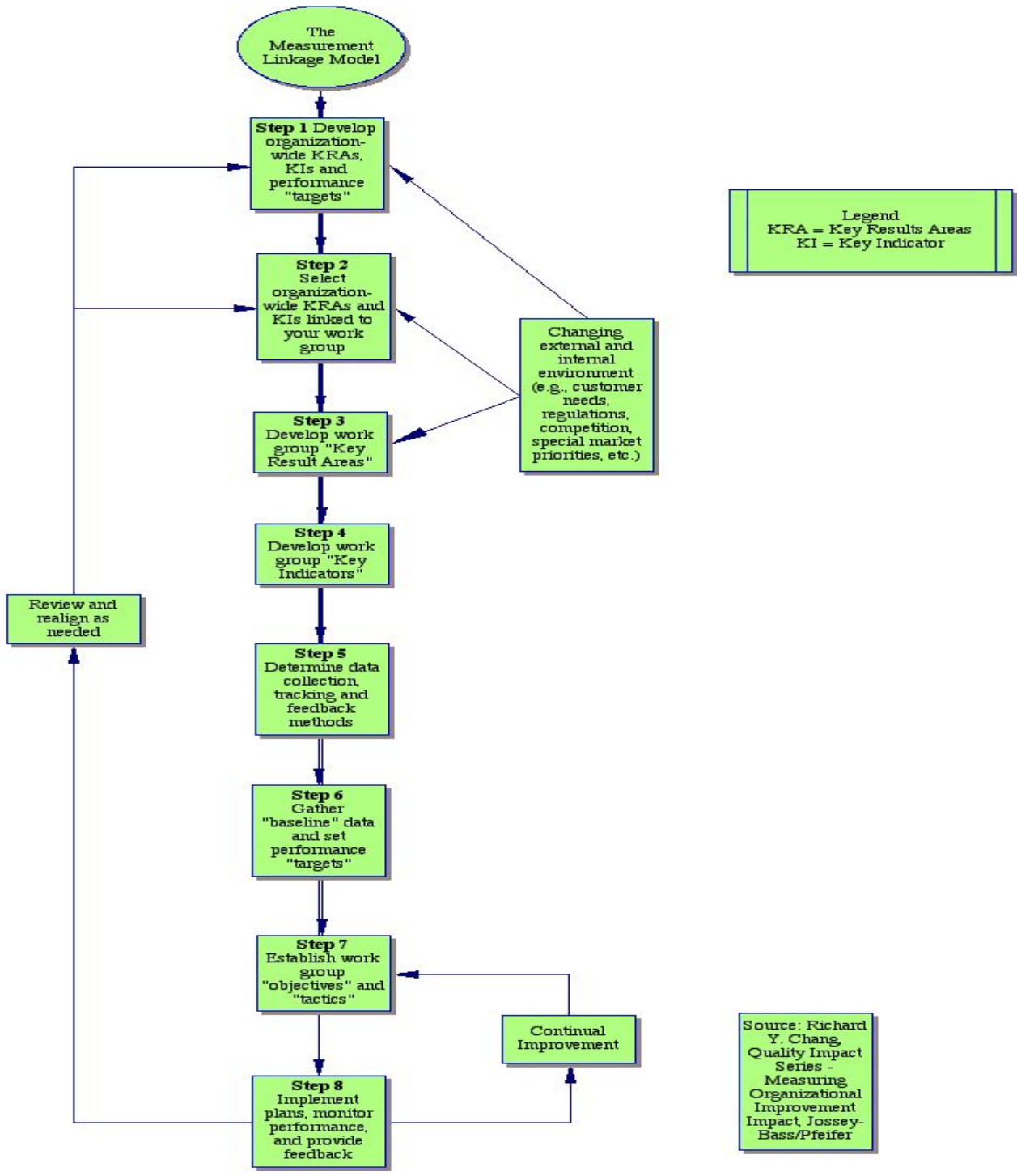
On Scale of 1-5, Rate How Well Your Organization Executes Each Action

- | | |
|--|----|
| 1. ID processes needed for QMS and their application throughout the organization | 1. |
| 2. Determine sequence and interaction of these processes | 2. |
| 3. Determine criteria & methods needed to ensure that both operation & control of processes are effective | 3. |
| 4. Ensure availability of resources and information necessary to support operation and monitoring of these processes | 4. |
| 5. Monitor, measure and analyze these processes | 5. |
| 6. Implement actions necessary to achieve planned results and continual improvement of these processes. | 6. |

8 Measurement, Analysis & Improvement

■ 8.1 General

- The organization shall plan and implement the monitoring, measurement, analysis and improvement processes need.
- This shall include **determination of applicable methods**, including statistical techniques, and the extent of their use.
 - **You** need to plan how **you** intend to carry out monitoring and measuring activities **you** are going to use.



Legend
 KRA = Key Results Areas
 KI = Key Indicator

Source: Richard Y. Chang, Quality Impact Series - Measuring Organizational Improvement Impact Jossey-Bass/Pfeifer

Linkage Model Steps 1-4

- Summary of Steps
 - Develop Key Result Areas reflecting the Mission, Vision and Strategic Goals
 - Develop Key Indicators of success for the Key Result Areas and set Performance Targets
 - Deploy to Work Groups (KRAs, KIs, Targets)
- Terms
 - Key Results Areas (KRA)
 - Key Indicators (KI)
 - Performance Targets

Key Result Areas (KRA)

- Critical, must achieve, make or break performance categories
 - Customer Loyalty
 - Quality
 - Innovation
 - Productivity

Key Indicators (KI)

- Specific measure which helps determine how well you are performing in a given Key Result Area (KRA)
 - Break each KRA into measurable components
 - Answer the question, “What concrete measure could be used to show how your organization/work group is doing on each KRA?”
 - KRA = Quality
 - KI 1: Defects/units of production
 - KI 2: Order fulfillment cycle time
 - KI 3 : # of correct shipments/total shipments

Specific Characteristics of KIs

From: Richard Y. Chang and Associates

- Provide important data
- Controllable by your actions
- Track actual performance change
- Align with existing data or can be clearly established
- Measure efficiency (timeliness, throughput, quantity, etc. And/or effectiveness (quality, contribution))

Set Performance Targets



- Performance Targets :
 - Provide clear direction
 - Achievable (I.e., realistic)
 - Specific, reflecting **quantification** of KIs
 - Aligned with KRA/objectives
 - KRA = Quality
 - KI 1: Defects/units of production
 - **Annual average of .05%, batch average never to exceed 1%**
 - KI 2: Order fulfillment cycle time
 - **98% of orders filled within 48 hours**
 - KI 3 : # of correct shipments/total shipments
 - **.998 level**

3 Type Of KIs To Track

- Do new things
 - New processes
- Do things better
 - Processes needing improvement
- Stop doing non-value added things
 - Going back to doing things the “old” way
 - Using a previous version of a procedure

KI Ownership

- Efficiency of a performance improvement approach is directly linked to the degree of penetration of the approach throughout the organization. (5.5.1 Responsibility & Ownership)
- It is not sufficient to merely set objectives for the organization and its processes

Organizational Responsibility For KI Realization- **KIs Must Have Owner**

- Type of Objective

- Organizational

- Process

- Job/Role Level

- Persons Accountable

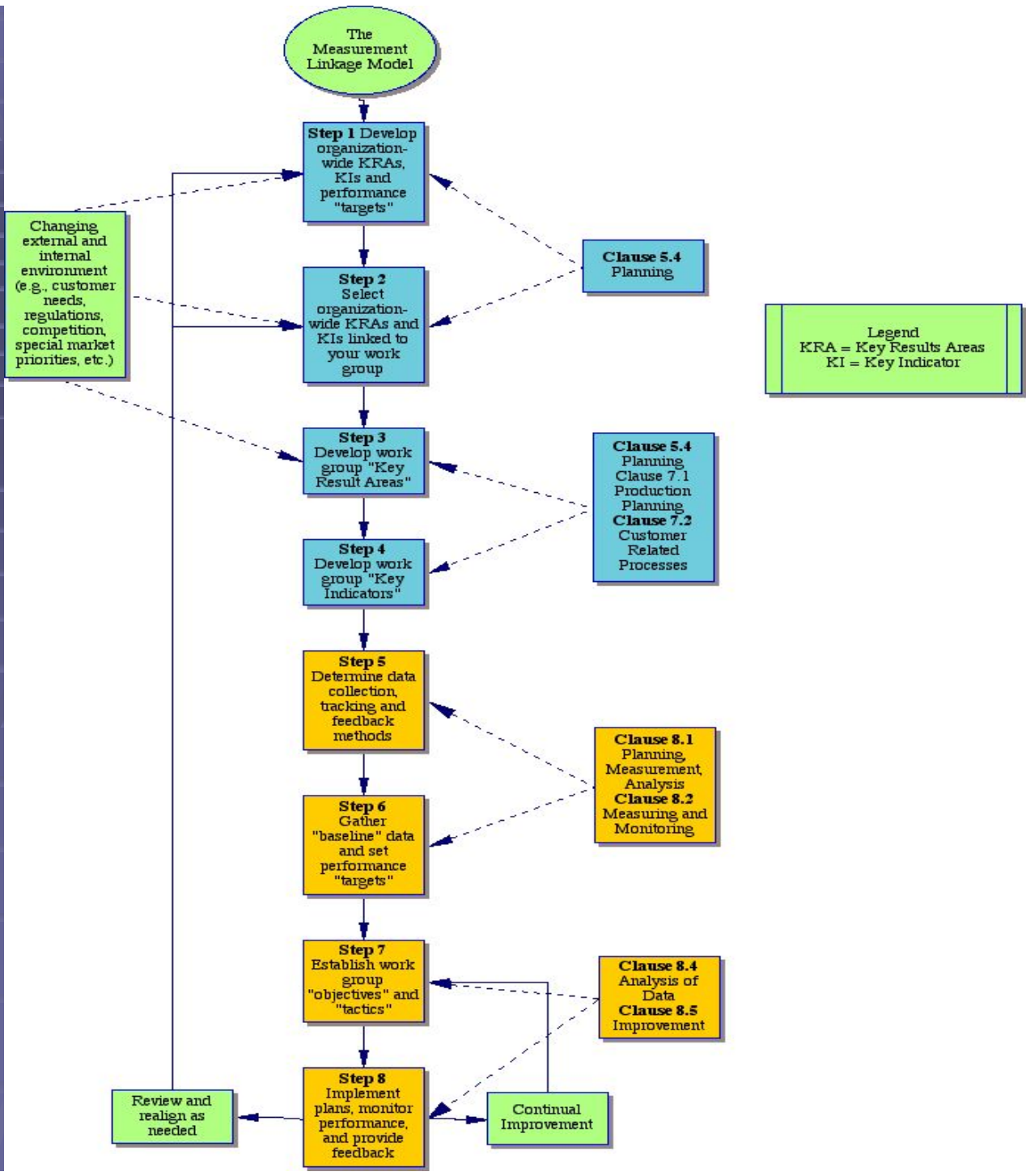
- Executive

- Senior & Middle Mgmt,
Process Owners

- Each Individual

Linkage Model Steps 5-8

- Summary of Steps
 - Establish data collection and tracking methods with reporting criteria
 - Use “baseline” data to set Performance Targets
 - Define Work Group implementation
 - Implement the program and review results (e.g. at Management Review) and refine Targets
 - Realign or Improve processes



Relationship to ISO 9001

- Clause 5.4 Planning
 - Top-level planning
 - Work Group (production) planning
- Clause 7.1 Production Planning
 - Product Realization Planning (7.1)
 - Determine Product Requirements (7.2)
 - Product monitoring (7.1)
- Clause 7.2 Customer Related Processes
 - Requirements, review and customer communication (7.2)

Relationship to ISO 9001

- Clause 8.1 Planning, Measurement and Analysis
 - Step 5: Activity to measure, monitor, etc.
- Clause 8.2 Measuring and Monitoring
 - Step 6: Baseline and Target validation
 - Step 8: Implement program
- Clause 8.3 Analysis of Data
 - Step 6: Refine Targets
 - Step 8: Analysis for Target achievement
- Clause 8.5 Improvement
 - Step 8: Identify realignment or improvement

Other ISO 9001 Requirement Examples

- Providing people with the right information
 - 4.2.3 Control of Documents
 - 4.2.4 Control of Records
- At the right time
 - 5.5.3 Internal Communication
- In the right format
 - 8.2 Measuring and Monitoring
- To the right people
 - 5.6 Management Reviews
 - 8.5 Improvement

Comments

- How does this approach compare to the approach you are currently using?
- Feedback and comments?
- Next steps?

Thank-You

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References

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- Managing Organizational Change During SAP Implementations, SAP Press
- ISO 9001:2008 Quality Management Systems - Requirements