Module II: QMS Requirements

Clause 4:

Context of the Organization
Clause 4: Context of the Organization

4. Context of the Organization

4.1 Understanding the Organization and its context
4.2 Understanding the needs and expectations of interested parties
4.3 Determining the scope of the QMS
4.4 QMS and its processes
4.1 Understanding the organization and its context

- The organization SHALL determine external and internal issues relevant to the organization’s purpose and strategic direction affecting its ability to achieve the QMS’ intended results.
4.1 Understanding the organization and its context

Organization’s context often referred to by other terms such as:

- Organizational environment
- Business environment
- Ecosystem of an organization

...relative to its products, services, investments, and behavior towards its relevant interested parties.
Clause 4: Context of the Organization

4.1 Understanding the organization and its context

Note 1: Issues can include positive and negative factors or conditions for consideration.

Note 2: Understanding the external context can be facilitated by considering issues arising from legal, technological, competitive, market, cultural, social and economic environments, whether international, national, regional or local.

Note 3: Understanding the internal context can be facilitated by considering issues related to values, culture, knowledge and performance of the organization.
4.1 Understanding the organization and its context

**University Mandate**
CvSU is mandated "to provide excellent, equitable and relevant educational opportunities in the arts, sciences and technology through quality instruction, and responsive research and development activities. It shall produce professional, skilled and morally upright individuals for global competitiveness."

**University Vision**
The Premier University in historic Cavite recognized for excellence in the development of globally and morally upright individuals.

**University Mission**
Cavite State University shall provide excellent, equitable, and relevant educational opportunities in the arts, sciences and technology through quality instruction and responsive research and development activities.

It shall produce professional, skilled and morally upright individuals for global competitiveness.
The organization \textbf{SHALL} monitor and review information on external and internal issues through various tools and techniques.

- **SWOT Analysis**
- **PESTLE Analysis**
Clause 4: Context of the Organization

4.1 Understanding the organization and its context

Sample Tools and Techniques

[SWOT Matrix Diagram]

- **Helpful Strengths**
- **Harmful Weaknesses**
- **External Opportunities**
- **Internal Threats**
## SAMPLE OF SWOT ANALYSIS

<table>
<thead>
<tr>
<th></th>
<th>STRENGTHS</th>
<th>WEAKNESSES</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>INTERNAL</strong></td>
<td><strong>Advantages</strong></td>
<td><strong>Gaps in capabilities</strong></td>
</tr>
<tr>
<td></td>
<td>- Accreditations</td>
<td><strong>Financials</strong></td>
</tr>
<tr>
<td></td>
<td>- Qualifications</td>
<td>- Cash flow, start-up cash drain</td>
</tr>
<tr>
<td></td>
<td>- Certifications</td>
<td>- High cost structure</td>
</tr>
<tr>
<td></td>
<td>- Location and geography</td>
<td><strong>Our vulnerabilities</strong></td>
</tr>
<tr>
<td></td>
<td>- Innovative aspects</td>
<td>- Timescales, deadlines and, pressures</td>
</tr>
<tr>
<td></td>
<td><strong>Resources, Assets, People</strong></td>
<td>- Reliability of data</td>
</tr>
<tr>
<td></td>
<td>- Processes, systems, IT, communications</td>
<td>- Plan predictability</td>
</tr>
<tr>
<td></td>
<td>- Culture, attitudes, behaviours</td>
<td><strong>Processes and systems</strong></td>
</tr>
<tr>
<td></td>
<td>- Experience, knowledge, data</td>
<td>- Succession, morale, commitment, leadership</td>
</tr>
<tr>
<td></td>
<td>- Patents</td>
<td><strong>THREATS</strong></td>
</tr>
<tr>
<td><strong>EXTERNAL</strong></td>
<td><strong>Partnerships</strong></td>
<td>- Seasonal, weather effects</td>
</tr>
<tr>
<td></td>
<td>- Unfulfilled customer needs</td>
<td>- Political effects</td>
</tr>
<tr>
<td></td>
<td>- New technologies</td>
<td>- Legislative effects</td>
</tr>
<tr>
<td></td>
<td>- Loosening of regulations</td>
<td>- New technologies, IT developments</td>
</tr>
<tr>
<td></td>
<td>- Industry</td>
<td>- Changing customer needs</td>
</tr>
<tr>
<td></td>
<td></td>
<td>- New regulations</td>
</tr>
</tbody>
</table>
4.1 Understanding the organization and its context

**PESTLE**

- **Political**
  - Stability of Government
  - Potential changes to legislation
  - Global influences

- **Economic**
  - Economic growth
  - Employment rates
  - Inflation rates
  - Monetary policy
  - Consumer confidence

- **Social/Cultural**
  - Income distribution
  - Demographic influences
  - Lifestyle factors

- **Technology**
  - International influences
  - Changes in information technology
  - Take up rates

- **Legal**
  - Taxation policies
  - Employment laws
  - Industry regulations
  - Health and Safety

- **Environment**
  - Regulation and restriction
  - Attitudes of customers
### SAMPLE OF PESTLE ANALYSIS

<table>
<thead>
<tr>
<th>Political</th>
<th>Economic</th>
<th>Social</th>
<th>Technological</th>
<th>Legal</th>
<th>Environmental</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Schools being privatised</td>
<td>• Central or local government funding decisions may affect school finances</td>
<td>• Local population changes</td>
<td>• Changes to standards/equipment required</td>
<td>• New legislation may create risk of noncompliance with the law/create administrative burden</td>
<td>• New highway layout may pose danger to students</td>
</tr>
<tr>
<td>• A government initiative creates the risk that the school may fail to deliver the policy or be diverted away from priorities</td>
<td>• Closure of local industry may affect funding plans</td>
<td>• Closure of local firms providing employment</td>
<td>• Risks of selecting the wrong technology at times of change</td>
<td>• Changes to child protection legislation</td>
<td>• Waste disposal</td>
</tr>
<tr>
<td>• Changes to curriculum with short lead times</td>
<td>• Cost of providing resources (staff/technology support/basic)</td>
<td>• Social networking</td>
<td>• New computer viruses may affect operations</td>
<td>• Changes in age in starting school</td>
<td>• Reduction of green space available for activities</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• Integration of students with special needs</td>
<td>• Move from paper-based books to e-books reader</td>
<td>• Change in school opening hours</td>
<td>• Changes to local transportation routes</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• Parental preference</td>
<td>• Computer hardware/software being outdated</td>
<td>• Health and safety legislation</td>
<td>• Using significant amount of toner and paper to produce printed information</td>
</tr>
</tbody>
</table>

Source, PESTLE analysis for schools and education, RAPIDbi
4.2 Understanding the needs and expectations of interested parties

The organization SHALL:
1. **Determine** the:
   a. Interested parties that are relevant to the QMS
   b. Requirements of these interested parties that are relevant to the QMS

2. **Monitor and review information** on these interested parties and their requirements
4.2 Understanding the needs and expectations of interested parties

Clause 4: Context of the Organization

- Interested party refers to **stakeholders**
- Relevant interested parties (RIPs) provide significant risk to organizational sustainability if their needs and expectations are not met.

**STAKEHOLDER**
- A person or an organization that can affect, be affected by, or perceive itself to be affected by a decision or activity.
Clause 4: Context of the Organization

4.2 Understanding the needs and expectations of interested parties

Identify, monitor and review information on relevant interested parties and their requirements
Interested Parties

The Organization

Top Management
Those accountable for QMS policy and its implementation

Those who implement and maintain the QMS

Those who maintain QMS and risk procedures

Other staff
Contractors

Citizens
Customers
Shareholders
Distributors
Investors
Owners
Insurers
Government
Regulators
Recovery Service Suppliers

Competitors
Media
Commentators
Trade Groups
Neighbors
Pressure Groups
Emergency Services
Other Response Agencies
Transport
Dependents of Staff
## SAMPLE OF RELEVANT INTERESTED PARTIES

<table>
<thead>
<tr>
<th>Relevant Interested Party</th>
<th>Type</th>
<th>Requirements</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td><strong>Needs</strong></td>
</tr>
</tbody>
</table>
| Staff                     | Internal | • Training and support  
                           |                           | • Safe working conditions |
| Contractors               | External | • Agreements  
                           |                           | • Payment terms          |
|                           |       | **Expectations**                                                             |
|                           |       | • Timely and fair provision                                                  |
|                           |       | • Adherence to agreements  
                           |                           | • Timey processing of     |
                           |       | payments                                                                     |
The QMS **SCOPE** defines the **boundaries and applicability** of the QMS taking into consideration:

- internal and external issues (the context of the organization),
- requirements of relevant interested parties, and,
- products and services.
4.3 Determining the scope of the QMS

1. Consider issues, requirements of interested parties, and products and services
2. Be maintained as documented information
3. State the type of products and services covered
4. Provide justification for any ISO 9001:2015 requirement that is claimed to be “not applicable” to the organization
Clause 4: Context of the Organization

4.3 Determining the scope of the QMS

- Determine the QMS scope and provide justification (if any) if a specific requirement of the ISO 9001 standard is not applicable.
- Maintain and ensure availability of documented information on these.

Based on:

- a. Mandate
- b. Products and Services
- c. Sites
- d. ISO 9001:2015 standard
4.3 Determining the scope of the QMS

- The organization SHALL apply all the requirements within the determined scope of its QMS.
- Conformity to the standard may only be claimed IF the requirements determined as not being applicable do not affect
  (a) the organization’s ability or responsibility to ensure conformity of its products and services and the
  (b) enhancement of customer satisfaction.
Clauses 4: Context of the Organization

4.3 Determining the scope of the QMS

Who are we?
ISO 9000:2015 defines “organization” as a “person or group or people that has its own functions with responsibilities, authorities and relationships to achieve its objectives”.

What do we do?
ISO 9000:2015 defines “output” as the “result of a process”.

Who are our customers?
ISO 9000:2015 defines “customer” as the “organization or person that could or does receive a product or a service that is intended for or required by this person/org”. The customer may be internal or external.

- Identify the nature of the organization and what parts of the organization are included in the management system being developed.
- Identify the type of QMS that needs to be implemented.
- Complete the description of the interrelationship between the “organization” and the “customer”.
4.4 QMS and its processes

4.4.1 The organization SHALL

...a quality management system, including the **PROCESSES** needed and their **interactions**
Clause 4: Context of the Organization

4.4 QMS and its processes

1. Determine the processes needed for the QMS and their application
2. Determine the inputs required and the outputs expected from these processes
3. Determine the sequence and interaction of these processes
4. Determine and apply criteria and methods, including monitoring, measurement, and related performance indicators to ensure effective operation and control of these processes
Clause 4: Context of the Organization

4.4 QMS and its processes

5. Determine the resources needed for these processes and ensure their availability

6. Assign the responsibilities and authorities for these processes

7. Address the determined risks and opportunities
Evaluate these processes and implement any changes needed to ensure that these processes achieve their intended results.

Improve the processes and the QMS.
4.4 QMS and its processes

4.4.2 To the extent necessary, the organization SHALL:

Example

- Maintain: Manuals, Process flowcharts, Instructions, Internal issuances, Blank forms
- Retain: Files, Reports, Filled-out checklists and forms

a. **Maintain** documented information to support the operation of its processes

b. **Retain** documented information to have confidence that the processes are being carried out as planned.
Clause 4: Context of the Organization

4.4 QMS and its processes

- Determine the processes (input-process-outputs-controls)
- Document the processes, as necessary

HOW TO ADDRESS

QMS PDCA MODEL
PROCESS MAP
PROCESS MATRIX
QMS Processes

- Organization and its context (4)
- Customer Requirements
- Needs and Expectations of Relevant Interested Parties (4)
- Customer Satisfaction
- Results of the QMS
- Products and Services

QMS PDCA Cycle

- Planning (6)
- Leadership (5)
- Improvement (10)
- Support (7)
- Operations (8)
- Performance Evaluation (9)
A process map shows process-related activities, including input/output, and cross-functional interfaces. The main goal of the map is to provide an overview of the relevant business processes.
## Categories of Processes:

<table>
<thead>
<tr>
<th>Management Processes</th>
<th>A process needed for oversight and governance of the agency to comply with the applicable legislation, policies, and Standards (e.g. Corporate Planning, Management Reviews, Internal Audits, etc.)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Core Processes</td>
<td>A process needed to achieve the overall mission and objectives of the agency</td>
</tr>
<tr>
<td>Categories of Processes:</td>
<td></td>
</tr>
<tr>
<td>--------------------------</td>
<td>--------------------------</td>
</tr>
<tr>
<td><strong>Operational Processes</strong></td>
<td>The operational part of the core process that allows the agency to provide goods and services that meet the needs and expectations of citizens.</td>
</tr>
<tr>
<td><strong>Support Processes</strong></td>
<td>A process needed to ensure the satisfactory performance of the core processes (e.g. human resource management, financial, material procurement, IT management, etc.)</td>
</tr>
</tbody>
</table>
MANAGEMENT PROCESS

- Strategic Planning
- Performance Review
- Manage Improvements

CORE PROCESS

- Admission and Enrolment
- Management of Learning (Curriculum Development, Outcomes-Based Teaching/Learning Process, Design, Implementation and Evaluation of Research and Extension Programs)
- Promotion and Conferment of Degrees

OUTSOURCED PROCESS

- Manage Human Resources
- Manage Supplies, Materials and Services
- Students’ Support Services
- Manage Information
- Manage Financial Resources

Food Services, Contractual Services
Repair of Equipment and Facilities, Construction Services, Communication Services
Module II: QMS Requirements
Clause 4: Context of the Organization