

# Welcome to the Risk Management Webinar Series

## Standard Operating Procedures (SOPs)

Joy McElroy

McElroy Training and Consultancy, LLC

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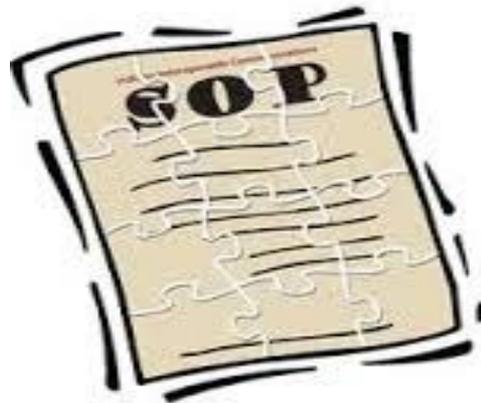
## Standard Operating Procedures (SOPs)

A set of written instructions that document a routine or repetitive activity which is followed by employees in any organization. We know that the development and use of SOPs are an integral part of a successful quality system which provides us an information to perform a job properly and consistently in order to achieve pre-determined specification and quality end result.



# What is an SOP?

- SOP's are written instructions that document a routine or repetitive activity followed by an organization.
- They addresses all requirements to perform the job or process safely.
- SOPs will fail if they are not followed, therefore, the use of SOPs needs to be reviewed and re-enforced by management.



# The Purpose of SOP's

- SOPs detail the regularly recurring work processes that are to be conducted or followed within a company.
- They document the way activities are to be performed to maintain consistency with technical operations and to support data quality.
- They describe the analytical processes, validation and qualification processes, processes for maintaining, calibrating, and using equipment.
- SOP's maintain quality control and quality assurance processes and ensure compliance with governmental regulations.
- SOPs are usually specific to the industry or manufacturing facility

# Components of an SOP

- **SOPs must address:**
  - Purpose
  - Process or Procedure Identification
  - Scope
  - Responsibilities
  - Accountability
  - Procedure
  - Safety
  - Training



# What SOPs Need

- SOPs should detail the regularly recurring work processes that are to be conducted or followed within an organization. They document the way activities are to be performed to facilitate consistent conformance to technical and quality system requirements and to support data quality.
- They may describe for example fundamental or programmatic or technical actions such as analytical processes, processes for maintaining as well as calibrating and using equipment.
- SOP must contain step by step instructions that employ must refer in daily work to complete various tasks more reliably and consistently.

# SOPs

SOP's makes clear about followings things;

- What is the objective of SOP (Purpose)
- What are the applicability and use of SOP (Scope)
- Who will be performing tasks (Responsibility)
- Who will ensure implementation of procedure (Accountability)
- How tasks will be performed (Procedure)



# Benefits

- To provide people with all the safety as well as health and environmental and operational information necessary to perform a job properly.
- To ensure that production operations are performed consistently to maintain quality control of processes and products.
- Processes continue uninterrupted and are completed on a prescribed schedule.
- To assure no failures will occur in manufacturing and other processes that would harm anyone in the surrounding community.
- Approved procedures are followed in compliance with company and Government regulations.

## Benefits

- To serve as a training document for teaching users about the process for which the SOP was written.
- To serve as a checklist for co-workers who observe job performance to reinforce proper performance.
- To serve as a checklist for auditors.
- To serve as an historical record of the how or why and when of steps in an existing process so there is a factual basis for revising those steps when a process or equipment are changed.
- To serve as an explanation of steps in a process so they can be reviewed in accident investigations.

# Benefits

- It helps to prevent the introduction of errors, variations and misunderstanding.
- It improve the planning's and organization.



## How to Write SOPs

- SOPs shall be written in a proper and concise, it must be step by step and easy to read and follow format.
- The information presented should be unambiguous and should not be complicated and the active voice and present verb tense should be used.
- SOP shall be simple and short.
- Information should be conveyed clearly and explicitly to remove any doubt as to what is required.
- Flow chart shall also be used to illustrate and explain in brief about the process.

# Formatting Your SOP

## Simple Steps Format

- This is for routine procedures that are short, have few possible outcomes, and are fairly to the point.
- Apart from the necessary documentation and safety guidelines, it's really just a bullet list of simple sentences telling the reader what to do.



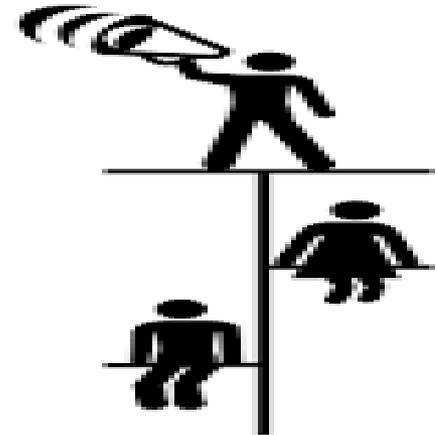
# Example of Simple Steps SOP

## Gowning SOP

1. Enter Gown In Area II, room 2118
2. Don hairnet, use mirror to ensure ears are covered.
3. Don a beard cover, if applicable.
4. Put on coveralls, keeping sleeves off the floor.
5. Put on shoe covers, while crossing the bench so that the shoe covers only come in contact with the cleanest side of the room.
6. Sanitize hands.
7. Use mirror to check for proper gowning.

# Heirarchical Steps Format

- This is usually for long procedures -- ones with more than ten steps
- Involves a few decisions to make, clarification and terminology.
- This is usually a list of main steps all with substeps in a very particular order.



# Example of Hierarchical Sanitization Cycle

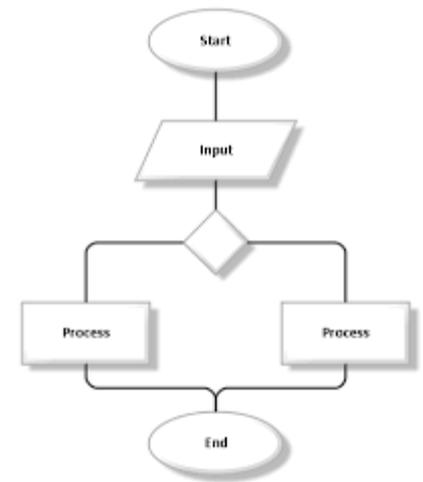
1. If a complete sanitization cycle has completed and the USP Purified Water point of use valves were flushed,
  - A. The operator will complete the sequence as follows:
  - B. The operator will command the USP PW point of use valve flush point to “FINISHED”
  - C. The cycle will complete normally
2. See Sanitization Complete section.

# Example of Hierarchical Sanitization Cycle

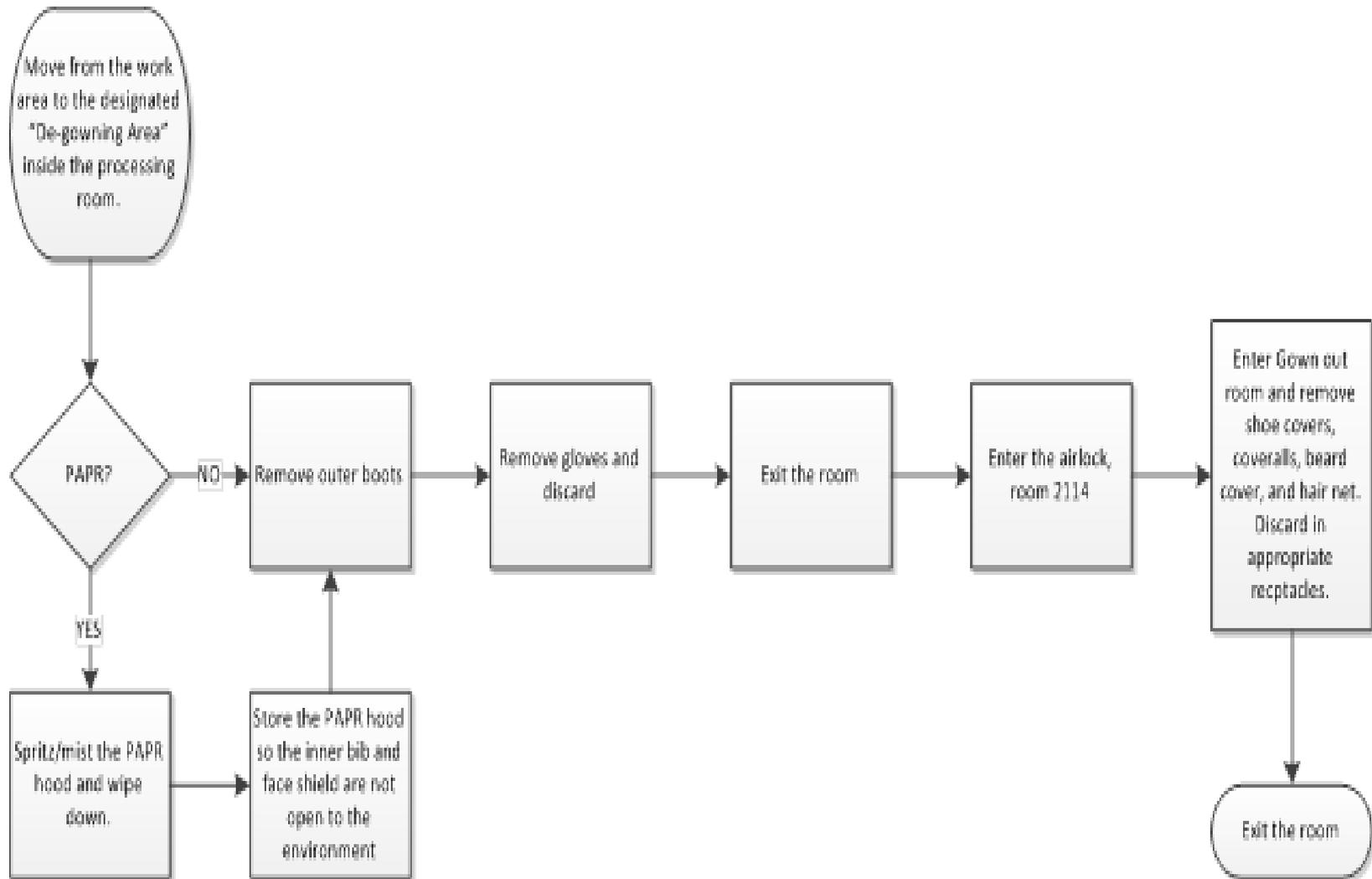
1. If a sanitization cycle has NOT completed and the USP PW point of use valves were flushed;
    - A. The operator must troubleshoot why the return temperature could not achieve and maintain 185°F for 60 minutes.
    - B. After the problem has been corrected, the operator must take the system out of the sanitization cycle as follows:
    - C. The operator will command the BMS point SANITIZ to “DISABLED”
  2. See Sanitization Complete section.
- *Note: In this condition, the operator must re-start the sanitization cycle again*

# Flowchart Format

- If the procedure is more like a map with an almost infinite number of possible outcomes, a flowchart may be your best bet.
- This is the format you should opt for when results aren't always predictable.



# Example of Flow Chart SOP



# SOP Preparation

- The organization should have a procedure in place for determining what procedures or processes need to be well documented and all those SOPs should then be written by any individuals which are knowledgeable with the activity and the organization's internal structure .
- Ideally these individuals are essentially subject-matter experts who actually perform the work or use the process.
- A team approach can be followed for better results.



# SOP Preparation

- It is not necessary that SOPs be written by only an individual who routinely performs the tasks or someone who is directly responsible for the performance of the task.
- It is necessary that the person writing the SOP have access to an individual who routinely performs the tasks or to someone who is directly responsible for the performance of the task



## Individuals Who take Part In SOP Writing

- Those who will perform the job
- Those who will perform maintenance on equipment involved in an SOP
- Engineers or others who design equipment and processes
- A Technical initiator
- Safety personnel
- An Environmental personnel
- An Equipment manufacturers



## Team Writing SOPs

- Ensures that comprehensive knowledge acquired from different perspectives is applied to the SOP.
- Creates "buy-in," which increases the likelihood that the SOPs will be implemented under the guidance of the initiator.
- Trains trainers, the people who write the SOP. Now having participated in the in-depth decision making about the SOP, the initiator knows it intimately and is more likely to be an effective trainer.



# Team Writing SOPs

- Involves people from diverse parts of the operations as a whole which helps to ensure that when new and modified processes are implemented then after someone goes back and updates the SOP.
- Encourages employees to follow the SOP and listen to the coaches because the employees know that the initiator invested time and effort on behalf of the employees.



# Team Writing SOPs

- They can write or edit parts of an SOP independently and then one person can combine all the individual contributions.
- After combined, circulate the draft SOP for review among the team before editing a final draft for review by supervisors and management.
- Ideally a writing team should meet at least once in the beginning of a project to establish writing objectives as well as targets and responsibilities, and also to work semi-independently with one person serving as coordinator.
- Most important , SOPs should be reviewed by several people qualified to evaluate the SOP in terms of its completeness and clarity of subject matter.



# Ideas to Keep In Mind

- How much someone knows about an entire process or job affects the way he or she does the job.
- Incorporate safety and health and environment into the traditional how to operate or to do steps.
- Teaches the person comprehensively so that he or she has a complete picture of the responsibilities for doing a job well.
- This knowledge base simplifies follow-up training.



# Ideas to Keep In Mind

- Write an SOP to be as long as necessary for a specific job.
- All jobs differ in the number of steps required to complete properly.
- Short changing someone by providing short and incomplete SOP sets up failure.
- Write an SOP to satisfy the definition and purpose of the SOP- not a standard company format that no one has thought about in years.



# Ideas to Keep In Mind

- **Make your writing concise and easy to read.**
  - Odds are your audience isn't choosing to read this for fun.
  - **You want to keep it short and clear** -- otherwise their attention will stray or they'll find the document formidable and hard to grasp.
  - In general, keep your sentences as short as possible.

# Ideas to Keep In Mind

Here's a *bad* example:

Make sure that you clean out all of the dust from the air shafts before you begin using them.



# Ideas to Keep In Mind

Here's a *good* example:

Vacuum all dust from air shafts before use.

**In general, don't use "you." It should be implied. Speak in the active voice and start your sentences with command verbs.**

# Ideas to Keep In Mind

- People tend to ignore long SOPs because they cannot remember more than 7 to 13 steps.
- If your SOP goes beyond 9 to 10 steps, consider these solutions:
  - Break the long SOP into several logical sub-job SOPs
  - Write an accompanying shortened SOP that lists only the steps but not detailed explanations of those steps
  - Make the long-form SOP a training document or manual to supplement the shorter sub-job SOPs mentioned earlier.



# Ideas to Keep In Mind

- Prepare the longer comprehensive training SOP first to get a picture of what training is needed. And then decide how to break it into shorter sub-job SOPs. Now writing sub-job SOPs first, and then trying to put them together, and may leave out linkage steps that make sub-jobs interdependent.



# Ideas to Keep In Mind

Write SOPs for people who perform under different interpersonal circumstances.

- Write some SOPs for people who work alone.
- Write some SOPs for two or more people who work together as a team.
- Write some SOPs for people who will supervise other people doing a job.
- Write some SOPs for the people who are not familiar with rules generally understood by your employees.



# Ideas to Keep In Mind

- Consider the work culture within which people will work. Now If you write for people in a culture in which shortcuts are accepted as practice, explain the reasons behind certain steps so that SOP users will understand the importance of following all the steps in the proper order.
- Consider the age, education and knowledge as well as skill, experience and training-and work culture of the individuals who will be performing the SOP steps.



# Ideas to Keep In Mind

- Keep in mind that many people do not read all the steps before starting on step one.
- Many people read one step, perform it and read the next step, perform it and so on.
- Try to get around this habit, and forecast future effects and steps at certain points in the SOP to tell the reader things they should know in advance such as upcoming steps that require caution and precision or timing and assistance and personal protective equipment.



# Ideas to Keep In Mind

- **Make sure each page has control document notation.**
  - Your SOP is probably one of many SOPS -- because of this
    - your organization should have some type of larger database cataloguing everything within a certain reference system.
    - Your SOP is part of this reference system, and therefore needs some type of code in order to be found.
    - Each page should have a short title or ID #, a revision number, date, and "page # of #" in the upper right hand corner (for most formats).
    - You may or may not need a footnote (or have these in the footnote), depending on your organization's preferences.

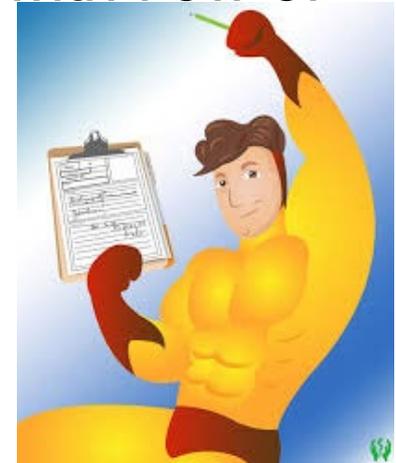
# Ideas to Keep In Mind

- Review the effectiveness of SOPs after a few weeks and make necessary changes if in-the-field practice suggests that descriptions should be improved.
- Review SOPs when processes and equipment are changed.



# What Constitutes Good Documentation

- **Legible:** everyone should be able to read what is written regardless of who, where or what has been written.
- **Concise:** the document must provide clear information that is understood by all customers
- **Traceable:** who recorded it, where and why
- **Contemporaneous:** the information should be documented at the correct time frame along with flow of events
- **Enduring:** Long lasting and durable
- **Accessible:** Easily available for review.



# Common Documentation Errors

- Missing signature and dates at the time of activity performed.
- The write-over
- Non-uniform date and signature entry
- Writing a note that activity was performed on one day and signed for on other day.
- Blank spaces
- Illegible writing
- Too many corrections



# Principles of Good Documentation Practice

- A document bearing original signatures should never be destroyed.
- Never falsify information
- Never use a White-out and cover-over-tapes
- Never obliterate information or record
- Never over-write a record.
- Never use pencil – all information should be completed in permanent Black or Blue ink
- No spaces, lines or fields are to be left blank
- Never use symbols e.g ditto marks or arrows to indicate repetitive and consecutive

# Benefits of Good Documentation Practice

- Build confidence in the Quality System
- Reduce efforts to compliance with regulatory bodies
- Allows for achievements of required results.
- Correct, complete, current and consistent information effectively meets customers and stakeholders' requirements.
- Enables the activities to be arranged into functional patterns for specific action.
- Create structures so that staff can systematically coordinate to conduct business.
- Training of staff.
- Solve complicated problems
- Reduce or eliminate assumptions and second-guessing.

# Benefits of Good Documentation Practice

- Eliminate the need to re-ask the same questions
- Specify clear instructions for staff



# Questions

Joy McElroy

McElroy Training and Consultancy, LLC

[joy@mcelroytrainingnconsultancy.com](mailto:joy@mcelroytrainingnconsultancy.com)

252-373-8053

