ISO 9001:2015

Subject: Quality Management System

Clause 9 & 10 – Performance Evaluation & Improvement
Contents
ISO 9001:2015

ISO 9001:2015 CLAUSES

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Context of the organization

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Support

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Operation

CLAUSE 9
Performance evaluation

CLAUSE 10
Improvement
CLAUSE 9 – Performance Evaluation

Requirements


9.2 Internal Audit

9.3 Management Review
CLAUSE 9 – Performance Evaluation

The organization shall determine:

- **What** needs to be monitored and measured
- **The methods** for monitoring, measurement, analysis and evaluation
- **When** the monitoring and measuring shall be performed
- **When** the results from monitoring and measurement shall be **analyzed** and **evaluated**
CLAUSE 9 – Performance Evaluation

THE ORGANIZATION SHALL EVALUATE

the performance and the effectiveness of the quality management system

THE ORGANIZATION SHALL RETAIN

appropriate documented information as evidence of the results
Customer satisfaction

The organization shall monitor the customers’ perception of the degree to which their needs and expectations have been fulfilled.

The organization shall determine the methods for obtaining, monitoring and reviewing this information.
## Customer satisfaction

### Examples

<table>
<thead>
<tr>
<th></th>
<th>Example</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Customer surveys, customer feedback (praise, complaints...)</td>
</tr>
<tr>
<td>2</td>
<td>Meetings with customers</td>
</tr>
<tr>
<td>3</td>
<td>Market-share analysis</td>
</tr>
<tr>
<td>4</td>
<td>Compliments, warranty claims</td>
</tr>
<tr>
<td>5</td>
<td>Dealer reports</td>
</tr>
</tbody>
</table>
**Customer Satisfaction Survey**

**Instructions:** Please fill out the form below and fax it back to [Fax] or email to [General Company Email Address].

<table>
<thead>
<tr>
<th>Survey Question</th>
<th>Rating</th>
</tr>
</thead>
<tbody>
<tr>
<td>Are you satisfied with our services?</td>
<td>□</td>
</tr>
<tr>
<td>How would you rate our level of quality?</td>
<td>□</td>
</tr>
<tr>
<td>How would you rate our level of customer service?</td>
<td>□</td>
</tr>
<tr>
<td>Do you feel we adequately respond to and correct any problems or issues that may arise?</td>
<td>□</td>
</tr>
<tr>
<td>How would you rate our overall performance?</td>
<td>□</td>
</tr>
</tbody>
</table>

**Comments:**

Customer Name: ___________________________ Contact Name: ___________________________
Customer Fax: ___________________________ Date: ___________________________
An organization-wide program that integrates all functions and processes of the business so that **design, planning, production, distribution and services** are focused on maximizing **customer satisfaction** through continued improvement.

**Gary Dessler** (Author in Human Resource Management)
DETERMINANTS OF SERVICE QUALITY (SERVQUAL)

A system approach of the customer satisfaction through the different attributes of service quality

**Input - Customer Requirements**

- Responsiveness
- Availability/Access
- Courtesy/Friendliness
- Reliability
- Communication
- Competence
- Tangibles

**Output - Customer Satisfaction**

- Empathy
- Assurance
- Credibility
- Assurance/Security
- Time
- Courtesy
- Understanding Customers
DATA AND ANALYSIS
The results of analysis shall be used to evaluate:

a. Conformity of products and services
b. the degree of customer satisfaction
c. the performance and effectiveness of the quality management system
d. if planning has been implemented effectively
e. effectiveness of actions taken to address risks and opportunities
f. the performance of external providers
g. the need for improvements to the quality management system
# Failure Mode Effect Analysis (FMEA)

<table>
<thead>
<tr>
<th>PROCESS NAME</th>
<th>PROCESS NUMBER</th>
<th>Date:</th>
<th>Revision:</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Failure Mode</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>1. Select wrong color seat belt</td>
<td>5</td>
<td>4</td>
<td>3</td>
</tr>
<tr>
<td>2. Seat belt bolt not fully tightened</td>
<td>9</td>
<td>2</td>
<td>8</td>
</tr>
<tr>
<td>3. Trim cover clip misaligned</td>
<td>2</td>
<td>3</td>
<td>4</td>
</tr>
</tbody>
</table>
**FIVE WHY ANALYSIS**

The 5 Whys is a question-asking method used to explore the cause of a particular problem and to understand cause-and-effect relationships.

<table>
<thead>
<tr>
<th>WHY?</th>
<th>REASON</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>WHY 1</strong> Why was our customer unhappy?</td>
<td>The service has been delivered late. The customer was unsatisfied.</td>
</tr>
<tr>
<td><strong>WHY 2</strong> Why was the service not prepared on time?</td>
<td>We did not prepare the service on time because it took much longer than we expected.</td>
</tr>
<tr>
<td><strong>WHY 3</strong> Why did it take so long?</td>
<td>Because we did not receive all approvals on time and underestimated the duration of the project.</td>
</tr>
<tr>
<td><strong>WHY 4</strong> Why did we underestimate the project duration?</td>
<td>Because we forgot to prepare a detailed list of all tasks.</td>
</tr>
<tr>
<td><strong>WHY 5</strong> Why did we forget it?</td>
<td>Because we were running behind on other projects and failed to review our task list and time estimation during the project.</td>
</tr>
</tbody>
</table>

**Root Cause**

We did not have checklists to track our tasks and to estimate the duration of the project. For future projects, these factors shall be considered.

*Note the root cause(s) of the problem here. Only the one who experienced the problem is qualified to perform the analysis. There is usually more than one root cause.*
INTERNAL AUDIT
INTERNAL AUDIT

The organization shall

- conduct internal audits
- at planned intervals

to provide information on whether the quality management system conforms to

- the organization’s own requirements for its quality management system
- and the requirements of this International Standard
INTERNAL AUDIT
The organization shall

- plan
- establish
- implement and
- maintain
- one or more audit program(s)
INTERNAL AUDIT

In doing so, it shall be considered:

- frequency of audits
- methods
- responsibilities
- planning requirements and reporting

which is dependent on:

- importance of the processes concerned
- changes affecting the organization and
- the results of previous audits
INTERNAL AUDIT

The organization shall:

- **define** the **audit criteria** and
- **scope** for each audit

select auditors and conduct audits to

- **ensure objectivity**
- and the **impartiality** of the **audit process**.
INTERNAL AUDIT

It shall be ensured that

- the results of the audits are reported to relevant management.

If correction and corrective actions are necessary, they shall be implemented without undue delay.

Example – Internal audit report
MANAGEMENT REVIEW
Top management shall

- review the organization’s quality management system
- at planned intervals
- to ensure its continuing suitability
- adequacy and
- effectiveness and
- alignment with the strategic direction

of the organization.
The **management review** shall be **planned** and **carried out**, taking into consideration the **following aspects** (inputs):

- **Status** of the **actions** from **previous management reviews**
- **Changes** in **external** and **internal issues** that are relevant to the quality management system
- **Information** on the **performance** and **effectiveness** of the quality management system
- The **adequacy of resources**
- The **effectiveness of actions taken** to **address risks** and **opportunities**
- **Opportunities** for improvement
MANAGEMENT REVIEW
The outputs of the management review shall include decisions and actions related to:

- opportunities for improvement
- any need for changes to the quality management system
- resource needs

Example – Management Review Meeting Minutes
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Context of the organization

Leadership

Support

Planning

Performance evaluation

Improvement
CLAUSE 10 – Improvement
Requirements

10.1 GENERAL

10.2 NONCONFORMITY AND CORRECTIVE ACTION

10.3 CONTINUOUS IMPROVEMENT
The organization shall:

- **determine** and **select opportunities** for **improvement** and
- **implement** any necessary **actions**
- to **meet customer requirements** and
- **enhance customer satisfaction**
General

These shall include:

- Improving products and services to meet requirements as well as to address future needs and expectations
- Correcting, preventing or reducing undesired effects
- Improving the performance and effectiveness of the quality management system
Examples of improvements can include:

- corrections
- corrective actions
- continual improvement
- breakthrough change
- innovation
- re-organization
NONCONFORMANCE AND CORRECTIVE ACTION
NONCONFORMITY AND CORRECTIVE ACTION

When a nonconformity occurs (whether determined internally or externally), the organization shall

a. react to the nonconformity and, as applicable, take action to control and correct it to deal with the consequences
b. evaluate the need for action to eliminate the cause(s) of the nonconformity, in order that it does not recur or occur elsewhere
c. implement any action needed
d. review the effectiveness of any corrective action taken
e. update risks and opportunities determined during planning, if necessary
f. make changes to the quality management system, if necessary
CONTINUOUS IMPROVEMENT
CONTINUAL IMPROVEMENT

THE ORGANIZATION SHALL CONTINUALLY IMPROVE THE

- Suitability
- Adequacy
- Effectiveness

QMS
The organization shall consider:

- The results of analysis and evaluation
- The outputs from management review

...to determine if there are needs or opportunities that shall be addressed as a part of continual improvement.
Strategy is a style of thinking, a conscious and deliberate process, an intensive implementation system, the science of insuring future success.

Peter Johnson (American pianist)