Workshop on QMS Documentation

Development of ISO 9001:2015 Quality Management System for the Department of Energy

May 28 – 31, 2018

DOE Bldg., Bonifacio Global City, Taguig City

Approved Quality Manual

1. Approved Quality Policy
2. Statement of QMS Scope including the Process Model/Map showing the processes, products and services covered by the QMS
3. Justification for ISO 9001 requirement(s) that is (are) not applicable to the scope of the QMS, if there is any
4. Description of the organizational context, e.g. PESTLE (Political, Economic, Social, Technological, Legal and Environmental), SWOT (Strength, Weakness, Opportunity and Threat) or other framework or tool to analyze and monitor internal and external issues that have impact in the organization
5. Description of relevant interested parties and their requirements
6. Description of the processes covered by the QMS, e.g. management, operational and support processes, including the responsibilities and basic controls applied to ensure effective operations
7. Description of type of control of external providers to ensure that externally provided processes, products and services meet requirements

Approved Quality Manual

8. Approved list of identified risks and opportunities with corresponding action plans
9. Approved list of identified relevant interested parties including their issues, and corresponding action plans to address the issues
10. Approved quality objectives of all offices/units, e.g. OPCR and DPCR, quality objectives and plans, balanced scorecards, and other documented performance targets demonstrating current Administration's directive to improve frontline or core processes' performance
11. List of internal and externally-generated references/ documents necessary for the effective planning and operations of the QMS, include the document title, document code, originator (source of document), effective date, and revision number, if applicable

Approved PAWIM

1. Standard Operating Procedures/Process Flow Charts
2. Tools, forms, templates, guidelines or procedures, for the following processes:
    a. Control of Documented Information
    b. Internal Audit for the QMS
    c. Control of Non-Conforming Outputs
    d. Nonconformity and Corrective Action
    e. Monitoring and Measurement of Client Satisfaction
    f. Management Review

Session Objectives

- Draft the process map
- Develop an in-depth understanding of the Agency's mission, vision, commitment to quality, and relevant issues that it may need to address through risk-based quality planning
- Identify risks and opportunities related to organizational context, i.e. internal and external issues, and issues of the relevant interested parties
- Formulate action plans to address risks and take advantage of opportunities
- Review the existing quality objectives

Target Outputs

1) Finalized Process Map
2) Finalized Quality Policy
3) Draft Risk Register and Action Plans

Workshop on Quality Manual and PAWIM

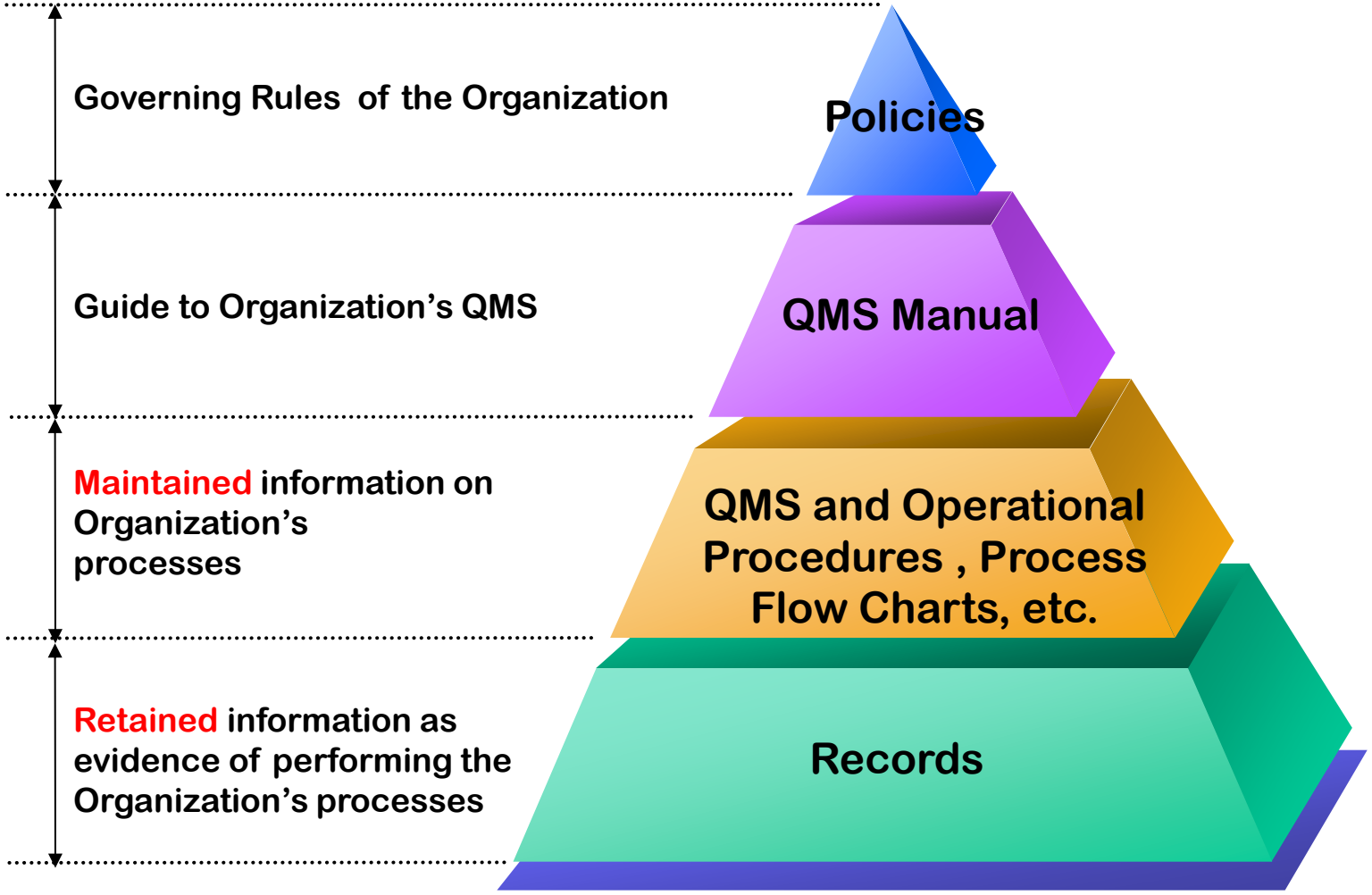
Session Objectives

- Formulate/Review the structure and controls for QMS information necessary for the effective implementation of QMS
- Develop an in-depth understanding of the information management approaches

Expected Outputs

- Draft QMS Manual
- Draft Procedures, Tools or Forms for the following
  - Control of Documents
  - Control of Records
  - Internal Audit
  - Control of NC outputs
  - Corrective action
  - Monitoring and measuring customer satisfaction
  - Management review

Typical QMS Document Structure



QMS Manual


Government Quality Management Program
Citizen-focused


dap


DEPARTMENT OF ENERGY
PHILIPPINES

Notes in Writing the QMS Manual

- No required **quality manual** in ISO 9001:2015, the 2008 version required it
- Documented information may be in any form, e.g. Memo, Office Order, etc.
- Most auditors still find it useful to have a QMS manual to systematically address the documented information required by the standard
- The form of documentation of the required information is decided by the organization based on existing documentation practices and suitability to the type of operations

Proposed Contents

Quality Manual

1. Approved Quality Policy
2. Statement of QMS Scope including the Process Model/Map showing the processes, products and services covered by the QMS
3. Justification for ISO 9001 requirement(s) that is (are) not applicable to the scope of the QMS, if there is any
4. Description of the organizational context, e.g. PESTLE (Political, Economic, Social, Technological, Legal and Environmental), SWOT (Strength, Weakness, Opportunity and Threat) or other framework or tool to analyze and monitor internal and external issues that have impact in the organization
5. Description of relevant interested parties and their requirements
6. Description of the processes covered by the QMS, e.g. management, operational and support processes, including the responsibilities and basic controls applied to ensure effective operations (Narrative Description or Flow Charts)
7. Description of type of control of external providers to ensure that externally provided processes, products and services meet requirements

Proposed Contents

Quality Manual

8. Approved list of identified risks and opportunities with corresponding action plans
9. Approved list of identified relevant interested parties including their issues, and corresponding action plans to address the issues
10. Approved quality objectives of all offices/units, e.g. OPCR and DPCR, quality objectives and plans, balanced scorecards, and other documented performance targets demonstrating current Administration's directive to improve frontline or core processes' performance
11. List of internal and externally-generated references/ documents necessary for the effective planning and operations of the QMS, include the document title, document code, originator (source of document), effective date, and revision number, if applicable (Reference Matrix)

Proposed Outline of QMS Manual

A. Introduction
B. History
C. Organizational Structure and Functional Descriptions
D. Scope of QMS: Process Map and the Narrative Description (Include justification for exclusion, if there is any)
E. List of Interested Parties' Requirements
F. Risk Identification and Planning Guidelines
G. Risk Registry
H. Quality Policy
I. Control of External Providers
J. QMS Reference Matrix

Annex: OPCRs/ DPCRs

Let's draft the QMS Manual…

Section	To Do	Assigned Team
A. Introduction	Give a short introduction on the content and purpose of the manual	
B. History	Provide a brief history of the agency; emphasize the significant milestones	
C. Organizational Structure and Functional Descriptions	Capture the updated approved org structure and provide narrative descriptions of the offices	
D. Scope of QMS: Process Map and the Narrative Description (Include justification for exclusion, if there is any)	Provide introductory statement for the process map; give a narrative description of the process map, and mention the responsible units and how they interact to be able to deliver the outputs of the agency and finalize the process map	
E. List of Interested Parties' Requirements	Provide introductory statement and review the list	

Use the template/matrix provided please.

Proposed Outline of QMS Manual

Section	To Do	Assigned Team
E. List of Interested Parties' Requirements	Provide introductory statement and review the list	
F. Risk Identification and Planning Guidelines	Provide introductory statement; mention the process of identifying risks and what are the stages of planning to address the risks; mention if risks are identified at various levels	
G. Risk Registry	Review and finalize	
H. Quality Policy	Review and finalize (as needed)	
I. Control of External Providers	Provide introductory statement; mention the applicable statutory and regulatory laws and the responsible units	
L. QMS Reference Matrix	Develop a reference matrix using the template for each office.	

Use the template/matrix provided please.

Let’s draft the other documented information…

Process	Sub Process(es)	References	Responsible Unit/s

Plenary Review of the Outputs

QMS Procedures, Guidelines and Tools

Proposed Contents

PAWIM

Tools, forms, templates, guidelines or procedures, for the following processes:

a. Control of Documented Information
b. Organizational Knowledge
c. Internal Audit for the QMS
d. Control of Non-Conforming Outputs
e. Nonconformity and Corrective Action
f. Monitoring and Measurement of Client Satisfaction
g. Management Review

What is Documented Information?

- Information required to be controlled and maintained by an organization and the medium on which it is contained
- Refers to documents and records

Document – information and the medium on which it is contained

- QMS Manual
- SOPs (Procedures and Work Instructions Manual / Operations Manual)
- Guidelines
- Plans
- Contracts

Record – special type of document stating results achieved or providing evidence of activities performed

- Reports
- Accomplished Forms

Control of Documented Information

- Appropriate identification and description
- Appropriate format and media
- Review and approval for suitability and adequacy
- Controlled to ensure availability and suitability for use where and when it is needed
- Adequately protected (e.g. from loss of confidentiality, improper use, or loss of integrity)

Documented Information

Address the following, as applicable:

- Distribution, access, retrieval and use
- Storage and preservation, including legibility
- Control of changes (e.g. version control)
- Retention and disposition
- Identification and controls for documented information of external origin
- Protection from unintended alterations

Tips in Writing Control of Documents Procedure

- Study the template provided
- Integrate in the template the existing practices
- Note that the procedure, , as well as to the forms and templates, only apply to the QMS documents
- Existing controls for policies, memo, office orders, and the like shall be maintained
- Identify responsibilities considering existing responsible units
- Only write implementable and practical activities

Tips in Writing Control of Records Procedure

- Study the template provided
- Integrate in the template the existing practices
- Note that the procedure applies the records management of all offices in CO, RSSOs and PSOs
- Identify responsibilities considering existing responsible units
- Only write implementable and practical activities

9.2 Internal Audit

9.2.1 The organization shall conduct internal audit at planned intervals to provide information on whether the quality management system:

a. conforms to:
   - The organization's own requirements for its QMS;
   - The requirements of this International Standard;

b. is effectively implemented and maintained.

9.2 Internal Audit

9.2.1 The organization shall conduct plan, establish, implement, and maintain an audit programme/s including the:

- Frequency
- Methods
- Responsibilities
- Planning requirements and reporting

9.2 Internal Audit

9.2.1 Factors to consider in Audit Programme

- Importance of the processes concerned
- Changes affecting the organization
- Results of previous audit
- Define the audit criteria and scope for each audit
- Select auditors and conduct audits
- Select auditors and conduct audits
- Ensure that the results of the audits are reported to the relevant management
- Take appropriate correction and corrective actions without undue delay.

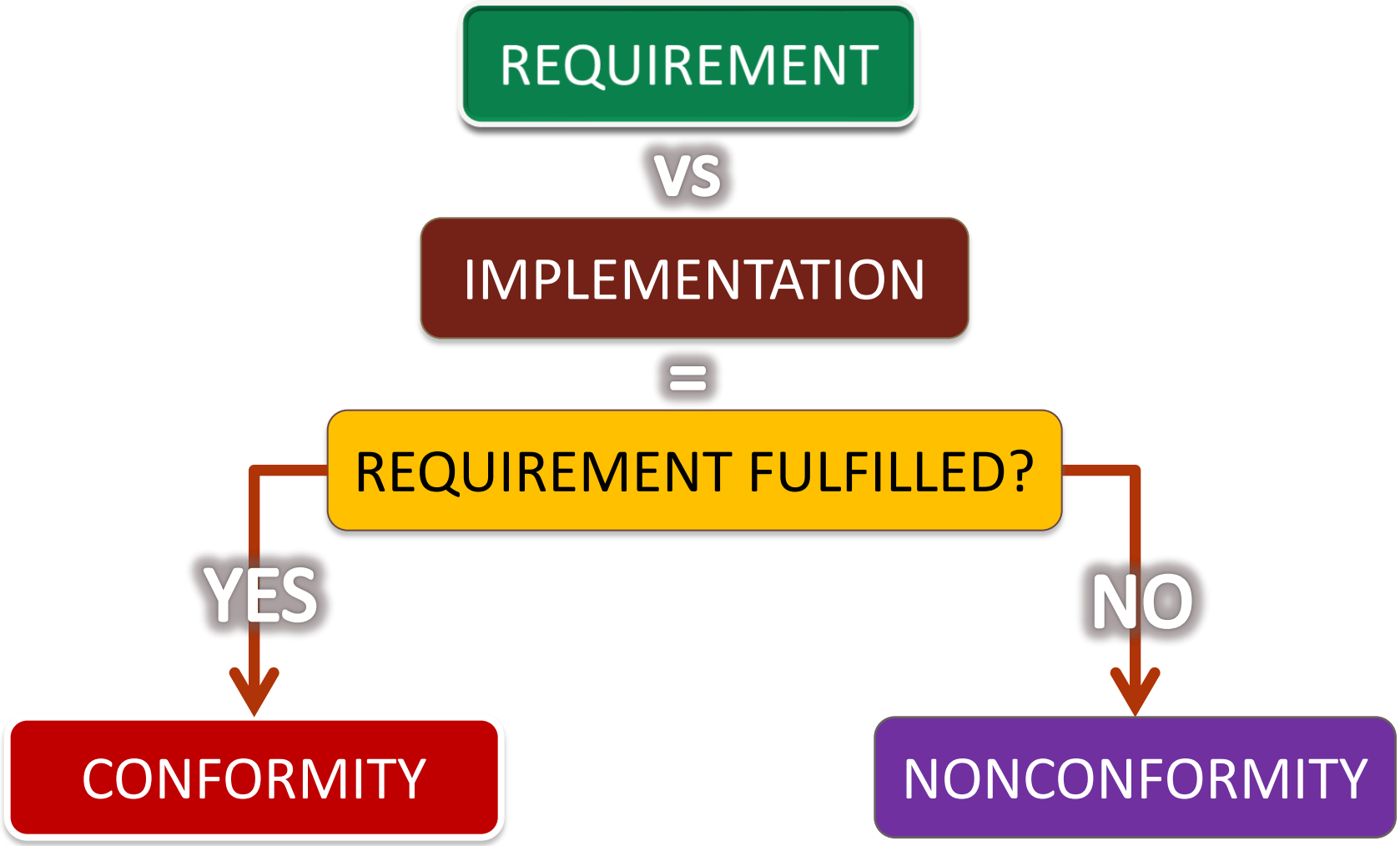
Tips in Writing Internal Quality Audit Procedure

- Study the template provided
- Integrate in the template the existing practices
- Identify responsibilities considering existing responsible units
- Indicate timelines for the submission of reports
- Only write implementable and practical activities

8.7 Control of Nonconforming Outputs

- Ensure that outputs that do not conform to requirements are identified and controlled to prevent unintended use or delivery
- Correct nonconforming outputs and subject to re-verification to demonstrate conformity
- Take action when nonconforming outputs are identified after delivery or use

Defining Nonconformity



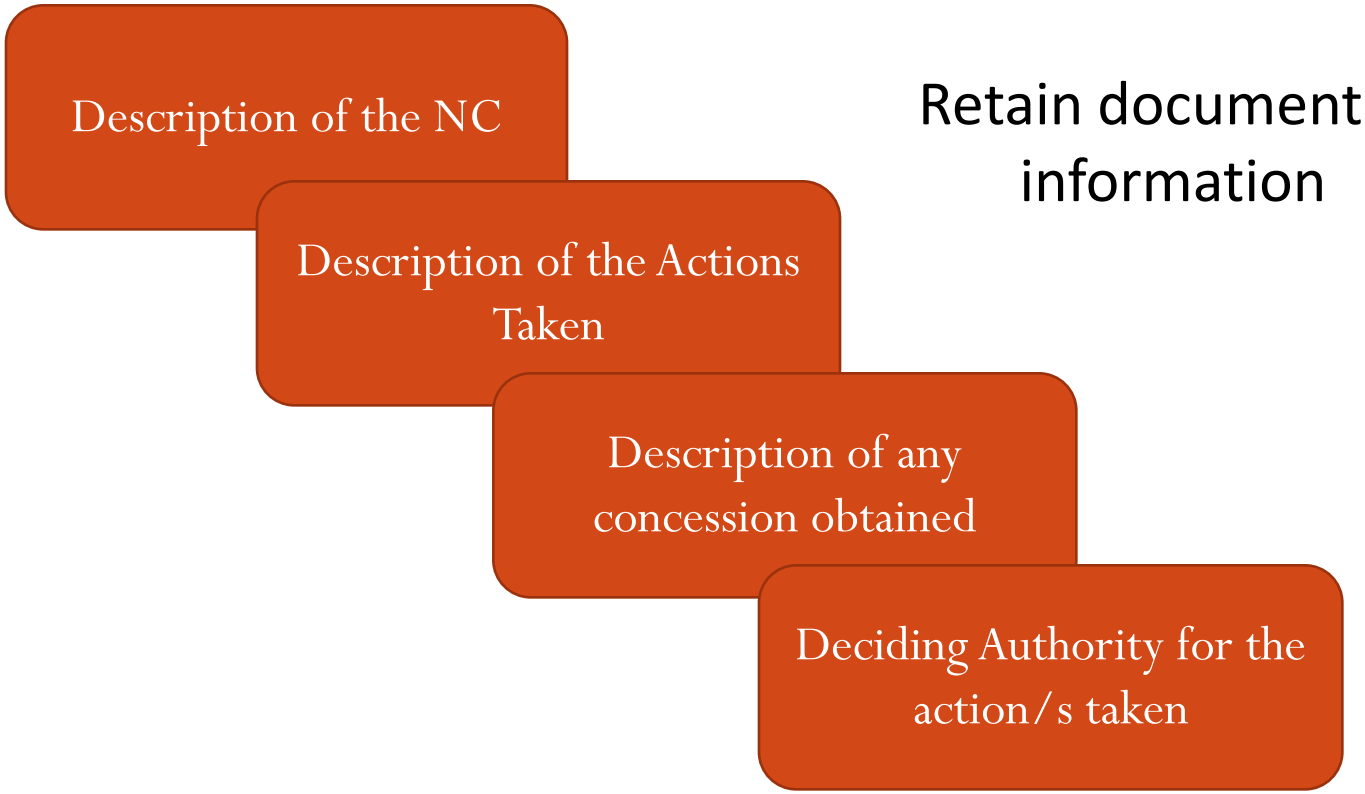
8.7 Control of Nonconforming Outputs

Deal with nonconforming outputs through any or combination of the following:

- Correction
- Segregation, containment, return, or suspension of provision
- Informing the customer
- Obtaining authorization for acceptance under concession

* Verify nonconforming outputs when corrected

8.7 Control of Nonconforming Outputs



Retain documented information

Concession *– Permission to use or release nonconforming outputs*

Tips in Writing Control of Non-Conforming Outputs Procedure

- Study the template provided
- Integrate in the template the existing practices
- Identify who will be responsible in monitoring this procedure
- Indicate timelines for the submission of reports
- Complete the Control of NC Matrix

10.2 Nonconformity and Corrective Action

When a nonconformity occurs, the organization shall:

a) react to the nonconformity, and as applicable

- take action to ***control and correct it, and***
- ***deal with the consequences;***

b) evaluate the need for action to eliminate the causes of the nonconformity, ***in order that it does not recur or occur elsewhere, by***

- reviewing the nonconformity
- ***determining the causes of the nonconformity, and***
- determining if similar nonconformities exist, or could potentially occur;

c) implement any action needed;

d) review the effectiveness of any corrective action taken; and

e) make changes to the quality management system, if necessary."

Tips in Writing Corrective Action Procedure

- Study the template provided
- Integrate in the template the existing practices
- Identify who will be responsible in monitoring this procedure
- Identify timelines for the submission of action plan

9.1.2 Customer Satisfaction

- Monitor information relating to customers' perception of the degree to which their needs and expectations have been fulfilled.
- Determine the methods for obtaining, monitoring, and reviewing the information.

9.1.2 Customer Satisfaction

This requirement can be demonstrated through the following examples:

Structured Approach:

- Training/program evaluation
- Project /program evaluation
- Client satisfaction/dissatisfaction survey
- Project deliverable acceptance

Unstructured Approach:

- Regular meetings (briefings/debriefings/ assessment) with clients
- Website feedback tab/window
- Suggestion box
- Focus Group Discussions (FGD)

Tips in Writing Guidelines for Monitoring and Measuring Customer Satisfaction

- There is no template provided
- Make an inventory of the existing practice of monitoring and measuring customer satisfaction in CO, RSSOs and PSOs
- Review the existing tools
- Do you need to develop more feedback or customer satisfaction tool? What are these?
- Develop a guideline (maybe specific to each tool) to systematically gather data and link to Corrective Action Procedure
- Establish responsibilities (in CO, RSSOs and PSOs) and frequency of reporting and analysis

9.3.1 Management Review

Top management shall review the organization's QMS, at planned intervals, to ensure its continuing suitability, adequacy, effectiveness, and alignment with the strategic directions of the organization.

9.3 Management Review

9.3.2 Inputs

a. Status of actions from previous Management Reviews
b. Changes in QMS-relevant internal and external issues
c. Information on the performance and effectiveness of the QMS (next slide)
d. Adequacy of resources
e. Effectiveness of actions taken to address risks and opportunities
f. Opportunities for improvement

9.3 Management Review

Information on the performance and effectiveness of the QMS

- Customer satisfaction and feedback from stakeholders
- Quality objectives attainment
- Process performance and conformity of products & services
- Nonconformities and corrective actions
- Monitoring and measurement results
- Audit results
- Performance of external providers

9.3 Management Review

9.3.3 Outputs

The outputs of the management review shall include decisions and actions related to:

- Opportunities for improvement
- Any need for changes in the QMS
- Resource needs

9.3 Management Review

9.3.3 Outputs

The organization shall retain documented information as evidence of the results of management reviews.

Examples of Documented Information
- Minutes of Meeting (MOM)
- Action Plan
- Resolutions

Tips in Writing Guidelines for Management Review

- There is no template provided
- Consider existing practices in conducting Management Meetings
- Review the existing tools
- Are there practices that need improvement? What are these?
- Develop a guideline to systematically conduct and record management reviews
- Establish responsibilities and frequency of meeting
- Ensure that MR inputs indicated in the ISO 9001 requirement are part of the agenda

Let’s draft the documents…

Document	Assigned Team
Control of Documents	
Control of Records	
Organizational Knowledge	
Internal Audit for the QMS	
Control of Non-Conforming Outputs	
Nonconformity and Corrective Action	
Monitoring and Measurement of Client Satisfaction	
Management Review	

Use the template/matrix provided please.

Plenary Review of the Outputs