Instructions, User Manuals and SOPs

Standard Operating Procedures

SOP is a set of instructions that document routine or repetitive technical or administrative activities in business/industry

Reference for ensuring accuracy of procedures

Standard Operating Proce ES

Both hard copy and electronic

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SOPs Vs. Instructions

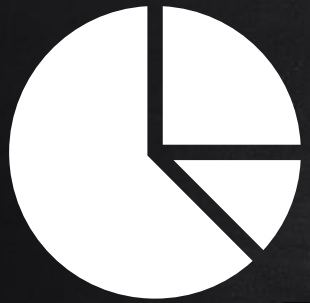
Instructions show an uninitiated person how to perform a task.

Procedures provide rules and guidance for people who usually know how to perform the task but who are required to follow accepted practice.

To ensure that everyone does something in the **same** way, procedures typically are aimed at groups of people who need to coordinate their activities so that everyone's performance meets a certain standard.

SOPs are used in

- Science
- Healthcare
- Biomedical technology
- Military
- Computer industry



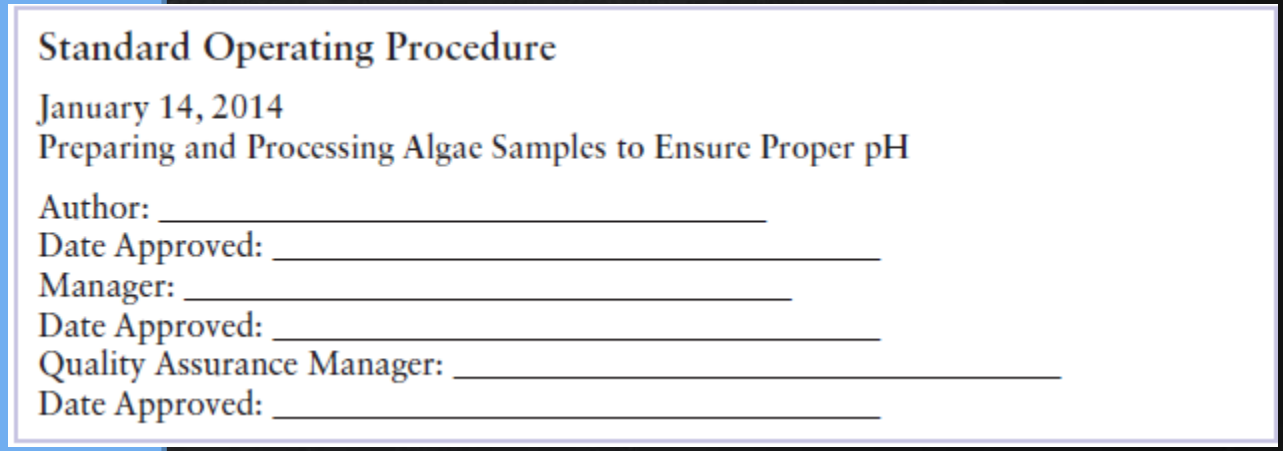
Components of SOPs

- Title Page
- Table of Contents
- Scope and Applicability
- Summary of Method
- Definition of Terms
- Safety, Warnings and Cautions
- Interferences
- Personnel Qualifications/Responsibilities
- Equipment and Supplies
- Data and Records
- References

Title Page

- Topic
- Date of SOP
- Purpose of SOP
- Routing List

EXAMPLE



Standard Operating Procedure

January 14, 2014
Preparing and Processing Algae Samples to Ensure Proper pH

Author: _____
Date Approved: _____
Manager: _____
Date Approved: _____
Quality Assurance Manager: _____
Date Approved: _____

Scope and Applicability

- 3-5 sentences typically
- Exceptional scenarios have several paragraphs long
- Why (purpose) is it being written
- Meets regulatory requirements
- Limits for use of procedure (if any)
- Applicability of procedure

EXAMPLE

Scope

The purpose of this SOP is to establish uniform procedures for water compliance inspections (WCIs) performed by the Georgia Science and Assessment Division (GSAD). The WCIs evaluate the effectiveness and reliability of the state agency's inspection procedures to meet regulations of the Clean Water Act (CWA). The SOP will ensure thoroughness of all water compliance inspections and reports. The inspector may alter SOPs due to unexpected or unique problems in the field. Deviations from the SOP must be reported.

Applicability

The policies and procedures of the SOP apply to all personnel who take part in the WCIs.

Summary of Method

Summary of procedure

3-5 sentences or brief short paragraphs

Determined by topic of SOP

Title of people involved
Roles and duties
Sequence of their involvement
Sequence of activities performed

EXAMPLE

Summary of the Method

During the WCI, the state inspector is the lead person supervising all tests. The state inspector manages a staff of scientists who gather water samples either manually or automatically with a portable compositor. Once the samples are collected, the state scientists divide the collection into containers, preserve the samples in ice, and ship the collection to a state laboratory for analysis. The laboratory technicians compare

Interferences

Includes any components of the process that may interfere with the accuracy of the final product.

Includes but not limited to:

- Humidity
- Temperature
- Depth
- Altitude
- Weather
- Cleanliness
- Sample size
- Contamination

EXAMPLE

Interferences

If the water has high concentrations of chlorine, this can interfere with test results. Therefore, if the inspector determines that chlorine is present, add sodium sulfide to the sample bottle before autoclaving.

Personnel Qualifications/Responsibilities

Required experience and certifications of the individuals performing the SOP

Can include

- **Education**
- **Years of experience**
- **Courses taken**
- **Continuing education hours completed**

EXAMPLE

Personnel Qualifications/Responsibilities

This SOP is written specifically for water compliance inspections (WCIs) performed by the Georgia Science and Assessment Division (GSAD). All personnel who perform this activity must have the Basic Inspector Training for Water Compliance certification and have taken the state-required, 8-hour continuing education class. Additional training qualifications include GSAD regulation certification as well as on-the-job training.

Personnel performing this SOP have the following responsibilities:

1. WCI inspector—this person must have a minimum of a Bachelor of Science in chemistry (or related discipline), five years field work experience, three years laboratory work, and must be certified in state water compliance regulations. This inspector is responsible for coordinating staff and conducting the WCI test to meet deadlines. The inspector must be able to enforce the policies and procedures outlined in this SOP.
2. Scientists and laboratory technicians—these employees must have a minimum of an Associate of Science in chemistry, biotechnology, or a related field. These employees also must have passed state-level training in water compliance regulations. Scientists and laboratory technicians must meet deadlines for the WCI, submit all samples in accordance with regulatory policies, and adhere to the SOP.

Equipment and Supplies

Can include the following items necessary to perform the SOP

If the steps in the process break down into multiple sections, you can divide the equipments and supplies into the units in a chronological Organization pattern.
*Include quantities of items if needed to perform different tests in the process.

- Tools
- Equipment
- Reagents needed for the procedure
- Standards for the chemicals
- Biological Specimens

EXAMPLE

Equipment and Supplies

1.1 Sample Collection
- 1.1.1 Sterile sample jars
- 1.1.2 Syringes with carbon filters
- 1.1.3 Sterile screw-top lids

1.2 Lab Analysis
- 1.2.1 Air incubator
- 1.2.2 Water bath
- 1.2.3 Disposable sterile pipettes
- 1.2.4 Sterile applicator sticks
- 1.2.5 Sterile culture tubes
- 1.2.6 Sterile screw-cap tops
- 1.2.7 Pyrex graduated cylinders
- 1.2.8 Culture tube racks

Data and Records Management

Include the following information in this unit of the SOP

- Calculations to be performed during the procedure
- Forms for the reports
- Reporting intervals
- Report recipients
- Process to follow for recording and storing data and information generated by the SOP

EXAMPLE

Records Management

1. Appropriate SOPs will be kept in the laboratory library in black binders. All SOPs will be available to management and employees. When an SOP is removed from the library, sign your name and add the checkout date on the posted SOP inventory sheet.
2. No SOPs can leave the laboratory area.
3. The laboratory director will update the SOP binders as procedures or regulations change.
4. Staff will read all revised SOPs within five working days and sign and date the updated SOP list.

Quality Control and Quality Assurance

Helps you ensure that you are checking for the highest quality and consistency of the procedure

- Explain how will you verify work through quality control
- Include the self check intervals for retesting, recounting, or recalibrating
- State how and to whom will you report the results of QC

Which self-checks will you implement?

EXAMPLE

Quality Control

To achieve quality assurance, the laboratory will follow this procedure:

- Sterility—each sample is incubated for 24 hours at 0.5°C and examined for contaminants. If a sample tests positive for contaminants, the entire lot is discarded.
- pH—if the pH does not meet manufacturer's specifications prior to autoclaving, pH can be adjusted according to EPA specifications. If the pH does not meet specifications after autoclaving, the entire sample must be discarded.
- Testing—the laboratory will test samples twice a year (January and June).

References

- Cite the documents or procedures used in or referred to in your SOP
- Documentation of additional SOPs referenced
- Literature researched
- Additional instruction manuals

Test for Usability

Usability testing is to review the effectiveness of a document

For SOP testing, usability testing can be conducted following these steps

Select a test audience

- Best audience would include a varied audience (varied expertise)
- Reliable feedback

Ask the audience to test instructions

- Attempt procedure step by step

Monitor the audience

- Challenges within instructions
- Tools/equipment listed, terms defined, hazard notations, avoiding overloaded steps etc.

Time the Team Members

- Why does it take longer for some team members?

Quantify the audience's responses

- Debrief the audience about problems at the end

EXAMPLE

Basic Usability Survey

1. Briefly describe why this document is used. _____
   _____
2. Evaluate the *content:*
   - Identify any irrelevant information. _____
     _____
   - Indicate any gaps in the information. _____
     _____
   - Identify any information that seems inaccurate. _____
     _____
   - List other problems with the content. _____
     _____
3. Evaluate the *organization:*
   - Identify anything that is out of order or hard to locate or follow. _____
     _____
   - List other problems with the organization. _____
     _____
4. Evaluate the *style:*
   - Identify anything you misunderstood on first reading. _____
     _____
   - Identify anything you couldn't understand at all. _____
     _____
   - Identify expressions that seem wordy, inexact, or too complex. _____
     _____
   - List other problems with the style. _____
     _____

EXAMPLE

5. Evaluate the *design:*
   - Indicate any headings that are missing, confusing, or excessive. _____
   - Indicate any material that should be designed as a list. _____
   - Give examples of material that might be clarified by a visual. _____
   - Give examples of misleading or overly complex visuals. _____
   - List other problems with design. _____
6. Identify anything that seems misleading or that could create legal problems or cross-cultural misunderstanding. _____
7. Please suggest other ways of making this document easier to use. _____

Activity 1

Find the worksheet on classroom titled “Instructions in Technical Writing: Style and Design” and do as directed

Activity 2

Think of any household chore and design standard operating procedure for it filling in the template provided.