# Workshop on the Enhancement of Quality Management System Documentation and QMS Implementation Planning

GQMP 2021:

Expansion of the ISO 9001:2015-Certified Quality Management System

**Department of Environment and Natural Resources**

July 28-30, 2021

# Objective of the Workshop

- To enhance awareness and acquire deeper understanding on the relevant QMS documented information of the various functions and offices that will be covered by the expansion of DENR's ISO 9001:2015 scope of certification.
- To review the existing QMS documented information that will be adopted by the process owners of the expanded scope of certification and identify areas for enhancement to ensure effective implementation of the QMS.
- Review the status of the previously assigned documented information (e.g. revision of the QMS Scope,, Risks/Opportunities Analysis and Actions Planning, etc.)

# Workshop Outline

**Day 1**

- Intention and Requirements on QMS Documentation
- Maintained Documented Information VS Retained Documented Information
- DENR's Quality Manual
- WORK 1: Review of the QMS Scope in the Quality Manual
- Discussion on DENR's Procedure
  - Section 1 – Purpose
  - Section 2 – Expected Outputs
  - Section 3 – Process Scope
  - Section 4 – Definition of Terms
  - Section 5 – Responsibilities
  - Section 6 – Process Inputs
  - Section 7 – Process Steps
- WORK 2: Integrate the Actions in ROAAP into the Process Steps

# Workshop Outline

**Day 2**

- Discussion on DENR's Procedure
  - Section 8 – Control of Nonconforming Outputs
- WORK 3: Describe the Controls on Nonconforming Outputs
  - Section 9 – Interface
  - Section 10 – Revision History
- Control of Documented Information
  - Procedure on Control of Documents
  - Procedure on Control of Records
- Nonconformity and Corrective Action
  - Requirements of ISO 9001:2015
  - Corrective Action Procedure
  - Documenting Nonconformities
  - Causes and Risks

# Workshop Outline

**Day 3**

- Internal Audit
  - Requirements of ISO 9001:2015
  - Internal Audit Procedure
  - Assignment: Correlation Between Processes and Clauses
  - Comments on Existing Audit Findings Reports
- Organizational Knowledge
- Customer Satisfaction
- Management Review

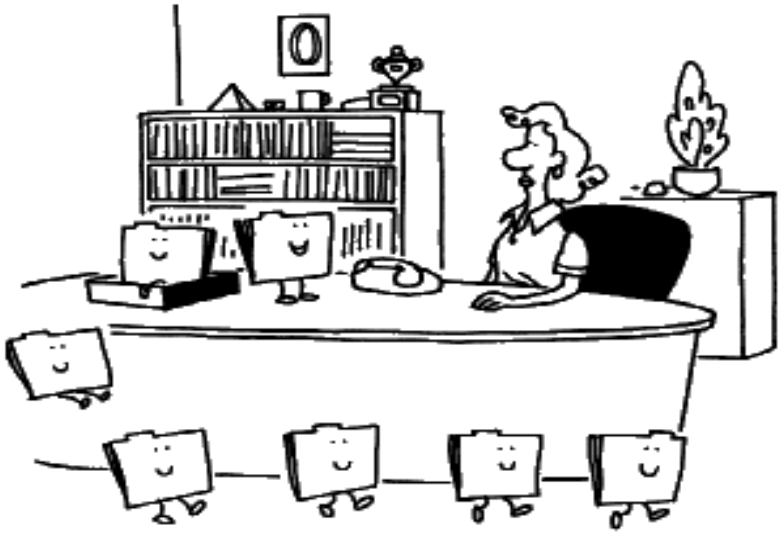
# Intent of ISO 9001

It is stressed that ISO 9001 requires (and always has required) a

*"Documented quality management system,"*

*and not a "system of documents."*

- ISO/TC 176/SC2/N1286



"Thank goodness! It's about time that they realize you don't need instructions on how to use telephones."

# How much documentation do we need?

- The type and extent of the documented information will depend on:
  - the size of the organization and type of activities, processes, products and services;
  - the complexity of processes and their interactions;
  - the competence of personnel; and
  - the need to demonstrate fulfilment of legal and other requirements

Analysis of the processes should be the driving force for defining the amount of documented information needed for the quality management system, taking into account the requirements of ISO 9001:2015. It should not be the documented information that drives the processes.

# Objectives of Documentation

- Communication of information
- Knowledge sharing and utilization
- Evidence of conformity


"Do people read these?"

ISO 9001 Clause 4.4.2; 7.1.6; 7.4; 7.5.1

# Definition of Document

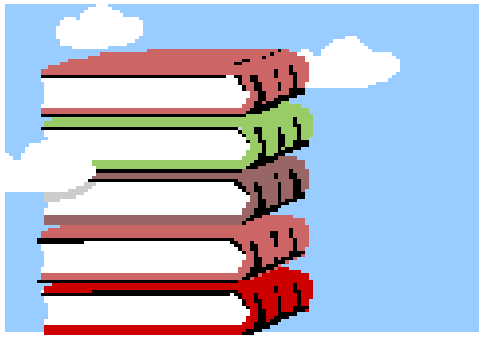
- ***information** and the medium on which it is contained*

**Information** – meaningful data

**Documented Information** – information required to be controlled and maintained by an organization and the medium on which it is contained.

Documents may be in any form or type of medium:

- ✓ Paper
- ✓ Magnetic
- ✓ Electronic
- ✓ Photograph
- ✓ Video
- ✓ Master sample



# General Requirements for Documented Information

- The organization's quality management system shall include:

a) documented information required by this International Standard;

**Mandatory by ISO 9001**

b) documented information determined by the organization as being necessary for the effectiveness of the quality management system.

**As necessary by DENR**

ISO 9001 Clause 7.5.1

# Documented Information for the QMS and its processes

- To the extent necessary, the organization shall:

  **a)** **<u>maintain</u>** documented information to support the operation of its processes;

  **b)** **<u>retain</u>** documented information to have confidence that the processes are being carried out as planned.

ISO 9001 Clause 4.4.2

# “Maintain” VS “Retain”

| MAINTAIN | RETAIN |
|---|---|
| Maintain – *enable to continue (ISO 9000 Glossary)* | Retain – *keep (ISO 9001 Glossary)* |
| Documented information that will need to be reviewed periodically and be revised to kept up to date. | Documented information that will need to be protected from alterations (unless a correction is authorized) to demonstrate conformity and to demonstrate activities are carried out as planned. |
| Examples: documented procedures, manuals, policies, objectives, standards, implementing rules and regulations, department/office orders, circulars, work instructions, drawings, production schedules, forms | Examples: records, reports, minutes of the meeting, inspection and audit reports, appraisal results, report cards, training certificates, calibration certificates, document registers, accomplishment reports, logbooks |
| For audit purpose, these documented information serve as the *audit criteria*. | For audit purpose, these documented information serve as the *audit evidences*. |

# Required by ISO 9001 to be Maintained

- The scope of the quality management system (clause 4.3).
- The quality policy (clause 5.2).
- The quality objectives (clause 6.2).

# Documented Information to be Maintained As Necessary

- Organization charts
- Process maps, process flow charts and/or process descriptions
- Procedures
- Work and/or test instructions
- Specifications
- Documents containing internal communications
- Production schedules
- Approved supplier lists
- Test and inspection plans
- Quality plans
- Quality manuals
- Strategic plans
- Forms

*These are just examples. There can be other documented information that an organization may need to establish.*

# Required by ISO 9001 to be Retained

| REQUIREMENTS OF ISO 9001 | EXAMPLES |
|---|---|
| Evidence of fitness for purpose of monitoring and measuring resources (7.1.5.1). | DRARs of evaluation/appraisal forms, calibration records |
| Evidence of the basis used for calibration of the monitoring and measurement resources (when no international or national standards exist) (7.1.5.2). | Traceability records, measurement system analysis records, design of experiments (DOE) records |
| Evidence of competence of person(s) doing work under the control of the organization that affects the performance and effectiveness of the QMS (7.2). | Records of achieving intended results (output of the process, MFO, targets), test and examination results |
| Results of the review and any new requirements for the products and services (8.2.3). | Approval of applications, contract review records, approval of revised procedures/rules |
| Records needed to demonstrate that design and development requirements have been met (8.3.2) | Approval of project/program proposals |
| Records on design and development inputs (8.3.3). | Records of consultation with stakeholders |
| Records of the activities of design and development controls (8.3.4). | User acceptability test results |

# Required by ISO 9001 to be Retained

| REQUIREMENTS OF ISO 9001 | EXAMPLES |
|---|---|
| Records of design and development outputs (clause 8.3.5). | Project/program proposals, project concept, draft policies |
| Design and development changes, including the results of the review and the authorization of the changes and necessary actions (clause 8.3.6). | Approval of revisions on project proposals, project concept or draft policies |
| Records of the evaluation, selection, monitoring of performance and re-evaluation of external providers and any and actions arising from these activities (clause 8.4.1) | BAC evaluation records, evidence of compliance to Section 9e and Appendix 23, section 5.5 of IRR of RA 9184 |
| Evidence of the unique identification of the outputs when traceability is a requirement (clause 8.5.2). | eDATS, LAMS, Online application systems |
| Records of property of the customer or external provider that is lost, damaged or otherwise found to be unsuitable for use and of its communication to the owner (clause 8.5.3). | Notice to applicants or permitees |
| Results of the review of changes for production or service provision, the persons authorizing the change, and necessary actions taken (clause 8.5.6). | Approval of revisions on service delivery, notices on change of policy |

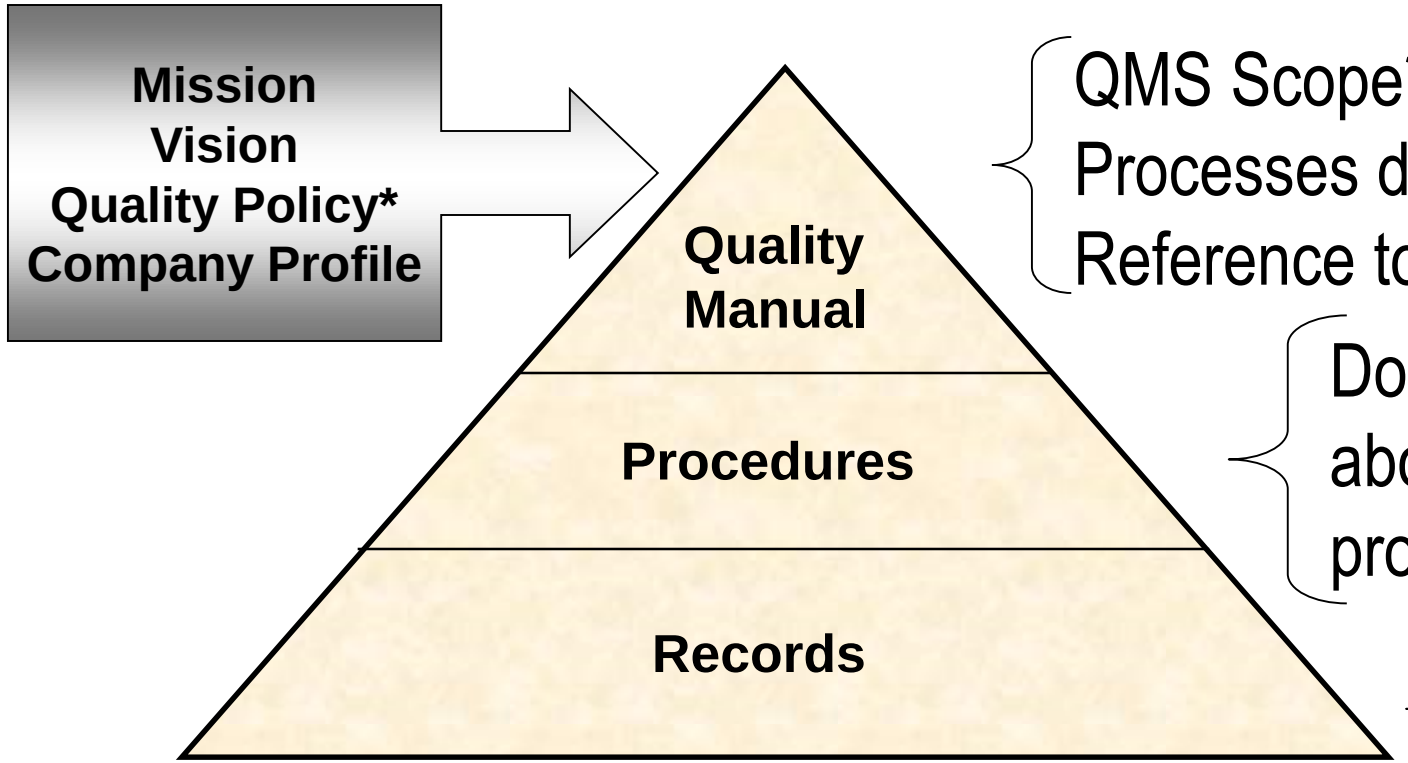
# Required by ISO 9001 to be Retained

| REQUIREMENTS OF ISO 9001 | EXAMPLES |
|---|---|
| Records of the authorized release of products and services for delivery to the customer including acceptance criteria and traceability to the authorizing person(s) (clause 8.6). | Checking of completeness of documents, review and approval of permits |
| Records of nonconformities, the actions taken, concessions obtained and the identification of the authority deciding the action in respect of the nonconformity (clause 8.7). | Nonconformity Log Book, Corrective Action Request (CAR) |
| Results of the evaluation of the performance and the effectiveness of the QMS (clause 9.1.1) | Evaluation of the OPCRs, audit reports |
| Evidence of the implementation of the audit programme and the audit results (clause 9.2.2). | Audit reports, CAR, minutes of the Management Review |
| Evidence of the results of management reviews (clause 9.3.3). | Action plans for improvement, monitoring of action plans |
| Evidence of the nature of the nonconformities and any subsequent actions taken (clause 10.2.2). | CAR, minutes of the Management Review |
| Results of any corrective action (clause 10.2.2). | CAR, minutes of the Management Review |

# ISO 9001 Clauses with Documented Information

| | Mandatory (7.5.1a) | As Necessary (7.5.1b) |
|---|---|---|
| **Maintain (4.4.2a)** | 4.3; 5.2.2a; 6.2.1 | 4.4.2a; 8.1e1; 8.1e2 |
| **Retain (4.4.2b)** | 7.1.5.1; 7.1.5.2a; 7.2d; 8.3.3; 8.3.4f; 8.3.5; 8.3.6a; 8.3.6b; 8.3.6c; 8.3.6d; 8.4.1; 8.5.2; 8.5.3; 8.5.6; 8.6a; 8.6b; 8.7.2a; 8.7.2b; 8.7.2c; 8.7.2d; 9.1.1; 9.2.2f; 9.3.3; 10.2.2a; 10.2.2b | 4.4.2b; 8.1e1; 8.1e2; 8.2.3.2a; 8.2.3.2b |

# Typical QMS Documentation Structure




QMS Scope*
Processes descriptions and interactions
Reference to procedures

Documents that provide information about how to perform activities and processes consistently

Documents stating results achieved or providing evidence of activities performed

**maintain**

**retain**

* *ISO 9001:2015 mandatory documented information*

ISO 9001 Clause 4.4.2

# ISO 9001:2008 Requirements for a Quality Manual

**4.2.2 Quality manual**

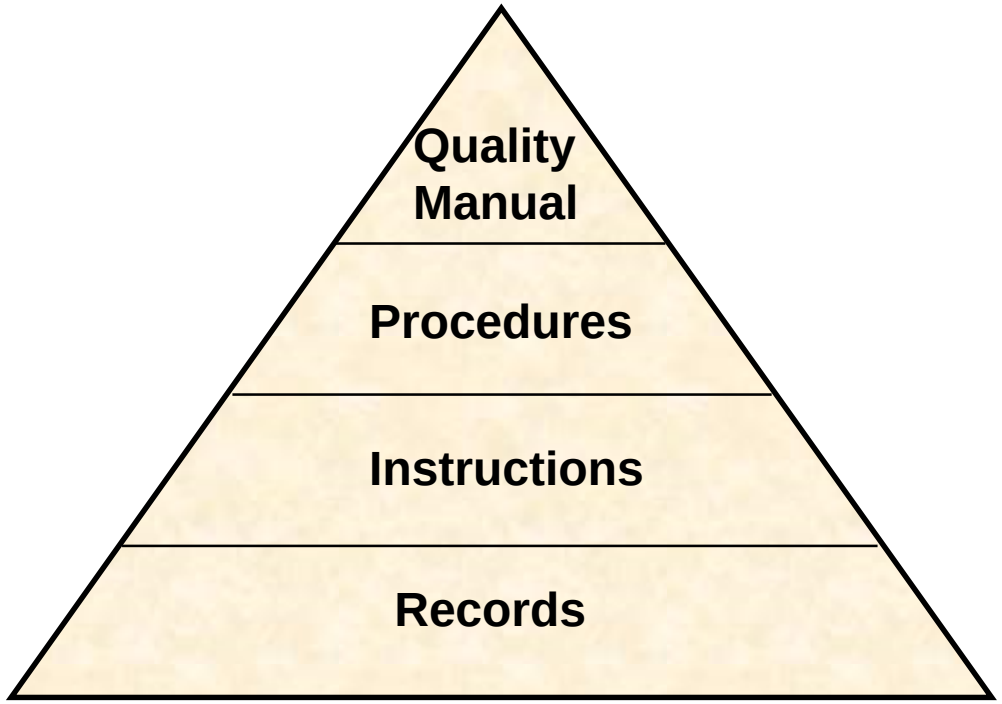
The organization shall establish and maintain a quality manual that includes

a) the scope of the quality management system, including details of and justification for any exclusions (see 1.2),

b) the documented procedures established for the quality management system, or reference to them, and

c) a description of the interaction between the processes of the quality management system

# What should be documented first?




The ***Quality Manual*** should be completed once the ***Procedures*** are already established and documented.

# Quality Manual documentation checklist

| ITEMS TO CHECK | YES | NO | REMARKS |
|---|---|---|---|
| 1. Does the QM include the QMS Scope? | | | |
| 2. Does the QMS Scope conform to the requirements of clause 4.3? | | | |
| 3. Does it include justification to clauses that are not applicable? | | | |
| 4. Does it include a description of the interaction of the QMS processes? | | | |
| 5. Does it include the documented procedures or reference to them? | | | |

# Outline of DENR's Quality Manual

I. Introduction (Purpose, Revision)
II. Terms and Definition
III. DENR Profile (Organizational Structure, Mandate, Vision, Mission, Quality Policy, SPMS)
IV. Scope of the DENR Quality Management System (Scope and Exclusion, Process Map, Processes, Products and Services)
V. Management Processes
    I. Strategic and Operational Planning
    II. Policy Issuance and Standards Development
    III. Improvement and Operational Development
    IV. Performance Evaluation

ISO 9001 Clause 4.4.2

# Outline of DENR's Quality Manual

VI. Core Processes
   I. ENR Conservation and Development
   II. ENR Regulation and Permitting
   III. ENR Law Enforcement and Monitoring

VII. Support Processes
   I. Financial Management
   II. Human Resource Management
   III. Knowledge and Information Systems Management
   IV. Procurement, Supply and Property Management
   V. General Services
   VI. Documented Information Management
   VII. Legal Support
   VIII. Issue Management
   IX. Information, Education and Communication

The processes have narrative descriptions that highlights the:

- Purpose of the process/sub-processes
- Major activities
- Process owners and key responsibilities
- References

ISO 9001 Clause 4.4.2

# WORK1: Review of the QMS Scope in the Quality Manual

- As indicated in the Project Inventory, the assigned function/s will need to present the final versions of the:
  - DENR's QMS Scope Statement

# Procedures

*"Specified way to carry out an activity or a process."*

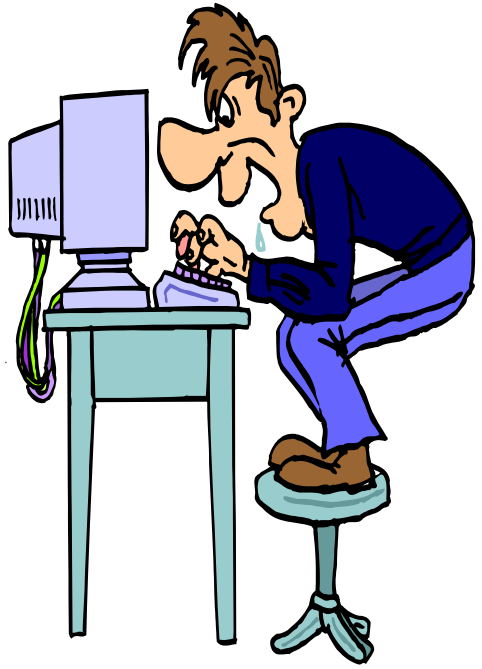
Note: Procedures can be documented or not

*Process - set of interrelated or interacting activities that use inputs to deliver an intended result*

- Procedures can be in any appropriate media.
- There is no set format.
- Format should be chosen to meet the needs of the user.
- Typical formats may include:
  - Narrative
  - Flow diagrams
  - Illustrations
  - A combination of these

ISO 9001 Clause 4.4.2

# Who will write the Procedures?



- Each process owner must be responsible for writing their procedures
- Heads of offices (i.e. Designated QMR) must approve all procedures under their areas of responsibility

# Developing Procedures

- Establish the process purpose and the expected outputs i.e. what is the process trying to achieve (planned results)
- Clarify the scope of the process to be documented
- Clarify the terminologies employed within the process
- Indicate the inputs necessary for the process
- Define the key activities in the process and their sequence (planned activities)
- Identify who does what
- Identify the key documented information with each activity
- Define the controls when outputs don't come out as planned
- Identify relevant references

ISO 9001 Clause 4.4.2

# Sections of DENR's Documented Procedures

1. Purpose – *to establish the intention of specifying the controls for the process and the desired outputs of the process*
2. Expected Outputs – *to establish the planned results or desired outcomes of the process*
3. Scope – *to define the applicability and the major activities of the process*
4. Definition of Terms – *to clarify terminologies making the procedure user friendly*
5. Responsibilities – *to define roles, authorities, accountabilities*
6. Process Inputs – *to define the needed resources, information, materials for the process*
7. Process Steps – *to describe the sequence of activities, the criteria, methods and controls within each activity*
8. Control of Nonconforming Outputs – *to establish controls when outputs do not conform with the requirements*
9. Interfaces – *to establish interaction with other documented information*
10. Revision History – *to determine changes made on the procedure*

Sample Procedure

ISO 9001 Clause 4.4.2

# Define the Purpose (Section 1)

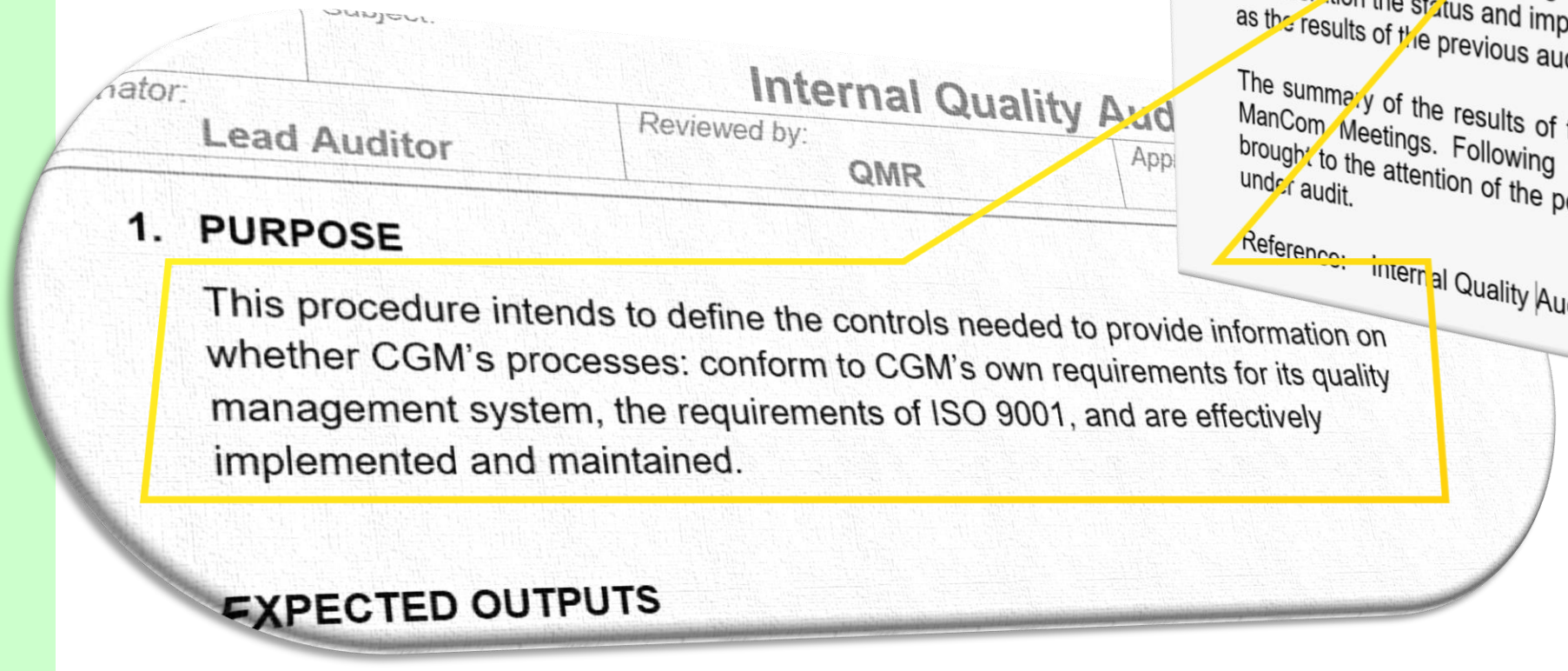
- In defining the Purpose statement, the following should be considered:
  - Describe the intention for defining the controls needed for the process;
  - It answers “Why do we need to define the controls?”
  - It should be compatible with the narrative description of the QMS processes in the Quality Manual;
  - It sets the framework for establishing the expected outputs of the procedure;
- For Example: the procedure for “Control of Documents” can have a Purpose statement like:

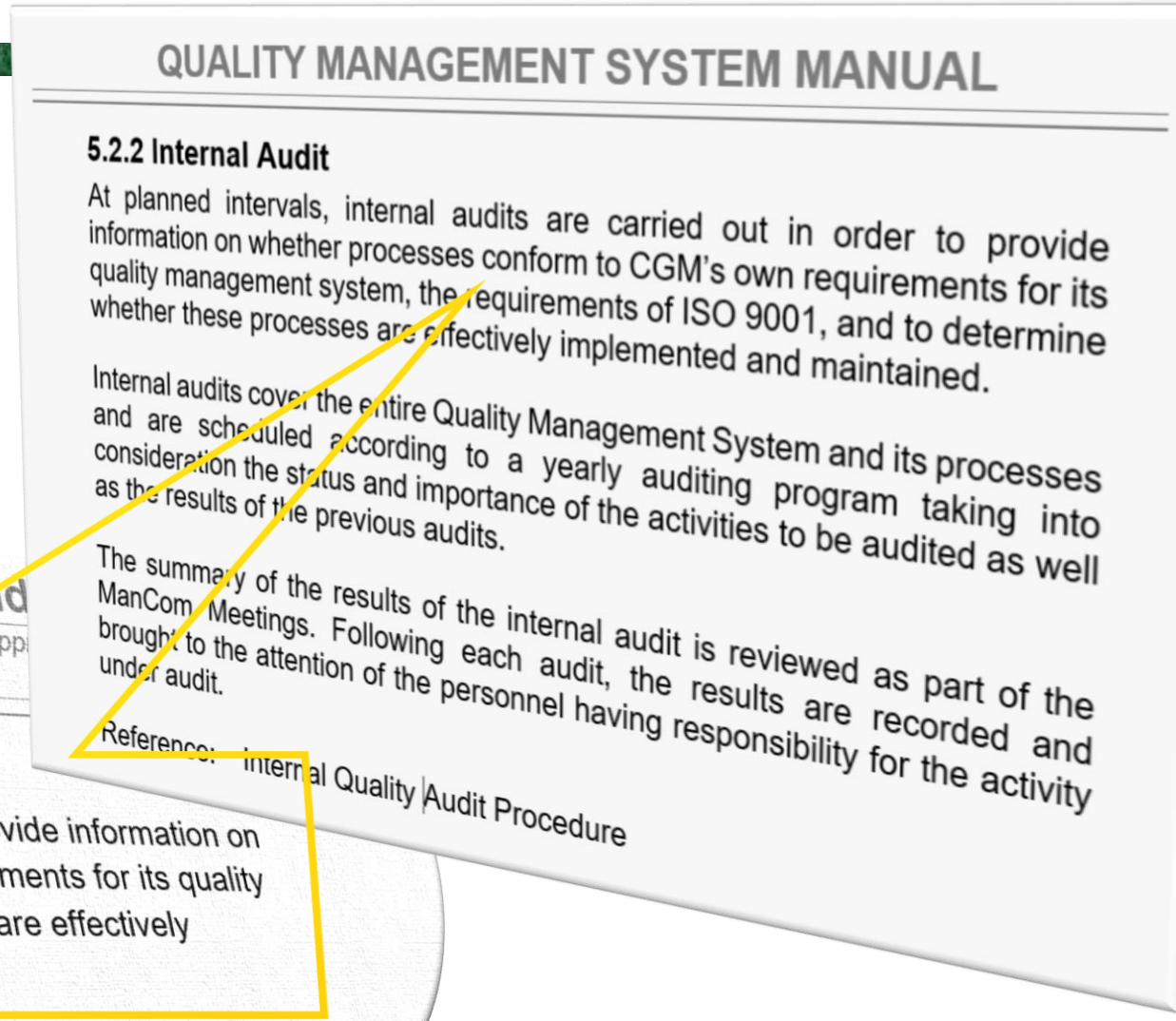
> 1. *Purpose:*
>
>    *This procedure intends to define the **controls** needed to ensure that documents necessary for effective operation of DENR’s processes are available and suitable for use, where and when it is needed.*

ISO 9001 Clause 4.4.2

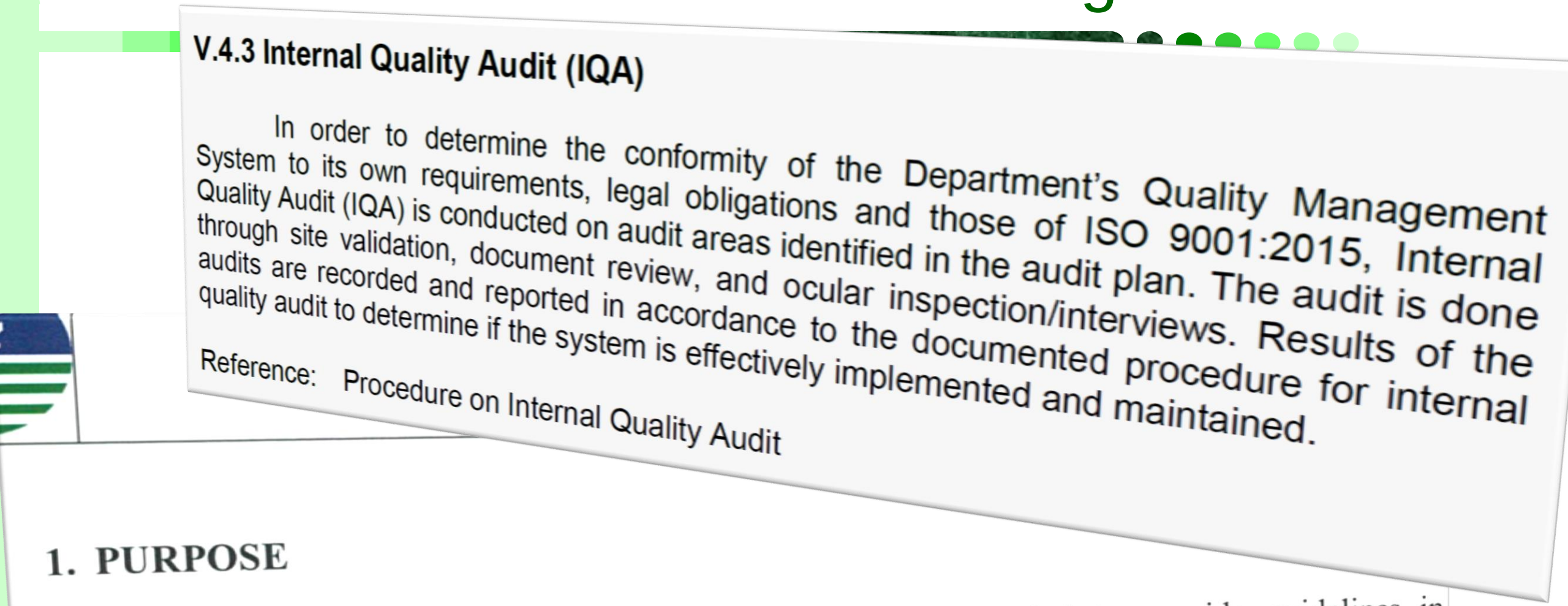
# Compatibility with the Quality Manual

- Sample from another organization



# DENR Manual and Procedure Alignment



**V.4.3 Internal Quality Audit (IQA)**

In order to determine the conformity of the Department's Quality Management System to its own requirements, legal obligations and those of ISO 9001:2015, Internal Quality Audit (IQA) is conducted on audit areas identified in the audit plan. The audit is done through site validation, document review, and ocular inspection/interviews. Results of the audits are recorded and reported in accordance to the documented procedure for internal quality audit to determine if the system is effectively implemented and maintained.

Reference: Procedure on Internal Quality Audit

**1. PURPOSE**

This procedure intends to define the controls needed to provide guidelines in undertaking internal quality audit of all processes of the DENR on the basis of independent and objective evaluation on the effectiveness of internal controls.

# Establish the Expected Outputs (Section 2)

- In describing the Expected Outputs, the following should be considered:
  - Definition of Output as the “result of a process”;
  - Intention of ISO 9001:2015 clause 4.4.1a;
  - Intention of ISO 9001:2015 clause 8.5.1a.2;
  - Identify Expected Outputs in the perspective of the “Receiver of the Outputs”;
  - Outputs satisfy the needs and expectations of interested parties;
  - Consistency with the Planned Results column of the Risks/Opportunities Assessment and Actions Planning form (i.e. Expected Output, MFO, Objective);
  - Alignment with the Office Performance and Commitment Review MFOs and Success Indicators.

# Clauses Relevant to Expected Outputs

- ISO 9001:2015 Clause 4.4.1a

  *"The organization shall determine the processes needed for the quality management system and their application throughout the organization, and shall: determine the inputs required and the outputs expected from these processes"*

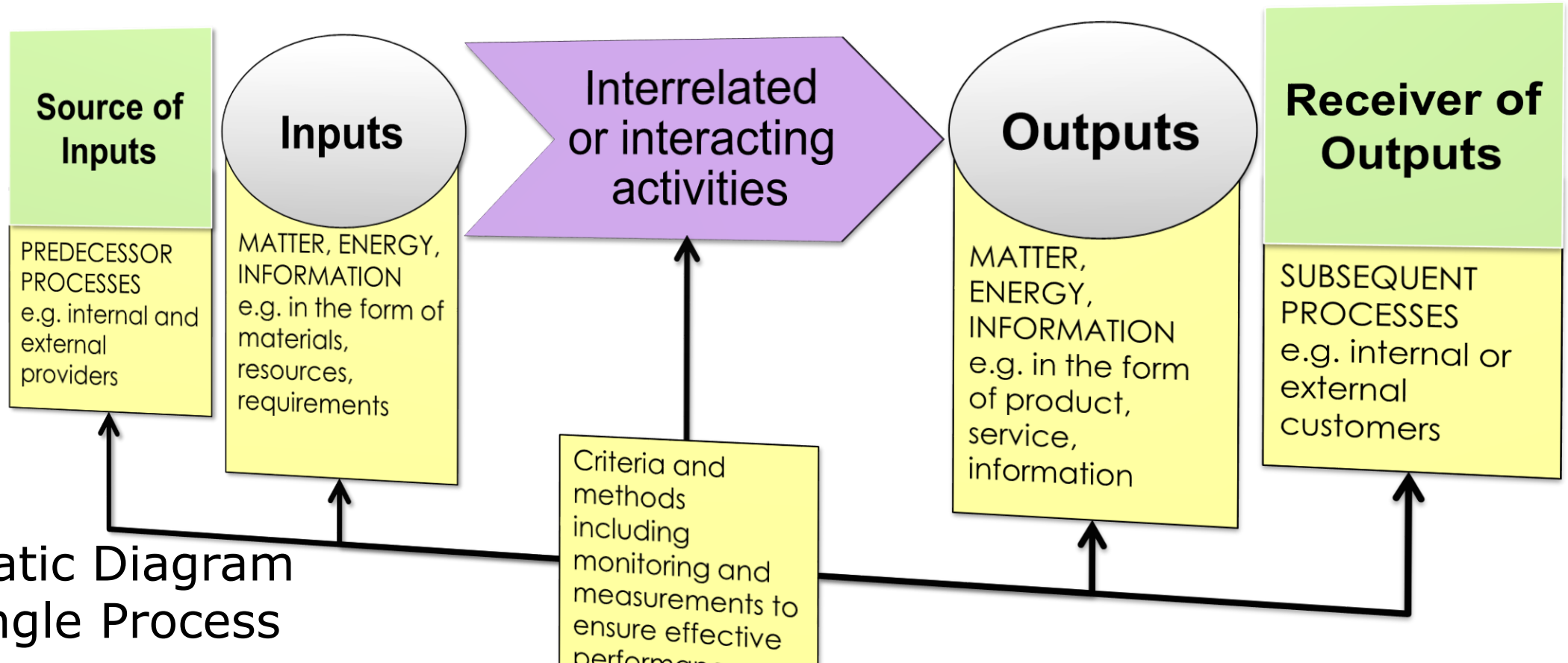
- ISO 9001:2015 Clause 8.5.1a.2

  *"The organization shall implement production and service provision under controlled conditions. Controlled conditions shall include, as applicable: the availability of documented information that defines: the results to be achieved"*

# Expectations of the Receiver of the Outputs

"Expected outputs should be considered from the viewpoint of what is expected either by the customers or the subsequent processes"

*- 4.4.1a of ISO/TS 9002:2016*




Schematic Diagram of a Single Process

# Who are the Receiver of the Outputs?

| **CUSTOMER – person or organization that could or does receive a product or a service that is intended for or required by this person or organization.** | **INTERESTED PARTY – stakeholder – person or organization that can affect, be affected by, or perceived itself to be affected by a decision or activity.** |
|---|---|
| Examples: consumer, client, end-user, retailer, receiver of product or service from an internal process, beneficiary and purchaser.<br><br>Note: A customer can be internal or external to the organization | Examples: customer, owners, people in an organization, providers, bankers, regulators, unions, partners or society that can include competitors or opposing pressure groups. |

# Test the Understanding of the Expectations of the Receiver of the Outputs

| PROCESS | EXPECTED OUTPUTS | CORRECT/INCORRECT |
|---|---|---|
| Pizza Delivery | On-time delivery of freshly baked pizza | Correct |
| | Well maintained delivery vehicle | Incorrect |
| Procurement | Thorough inspection of goods prior to acceptance | Incorrect |
| | Goods endorsed to end-users are within specifications | Correct |
| Permit Issuance | Error-free permits released to the applicant | Correct |
| | Verification of documents submitted by the applicants | Incorrect |
| Internal Audit | Timely submission of Audit Reports | Correct |
| | Accurate audit findings | Correct |

# ROAAP Alignment with Procedures

**RISKS/OPPORTUNITIES ASSESSMENT & ACTIONS PLANNING**

**Process:** Infrastructure Management

**Process Owner:** General Services Office

**Interested Parties – Needs & Expectations:**

- Employees – equipment and utilities are always in good condition;
- Customer – conducive environment where transactions take place;
- Employees – repairs are done timely and reliably

**(±) Internal & External Issues:**

- (-) Most equipment, utilities and vehicles are old models
- (-) Procurement main criteria is price of commodity
- (+) GSO personnel have general knowledge/skills in equipment maintenance
- (+) With existing service contract with equipment suppliers

| Assessment | | | | | | | Action Plan | | | Re-Assessment | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Planned Results (Expected Output, MFO, Objective) | Risks that can adversely affect the planned results | Severity | Likelihood | Opportunities that can beneficially affect the planned results | Existing Controls | RPN | Recommended Action/Treatment | Responsible | Target Date | Action Taken Date Completed | Severity | Likelihood | RPN |
| Equipment are always in good condition | Improper use of equipment by end-users | 2 | 4 | Create own guidelines. | Regulatory requirement on the proper use of government property | 8 (M) | Document specific instructions on the proper use of equipment. | Engr. Juan dela Cruz | Dec. 18, 2018 | Instructions for the proper use of aircon units, photocopier, water dispensers, training room were issued, Dec. 12, 2018 | 2 | 3 | 6 (M) |

ORGANIZATION OF THE COMPANY | Rev.: 0 | Issue Date: September xx, 20

Subject: **Infrastructure Management Procedure**

Originator: General Services Department | Reviewed by: Alfredo Victoria Jr. | Approved by: Mayor

## 1. PURPOSE

This procedure intends to define the controls needed to Infrastructure Management's major function is to outline all the tasks and resources required to efficiently manage and maintain all City Owned Buildings, Structures, Facilities and Vehicles which provides a detailed overview of the ongoing management of the all City Infrastructures.

## 2. EXPECTED OUTPUTS

By implementing the controls defined in this procedure, the following specific outputs are expected:

2.1. Equipment are always in good condition.
2.2. Maintained facility of all City Department and Agencies operational;
2.3. Keep all Materials and Equipment working and functional;
2.4. Maintained the Cleanliness inside the Mandaluyong City Hall Complex;

## 3. SCOPE

The controls specified in this procedure apply to all City Departments and Agencies.

This procedure covers the activities from maintaining Building, Infrastructure, Facilities, Equipment and Materials of the City of Mandaluyong operational. Preparation and Submission of RCPPE and Insuring all City-Owned Properties, Buildings, Structures, Facilities and Vehicles.

## 4. DEFINITION

| | |
|---|---|
| Facilities | Place, amenity, or piece of equipment provided for a particular purpose |
| Repair and Maintenance | This involves functional check, repairing, replacing and/or servicing necessary parts of offices, buildings, Infrastructures (Including Carpentry, Masonry, Plumbing, Electrical, Aircon, Telephone, Steelworks etc. |
| Canvass | To look or search for the most appropriate and cost effective materials to be used in the Repair and Maintenance. |
| Estimate | Provision of List of Supplies and Materials needed for the Repair and Maintenance |
| Insurance | Contract represented by a Policy in which the City Properties, Building, Structures and Facilities receives |

# ROAAP Planned Results into Procedure's Expected Outputs

| Planned Results (Expected Output, MFO, Objective) | Risks that can adversely affect the planned result | Opportunities that can beneficially affect the planned result | Actions to Address Risks & Opportunities | |
|---|---|---|---|---|
| | | | Existing Controls of the Process | Recommended Additional Controls (by and when) |
| **Needed materials are available on time** | Requests for materials are sent with less time to prepare (i.e. ASAP) | | Requests for materials must be submitted a month earlier than the next month's production | No further action. |

## Material Procurement Procedure

1. Purpose:

   This procedure intends to define the controls needed to ensure that purchased production materials, parts, components and supplies conform to our specified requirements.

2. Expected Outputs:

   By implementing the controls in this procedure, the following specific outputs are expected:

   **2.1 Needed materials are available on time.**

   2.2 Discrepant incoming materials are identified and contained.

   2.3 Adequate stock is maintained.

# Alignment with OPCR's MFO

OFFICE PERFORMANCE COMMITMENT AND REVIEW (OPCR)

| MFO | SUCCESS INDICATOR | PROGRAMS / PROJECTS / ACTIVITIES | ALLOTTED BUDGET | ACCOUNTABLE | ACTUAL ACCOMPLISHMENTS | RATING | | | | REMARKS |
|---|---|---|---|---|---|---|---|---|---|---|
| | | | | | | Q | E | T | AVE | |
| Needed materials are available on time | 100% of materials accurately released within 24 hours from time of request | Automation of the stock replenishment process | Php 20,000.00 | MISD | 100% of materials released within an average time of 12 hours with 1 error | 4 | 5 | 5 | 4.7 | |

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# Expected Outputs of the Procedure

- For Example: the procedure for “Control of Documents” can have Expected Outputs like:

*2. Expected Outputs:*

*By implementing the **controls** defined in this procedure, the following specific outputs are expected:*

1. *Appropriate versions of documents are available at points of use;*
2. *Issued documents with suitable identification of revision status;*
3. *Obsolete documents are prevented from unintended use.*

# Defining the Process Scope (Section 3)

- In defining the Scope statement, the following should be considered:
  - Applicability of the procedure;
  - Description of the areas/activities covered or not covered;
  - Where and when the process starts and ends
- For Example: the procedure for “Control of Documents” can have a Scope statement like:

> 3. *Scope:*
>
> *The **controls** specified in this procedure apply to documented references, manuals, procedures, instructions and their associated forms generated from internal and external origin in any type of media.*
>
> *This procedure covers the activities from document creation, approval, registration, distribution and retrieval.*

ISO 9001 Clause 4.4.2

# EXAMPLE: Purpose, Expected Outputs and Scope

| | NAME OF AGENCY | Document Code: OFF.DIV.P.0X | |
|---|---|---|---|
| | | Rev.: 0 | Issue Date: September xx, 2020 |
| | Subject: Control of Documents | | |
| Originator: Document Controller | Reviewed by: QMR | Approved by: Director General | |

## 1. PURPOSE

This procedure intends to define the controls needed to ensure that documents necessary for effective operation of ABC's processes are available and suitable for use, where and when it is needed.

## 2. EXPECTED OUTPUTS

By implementing the controls defined in this procedure, the following specific outputs are expected:

2.1. Appropriate versions of documents are available at points of use;
2.2. Issued documents with suitable identification of revision status;
2.3. Obsolete documents are prevented from unintended use.

## 3. SCOPE

The controls specified in this procedure apply to documented references, manuals, procedures, instructions and their associated forms generated from internal and external origin in any type of media.

This procedure covers the activities from document creation, approval, registration, distribution and retrieval.

# Guidance in the Use of Terminologies

- The organization should use their own terminologies in developing their documented information. ISO 9001 provided the following guidelines:

*It is not the intent of this International Standard to imply the need for:*

- *uniformity in the structure of different quality management systems;*
- *alignment of documentation to the clause structure of this International Standard;*
- *the use of the specific terminology of this International Standard within the organization.*

*0.1 General – Introduction*

*There is no requirement in this International Standard for its structure and terminology to be applied to the documented information of an organization's quality management system.*

*Annex A.1 Structure and terminology*

# Clarify Terminologies (Section 4)

- To establish easy understanding of the terminologies to be employed in the documented procedures, the process owner should provide a description on this section.
- For Example: the procedure for “Control of Documents” can have Definition section like this:

*4. Definition*

| | |
|---|---|
| *Controlled Copy* | *Reproduced copy of the original document (i.e. Master Copy), latest issued document; indicated by blue “Controlled Copy” stamp and signed in blue ink by the Document Controller* |
| *Copyholder* | *Authorized recipient of official copies of DENR”s quality management system related documents.* |

# Assign Responsibilities (Section 5)

*Top management should determine how to communicate the relevant roles, responsibilities and authorities. This could be through the use of relevant documented information, e.g. job descriptions, work instructions, duty statements, organization charts, manuals,* ***procedures****.*

*Section 5.3 of ISO/TS 9002:2016*

- For Example: the procedure for “Control of Documents” can have Responsibilities section like this:

***5. Responsibilities***

| | |
|---|---|
| ***Document Controller*** | ***Ensures that the established documented procedures are properly identified, available at all essential locations and current for use. The DC is also responsible for the preparation and implementation of this procedure.*** |
| ***Copyholder*** | ***Ensures that all activities performed are based on the appropriate versions of the quality management system documents.*** |

# Responsibilities VS Tasks

Pay attention on the wordings of the Responsibilities.

| ***RESPONSIBILITIES*** | |
|---|---|
| Document Controller | Ensures that documented information that support the operation of the processes needed for the quality management system are properly identified, available at points of use and current for use. |

**Section 5**

| ***TASKS*** | |
|---|---|
| Document Controller | Enter the details of the approved document into the Master Document Register.<br><br>Assigns document code to the registered document. |

**Section 7**

# Identify the Process Inputs (Section 6)

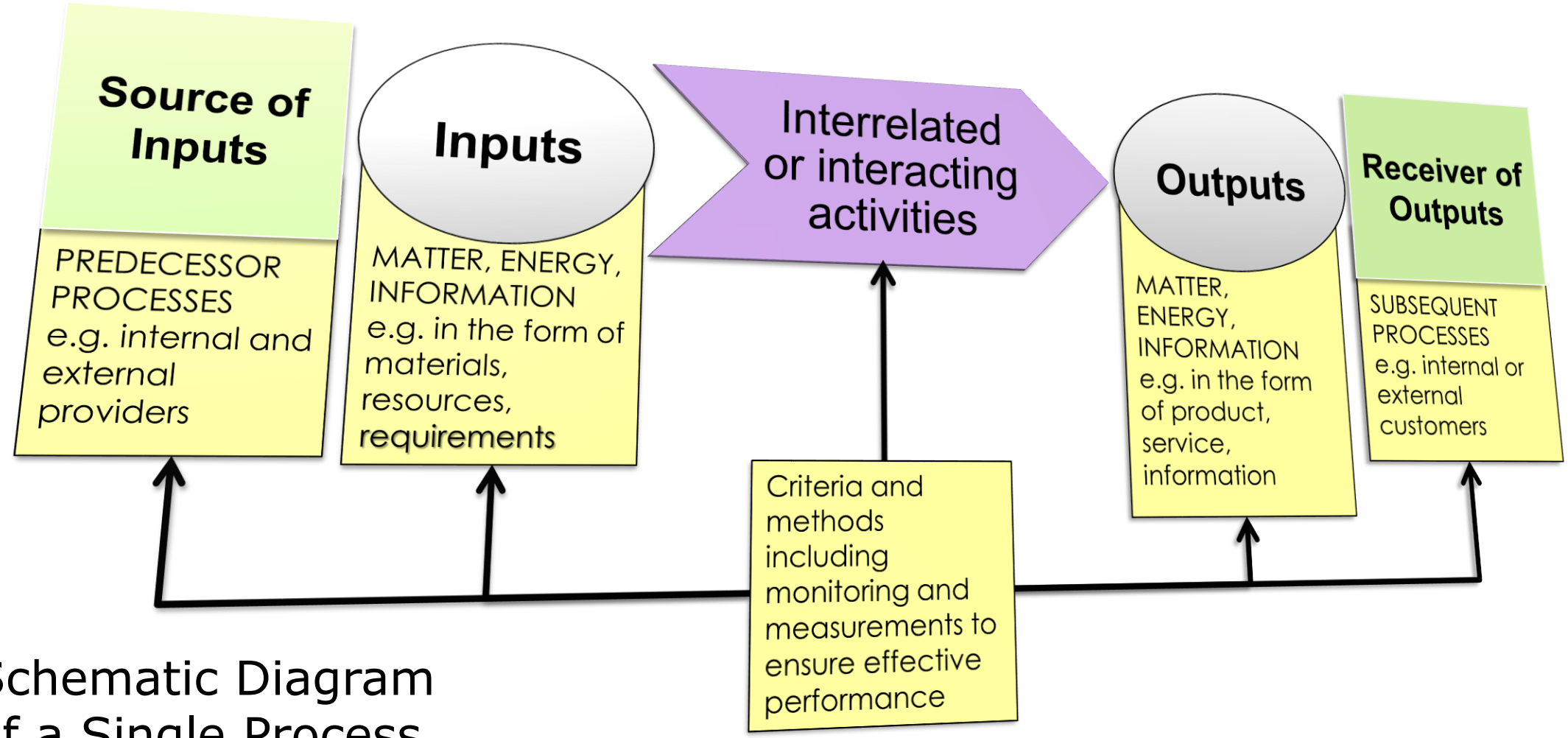
"Inputs required for the processes should be considered from the viewpoint of what is required for the implementation of the processes as planned".

*- 4.4.1a of ISO/TS 9002:2016*

Inputs can include:

- Matter
- Energy
- Information
  - E.g. in the form of materials, resources, requirements

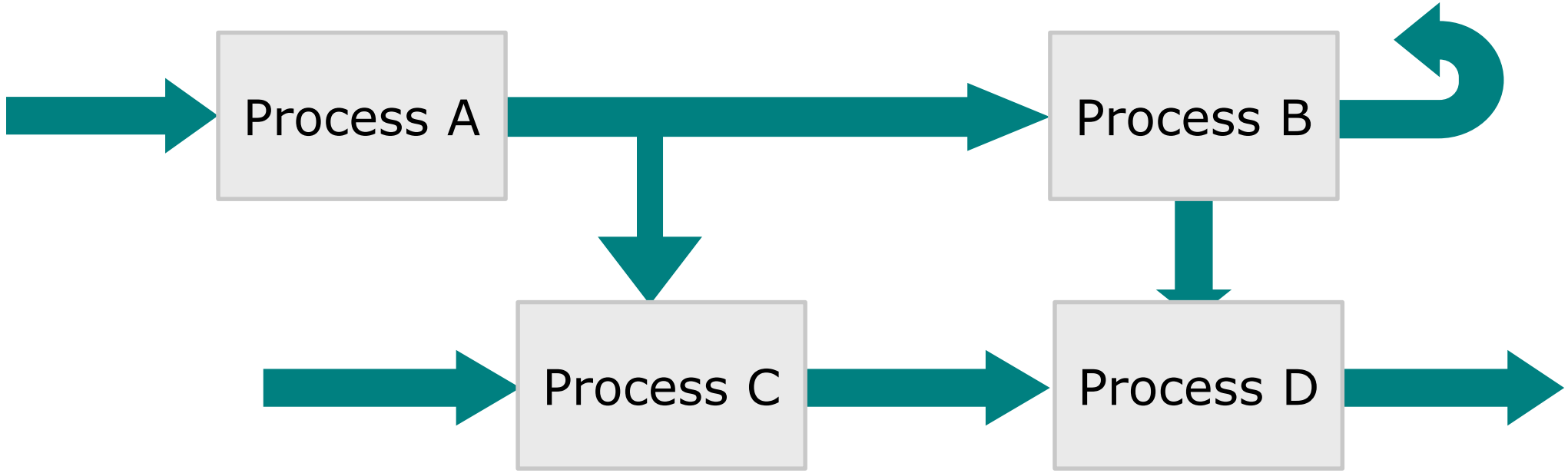
# Expectations of the Receiver of the Inputs




Schematic Diagram of a Single Process

# Inputs are Outputs Too

**Outputs of Predecessor Process are Inputs to Successor Process**



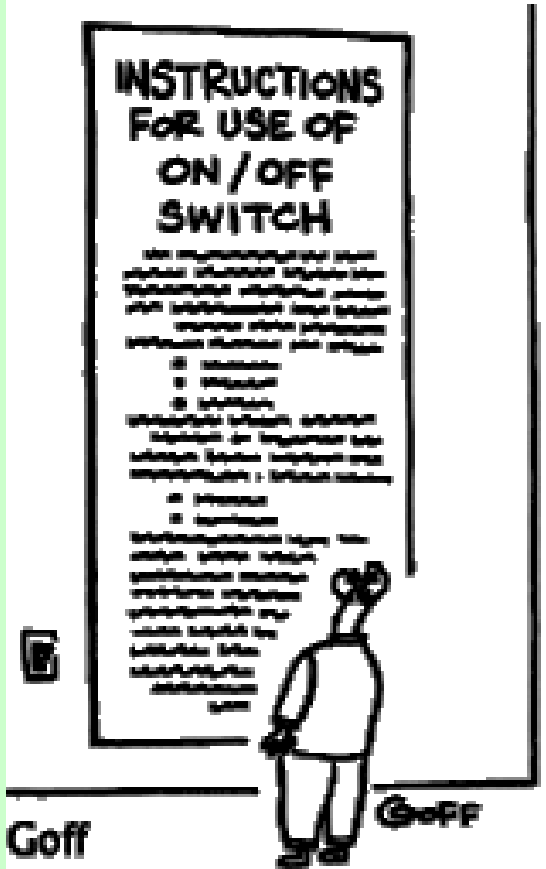

“The organization shall determine the processes needed for the quality management system and their application throughout the organization, and shall: determine the sequence and interaction of these processes”

*- Clause 4.4.1b of ISO 9001:2015*

# Process Steps Guide (Section 7)

- In developing the Process Steps, the following aspects should be considered as applicable:
  - establish what is to be done, by whom or by which organizational function; why, when, where and how;
  - describe the *actions/controls to address risks/opportunities* to ensure that expected outputs are achieved (see clause 6.1.2b.1);
  - define the monitoring and measurements (e.g. check, inspect, examines, review, verify, validate, etc.) to be taken;
  - define the appropriate documentation;
  - The intention of ISO 9001 clause 8.5.1a.1

# Requirements on ISO 9001 Clause 8.5.1a.1




The organization shall implement production and service provision under controlled conditions.

Controlled conditions shall include, as applicable:

a) the availability of documented information that defines:

1) the characteristics of the products to be produced, the services to be provided, or the activities to be performed.

# Expected Controls in the Process Steps for Core Processes as per the ISO 9001:2015 Relevant Clauses

| CONTROLS | ISO 9001:2015 CLAUSES | EXAMPLES |
|---|---|---|
| Controls in communicating information related to DENR's products/services | 8.2.1 | Posting of advisories |
| Controls in reviewing the requirements related to products/services | 8.2.3 | Checking the submitted application documents |
| Controls for identification and traceability | 8.5.2 | Use of logbooks, Document Tracking System, LAMS |
| Controls on property belonging to customer property | 8.5.3 | Safekeeping of submitted documents |
| Controls on preservation | 8.5.4 | Care of confiscated items |
| Controls on post-delivery | 8.5.5 | Project evaluation report, feedback handling |
| Controls on changes | 8.5.6 | Changes on the previously provided information |
| Controls on release of products/services | 8.6 | Review, approval prior to release |

# ROAAP Actions into Controls in the Procedure

## Material Procurement Procedure

1. Purpose:
   …
2. Expected Outputs:
   …
3. Scope:
   …
4. Responsibilities
   …
5. Procedure Details:

   5.1 Purchasing Process

   5.1.1 In the first week of each month Material Requisitions (MR) must be sent to the Materials Director specifying the materials required for production intended for the following month.

| Process Planned Results | Risks that can adversely affect the planned result | Opportunities that can beneficially affect the planned result | Actions to Address Risks & Opportunities | |
|---|---|---|---|---|
| | | | Existing Controls | Additional Controls (by and when) |
| Needed materials are available on time | Requests for materials are sent with less time to prepare (i.e. ASAP) | | **Requests for materials must be submitted a month earlier than the next month's production** | No further action. |

# Requirements to Integrate and Implement Actions Into the QMS Processes

| Clause | Requirement |
|---|---|
| *6.1.2b.1* | The organization shall plan how to ***integrate and implement the actions into its quality management system processes*** *(see 4.4)* |
| *4.4.1f* | The organization shall determine the processes needed for the quality management system and their application throughout the organization, and shall ***address the risks and opportunities as determined in accordance with the requirements of 6.1*** |
| *8.1* | The organization shall plan, implement and control the processes *(see 4.4)* needed to meet the requirements for the provision of products and services, and to ***implement the actions determined in Clause 6*** |

# WORK2: Integrate the Actions in ROAAP into the Process Steps (Section 7)

- Review some samples of ROAAPs and Procedures from the existing documentation, and
- Identify where in the Process Steps of the procedures that the Existing Controls as specified in the Risks/Opportunities Assessment and Actions Planning form are incorporated.

The completed ROAAP and Procedures will be re-checked during the Technical Guidance on Quality Management System and Service/Process Improvement Implementation. It will be expected that:

- ROAAP's Planned Results are consistent with the Procedure's Expected Outputs;
- ROAAP's Existing Controls are consistent with the controls in Section 7 (Process Steps).

# Control of Nonconforming Outputs

- The organization shall ensure that ***outputs that do not conform to their requirements*** are identified and controlled to prevent their unintended use or delivery.
- The organization shall take appropriate action based on the nature of the nonconformity and its effect on the conformity of products and services.
- This shall also apply to nonconforming products and services detected after delivery of products, during or after the provision of services.

WHERE IS THIS REQUIREMENT APPLICABLE?

ISO 9001 Clause 8.7

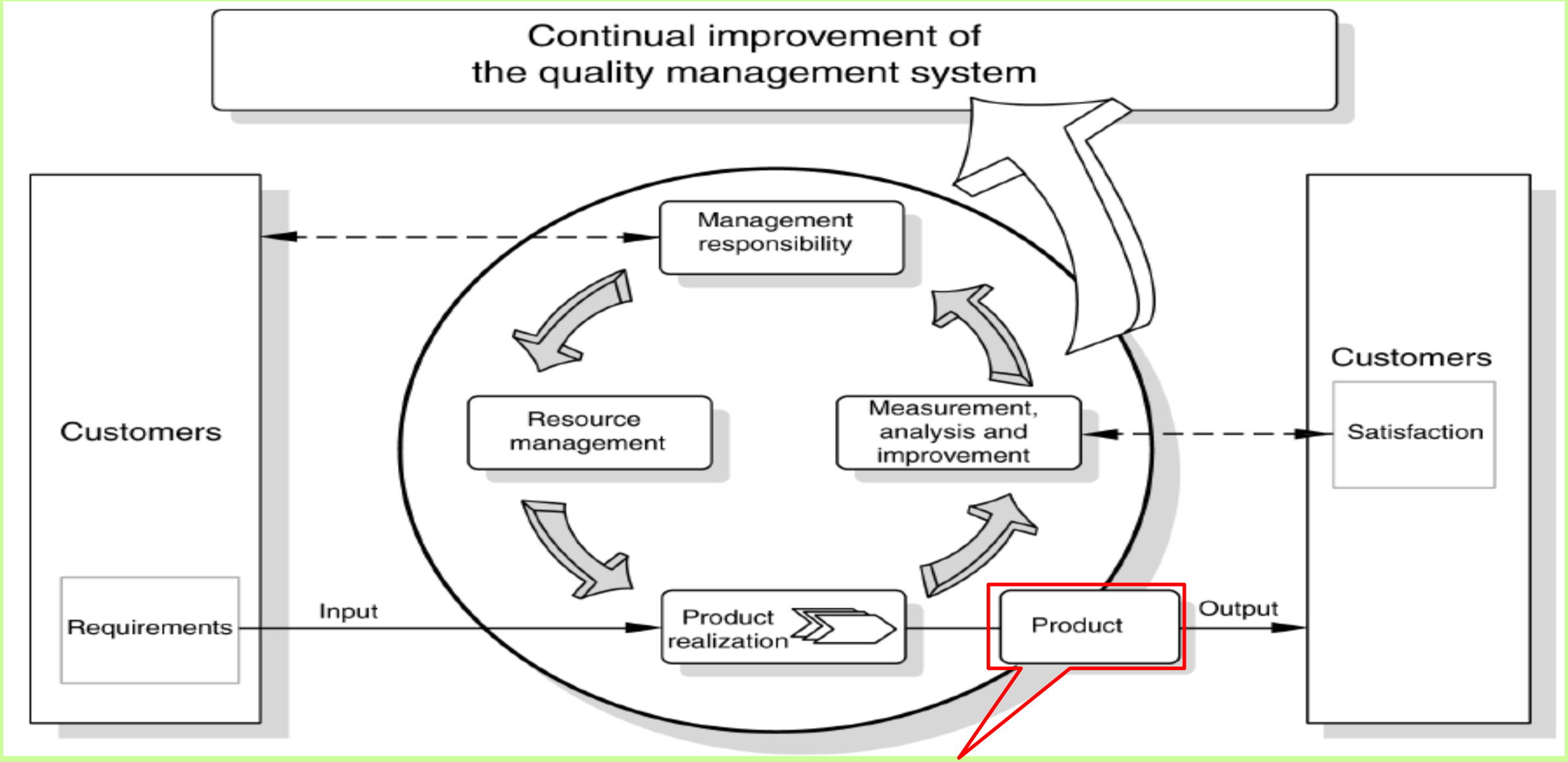
# Nonconforming Output vs Nonconforming Product

- Previously, ISO 9001 intent is limited to “controls” for “nonconforming product”
- ISO 9001:2015 change the title of the clause from “Control of Nonconforming Product” to “Control of Nonconforming Outputs”

| Product | Output |
|---|---|
| ***Output of an organization that can be produced without any transaction taking place between the organization and the customer.***<br><br>Service - Output of an organization with at least one activity necessarily performed between the organization and the customer. | ***result of a process.***<br><br>Process – set of interrelated or interacting activities that use inputs to deliver an intended result |

ISO 9001 Clause 8.7

# ISO 9001:2008 INTENT OF CLAUSE 8.3




**Control if Nonconforming!**

# ISO 9001:2015 INTENT OF CLAUSE 8.7

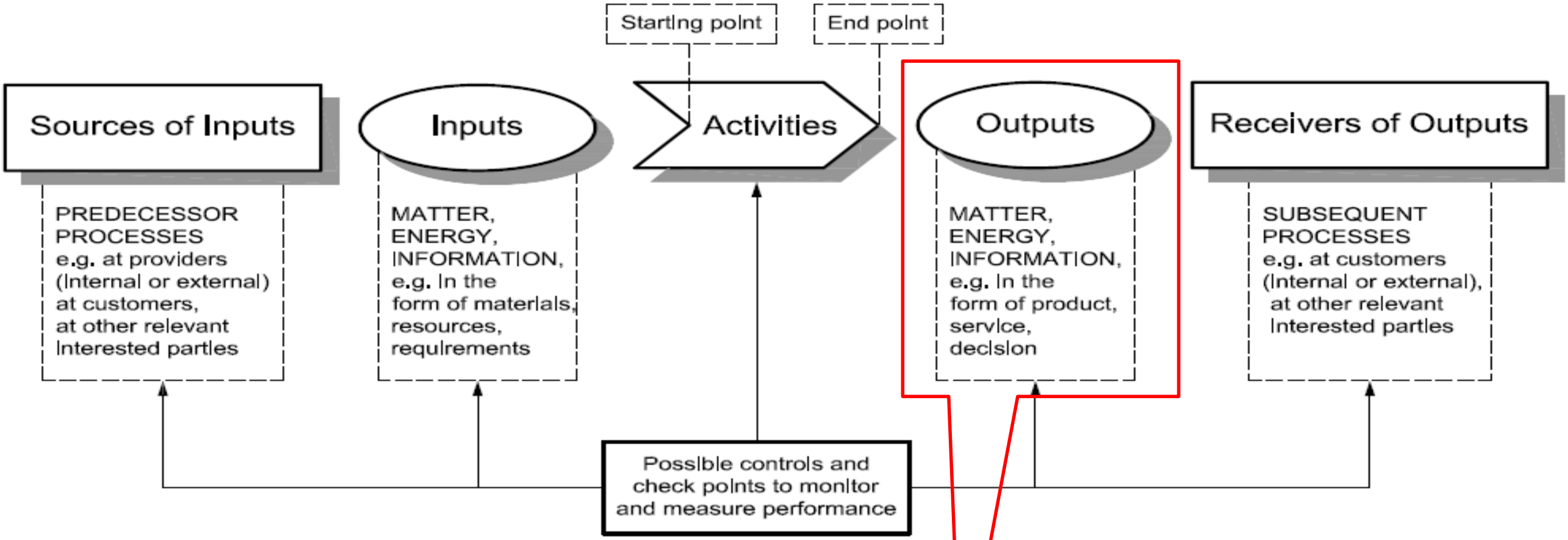



Figure 1 — Schematic representation of the elements of a single process

**Control if Nonconforming!**

# Control of NCO vs Controls on the Procedure

## Example NCO: **Missing ordered food item**

REACTIVE

8.7

### Control of Nonconforming Output

- If not yet served:
  - Call the attention of the Food Assembler to prepare the item.
- If already served:
  - Ask the customer re: missed item
  - Check the receipt vs the served items
  - Apologize
  - Served the missed item
  - Don’t charge for the missed item

PREVENTIVE

4.4.1; 6.1.2; 8.1

### Procedure Details

- Jot the order down using the Order Sheet then repeat the order to confirm
- Check the items being assembled against the Order Sheet
- Ask the customer about the completeness of the ordered food

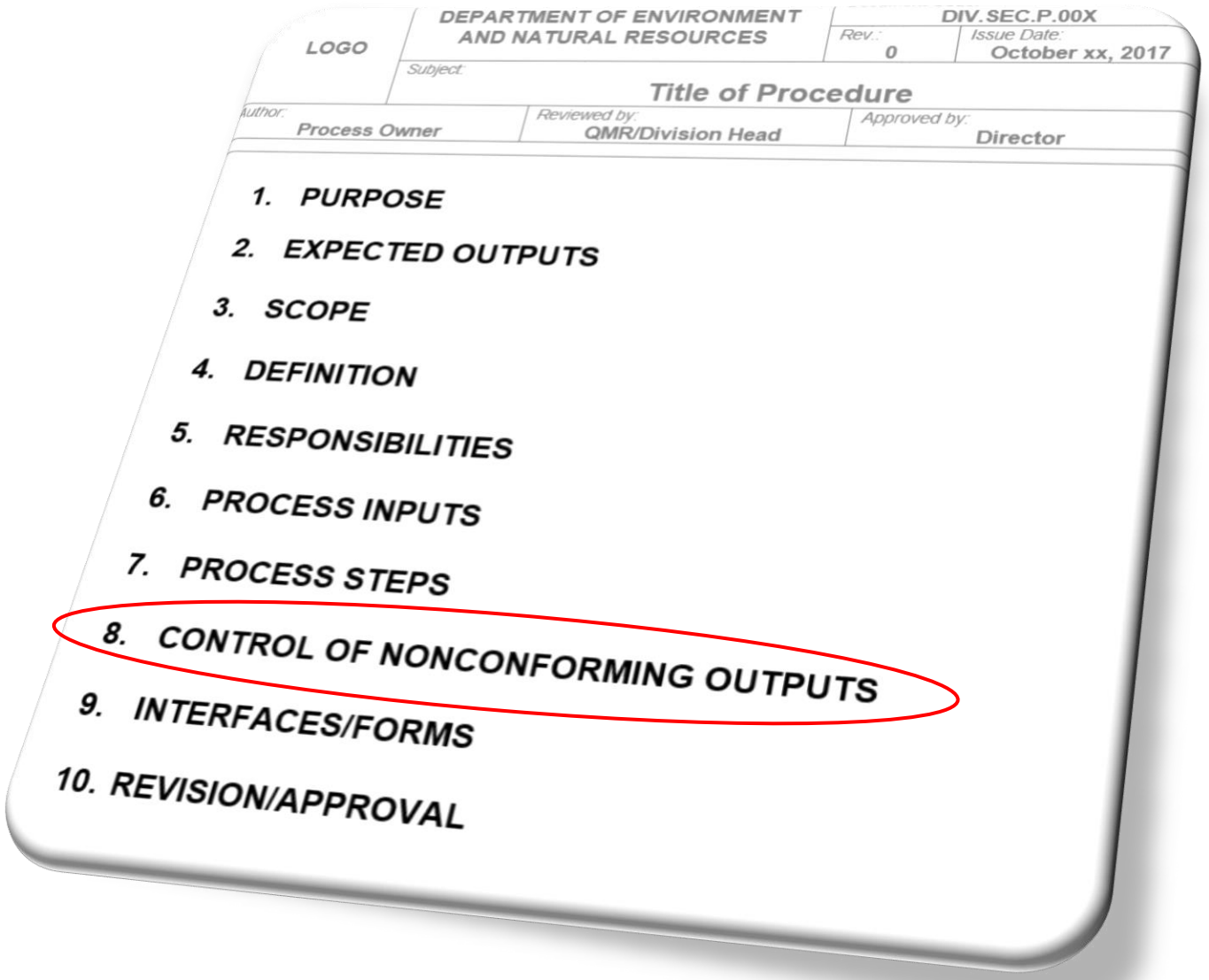
# Control of NCO (Section 8)

"The organization shall ensure that persons doing work under the organization's control are aware of the implications of not conforming with the quality management system requirements"

*ISO 9001:2015 Clause 7.3d*

"The organization can create awareness in many ways, such as *communicating clearly* how to handle complaints and the internal escalation steps *in the case of nonconforming outputs*"

*ISO/TS 9002:2016 Clause 7.3d*



# Documenting the Controls for Nonconforming Outputs

For Example: the procedure for "Control of Documents" can have Control of Nonconforming Output section like this:

**8. CONTROL OF NONCONFORMING OUTPUTS**

When the expected outputs are not achieved, the following measures are to be implemented:

| Nonconforming Output | Reactive Measures |
|---|---|
| Reference documents of internal origin without the approval of reviewing and approving authorities | 1. Submit the unofficial document to the reviewing and approving authority for approval.<br>2. Once approved with the accomplished DRAR, forward the draft document to the DC for registration.<br>3. Issue the Controlled Copy to Copyholders |
| Unsuitably identified obsolete documents are still in the custody of the Copyholder. | 1. DC will retrieve the obsolete document from the Copyholder.<br>2. Affix the Obsolete stamp and archive by the DC.<br>3. Issue the revised document to the Copyholder to replace the obsolete copy. |

ISO 9001 Clause 8.7

# Retaining Documented Information on NCOs

ISO 9001:2015 Clause 8.7.2:

*The organization shall retain documented information that:*

a) describes the nonconformity;
b) describes the actions taken;
c) describes any concessions obtained;
d) identifies the authority deciding the action in respect of the nonconformity.

Is this requirement applicable to all processes?

The intent of this subclause is to ensure that the organization retains documented information relating to:

a) nonconforming outputs, ***at all stages of production and service delivery***;
b) actions taken to correct nonconformities;
c) those persons who have the responsibility to approve release of ***nonconforming products or services***.

Where further action is needed (for example to respond to complaints and prevent recurrence) the requirements of Corrective Action should be applied

*- ISO/TS 9002:2016 Section 8.7.2*

# Documenting NCOs Related to Products and Services

- This documented information can also be used as a basis for analyses of trends in nonconformities.
- Examples of documented information can include:
  - databases with information about nonconforming outputs;
  - completed forms that are retained with the product;

| | A | B | C | D | E | F |
|---|---|---|---|---|---|---|
| 1 | **Description of Nonconforming Output** | **Date Happened** | **Identified Through** | **Action Taken** | **Completed On** | **Responsible** |
| 2 | | | | | | |
| 3 | | | | | | |
| 4 | | | | | | |
| 5 | | | | | | |
| 6 | | | | | | |
| 7 | | | | | | |
| 8 | | | | | | |

NCO Logbook

ISO/TS 9002:2016 Clause 8.7.2

# WORK3: Describe the Controls on NCO

- Revisit the existing documented procedures and check whether:
  - The identified Nonconforming Outputs mirror the Expected Outputs in the opposite direction;
  - The Reactive Measures are “after the fact” activities that are intended to correct, mitigate and/or prevent NCOs from unintended use or delivery.

# Interface for Interaction (Section 9)

- The organization shall establish, implement, maintain and continually improve a quality management system, including the processes needed and their interactions
- The organization shall determine the processes needed for the quality management system and their application throughout the organization, and shall: determine the sequence and interaction of these processes

# Interface for Interaction (Section 9)

The organization's quality management system shall include:

a. documented information required by this International Standard;
b. documented information determined by the organization as being necessary for the effectiveness of the quality management system.

NOTE The extent of documented information for a quality management system can differ from one organization to another due to:

- the size of organization and its type of activities, processes, products and services;
- the complexity of processes and their **interactions**;
- the competence of persons.

# Revision History (Section 10)

7.5.3.2c

- For the control of documented information, the organization shall address the following activities, as applicable… control of changes (e.g. **version** control)

A requirement to “maintain” documented information does not exclude the possibility that the organization might also need to “retain” that same documented information for a particular purpose, e.g. to retain previous **versions** of it.

# CONTROL OF DOCUMENTED INFORMATION

# Documented Information Creation and Update

- When creating and updating documented information, the organization shall ensure appropriate:
  - a) identification and description (e.g. a title, date, author, or reference number);
  - b) format (e.g. language, software version, graphics) and media (e.g. paper, electronic);
  - c) review and approval for suitability and adequacy.

ISO 9001 Clause 7.5.2

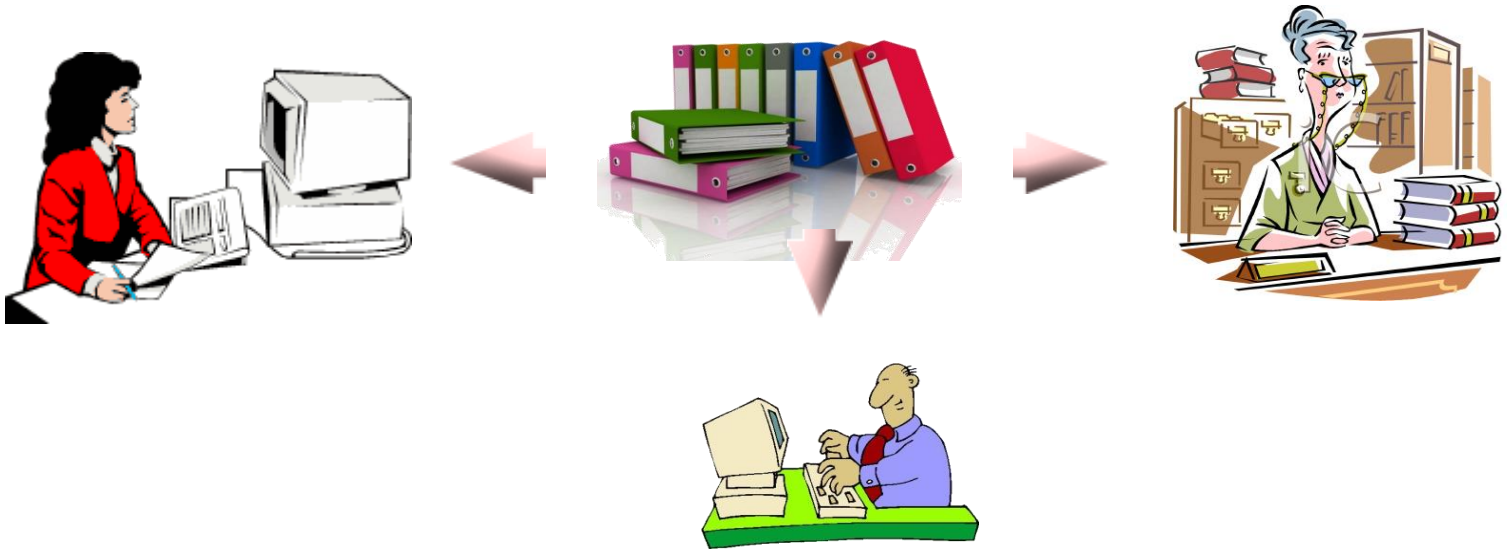
# Control of Documented Information

- 7.5.3.1 …Ensure:
  - a) it is available and suitable for use, where and when it is needed;
  - b) it is adequately protected (e.g. from loss of confidentiality, improper use, or loss of integrity).
- 7.5.3.2 …Address the following:
  - a) distribution, access, retrieval and use;
  - b) storage and preservation, including preservation of legibility;
  - c) control of changes (e.g. version control);
  - d) retention and disposition.

ISO 9001 Clause 7.5.3

# Procedure for Control of Documents

- Purpose
  - Ensure that documents necessary for effective operation of DENR's processes are available and suitable for use, where and when it is needed.

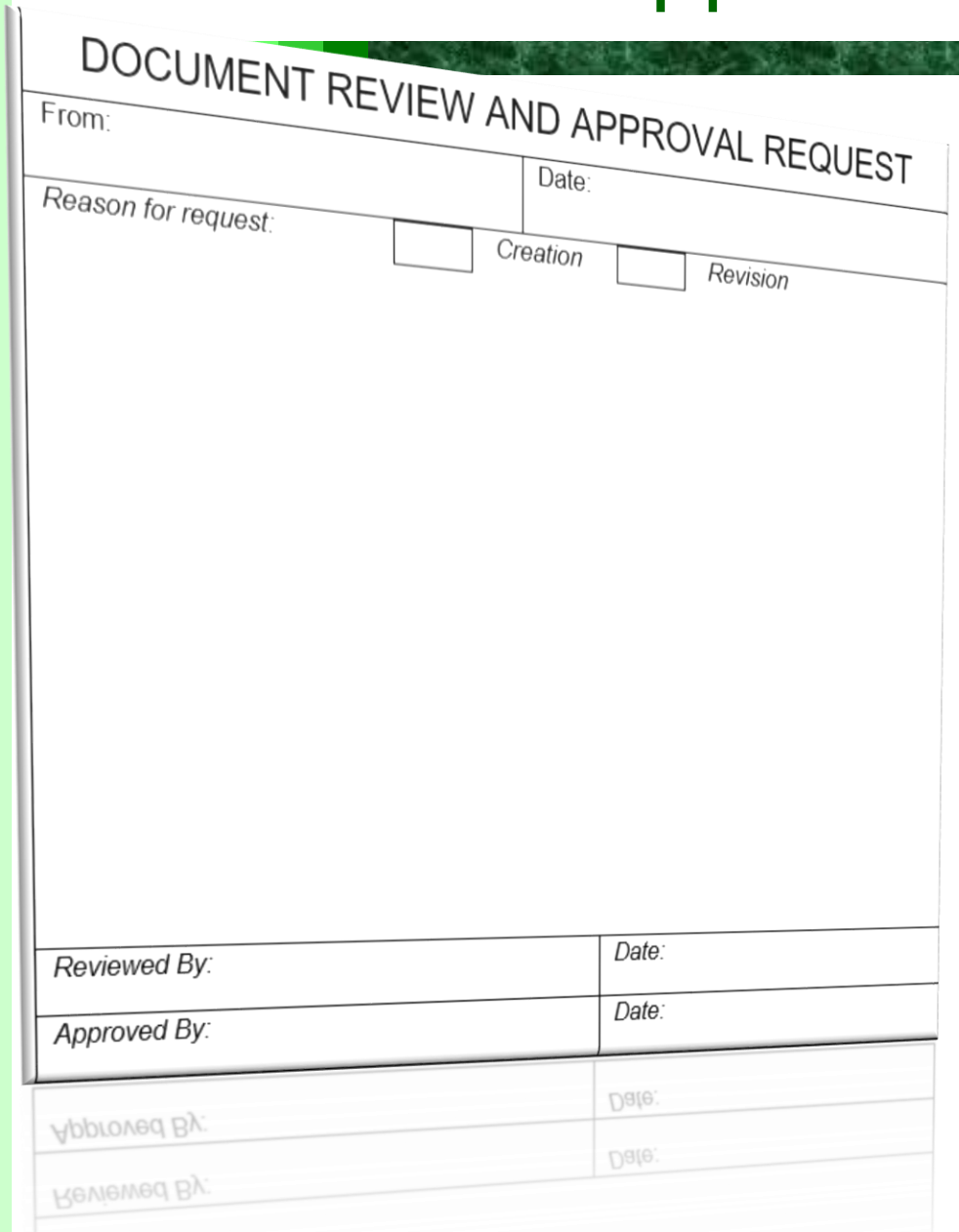


# Procedure for Control of Documents

- Scope of the procedure
  - applies to documented references, manuals, procedures, instructions and their associated forms generated from **internal** and **external** origin

| INTERNAL DOCUMENTS | EXTERNAL DOCUMENTS |
|---|---|
| Those that originate from within the company such as manuals, procedures, forms, etc. created to support the effective planning, operation and control of the company's processes. | Those that originate from outside the company such as manuals, standards, regulations, etc. acquired to provide for the effective planning, operation and control of the company's processes. |

# Review and Approval of Documents


DOCUMENT REVIEW AND APPROVAL REQUEST

From:

Date:

Reason for request:

Creation

Revision

Reviewed By:

Date:

Approved By:

Date:

1. Creation or revision is initiated by the process owner

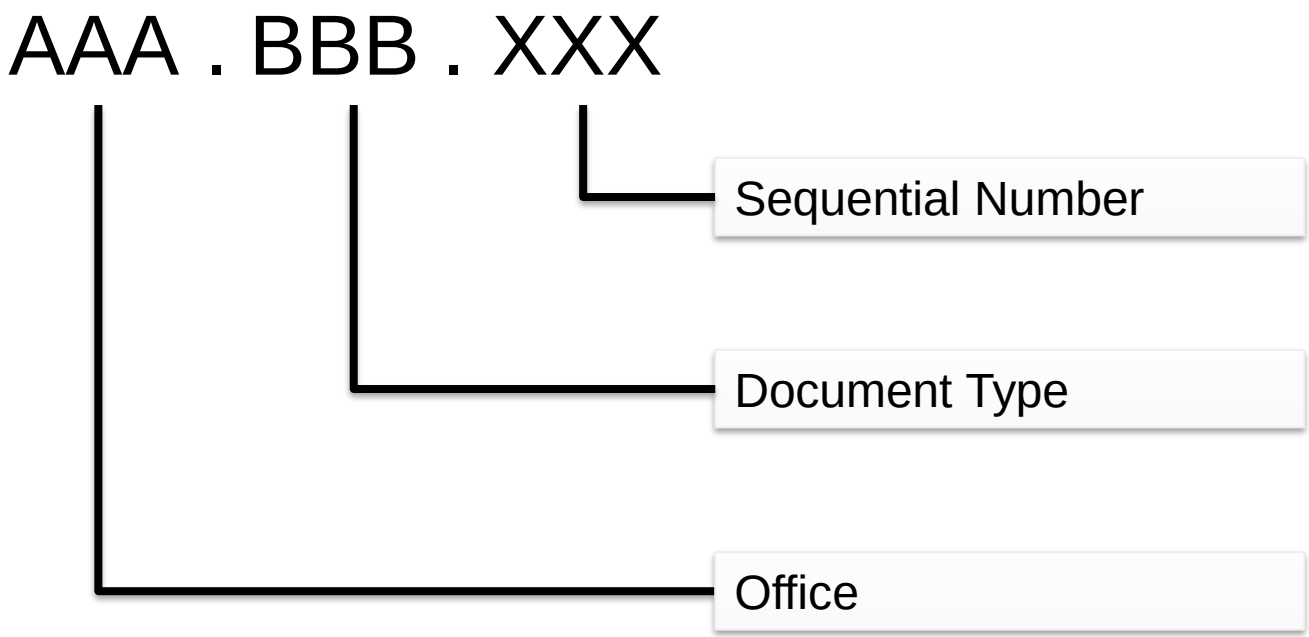
Evidence of review must be retained using the DRAR Form. This form should be attached with the draft document.

# Review and Approval of Documents

2. The Process Owner must seek review and approval from his/her Supervisor and the Designated Quality Management Representative respectively

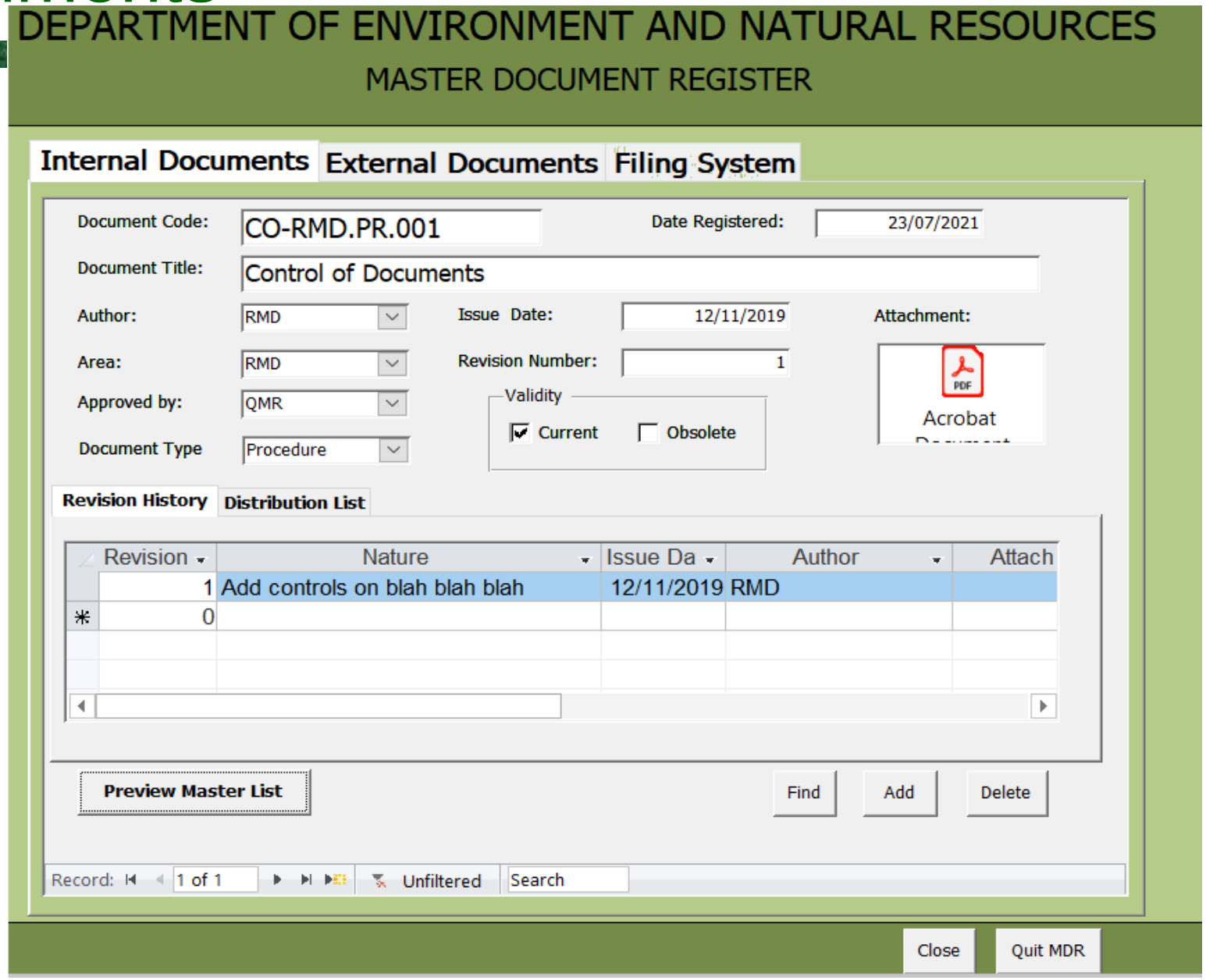
# Assigning of Document ID

2. Records Controller will assign a **document code** as specified below:



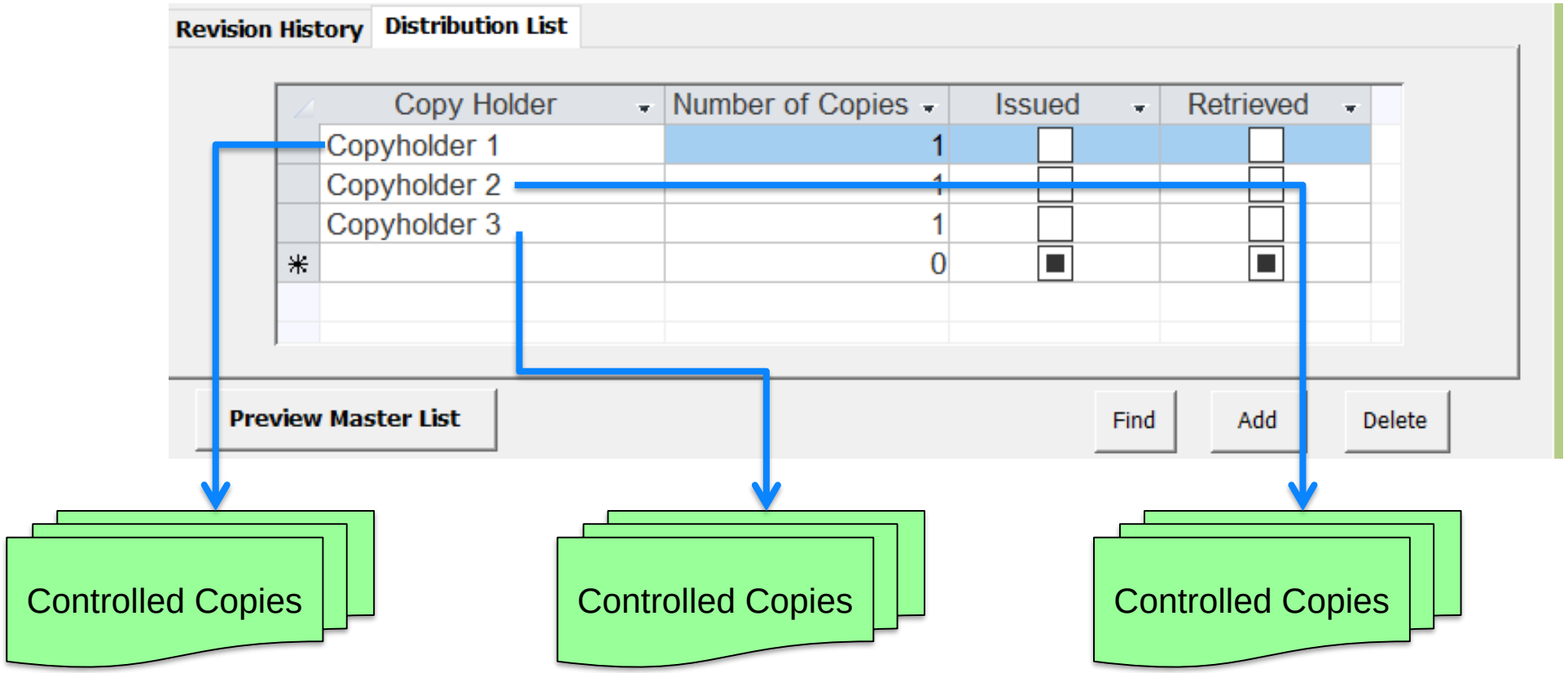
# Registration of Documents

3. The approved document, its softcopy and the accomplished DRAR form must be forwarded to the Records Controller for registration.



# Distribution of Documents

4. Records Controller will reproduce Controlled Copies to Copyholders as per the Distribution List.



# Distribution of Documents

5. Controlled Copies are stamped prior to issuance:


Color : Blue
Stamp Area: Lower rightmost corner of the first page

# Evidence of Issuance and Retrieval

- According to existing Control of Documented Procedure:
  - Manual distribution of documents is evidenced by using the Documents Distribution List.
  - Issuances to the field offices are evidenced by the use of Transmittal Report.
  - Electronic distribution is through the electronic mail and the RC prints proof of delivery.

# Retrieval and Disposal

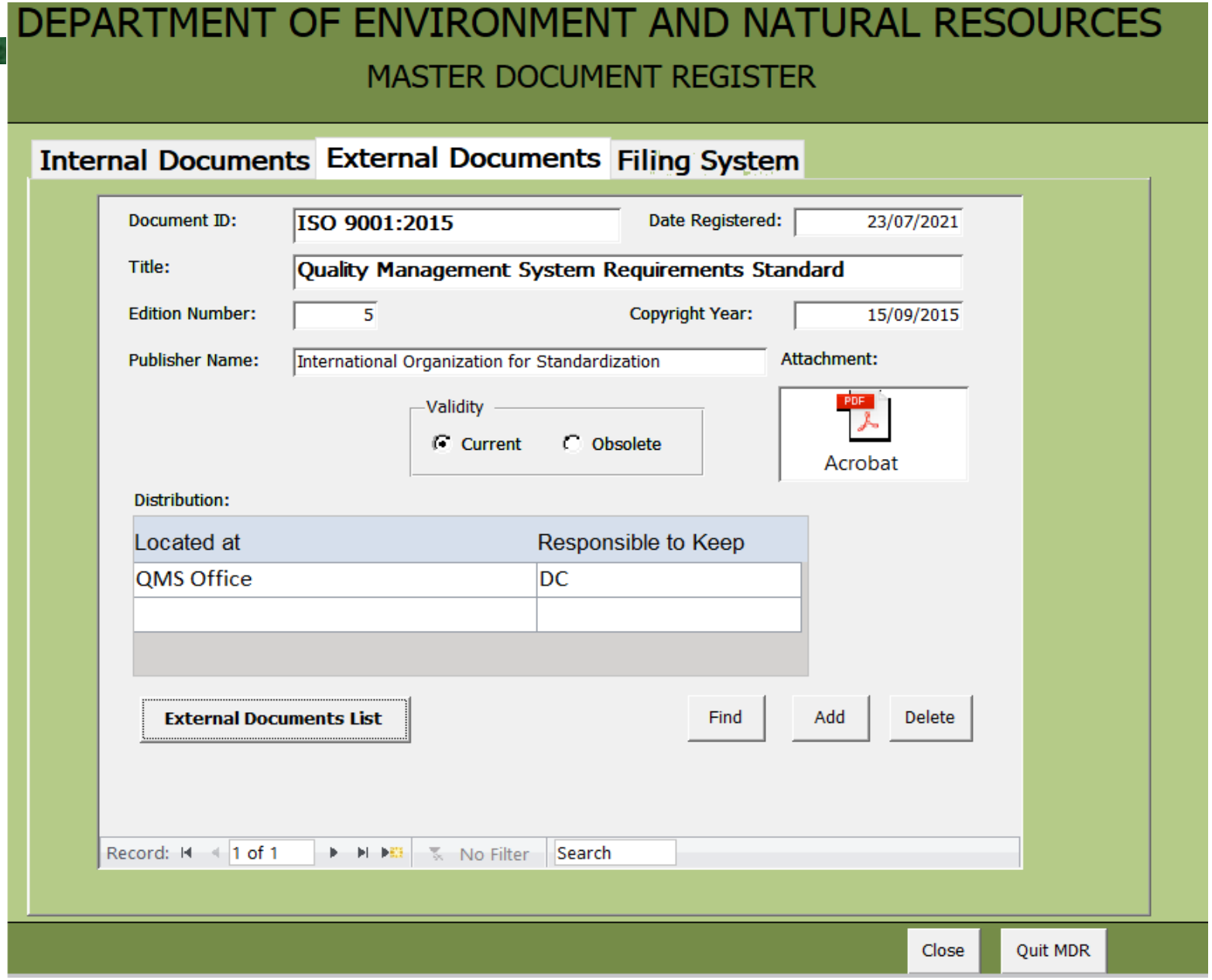
6. All retrieved obsolete documents must be stamped.


Color : Red
Stamp Area:
Center part of the first page

7. Disposal of obsolete documents will require approval and must follow the retention period as specified in the Records Disposition Schedule.

# Control of External Documents

- External documents being used as reference are registered into the Master Document Register.



# Control of External Documents

- The register of external documents is being maintained on a “rolling list” basis (i.e. new documents are added into the register and obsolete documents are archived).

## Master Documents Register

External Documents - Current

| Document ID | Title | Copyright Year | Edition Number |
|---|---|---|---|
| ISO 9001:2015 | Quality Management System Requirements Standard | 9/15/2016 | 5 |

# Control of Records

REFERENCE: ISO 9001:2008 Clause 4.2.4 Requirements:

- The organization shall establish a documented procedure to define the controls needed for the identification, storage, protection, retrieval, retention and disposition of records.

"Look what I found under all these reports and forms: a customer!"

- Records shall remain legible, readily identifiable and retrievable.

ISO 9001 Clause 7.5.3

# Definition of Terms Relevant to Records

| TERMINOLOGY | DEFINITION |
|---|---|
| Record | Document stating results achieved or providing evidence of activities performed (ISO 9000:2015)<br><br>Recorded information produced or received in the initiation, conduct or completion of an institutional or individual activity and that comprises content, context and structure sufficient to provide evidence of the activity (National Archives of the Philippines) |
| Active Records | Records that are currently being maintained, used and controlled. These records are normally kept in desk/ workstation drawers or nearby filing cabinets, shelves or racks for easy access and retrieval. |
| Inactive Records | Records that are very rarely or no longer referred to, and which must be transferred to another place (e.g. the Office Records Center). These records have already served their purpose but must be kept just the same for legal requirements or some compelling reasons. They are only destroyed the moment their retention periods have expired. |

# Procedure for Control of Records

- Purpose
  - The procedure aims to define the controls needed to ensure that documented information to have confidence that the processes are being carried out as planned and that provide evidence of conformity to requirements and of the effective operation of the quality management system are effectively retained.
- Expected Outputs
  - The controls defined in the procedure ensure that records are:
    - easily retrievable;
    - protected from physical deterioration, loss or damage, data tampering and/or unauthorized access.

# Procedure for Control of Records

- Scope
  - This procedure applies to all **internally/externally** generated documents and data that record the *effectiveness* and *efficiency* of DENR's quality management system.

**effectiveness**
*extent to which planned activities are realized and planned results are achieved*

**efficiency**
*relationship between the result achieved and the resources used*

# Procedure for Control of Records

- General Requirement
  - All records shall be legible, true, correct, accurate, and complete.
  - Records can be in the form of any type of media, such as hard copy or electronic media.
  - All records shall be reviewed and/or approved prior to issue or use.
  - Records shall indicate the person(s) authorizing its use.

> The organization shall establish a documented procedure to define the controls needed for the **identification**, **storage**, **protection**, **retrieval**, **retention** and **disposition** of records.
>
> Records shall remain legible, readily identifiable and retrievable.
>
> *- ISO 9001:2008 Clause 4.2.4*

# Controls for Identification

**Title**

**Control Number**

**Reference**

**Date**

**Name of originator, reviewer or approving person**

| Uncomplicated Inc. | PURCHASE ORDER | PO No.: | PO5254 |
|---|---|---|---|
| | | PR Ref# | PR-14-344 |
| | | Date: | 08/16/14 |

| To: | Saturn Electronics Phils., Inc. 14344 New York City, Philippines | Ship to: | *Uncomplicated Inc. 777 Gotham City, Philippines Phone: 8015722* |
|---|---|---|---|

| Item | Description | Quantity | Required Date | Unit Price | Total Price |
|---|---|---|---|---|---|
| 1 | Precision Flexible Circuits | 100 | 09/22/07 | 1,200 | 120,000 |
| 1. *PURCHSE ORDER NUMBER, PART NUMBER AND QUANTITY MUST SHOW ON EACH CARTON.* 2. *Inspection records must accompany each shipment.* | | TOTAL | | | 120,000 |

Special Ordering Instruction:

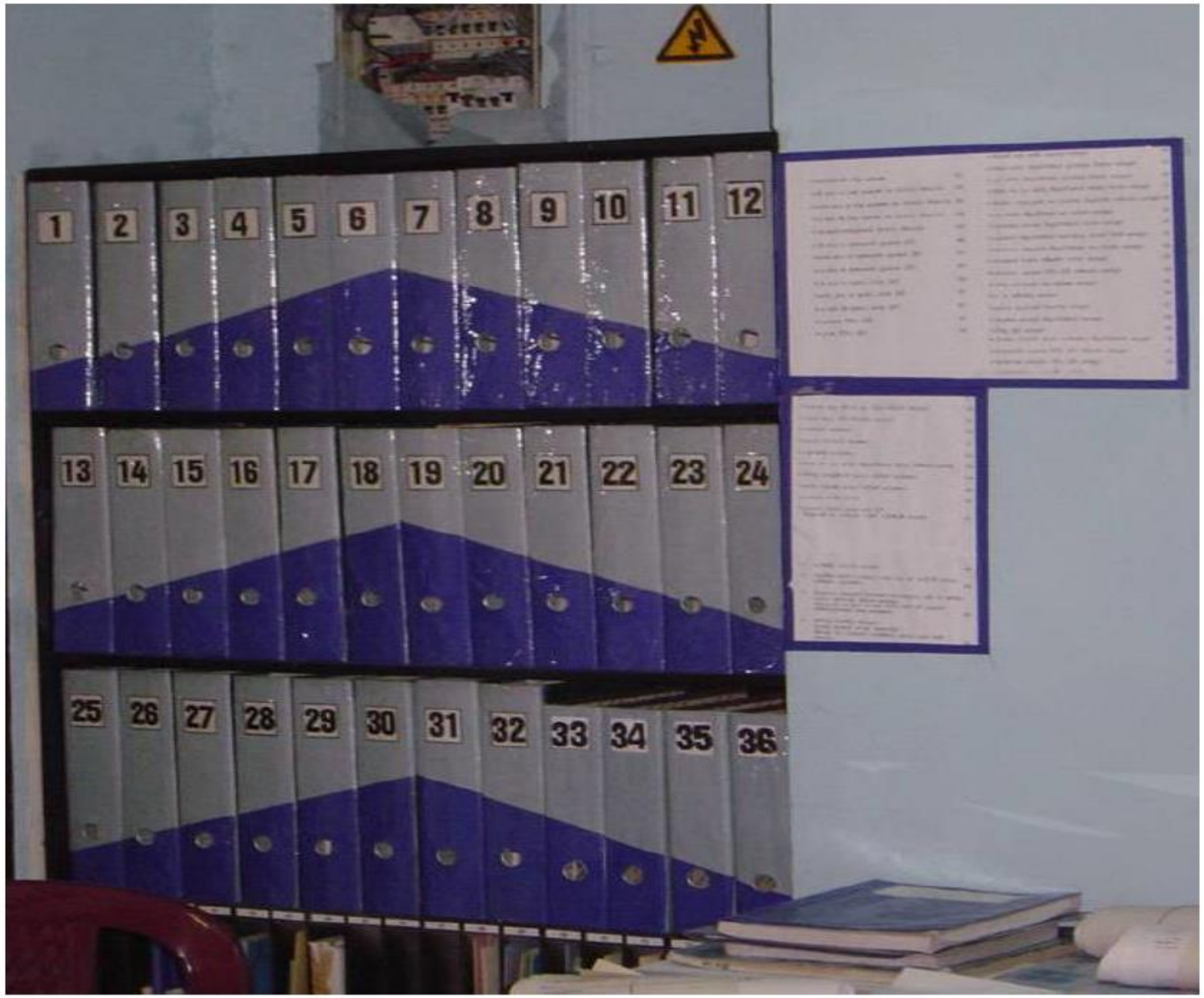
None

| (Name/Signature/Date): | Peter Parker Peter Parker 8/16/2014 | |
|---|---|---|
| Approved by (Name/Signature/Date): | Antonio Santos 8/16/2014 | Acknowledged by (Supplier/Signature/Date): |

# Controls for Storage

- Each office shall be responsible for the storage and keeping of their records.
- Filing cabinets, box files, folders, dividers, envelopes, etc. shall be provided to organize records.
- Electronic records shall be backed up on a periodical basis.

# Controls for Storage

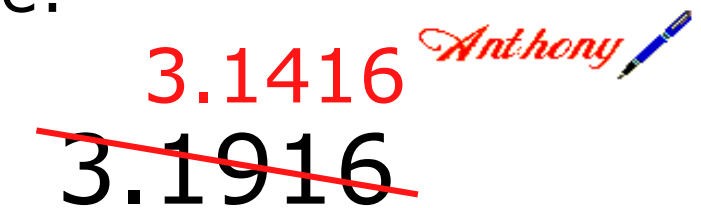


# Controls for Storage

# Controls for Protection

- Records shall be kept in a place where it can be protected from physical deterioration, damage, loss and data tampering.
- Permanent ink pens must be used to fill-out forms.
- Data corrections must be countersigned using red-inked pens.

For Example:



# Controls for Retrieval

- For easy retrieval:
  - Numbering system to all filing cabinets including cabinet shelves and proper labeling shall be established for boxfiles, folders, envelopes, etc.
  - Each department must maintain a List of Records
  - Backup copy of the list is maintained in the MDR



# Control of Records Procedure

- Controls for Retention
  - The List of Records shall specify each record's retention period
  - Inactive records shall be forwarded to the Records Officer for archiving
  - Adhere with the NAP General Circulars on Inventory of Records and Disposition Schedules

- Controls for Disposition
  - Disposal can be done by selling, by landfill, by shredding of by any other NAP-prescribed way
  - Must follow the IRR of R.A. 9470

# Sample List of Records

| Department: | ACCOUNTING | For the period covering: | Jan – Oct 2019 |
|---|---|---|---|
| Records Custodian: | Diana Prince | | |

| Document/Record (Code, Title) | Location | | Retention | | Mode of Filing<br>**C** – by date,<br>**N** – by number,<br>**A** – by name |
|---|---|---|---|---|---|
| | Active | Inactive | Active | Inactive | |
| Analysis of Cash Reports | Cab. A, Shelf 1, Accounting Office | Storage 1, Rack 3 | 1 year | 10 years | C |
| Audit Working Papers | Cab. A, Shelf 2, Accounting Office | Storage 1, Rack 3 | 1 year | 5 years after publication of AFR | C |
| Credit/Debit Advice | Cab. A, Shelf 4, Accounting Office | Storage 1, Rack 3 | 1 year | 10 years | C |
| Financial Reports | Cab. B, Shelf 2, Accounting Office | Storage 1, Rack 3 | 1 year | 5 years after publication of AFR | C |

Procedure

# NONCONFORMITY AND CORRECTIVE ACTION PROCEDURE

# Actions for Improvement

| | |
|---|---|
| Correction | *action to eliminate a detected nonconformity* |
| Corrective Action | *action to eliminate the cause of a nonconformity and to prevent recurrence* |
| Preventive Action* | *action to eliminate the cause of a potential nonconformity or other potential undesirable situation* |

*ISO 9001:2015 does not have a clause on Preventive Action

ISO 9001 Clause 10.2

# Conformity vs Nonconformity

| **Conformity**<br>fulfillment of a ***requirement*** | **Nonconformity**<br>non-fulfillment of a ***requirement*** |
|---|---|
| On-time delivery | Late, advance, overdue |
| Goods without damage | Goods with damage |
| Complete documents | Lacking, partial, unfinished |

- Requirement - need or expectation that is stated, generally implied or obligatory

# Nonconformity and Corrective Action Requirements

When a nonconformity occurs, including any arising from complaints, the organization shall:

a) react to the nonconformity and, as applicable:

   1) take action to control and correct it;

   2) deal with the consequences;


"It doesn't say anything about what to do when a stick-to-the-letter-of-the-book supervisor falls down an elevator shaft."

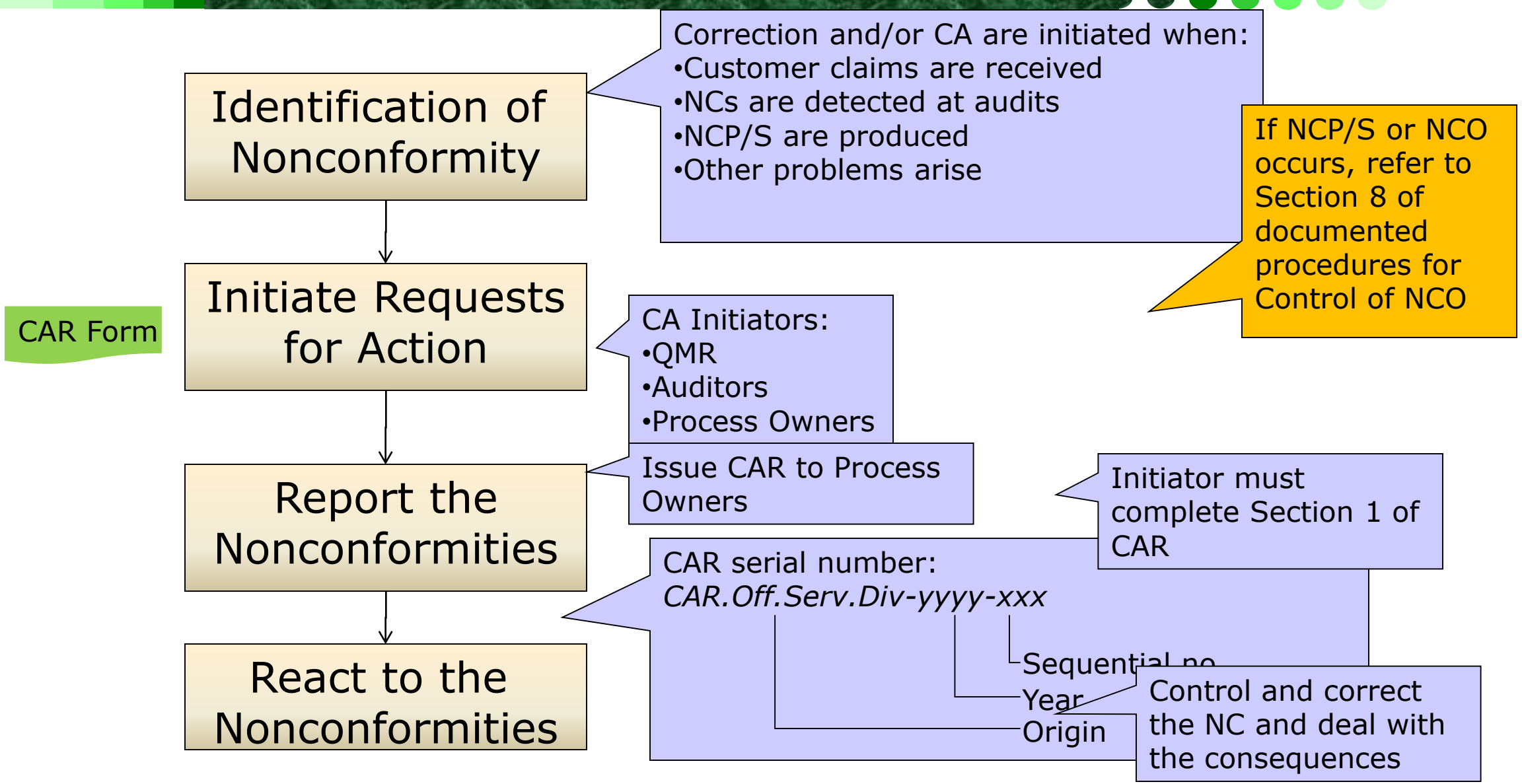
ISO 9001 Clause 10.2.1

# Nonconformity and Corrective Action Requirements

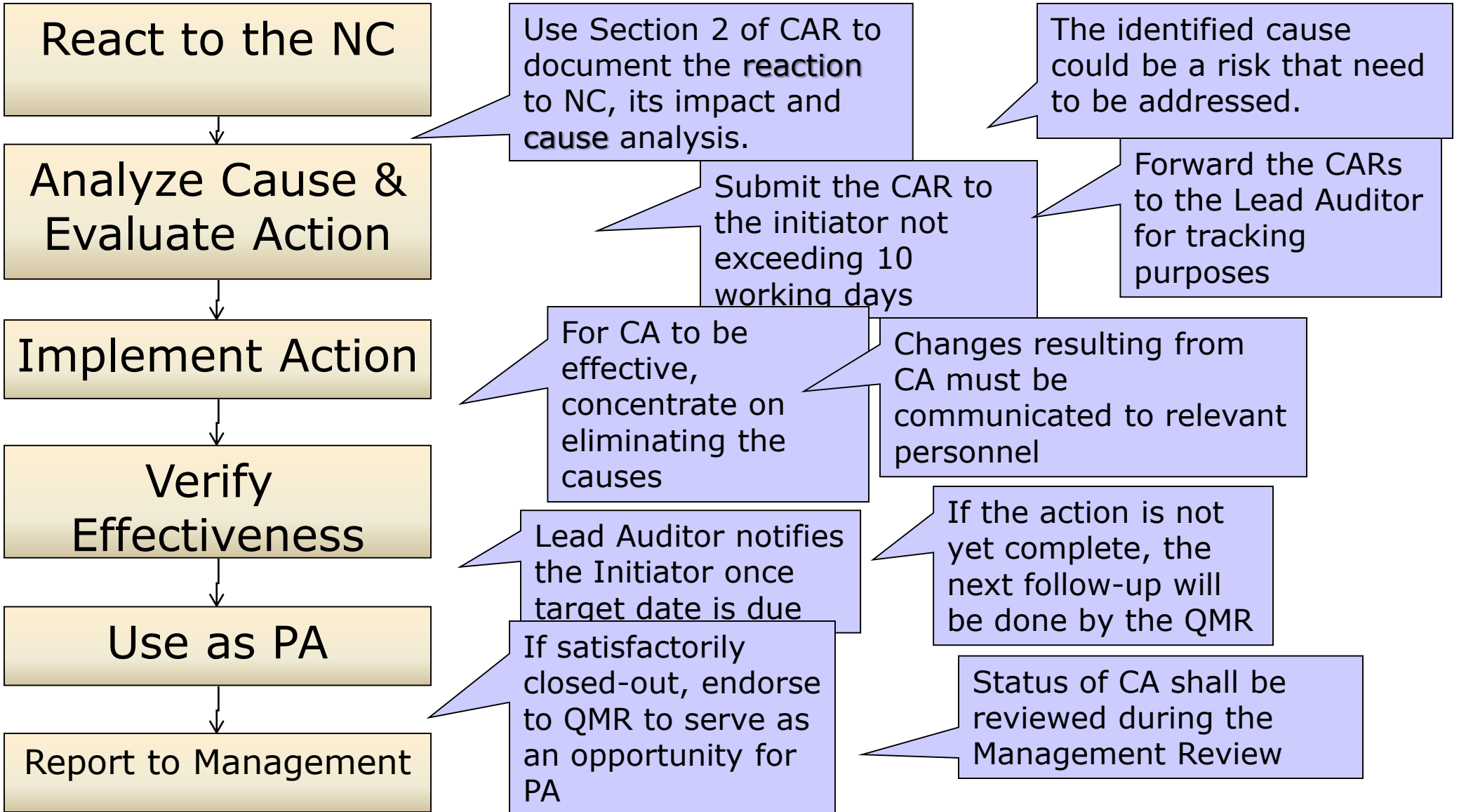
b) evaluate the need for action to eliminate the cause(s) of the nonconformity, in order that it does not recur or occur elsewhere, by:
   1) reviewing and analysing the nonconformity;
   2) determining the causes of the nonconformity;
   3) determining if similar nonconformities exist, or could potentially occur;
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.

ISO 9001 Clause 10.2.1

# Corrective Action Procedure



# Corrective Action Procedure



# Documenting Nonconformities

- **The statement of nonconformity drives the cause analysis, correction and corrective action by the auditee,** so it should always ensure that the following points are addressed:
  - The requirement (specified in the procedure, citizen charter, regulation, etc.) – exactly what the organization has committed itself to do . (i.e. audit criteria)
  - The exact evidence of non-fulfilment seen – exactly what the organization has or hasn't done that contradicts the requirement (i.e. audit evidence)
  - If there's any, the consequence on products, services, processes, operations, customers
  - The severity of the problem

# Sample Description of Nonconformity

## CORRECTIVE ACTION REQUEST

**RFA No.:** CARA-17-0023 **Date:** September 18, 2017

**Function:** General Services Department **Classification:** Major

**Reference:** Division 18 of the IRR of the Fire Code of the Philippines

**Description of Nonconformity:**

Criteria

According to the IRR of the Fire Code of the Philippines of 2008, monthly inspection shall be conducted by trained personnel.

However, the latest record of inspection presented was the Fire Safety Inspection Certificate issued by the City Fire Marshal on October 15, 2016 after renovations were made at the lobby area of the Day Care Center.

Evidence

This contributed to the small fire incident on August 12, 2017 caused by accumulated dirt and leaves on the outdoor parts of the window air conditioner.

Consequence

**Initiator:** Tony Stark

# Causes and Risks

**10.2.1 Nonconformity and Corrective Action**

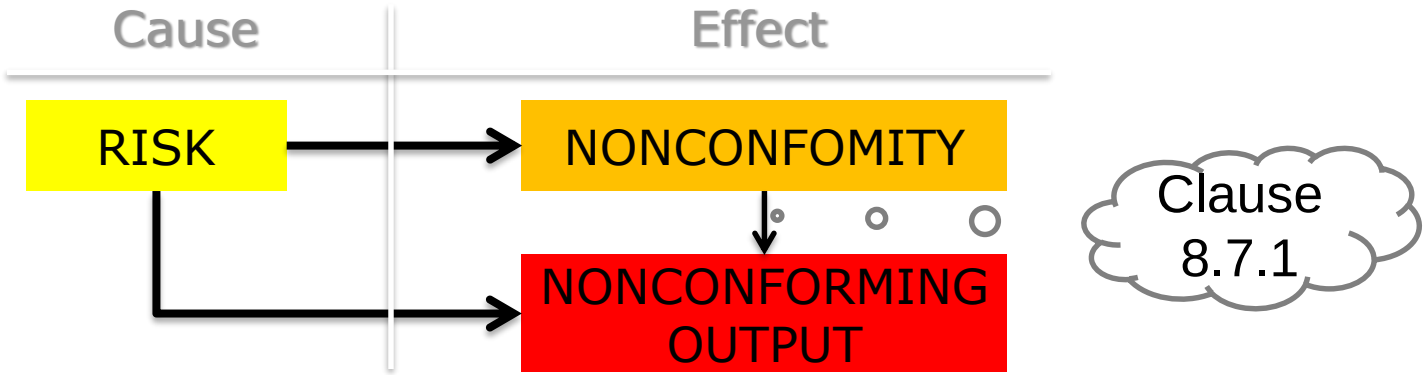
When a nonconformity occurs, including any arising from complaints, the organization shall:

b) evaluate the need for action to eliminate the **cause(s)** of the nonconformity,

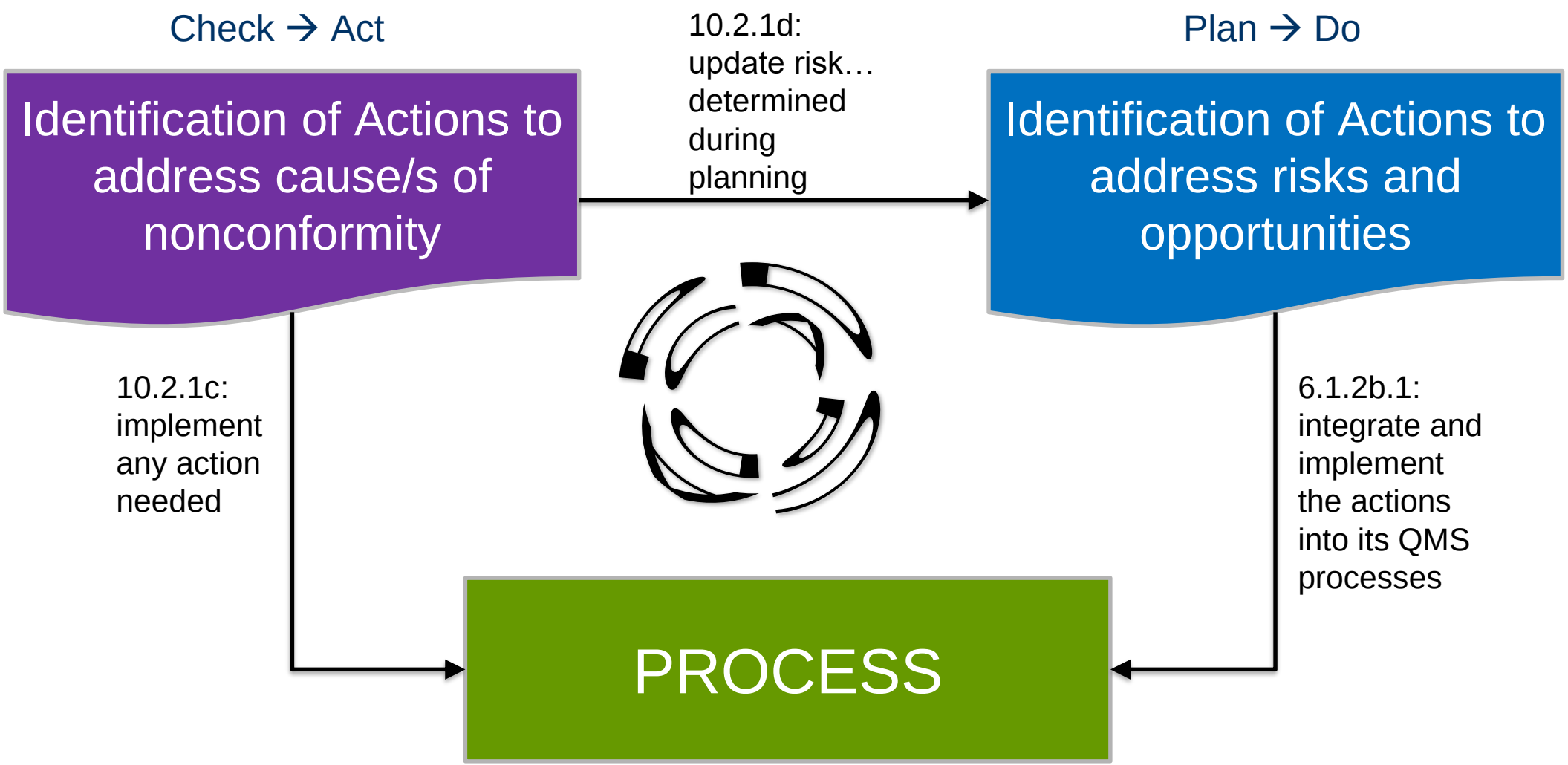
e) update **risks** and opportunities determined during planning, if necessary

# Purpose of Clause of 6.1.1 as per ISO/TS 9002:2016

- The intent of this subclause is to ensure that WHEN PLANNING THE quality management system PROCESSES, the organization determines its risks and opportunities and plans actions to address them.
- Its purpose is to *prevent nonconformities, including nonconforming outputs*, and to determine opportunities that might enhance customer satisfaction or achieve an organization's quality objectives.



# Actions to Address Causes are Actions to Address Risks



# Analysis of the Risks and Opportunities on a Process

| RISKS/OPPORTUNITIES ANALYSIS & ACTIONS PLANNING | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| Planned Results (Expected Output, MFO) | Analysis | | | Actions Planning | | | Evaluation of Effectiveness | |
| | Risk | Existing Controls | Opportunity | Recommended Additional Control | Responsible and Target Date | Action Taken and Date Completed | Planned Result Achieved? Y/N | Planned Activity Realized? Y/N |
| | | | | | | | | |

| CORRECTIVE ACTION REQUEST (SECTION 2) | | | | | |
|---|---|---|---|---|---|
| Determine the Appropriate Corrective Action/s – Propose to the management (not later than 10 working days) a list of appropriate actions which are concrete in nature and verifiable. The actions must be approved by the management prior to their implementation. | | | | | |
| Significant Causes | CA No. | Appropriate Action | Responsible | Target Date | Approval of the Office Head |
| | | | | | |

# INTERNAL AUDIT PROCEDURE

# Internal Audit Main Requirement

- The organization shall conduct internal audits at planned intervals to provide information on whether the quality management system:
  - a) conforms to:
    - 1) the organization's own requirements for its quality management system;
    - 2) the requirements of this International Standard;
  - b) is effectively implemented and maintained.

HOWs

WHATs

*"ISO 9001 specifies WHAT the organization must do but does not say HOW they must do it."*

ISO 9001 Clause 9.2.1

# WHAT & HOW in QMS

| ISO 9001's WHAT | COMPANY's HOW |
|---|---|
| Control of documented information… retention and disposition | Implementation of the Records Disposition Schedule |
| The quality policy shall… be communicated, understood and applied within the organization | Uploading of the QP to the website, issuance of ID-sized QPs, recital of QP, QP supported by KPIs |
| Top management shall review the organization's QMS at planned intervals | Conduct of the ExeCom or ManCom meetings |
| Determine the knowledge necessary for the operation of its processes | Competencies indicated in the Position Description, orientation on existing SOPs; maintaining instruction manuals |
| Determine and apply criteria for evaluation, selection, monitoring of performance, and re-evaluation of external providers | Technical working group (TWG) preparation of terms of reference (TOR), bids and awards (BAC) process, project site visits |

Organizations will be audited on both requirements

# Internal Audit Main Requirement

- The organization shall:
  - a) plan, establish, implement and maintain an audit programme(s) including the frequency, methods, responsibilities, planning requirements and reporting, which shall take into consideration the importance of the processes concerned, changes affecting the organization, and the results of previous audits;
  - b) define the audit criteria and scope for each audit;
  - c) select auditors and conduct audits to ensure objectivity and the impartiality of the audit process;

ISO 9001 Clause 9.2.2

# Internal Audit Main Requirement

- The organization shall:
  - d) ensure that the results of the audits are reported to relevant management;
  - e) take appropriate correction and corrective actions without undue delay;
  - f) retain documented information as evidence of the implementation of the audit programme and the audit results.

ISO 9001 Clause 9.2.2

# Audit Phases

- Phase 1 – Initiating the audit
- Phase 2 – Preparing for the audit
- Phase 3 – Conducting the audit
- Phase 4 – Reporting the results of the audit
- Phase 5 – Conducting audit follow-up

# Internal Audit Procedure Outline

| PHASE | DOCUMENTED INFORMATION | RESPONSIBLE |
|---|---|---|
| Initiating the audit | Audit Program, Audit Plan | Lead Auditor, Management Representative, Top Management |
| Preparing for the audit | Auditor's Notes | Auditor |
| Conducting the audit | Auditor's Notes | Auditor, Auditee |
| Reporting the results of the audit | Audit Findings Report, Corrective Action Request (CAR) | Auditor, Lead Auditor |
| Conducting audit follow-up | CAR Register, CAR | Lead Auditor, Auditor |

# Planning the Audit

**Planning as per ISO 9001 Clause 9.2.2a**

- plan, establish, implement and maintain an audit programme(s) including the frequency, methods, responsibilities, planning requirements and reporting, which shall take into consideration
  - the importance of the processes concerned,
  - changes affecting the organization, and
  - the results of previous audits.

# Other considerations when planning for the audit

- Most Certification Bodies' established interpretation for frequency of Internal Audit is that:

  ***"All the processes, areas, and applicable ISO 9001 clauses employed within the scope of the quality management system shall be audited at least once in a 12 month period".***

  ***"Regardless of scheme it must be shown by every organization that every 'shall' has been met as required"***

Audit Program

# ASSIGNMENT – Process VS Clauses

- In an organization implementing ISO 9001, you can see three types of processes namely:
  - **Customer Oriented Process – COP**
  - **Support Oriented Process - SOP**
  - **Management Oriented Process – MOP**
- Identify and list down all the processes that you know in the sheet provided (Correlation Matrix) and indicate whether the process is a CP, SP, MP.
- Indicate the applicable ISO 9001 Clauses

# Audit Plan

The Audit Plan should show:

- what the activity is trying to accomplish;
- the extent and boundaries of the audit;
- the audit approaches;
- the references against which conformity is to be determined;
- the assigned auditor(s);
- the identification of the auditee’s area(s) for the audit;
- the dates and approximate duration of each audit stage;
- Instructions upon consideration of risks and opportunities to the audit activities.

Audit Plan

# What to look for in a process?

- As per **4.4 QMS and its processes**, a process must:
  - have the required inputs and expected outputs;
  - have applied criteria and methods;
  - have monitoring, measurement and related performance indicators;
  - have the needed resources (e.g. people, infrastructure, environment);
  - have assigned responsibilities and authorities;

# What to look for in a process?

- As per **4.4 QMS and its processes**, a process must:
  - have actions to address the identified risks and opportunities;
  - be evaluated and implement any changes needed to achieve the intended results;
  - be improved;
  - to the extent necessary, maintain and/or retain documented information to support its effective operation;
  - be in accordance with the requirements of ISO 9001.

# Schematic Diagram for Process Approach Auditing

**Resources**:
- People
- Infrastructure
- Environment
- Monitoring and measuring
- Organizational knowledge

**Inputs**:
- Interested parties needs and expectations
- Voice of the process
- Information
- Materials
- Output of preceding process

**Criteria and Method**:
- Planned activities and planned arrangements
- Documented information (procedures, instructions, standards, manuals, etc.)
- Input and output criteria

**Realization of Planned Interrelated or Interacting Activities**

**Controls and Actions**:
- To address risks and opportunities
- To achieve planned results, including changes
- To external providers
- To deal with nonconforming outputs

**Intended Results**:
- Evidence of achieving the planned results/expected outputs
- Objective of the process
- Requirement of the next process

**Monitor, Measure & Analyze**:
- Measures of effectiveness and efficiency
- Retained documented information
- Indicators of performance and of continual improvement

# Process-Based Checklist


- The checklist should look into the expected results/outputs, inputs, resources, controls, personnel, information, performance measurements, records and monitoring of the product / process characteristics

***"We will discuss further the method in preparing a checklist (i.e. Auditor's Notes) and conducting the actual interview during the Training Course on Auditing a QMS"***

# Audit Report

- This should contain enough information to enable management to assess the effectiveness of the quality system in the area audited
- The audit report, therefore, should not only contain information about nonconformities but also the satisfactory aspects of the system

# Content of the Audit Report

- The audit findings report should include, or make reference to the following:
  - the audit objectives
  - the audit scope
  - acknowledgement of the auditee
  - the identification of the audit team
  - commendable findings
  - areas for improvements
  - summary of conformities / nonconformities

# Comments on Existing Audit Findings Reports

| COMMENTS | CASE IN POINT | RECOMMENDATIONS |
|---|---|---|
| Good to recognize good practices and recommend improvement | AFR R2 Accomplishment | Do the same to other processes. |
| Audit criteria is not explicitly described | AFR R2 Admin | State the specific requirement that must be fulfilled. Establish the reference (e.g. policy, procedure, manual, regulation) |
| The evidence obtained is not relevant to the criteria being assessed | AFR R2 Wildlife<br>AFR R2 Conserve | The evidence should mirror the statement of the criteria. |
| There's a criteria but no evidence collected | AFR R2 Protected Area | Describe the evidence collected and state the audit finding |
| Use of standard set of criteria | AFR R2 Illegal | Use of the same set of criteria is akin to "telegraphing the punches" |
| The Impact column is intended to the consequences of nonconformities, if there are any. | AFR R2 Monitoring | The Evidence and the Criteria columns can be merged into one and if there's consequence of not fulfilling a requirement, then this has to be described also. |

# ORGANIZATIONAL KNOWLEDGE MANAGEMENT

# What is Organizational Knowledge?

- *NOTE 1 Organizational knowledge is knowledge specific to the organization; it is gained by experience. It is information that is used and shared to achieve the organization's objectives.*

ISO 9001 Clause 7.1.6

Organizational knowledge is the specific knowledge of the organization coming either from its collective experience or from the individual experience of its persons.

Persons of the organization and their experience are the foundation of organizational knowledge.

*- ISO/TS 9002:2015 Clause 7.1.6*

# What is Organizational Knowledge?

- *NOTE 2 Organizational knowledge can be based on:*
  - *a) internal sources:*
    - *intellectual property;*
    - *knowledge gained from experience;*
    - *lessons learned from failures and successful projects;*
    - *capturing and sharing undocumented knowledge and experience;*
    - *the results of improvements in processes, products and services;*
  - *b) external sources:*
    - *standards;*
    - *academia;*
    - *conferences;*
    - *gathering knowledge from customers or external providers.*

ISO 9001 Clause 7.1.6

# Requirements on Organizational Knowledge

- *The organization shall determine the knowledge necessary for the operation of its processes and to achieve conformity of products and services.*
- *This knowledge shall be maintained and be made available to the extent necessary.*
- *When addressing changing needs and trends, the organization shall consider its current knowledge and determine how to acquire or access any necessary additional knowledge and required updates.*

# Determine, Maintain and Make Available the Organizational Knowledge

In determining, maintaining and making available organizational knowledge, the organization can consider:

a) learning from failures, near miss situations and successes;
b) debriefing sessions, discussions of what went right/wrong;
c) gathering knowledge from customers, external providers and partners;
d) capturing knowledge that exists within the organization, e.g. through mentoring, succession planning;
e) induction and orientation sessions;
f) echo-training of the acquired learnings;
g) benchmarking, capturing/sharing best practices;
h) integrating into the processes the actions to address problems encountered;
i) an intranet, libraries, document databases, awareness sessions, newsletters, etc.

# CUSTOMER SATISFACTION

# Requirements in 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 this information.

The organization should be able to *determine the degree of customer satisfaction* after the results are analyzed and evaluated and take action based on this information.

This information should be an *input to management review* and be used to determine if actions are necessary to improve customer satisfaction.

ISO 9001 Clause 9.1.2

# Methods for Obtaining, Monitoring and Reviewing Information on Customer Satisfaction

- These methods can include, but are not limited to:
  - opinion surveys;
  - customer data on delivered products or services quality;
  - compliments;
  - complaints;
  - social media, such as web sites and message boards;
  - published information, such as in newspapers or journals

- *ISO/TS 9002:2016 Clause 9.1.2*

# DENR's Existing Approach in Monitoring Customer Satisfaction

**V.4.4 Stakeholder Satisfaction (DENR's Quality Manual)**

- Feedback is collected using a client satisfaction survey form, readily available at the Public Assistance Complaints Desk (PACD).
- This feedback mechanism include gathering of positive and negative impressions on the provision of products/services, as well as an open ended clause to encourage suggestions and comments from clients.
- The feedback is summarized and reported on a regular basis to measure the degree of satisfaction of DENR's clientele and collect suggestions on how to provide better customer service to its stakeholders.

# MANAGEMENT REVIEW

# Purpose of Management Review

To review information on the performance of the QMS in order to determine if it is ***continually***:

a) suitable – does the QMS still fit its purpose?

b) adequate – do we still have what we need to implement an effective QMS?

c) effective – are we still achieving the intended results?

d) aligned – is it taking us to the status we envisioned to become?

# Question: Before We Proceed…

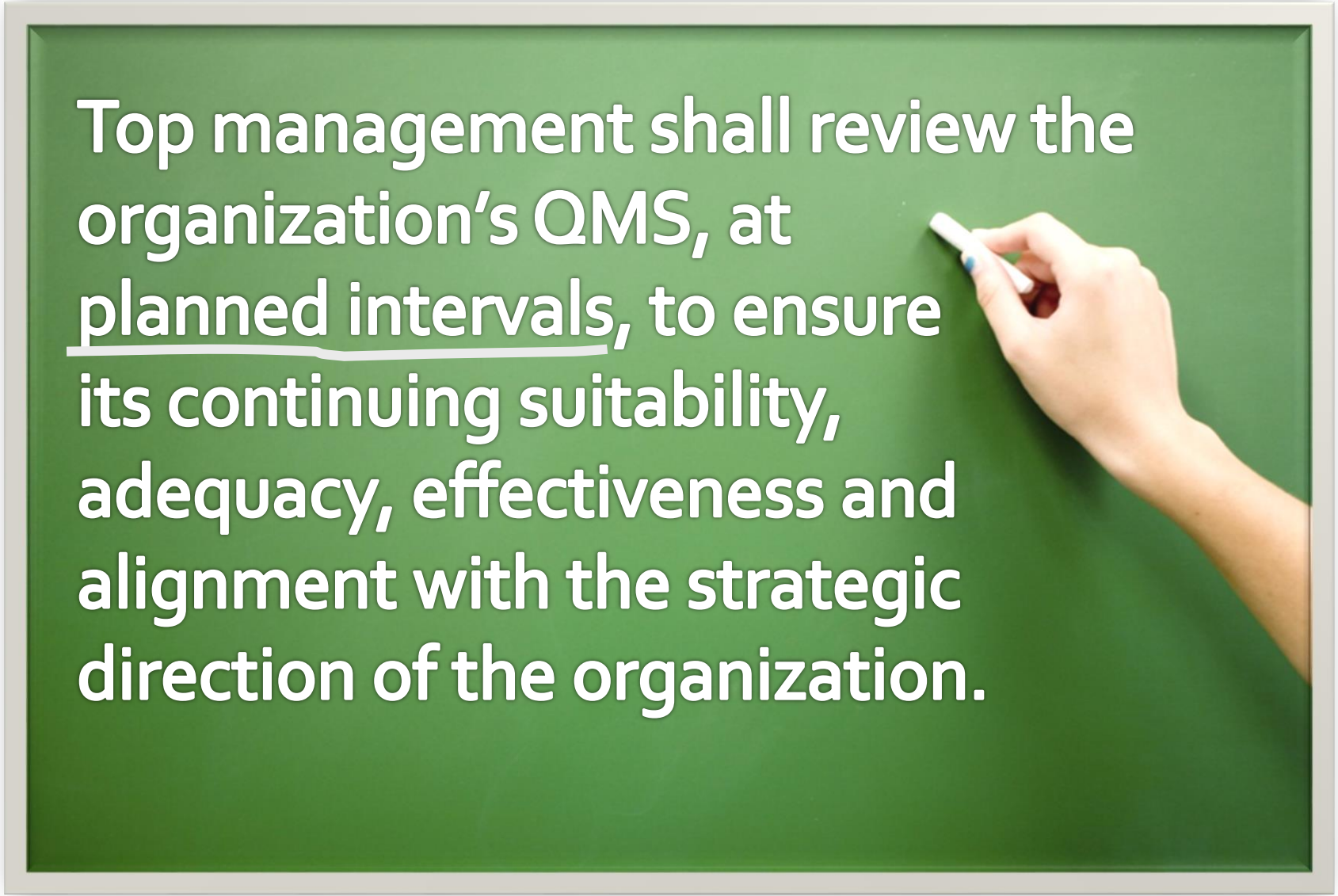
- Question.
  - Is it an ISO 9001:2015 requirement that an organization must conduct a management review at least once annually AND must cover all the specified inputs every time a management review meeting is held?

    a.) Yes AND Yes  b.) No AND No

    c.) Yes AND No  c.) No AND Yes

- Answer.
  - b.) No AND No

# Management Review - General



# Frequency of Management Review

***According to ISO/TS 9002:2016:***

Section 9.3.1

- this could be daily, weekly, monthly, quarterly, semi-annually or annually.
- management review activities may be carried out by various levels of the organization, provided the results are made available to top management.

> *Top management – person or group of people who directs and controls an organization at the highest level*
>
> *- 3.1.1 of ISO 9000:2015*

# Timing of Management Review

***According to ISO/TS 9002:2016:***

Section 9.3.1

- The organization may conduct management reviews as a standalone activity or in a combination of related activities (e.g. meetings, reports).
- The timing of management reviews can be scheduled to coincide with other business activities (e.g. strategic planning, business planning, annual meetings, operations meetings, other management system standards' reviews) to add value and to avoid redundant multiple meetings.

# Integrating Management Review with Existing Management Meetings

According to the International Accreditation Forum: Auditing Practices Group Guidance on Policy, Objectives and Management Review:

- The management review process should not be an exercise carried out solely to satisfy the requirements of the standard and the auditors; it should be an *integral* part of the organization's *business management process*.
- The review could be carried out at a separate meeting, but this is not a requirement of the standard.
- There are many ways in which Top Management can review the quality management system, such as receiving and reviewing a report generated by the management representative or other personnel, electronic communication, or as part of regular management meetings where issues such as budgets and targets are also discussed.

# What Does ISO 9001 and ISO 9002 Say About Integration?

According to Clause 5.1.1c of both standards:

**ISO 9001:2015**

- Top management shall demonstrate leadership and commitment with respect to the quality management system by… ensuring the integration of the quality management system requirements into the organization's business processes.

**ISO/TS 9002:2016**

- ensuring that the organization's quality management system processes are integrated and managed within its overall business processes, and not treated as "add-on" or conflicting activities

# Sample Approaches on “Planned Intervals”

| Kinds of Interval | Sample Statement in the Quality Manual |
|---|---|
| Regurgitated from ISO 9001 | *“Our MRC reviews our QMS at planned intervals, to ensure its continuing suitability, adequacy, effectiveness and alignment with the strategic direction of the organization. “* |
| At least once a year | *“The review of the established QMS is conducted at least once a year and/or whenever deemed necessary by the Quality Council to ensure continuing stability and effectiveness…”* |
| Twice a year | *“…top management periodically meets twice in a year (May & December) to review the QMS to ensure its continuing suitability…”* |
| Quarterly | *“Review of the QMS suitability, adequacy and effectiveness is carried out during the quarterly ManCom meeting.”* |

# Sample Approaches on “Planned Intervals”

<table>
<tr><th>Kinds of Interval</th><th>Sample Statement in the Quality Manual</th></tr>
<tr><td>During various meetings</td><td>“Performance review is undertaken during meetings at the unit, division and management level as detailed below:“
<table>
<tr><th>Review of:</th><th>Exe Com</th><th>Man Com</th><th>DU</th></tr>
<tr><td>1. Attainment of performance goals</td><td></td><td></td><td></td></tr>
<tr><td>2. Results of audits</td><td></td><td></td><td></td></tr>
<tr><td>3. Client feedback</td><td></td><td></td><td></td></tr>
<tr><td>4. Process performance and conformity</td><td></td><td></td><td></td></tr>
<tr><td>5. Status of corrective actions</td><td></td><td></td><td></td></tr>
<tr><td>6. Changes that could affect the QMS</td><td></td><td></td><td></td></tr>
<tr><td>7. Recommendations for improvement</td><td></td><td></td><td></td></tr>
</table></td></tr>
</table>

# Sample Approaches on “Planned Intervals”

| Kinds of Interval | Sample Statement in the Quality Manual |
|---|---|
| During staff meetings | *“Effective reviews require the assembly of meaningful performance data – performance of programs, services, processes and personnel – to allow factual based-decision making. The inputs on our staff meetings shall be reviewed as specified below:”* |

| *Inputs* | *Weekly* | *Monthly* | *Quarterly* | *Semestral* | *As the need arises* |
|---|---|---|---|---|---|
| *1. MMD/MSESDD Management and Regulation* | ■ | | | | |
| *2. MMD/MSESDD Enforcement and Monitoring* | ■ | | | | |
| *3. GSD Services* | ■ | | | | |
| *4. HR Management* | | | | | ■ |
| *5. Financial Management* | | | | | ■ |
| *6. Results of Audits* | | | ■ | | |
| *7. Evaluation of Performance Commitments and Targets* | | | | ■ | |
| *8. Customer Feedback* | | ■ | | ■ | |

# DENR's Approach in Reviewing Its QMS

Different levels of the DENR conduct regular meetings to discuss the inputs

| Office Level | Title of Meeting | Presiding Officer | Attendees |
|---|---|---|---|
| Central Office | Executive Committee | Secretary | Undersecretaries, Assistant Secretaries, Service Directors, Bureau Directors, Head of Attached Agencies, the HEad Executive Assistant, Directors of AdHoc Offices and representative of the employees union |
| Bureau | Executive Committee | Bureau Director | Assistant Director, Division Chiefs and concerned officers<br>For ERDB, includes Research Centers Head |
| Region Office | Expanded Management Conference (ManCon) | Director | Office, PENROs, CENROs |

# Management Review Inputs

- The management review shall be planned and carried out ***taking into consideration***:
  - Status of actions from previous reviews
  - Changes in external and external issues
  - Information on the performance and effectiveness of the QMS, including trends in:…

| | |
|---|---|
| ***consider*** | *means it is necessary to think about it but it can be excluded* |
| ***take into account*** | *means it is necessary to think about it but it cannot be excluded* |
| According to ISO 14001:2015, Annex 3 – Clarification of Concepts and Annex A.3 of ISO 45001:2018 | |

# So Must We Cover All Inputs On Each Review?

- ISO 9001 specifies a number of inputs to the management review process and these topics need to be addressed; however, these are not the only subjects that can be included in a review. It is also acceptable not to address them individually or simultaneously but as part of an overall review of the business.

*APG Guidance on Policy, Objectives and Management Review*

- It is *not required* that all the inputs to management review be addressed at one time, but instead they may be addressed during sequenced management reviews

- *9.3.1 of ISO/TS 9002:2016*

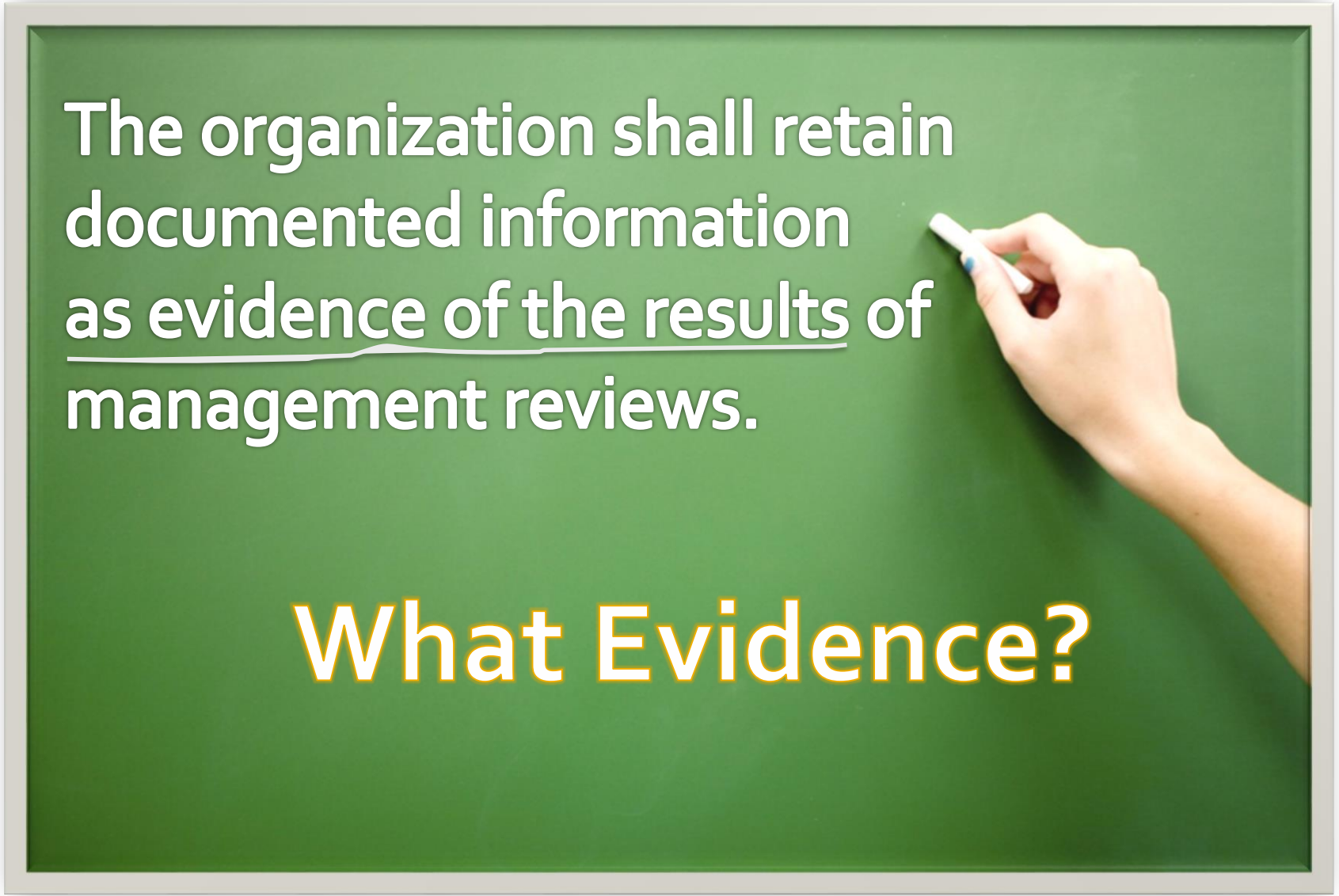
# “Inputs” are interrelated and need not be discussed as individual topic in a meeting

| Sample Agenda Discussed During a ManCom Meeting | Relevant Management Review Input |
|---|---|
| Results of the evaluation of the OPCRs and DPCRs | *9.3.2c.2; 9.3.2c.3; 9.3.2c.5* |
| Complaints of customers that need to be resolved | 9.3.2c.1; 9.3.2c.4 |
| Results of the evaluation of conformity with service-level agreements (SLA) for pertinent suppliers/contractors | 9.3.2c.7; 9.3.2c.5 |
| Negative audit findings by COA that need to be addressed | 9.3.2c.6; 9.3.2c.4 |
| Need for additional and modern IT equipment and systems for the new building | 9.3.2d; 9.3.2b |

# Sample Summary of ManCom Meetings

| | A | B | C | D | E | F | G | H | I | J | K | L | M | N | O | P | Q |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| 1 | AGENDA | Relevant QMS Review Inputs | | | | | | | | | | | | MANCOM MEETINGS FOR Y2018 | | | |
| 2 | | 9.3.2a | 9.3.2b | 9.3.2c.1 | 9.3.2c.2 | 9.3.2c.3 | 9.3.2c.4 | 9.3.2c.5 | 9.3.2c.6 | 9.3.2c.7 | 9.3.2d | 9.3.2e | 9.3.2f | JANUARY | FEBRUARY | MARCH | APRIL |
| 3 | Results of the evaluation of the OPCRs and DPCRs for 2nd Semester of Y2017 | | | | √ | √ | | √ | | | | | | MC.18.01 | | | |
| 4 | Results of the evaluation of conformity with service-level agreements (SLA) for pertinent suppliers/contractors | | | | | | | √ | | √ | | | | MC.18.01 | | | |
| 5 | Complaints of customers that need to be resolved | | | √ | | | √ | | | | | | | MC.18.01 | | | MC.18.03 |
| 6 | Need for additional and modern IT equipment and systems for the new building | | √ | | | | | | | | √ | | | | MC.18.02 | | |
| 7 | Negative audit findings by COA that need to be addressed | | | | | | √ | | √ | | | | | | MC.18.02 | | |
| 8 | Results of QMS Internal Audit | | | | | | √ | | √ | | | | √ | | | | MC.18.03 |
| 9 | Review of the actions to address risks and opportunities | | | | | | | | | | | √ | | | | | MC.18.03 |
| 10 | Follow-up on Improvement Actions from previous ManCom | √ | | | | | | | | | | | | | | | MC.18.03 |

# Management Review Outputs



# “evidence of the results”

To demonstrate fulfillment of the highlighted statement above, select the “more appropriate” evidences from the two sets of records:

a) Set A: action plans on the improvement initiatives that were raised, plans on the necessary changes and resources, monitoring of accomplishment of the plans
b) Set B: management review agenda program, notice of the meeting, accomplished attendance sheet, presentation materials, presented reports, minutes of the meeting showing all inputs are covered

**Answer:**
**a) Set A**

# Evidence of MR vs Evidence of the Results of MR

**4.1.3 Management review**

The supplier's management with executive responsibility shall review the quality system at defined intervals sufficient to ensure its continuing suitability and effectiveness in satisfying the requirements of this International Standard and the supplier's stated quality policy and objectives (see 4.1.1). Records of such reviews shall be maintained (see 4.16).

ISO 9001:1994

ISO 9001:2000

**5.6 Management review**

**5.6.1 General**

Top management shall review the organization's quality management system, at planned intervals, to ensure its continuing suitability, adequacy and effectiveness. This review shall include assessing opportunities for improvement and the need for changes to the quality management system, including the quality policy and quality objectives.

Records from management reviews shall be maintained (see 4.2.4).

# Evidence of MR vs Evidence of the Results of MR

**5.6 Management review**

**5.6.1 General**

ISO 9001:2008

Top management shall review the organization's quality management system, at planned intervals, to ensure its continuing suitability, adequacy and effectiveness. This review shall include assessing opportunities for improvement and the need for changes to the quality management system, including the quality policy and quality objectives.

Records from management reviews shall be maintained (see 4.2.4).

**9.3.3 Management review outputs**

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

a) opportunities for improvement;

b) any need for changes to the quality management system;

c) resource needs.

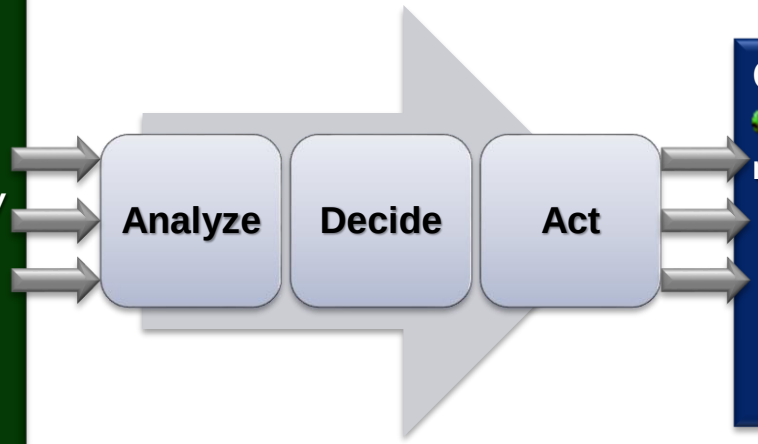
ISO 9001:2015

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

# Input Oriented vs Output Oriented

**INPUTS**

- Status of actions from previous reviews
- Changes in internal and external issues
- Info on the performance and effectiveness of QMS with trends in:
  - Customer feedback
  - Quality objectives
  - Process performance
  - Product/service conformity
  - NCs and CAs
  - Results of monitoring / measurement
  - Results of audits
  - External providers performance
- Adequacy of resources
- Effectiveness of actions to address risks and opportunities
- Opportunities for improvement




**OUTPUTS**

- Decisions and actions related to:
  - Opportunities for improvement
  - Any need for changes to QMS
  - Resources needs

Sample Minutes

Sample Actions

# TO ALL PARTICIPANTS…