

## SOP on SOPs

an approved SOP starting with 01. To identify draft SOPs the version number should start with 0.1, 0.2, 0.3 etc.

### 6.1.2 SOP page header (footer)

The header of each page should include the Company Name and Logo as well as the Department of the company where applicable. The title of the SOP, the number of the SOP including the version number as well as the number of pages is written in the header. Number of attachments including number of attachments pages where applicable is displayed in the header as well as the SOP effective date.

### 6.1.3 SOPs first page

The first page of the SOP is signed and dated at a minimum by the SOP author, the reviewer and the approver, indicating their name and function.

On the bottom of the first page (alternatively on the last page of the SOP) the change history of the SOP is described indicating which section had been changed and the reason for the change.

### 6.1.4 Table of content

On the second page a table of content is displayed indicating the headers and the sub headers with a chronological numbering system.

Each SOP includes as a minimum the following subheadings:

- Purpose: To clearly describe the purpose of the SOP
- Scope/Objective: To clearly define the operations, process and departments to which this SOP applies
- Regulatory Basis, Reference Documents
- Related documents
- Responsibilities and Accountabilities: To clearly define who is responsible for what
- Procedure: To describe clearly and concisely each individual step and the sequence of operations for a certain process.
- Definitions: When applicable
- Distribution: List of personnel and departments where authorized SOP copies were distributed
- Health, Safety and Environmental Considerations

### 6.1.5 SOP content

Standard Operating Procedures must be written in sufficient detail so that the process is reliably repeated using only the procedure and attachments.

Forms and flow charts are recommended to improve understanding and facilitate use of Standard Operating Procedures. When forms and flow charts are used, they must be an

| Document Type | Document ID     | Version | Status   | Page |
|---------------|-----------------|---------|----------|------|
| SOP           | XX_WWW_ZZZ_YYYY | 1.0     | Approved | 6/9  |