



DOCUMENT TITLE: Directions for Writing a Standard Operating Procedure (SOP)			
DOCUMENT NUMBER: SOP#12-001	REVISION #: Original	REVISION DATE:	EFFECTIVE DATE:
AUTHOR: (NAME/TITLE)		SIGNATURE:	
APPROVED BY: (NAME/TITLE)		SIGNATURE:	
APPROVED BY: (NAME/TITLE)		SIGNATURE:	

HEADER: The header (above) normally includes the title, document number, revision number, revision date, effective date, author (name/title), approved by (name/title), and three signature lines for the author, principal investigator and another senior personnel to sign and date.

- 1.0 Other section headings can be administered on an as needed basis. The section headings will be assigned numbers starting with 01.
- 2.0 The original cover sheet with a copy of the SOP will be maintained for future reference, an electronic copy will be maintained online.
- 3.0 A number will be assigned to the SOP by the following procedure. The section number followed by a three-digit number that has been assigned in a sequential fashion. For example, if an author wrote a SOP on trypsinizing and counting smooth muscle cells, a section number would be assigned to the SOP that would have similar SOP's. The number assigned would hence be ##-###.
- 4.0 A date will be attached to the document. A revision # will be assigned upon completion of the revision of the SOP. The revision number will include the original date of the SOP. For example, if the document was originally generated on 2/7/97 and the first revision was on 2/7/98, the revision number would be ##-001.2.07.98.

OBJECTIVE: To describe the process of writing a SOP. This section should briefly describe the objective of the SOP and should not exceed more than two sentences.



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MATERIALS:

1. This section should list all of the materials required for the procedure.
2. These are normally disposable items such as gloves, pipette tips, etc.
3. The list should include vendor and part numbers for each component.
4. In addition, if a material's composition or formulation is described in another SOP, the SOP number should be referenced.

EQUIPMENT AND SUPPLIES:

1. This section should list all of the equipment and supplies required for the procedure.
2. These are normally items that are not disposable like a microscope or software.
3. The list should include vendor and part numbers for each component.
4. In addition, if a material's composition or formulation is described in another SOP, the SOP number should be referenced.

PROCEDURE:

- 1.0 This section will provide a detailed description of the procedure at hand.
 - 1.1 The procedure should follow in a sequential fashion.
 - 1.2 Each step should be short and concise.
 - 1.2.1 If more details are needed for a particular task, the numbers for each section should be bracketed into further subsets as shown in this example.
 - 1.2.2 Reference other SOPs as needed. For example: If the SOP is describing how to change the filter on an incubator and the last step is to measure the CO₂ levels to make sure the machine is calibrated, you may refer to a separate SOP for how to measure CO₂ levels.
 - 1.3 Write the document so that somebody could follow it without any outside assistance. However, one can assume that the person reading the SOP has basic knowledge in the area.



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- 2.0 Revisions of a SOP can occur by inserting lines within a document or deleting specific lines from the document.
- 3.0 Once the document has been authored, the document should be signed and dated by the author and then submitted for review to two other personnel.
 - 3.1 The authorized signers should be two senior personnel. One person should be the primary investigator of the laboratory (or designated the primary investigator) and the other person should be knowledgeable in the area.
 - 3.2 The author should designate under what section the SOP should be filed. The section headings will be divided into different categories such as cell maintenance and growth, general laboratory practices, materials processing and handling, assays, and solutions and buffers.
- 4.0 A separate training record will be attached to each SOP. The document will have a space for name of trainer, name of trainee, date of training and date of re-training if necessary. The trainer will be the person who generated the SOP or another employee who is designated for that task.
- 5.0 A binder containing the SOP's will be available in every laboratory and should be used on an as needed basis. Copy will be maintained online.

REFERENCES: This section is optional. The purpose of this section is to provide further information on the specific techniques of the SOP. Articles, book chapters, handouts, other SOP's, etc. can be referenced in this section.

WORKSHEET: For certain SOP's a worksheet will be included. The worksheet will consist of a form to help guide the employee to perform the necessary dilutions and calculations for a specific task. The forms will be available in a convenient location to allow for easy accessibility. Upon completion, the forms can then be pasted into a laboratory notebook. The forms will be referenced by the SOP number and revision number. These forms can also be assembled as a batch record for the development or release criteria for the lot of the material.



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APPENDIX: The appendix section is optional and can be used for a general description of dilution's and calculations for a specific procedure. A general appendix can be used with multiple SOP's. However, the appendix will be located at the end of each SOP.

HELPFUL HINTS: Try to be concise in the text. If the document exceeds five pages, determine if the SOP can be divided into smaller sub-sections or if the information could be referenced to another SOP with more detailed instructions for that specific task. The document has to be easily followed and be used as a training and reference document for potentially complicated laboratory techniques.