Standard Operating Procedure (SOP) Development

Contents

In the face of a challenging regulatory environment, companies have found ways to improve quality in work and costs significantly. To drive this kind of beneficial change, companies must first create a culture where work objectives are transparent, well understood, and undoubtedly these goals can be achieved by following certain sets of procedures called as "Standard Operating Procedures" (SOP).

What is SOP?

| Set of written instructions that document a routine activity within your company/division/work group. | A documents which describes the operations of a certain work or job in order to ensure it's quality. | A set of compulsory instructions, systems, procedures or steps which is written so that other individuals can follow to complete the job safely |

Policy — a course or principle of action adopted or proposed by an organisation

Process — a series of actions or steps taken in order to achieve a particular end.

Procedure — Way of doing something.

We are talking about Standardisation of Procedure i.e. way of doing something !!

Minimizes Variation
minimizes variation and promotes quality through consistent implementation of a process or procedure within the organization

Good Practice
Ensures good practice is achieved at all times

Compliance with Government Regulation
Well-written SOPs help ensure that government regulations are satisfied.

Role Clarification
Help to avoid confusion over who does what

Benefits of SOP

On time completion
To ensure that processes continue and are completed on a prescribed schedule

Audit Function
Provide a contribution to the audit process and serves as checklist of auditor

Training New staff
They are useful tools for training new members of staff

03〉

Effectiveness

Increased effectiveness increases Value to customer

Effectiveness – What to do

Efficiency – How to do

02〉

Efficiency

Increased efficiency reduces cost to company

High			
	Die Quickly		**Thrive**
	Die Slowly		**Survive**
Low			

Efficiency- Doing things right

Low **Effectiveness – Doing the right things** High

The outcome of a well designed business process is increased effectiveness (value for customer) and increased efficiency (reduced costs for company).

Every Day

Annual Training

When

Orienting new staff

In Preparation and conduct of Audit and review

Level of details

Clarity

boundaries of the process

document control

degree of meeting both of business objectives & regulatory requirements.
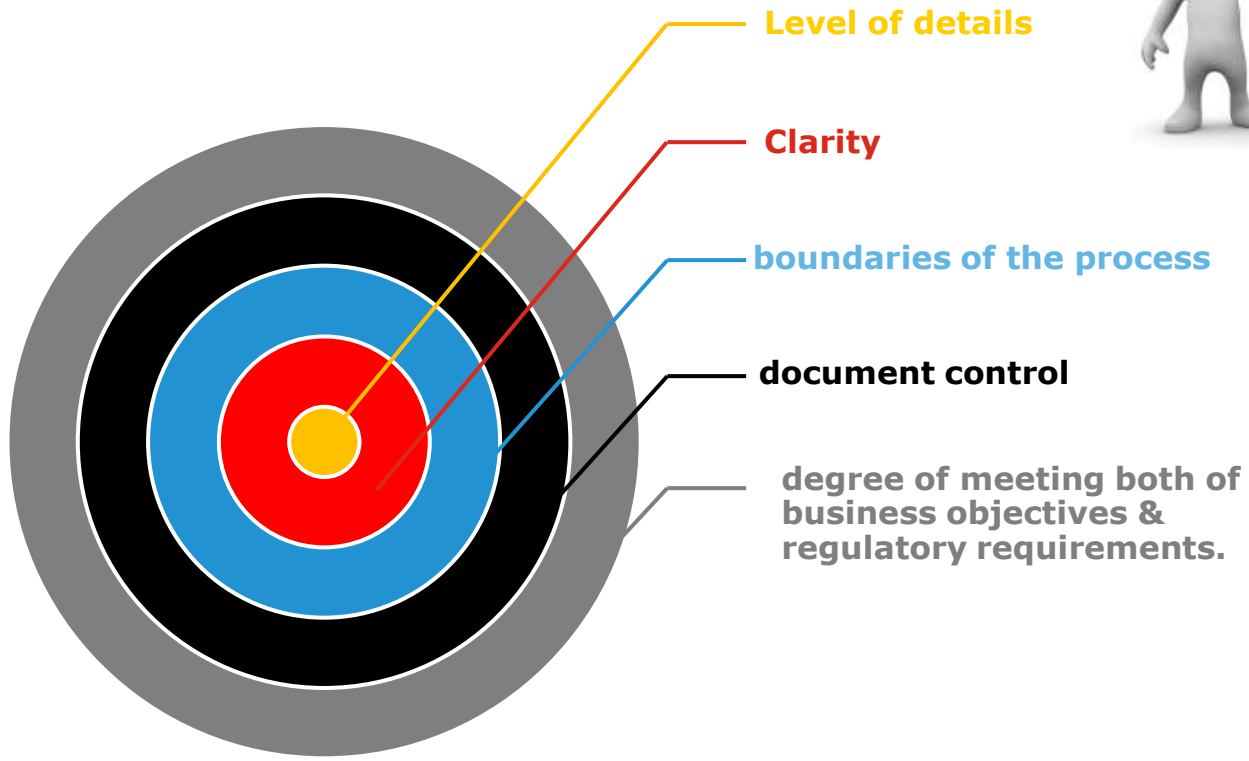
Technical SOP	Administrative or Fundamental Programmatic SOP
➢ Focuses more on technical activities such as instructing the user how to perform a specific analytical method to be followed in the laboratory or field (such as field testing using a kit), or how to collect a sample in order to preserve the sample integrity and representativeness (such as collection of samples for future analysis of volatile organic compounds or trace metals), or how to conduct a bio assessment of a freshwater site.	➢ Highlights on administrative processes such as reviewing documentation such as contracts, QA Project Plans and Quality Management Plans; inspecting (auditing) the work of others; determining organizational training needs; developing information on records maintenance; validating data packages; or describing office correspondence procedures.

People's actions are Centered

In order to produce, the necessary actions required by people are standardized.

Actions have a certain degree of repetitiveness

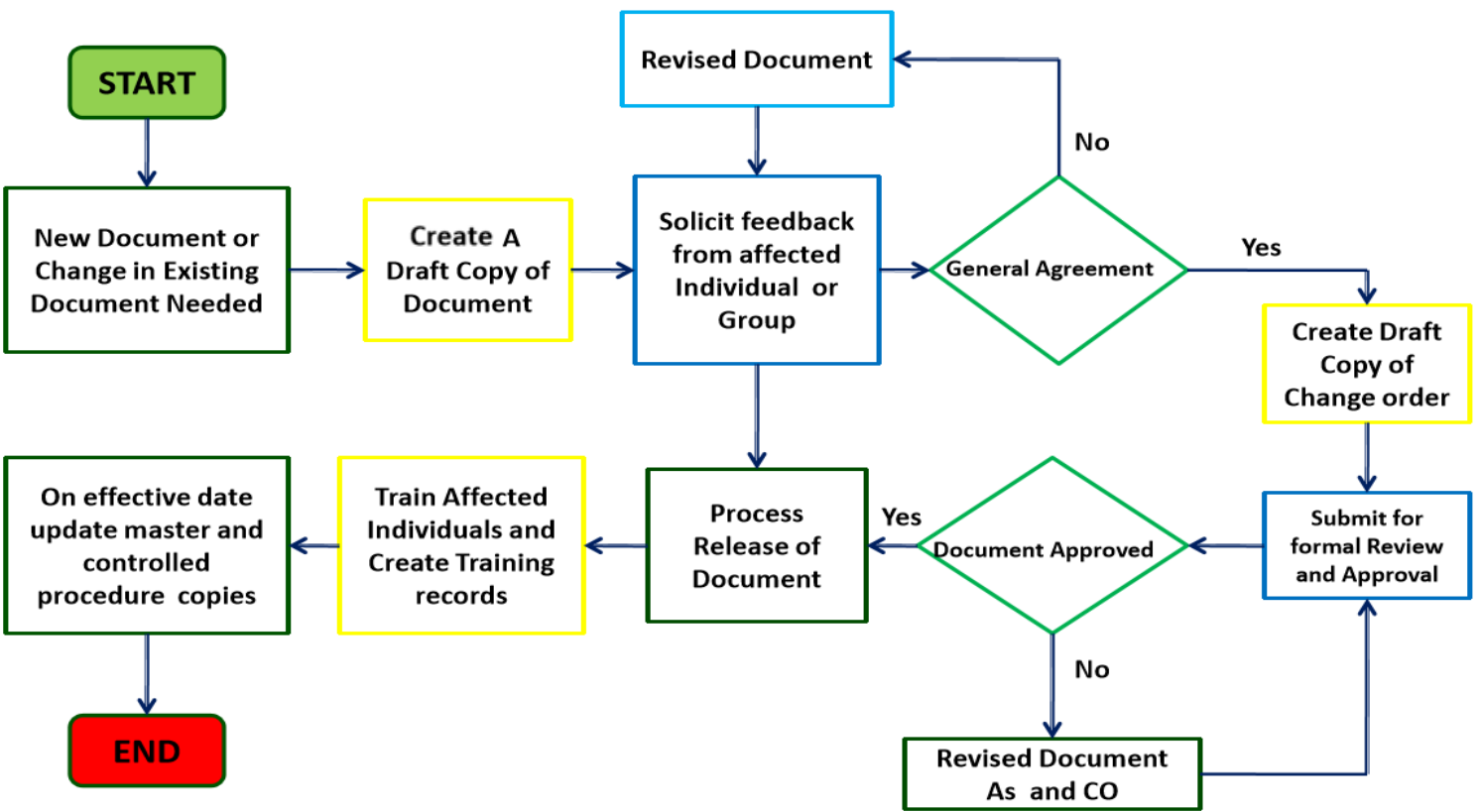Standardize the process steps for producing the same product each time.

Each time the work content is different, it cannot be standarised.

The operation that satisfies the above conditions can be standardized, so the machine processing Jobs (machine automation operations, etc.), abnormal operations (automatic production lines, etc.) are difficult to achieve standardization.

## Flowchart showing flow of activities involved in SOP Development

START

New Document or Change in Existing Document Needed

Create A Draft Copy of Document

Revised Document

Solicit feedback from affected Individual or Group

General Agreement

No — Yes

Create Draft Copy of Change order

Submit for formal Review and Approval

Document Approved

Yes — No

Process Release of Document

Train Affected Individuals and Create Training records

On effective date update master and controlled procedure copies

END

Revised Document As and CO

Insight

✓ The organization should have a procedure in place for determining what procedures or processes need to be documented.

✓ SOPs should then be written by individuals knowledgeable with the activity and the organization's internal structure. These individuals are essentially subject-matter experts who actually perform the work or use the process.

✓ A team approach can be followed, especially for multi-tasked processes where the experiences of a number of individuals are critical, which also promotes "buy-in" from potential users of the SOP.

✓ SOPs should be written with sufficient detail so that someone with limited experience with or knowledge of the procedure, but with a basic understanding, can successfully reproduce the procedure when unsupervised.

✓ The experience requirement for performing an activity should be noted in the section on personnel qualifications. For example, if a basic chemistry or biological course experience or additional training is required that requirement should be indicated.

Steps in preparation of Draft SOP

Review of SOP

Map the process

Write SOP

Define the process
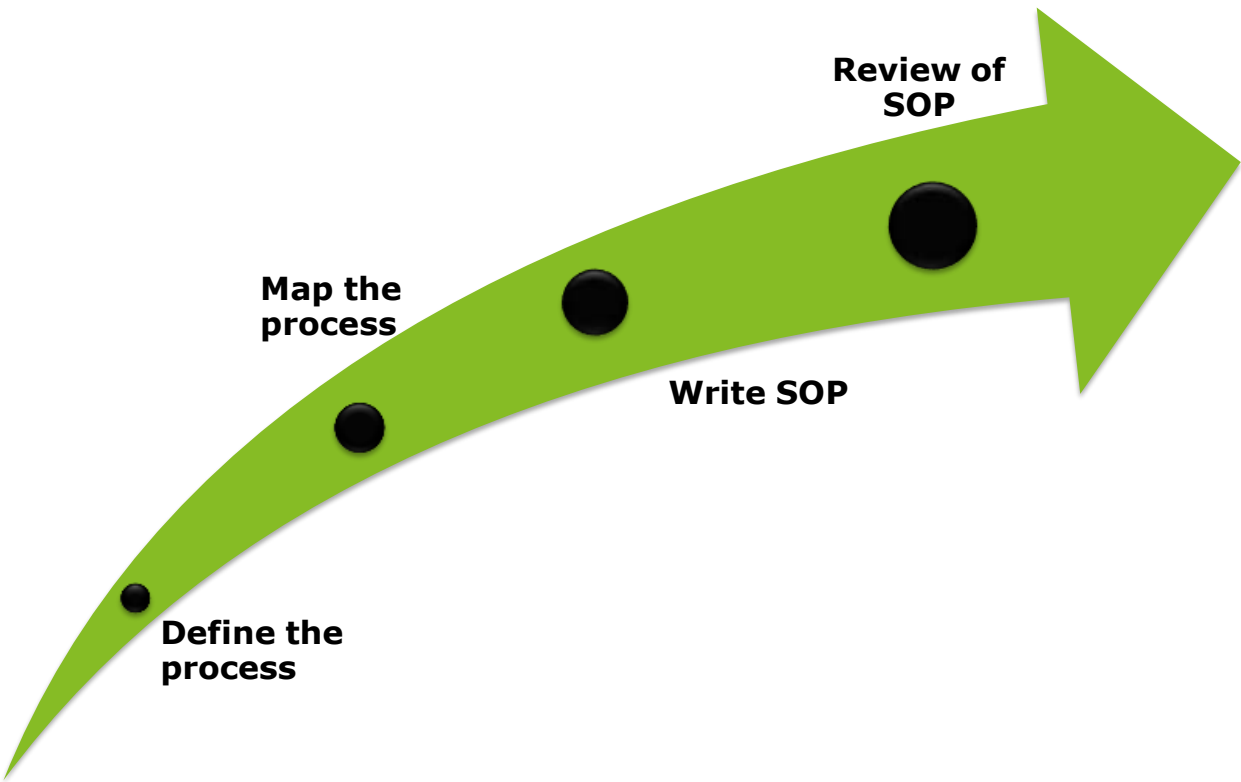
What is Process?

A set of linked activities that take an input and transform it to create an output with added value to a customer.

Types of process – Technical process and Administrative process

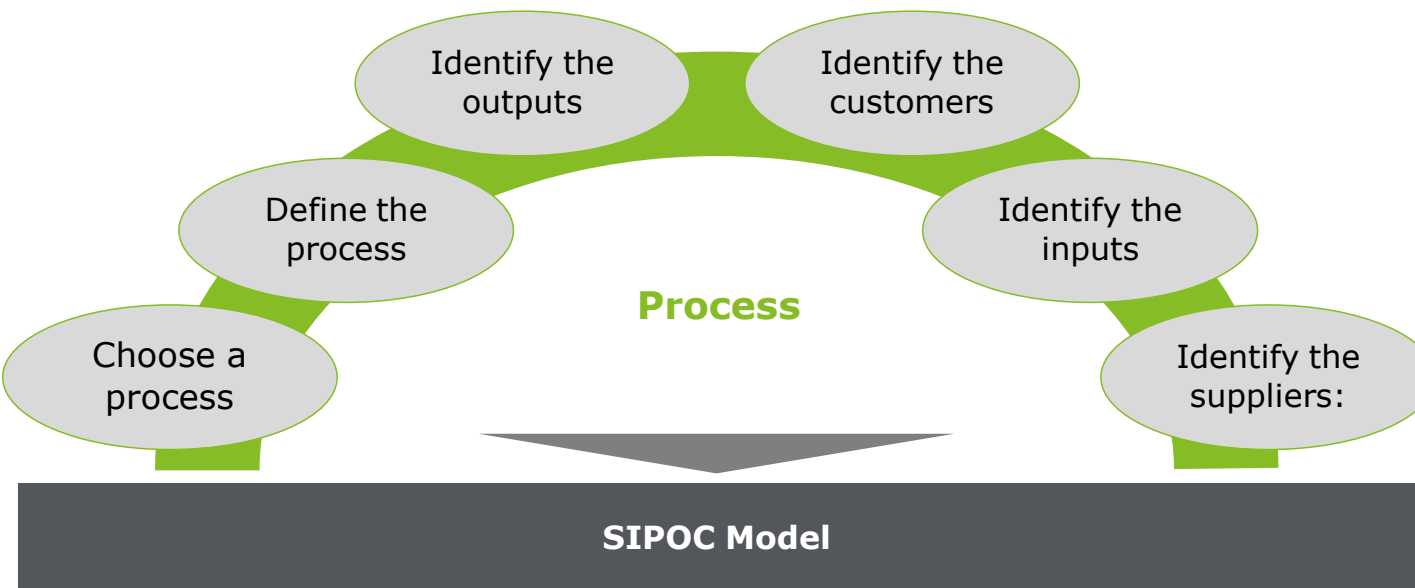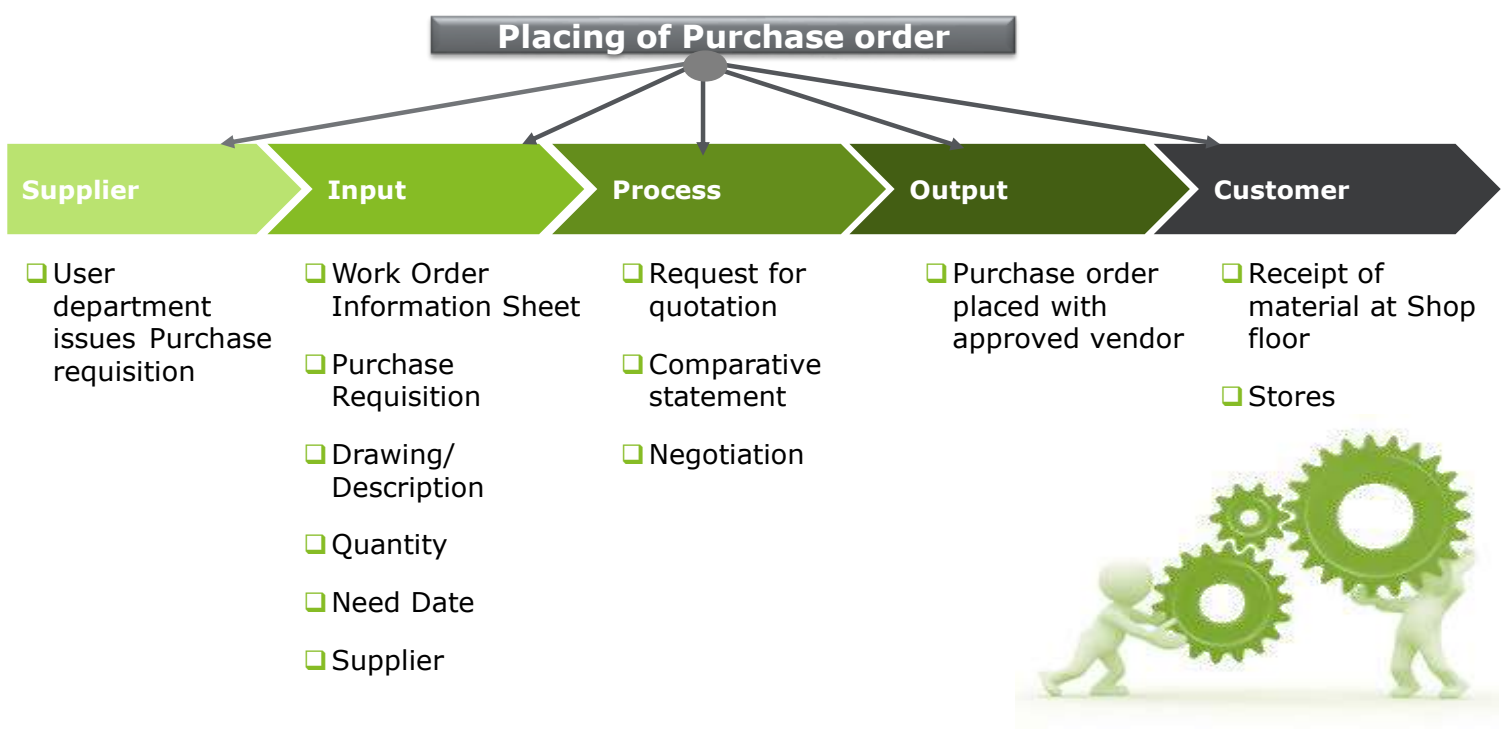| Thinks to consider	Characteristics of Process	How to define process
❑ Should Fully understand the process ❑ make interviews those associates performing the task regularly. ❑ Ask Experts (internal or External) in this task ❑ Take into consideration business objectives & regulatory requirements. ❑ A team approach can be followed , specially for cross functional processes.	❑ It should have a process owner ❑ Definable (Start & End) ❑ Order ❑ receiver of a process outcome (the customer) ❑ Value adding ❑ Cross-functionality (not regular)	❑ Develop Process KPI's ❑ Metric for measurement ❑ Identify activities within process ❑ Apply SIPOC Model (discussed in subsequent section)

SIPOC Model

A SIPOC (suppliers, inputs, process, outputs, customers) diagram is a visual tool for documenting a business process from beginning to end prior to implementation. SIPOC (pronounced sigh-pock) diagrams are also referred to as high level process maps because they do not contain much detail.

EXAMPLE

Placing of Purchase order

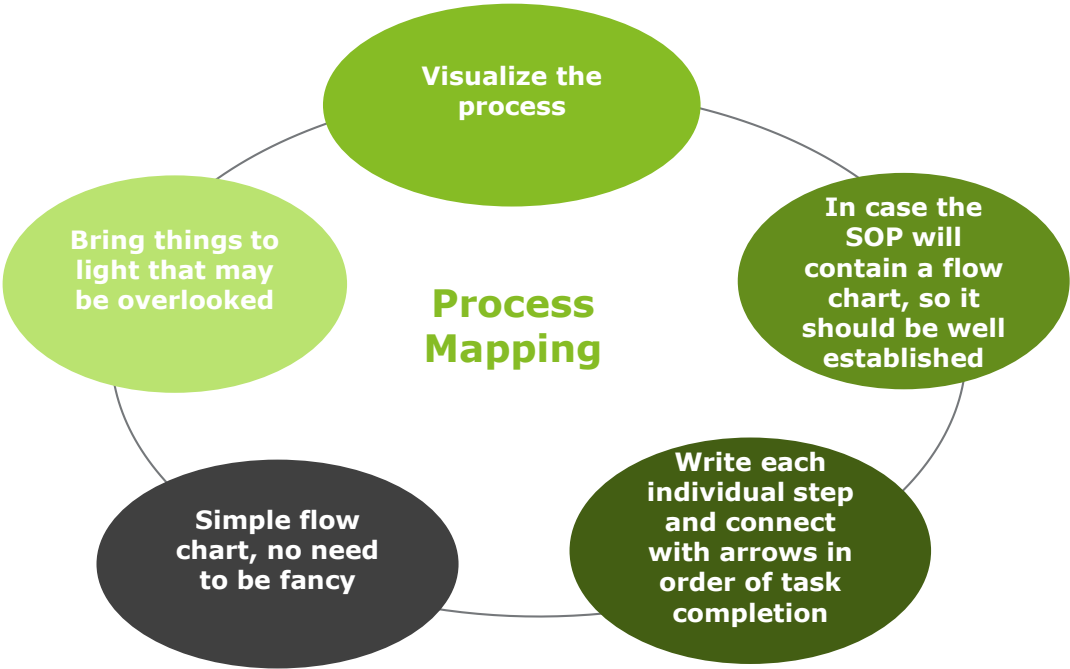| Supplier	Input	Process	Output	Customer
❑ User department issues Purchase requisition	❑ Work Order Information Sheet ❑ Purchase Requisition ❑ Drawing/ Description ❑ Quantity ❑ Need Date ❑ Supplier	❑ Request for quotation ❑ Comparative statement ❑ Negotiation	❑ Purchase order placed with approved vendor	❑ Receipt of material at Shop floor ❑ Stores

One of the purposes of process mapping is to gain better understanding of a process.

Process maps provide insight into a process, help teams brainstorm ideas for process improvement, increase communication and provide process documentation. Process mapping will identify bottlenecks, repetition and delays. They help to define process boundaries, process ownership, process responsibilities and effectiveness measures or process metrics.

Visualize the process

Bring things to light that may be overlooked

Process Mapping

In case the SOP will contain a flow chart, so it should be well established

Simple flow chart, no need to be fancy

Write each individual step and connect with arrows in order of task completion

- ✓ SOPs shall be written in a concise, step by step, easy to read and follow format.

- ✓ Information should not be complicated. The active voice and present verb tense should be used.

- ✓ Should be simple and short.

- ✓ Information should be conveyed clearly and explicitly to remove any doubt as to what is required.

- ✓ Include flow charts, diagrams and/or photos if these describe something better than words

- ✓ Refer to other SOPs rather than re-write instructions

- ✓ Avoid use of word "Should", instead use "Shall or must"

- ✓ Always use Active voice & Avoid passive voice

- ✓ Know your audience & Speak their language

- ✓ Use the SOP format & texting format approved by client

DO's

- ✓ Avoid ambiguity.
- ✓ Be concise.
- ✓ Keep the words short and get to point.
- ✓ Move from one step to another step in logical manner.
- ✓ Highlight exception. Use a symbol to flag that this is an exception and how to handle it.
- ✓ Highlight warning. Again warn users that caution must be used in this scenario. Warning must stand out; use a larger font or a warning icon.
- ✓ Reduce the word count where possible without altering the meaning of the text

Don'ts

- ✓ Introduce acronyms without explaining what it means.
- ✓ Don't use the word "may", "if possible" as it implies that the user can do something under conditions. Instead be positive and tell them what to do.
- ✓ Avoid unnecessary specifications
- ✓ Don't write the same content in more than one place, just link or refer to the other section or document (hyperlinks or document reference number)

EXAMPLE

- ❑ Manufacturing order is issued & Sent to Production department ✘

- ❑ Issue the manufacturing order & send it to production department ✔

- ❑ Planning officer issues the manufacturing order & sends it to production department ✔

EXAMPLE

- ❑ Safety officer classifies the reported Accident as serious according to the seriousness of the case ✘

- ❑ Safety officer classifies the reported Accident as serious in any of the following cases:
  - ➢ Results in death
  - ➢ Results in permanent disability
  - ➢ Requires hospitalization or prolongation of hospitalization
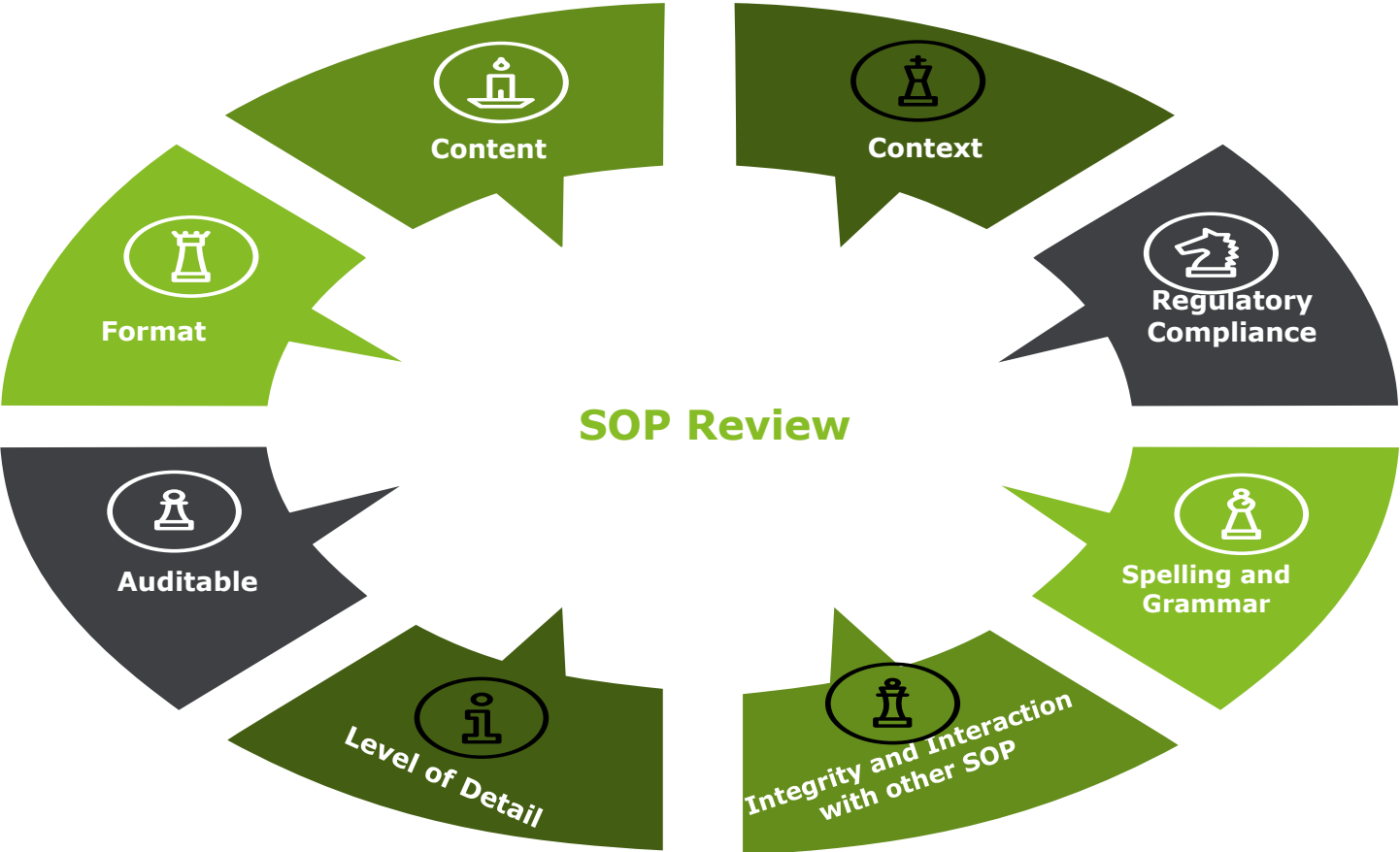 - ➢ Life threatening ✔

Standard Operating Procedure   20

Design of SOP:

In designing of SOP Following points are considered

- ✓ **Objective**: It shall define the purpose of the SOP.

- ✓ **Scope**: It shall define the area of application.

- ✓ **Responsibility**: Person Performing: Respective HOD"s of concerning departments Person Monitoring

- ✓ **Procedure**: All SOP"s shall be computer type. Each SOP has: I) Header, II) Signature block and III) Body.

- ✓ **Header**: Present on all the pages of SOP and includes Company Logo, Name, address & Concerned Dept

- ✓ **Document Type**: Standard Operating Procedure

- ✓ **Ref. No**: The reference number are very useful in identifying the SOP in use

- ✓ **Supersedes**: It is the Ref. No. of the earlier version.

- ✓ **Effective Date**: It is the date from which the SOP shall be put in use.
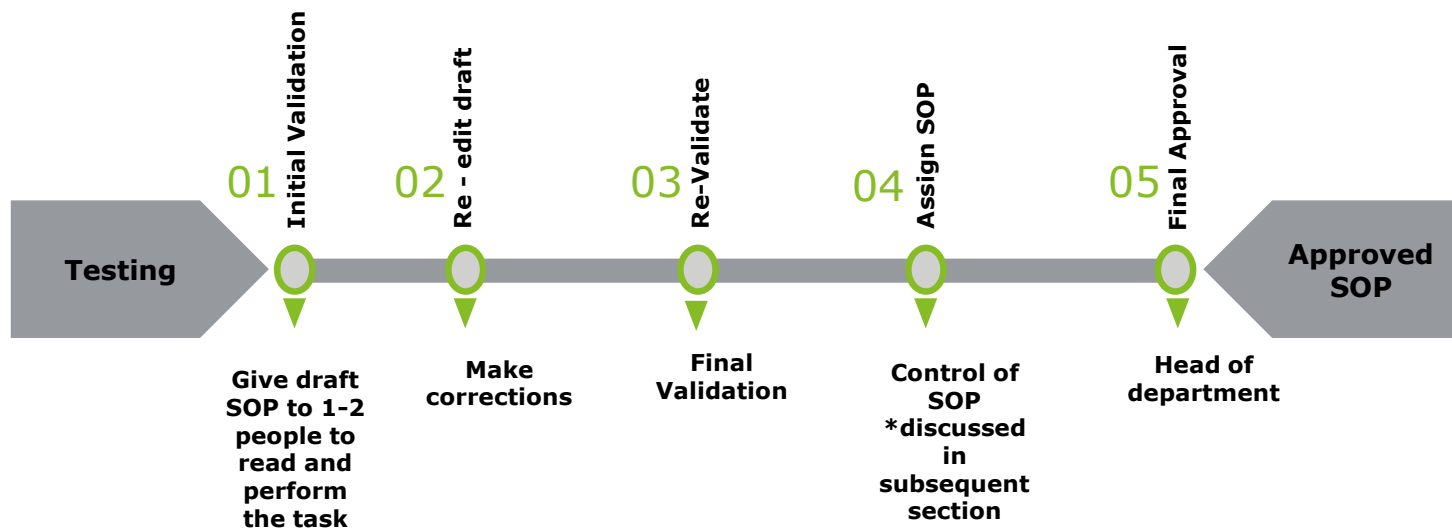
- ✓ **Review Date**: It is the Month & Year during which the SOP shall be revised

- ✓ **Page No**: It is like X OF Y. Where X is the individual page number and Y is the total number of pages.

- ✓ **Title**: It shall be clear and descriptive

- ✓ **Signature Block**: It shall be below the header and only on the first page of the SOP.

- ✓ **Prepared By**: Signature with date, name and designation of the person from user department who has drafted the SOP.

- ✓ **Verified By**: Signature with date, name and designation of the HOD or the person from user department who has verified the draft of the SOP.

- ✓ **Authorized By**: Signature with date, name and designation of the person authorizing SOP

- ✓ **Body**: It shall contain the subject matter.

SOP Review

- Content
- Context
- Regulatory Compliance
- Spelling and Grammar
- Integrity and Interaction with other SOP
- Level of Detail
- Auditable
- Format

Testing and Approval

✓ Ask many users to use this SOP

✓ Preferred to be associates who never performed the task before

✓ Test if the task could be successfully completed using only the written instructions

✓ Collect feedback & comments then make amendments & revalidate

✓ If OK, submit for approval as per company procedure

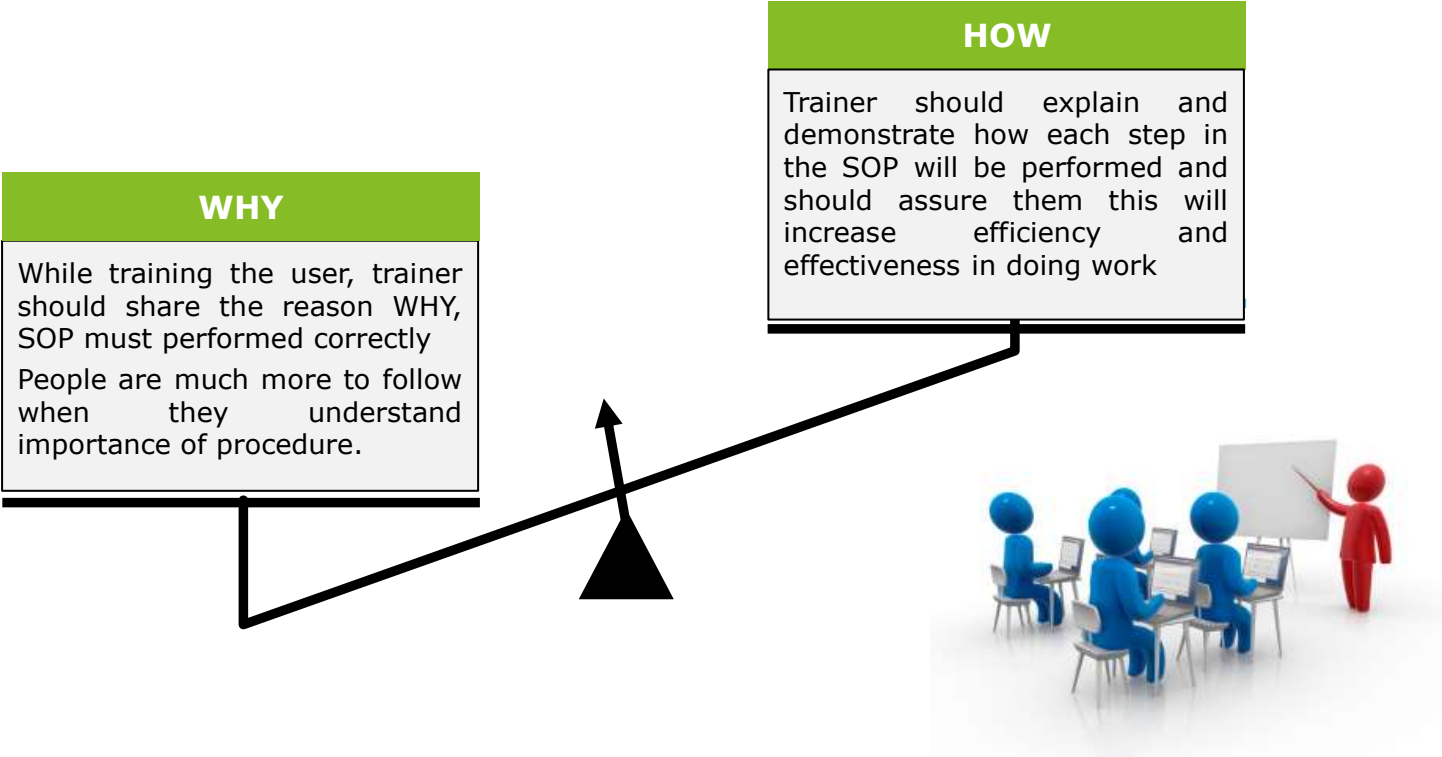| Testing	01 Initial Validation	02 Re – edit draft	03 Re-Validate	04 Assign SOP	05 Final Approval	Approved SOP
	Give draft SOP to 1-2 people to read and perform the task	Make corrections	Final Validation	Control of SOP *discussed in subsequent section	Head of department	

Training and Implementation

- ✓ After approval, it should be ensured that all users/concerned department gets training before implementation of the SOPs

- ✓ Records of such trainings should be maintained

- ✓ A training co-coordinator preferably the head of user department or any designated individuals shall be responsible for organizing the training.

- ✓ After successful implementation of training on any sops, the sops become effective.

1 Training before implementation of the SOPs

2 Records of such trainings

3 Training Coordinator – HOD or designated individual

4 SOP becomes effective
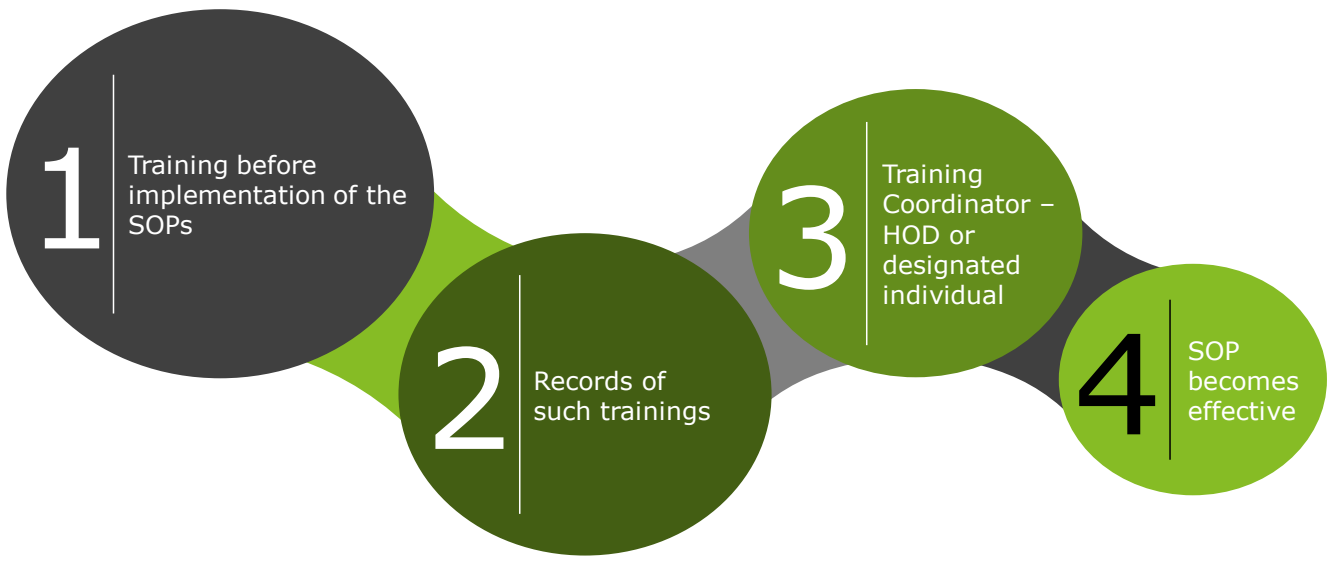
Training Approach

The most important step for implementing the SOP in working area, train or retrain the user.

HOW

Trainer should explain and demonstrate how each step in the SOP will be performed and should assure them this will increase efficiency and effectiveness in doing work

WHY

While training the user, trainer should share the reason WHY, SOP must performed correctly

People are much more to follow when they understand importance of procedure.

✓ Each organization should develop a numbering system to systematically identify and label their SOPs

✓ Generally, each page of an SOP should have control documentation notation:
   ❖ **Short Title /ID** A short title and identification (ID) number can serve as a reference designation.
   ❖ **Revision No and Date** -The revision number and date are very useful in identifying the SOP in use
   ❖ **Page No.-** When the number of pages is indicated, the user can quickly check if the SOP is complete.

✓ Generally this type of document control notation is located in the upper right-hand corner of each document page following the title page.

EXAMPLES

Short Title/ID# Rev # Date : Page 1 of

Standard Operating Procedure   27

✓ Organization should maintain a master list of all SOPs. This file or database should indicate the SOP number, version number, date of issuance, title, author, status, organizational division, branch, section, and any historical information regarding past versions.

✓ Individual should be designated for maintaining a file listing all current SOPs used within organization

✓ Sops distribution list should be maintained for issuance records.

✓ Change in sops need to be initiated through change request

✓ Stamping should be done.

SOP distribution list

Document Tracking and Archival

Master list

Change Request
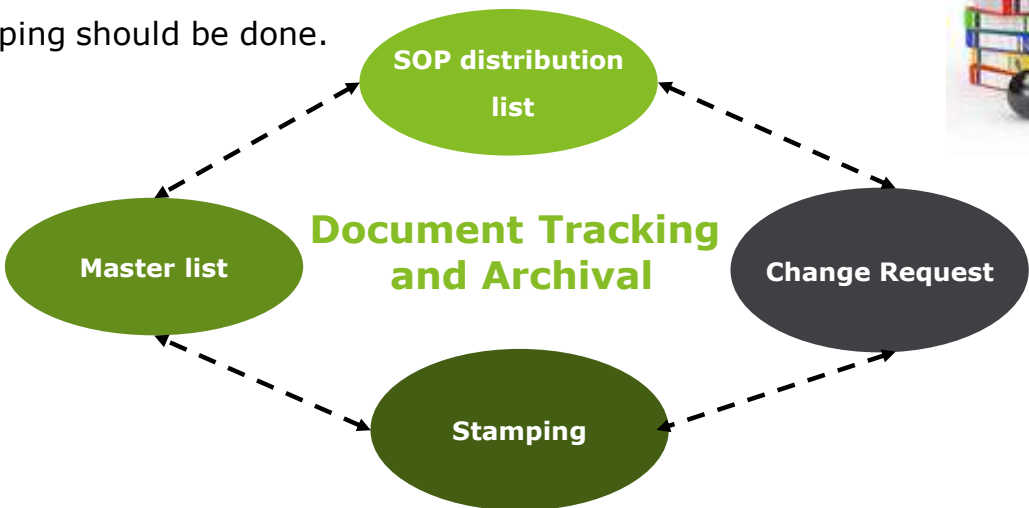
Stamping

Illustrative Distribution log book

Serial No	SOP title	SOP code	Version	Copy	Receiving department	Received by	Sign and Date

Illustrative stamping mechanism

Stamps	SOP copies
Original copy	Master signed copy
Controlled copy	used at actual working space
Uncontrolled copy	used for information purpose onl
Approved copy	for regulatory submission
Superseded (Cancelled) copy	Previous copy that replaced by new
Draft copy	SOP under review & test

When ?

✓ SOPs need to remain current to be useful.

✓ Whenever procedures are changed, SOPs should be updated and re-approved.

✓ Modify only the pertinent section of an SOP and indicate the change date/revision number for that section in the Table of Contents and the document control notation.

✓ SOPs should be also systematically reviewed on a periodic basis, e.g. every 1-2 years, to ensure that the policies and procedures remain current and appropriate, or to determine whether the SOPs are even needed.

✓ If an SOP describes a process that is no longer followed, it should be withdrawn from the current file and archived.

Standard Operating Procedure   30

How ?

✓ By process owner with the approval of HOD of the concerned department shall make changes in SOP

✓ Send a draft copy attached with change control request to custodian (or any other designated person) of SOPs describing:
  - ❖ The reason for change request
  - ❖ Sections that changes will take place

✓ Custodian (or any other designated person) assess the change request for its effect on the process as well as the whole system.

✓ If approved,
  - ❖ Assure that all functions & procedures affected by this change are also updated.
  - ❖ Training for all affected staff for the new version of the SOP
  - ❖ Distribution of the new SOPs
  - ❖ Withdrawal & cancellation of old obsolete SOPs

Standard Operating Procedure   31