# 1. Master SOP

## 2. Objectives & Scope

This SOP describes the development of SOPs, forms and annexes.

This SOP is applicable to all employees of the laboratory. Uniformly developing, changing and controlling SOPs, forms and annexes will lead to clarity and recognition.

## 3. Abbreviations and definitions

For general abbreviations, definitions and terms refer to quality manual chapter 1 “General”.

* SOP Standard Operating Procedure
* QM Quality Manual
* User: Person who uses the quality document

## 4. Tasks, responsibilities and accountabilities

|  |  |  |
| --- | --- | --- |
| **Task** | **Authorized** | **Responsible** |
| Determining verifiers of documents | LM | LM |
| Verification content-wise | User | Authorizer of document |
| Developing quality documents | User | Authorizer of document |

## 5. Procedure

### 5.1 SOPs

The laboratory uses three types of SOPs:

* Analysis SOPs
* Equipment SOPs
* Procedure SOPs

There is a specific framework for developing each type of SOP (see annex 1 to 3).

### 5.2 Developing quality documents

Every employee can take the initiative in writing SOPs. In discussion with the LM and the QO verifiers are determined. The author writes the SOP. This person should have the appropriate knowledge and expertise regarding the procedure for which an SOP is written.

Verification of quality documents is done by:

* At least one user of the quality document for compliance with practice
* The QO for compliance with the quality standard.

Authorization of quality documents is done by the LM.

Author:

1. The author makes him/herself known to the QO with the wish to write a new SOP.
2. QO makes a unique code for the new SOP and proposes (when not yet known) who the verifiers are and the authorizer.
3. The QO fills-out the header of the draft SOP and sends it to the author.
4. The author writes the SOP; use the appropriate framework for developing the document (see annex 1 to 4).
5. Save the SOP on the computer with the code and title, the year and month of developing the quality document and your initials as filename (for example: P15.Recording.2013.08.MG.docx).
6. Send the draft SOP via email to the verifiers, authorizer and possible other users for commenting.
7. Discuss the comments with the verifiers, authorizer and users, for example during a weekly staff meeting.
8. Process the comments into an improved version of the SOP.
9. Send the final SOP via email to the QO.

Subsequently:

1. The QO ensures that the SOP is printed and signed by the author, verifiers and authorizer.
2. The author, verifiers and authorizers sign the SOP with blue pen. The authorizer also places his/her signature in the header of each page. The last person who signs the SOP gives the SOP back to the QO.
3. The QO places the signed SOP at the appropriate location.

### 5.3 Coding of quality documents

Each SOP gets a unique code in the header of each page. Codes will not be changed after they have been assigned to a specific document.

Coding is done as shown below:

Quality Manual: QM + chapter number

Procedure SOP: P + index number

Equipment SOP: E + index number

Analysis SOP: A + index number

Forms: Code of SOP or QM chapter + F + index number

Annexes: Code of SOP or QM chapter + A + index number

*For example:*

Annex to the Master SOP: SOP P1A1.

## 6. Related Documents

* QM1 “General”
* Authorization Matrix

## 7. Related Forms

N/A

## 8. References

ISO 15189 Medical Laboratory – Requirements to quality and competence. International Organization for Standardization. Geneva 2012.

## 9. Attachments

* Annex 1: Framework for developing Procedure SOPs
* Annex 2: Framework for developing Equipment SOPs
* Annex 3: Framework for developing Analysis SOPs
* Annex 4: Framework for developing Annexes and Forms

# 1. [*Annex 1: Framework for developing Procedure SOPs*]

[*Change the above title into the title of the Procedure SOP that is going to be written*]

## 2. Objectives & Scope

[*Describe briefly the objective of the SOP, the scope and to whom this SOP is applicable*]

## 3. Abbreviations and definitions

[*List the abbreviations and terms that are present in this SOP and give their definition. For abbreviations that are general and used in all the quality documents, refer to the first chapter of the quality manual that lists all the frequently used abbreviations*]

## 4. Tasks, responsibilities and accountabilities

[*Describe, in the table below, the responsibilities and authorizations related to the execution of the procedure as described under paragraph 5. “Procedure” of this SOP*]

For general authorizations refer to the Authorization Matrix.

|  |  |  |
| --- | --- | --- |
| **Task** | **Authorized** | **Responsible** |
|  |  |  |
|  |  |  |

## 5. Procedure

[*Describe the steps of the procedure in chronological order (make a numbered list). Take into account the following point:*

* *Write in imperative as much as possible*
* *Take the basic knowledge of the user into account when writing this procedure*
* *Describe all the activities of the procedure: technical, administrative and control activities*
* *This chapter can be divided into different paragraphs at its discretion (think of introduction, safety, materials needed, method, storage, controls, waste disposal, labeling, archiving, etc.)*
* *Refer to other SOPs if necessary*
* *For labeling of reagents and chemicals and waste disposal: refer to the biosafety manual*]

## 6. Related Documents

[*Provide a list of related document such as related SOPs, QM chapters, log sheets, package inserts, evaluation/assessment reports, equipment manuals, software manuals, etc. When the documents are not coded according to the quality management system: provide for each document the location where it can be found.*

*For example:*

* *QM1 “General”*
* *Biosafety Manual, in every laboratory room and the administration office*]

## 7. Related Forms

[*Provide a list of forms that are relevant to this SOP such as request forms, work-forms, batch forms, etc. Provide for each document the location if it is not controlled (coded) according to the quality management system.*

*For example:*

* *P43F1 “Induction checklist”*]

## 8. References

[*Refer to literature used for writing this SOP.*

*Book: Title, edition, author(s), publisher, year, city, first page – last page*

*Journal: Journal name, year + volume + issue, title of article, author(s), first page – last page*]

## 9. Attachments

[*Provide a list of annexes. These can both be controlled documents and uncontrolled documents. For documents without code: provide the location where they can be found.*

*For example:*

* *P1A1 “Framework for developing Procedure SOPs”*]

# 1. [*Framework for developing Equipment SOPs*]

[*Change the above title into the title of the Equipment SOP that is going to be written*]

## 2. Objectives & Scope

[*Describe briefly the objective of the SOP, the scope and to whom this SOP is applicable*]

## 3. Abbreviations and definitions

[*List the abbreviations and terms that are present in this SOP and give their definition. For abbreviations that are general and used in all the quality documents, refer to the first chapter of the quality manual that lists all the frequently used abbreviations*]

## 4. Tasks, responsibilities and accountabilities

[*Describe, in the table below, the responsibilities and authorizations related to the execution of the procedure as described under paragraph 7. “Startup procedure (calibration and controls) and maintenance” and 8. “Operation” of this SOP*]

For general authorizations refer to the Authorization Matrix.

|  |  |  |
| --- | --- | --- |
| **Task** | **Authorized** | **Responsible** |
|  |  |  |
|  |  |  |

## 5. Description of the piece of equipment

[*Write a short introduction and provide a short description of the piece of equipment: name, type, brand, supplier, function, method, principle, range of measurement, and, if necessary, a photo. References to a manual are allowed but indicate in chapter 10. “Related Documents” of this SOP which manual and where this can be found*]

## 6. Safety and Environment

[*Describe the possible risks for safety and the environment related to working with the piece of equipment. Only describe the specific dangers related to working with this piece of equipment and refer to the biosafety manual regarding the general safety rules.*

*Practical issues such as waste segregation, personal protection and the use of laminar flow cabinets can be described in chapter 7. “Startup procedure (calibration and controls) and maintenance” and 8. “Operation” of this SOP.*

*Refer to the biosafety manual for waste disposal and labeling of reagents and chemicals*]

## 7. Startup procedure (calibration and controls) and maintenance

* [*Describe in separate paragraphs the chronological sequence of performing calibration, controls and maintenance of the piece of equipment.*
* *Write in imperative as much as possible*
* *Refer to the log sheets for the piece of equipment*
* *Refer, if necessary, also to manuals and Analysis SOPs related to this SOP*]

### 7.1 Calibration

[*Describe, if applicable:*

* *When and how the piece of equipment must be calibrated and when automatic calibration takes place*
* *How results of calibration must be interpreted and processed*
* *How error codes must be interpreted, which actions should be undertaken and by whom*
* *When extra calibrations must be performed*
* *Which data must be recorded in log sheets/logbooks*]

### 7.2 Controls

[*Describe:*

* *When internal and external controls of the piece of equipment must be performed and by whom*
* *How results of controls must be interpreted and processed*
* *How error codes must be interpreted, which actions should be undertaken and by whom*
* *Which data must be recorded in log sheets/logbooks*]

### 7.3 Maintenance

[*Describe:*

* *When, by whom and how maintenance must be performed. Distinguish between maintenance done by laboratory staff and maintenance done by a technical expert (daily-, weekly-, monthly-, and yearly maintenance)*
* *Which data must be recorded in log sheets/logbooks (provide the name of the logbook).*

*If necessary, make a separate procedure or annex for maintenance that must be performed by a technical expert.*]

## 8. Operation

* [*Describe in chronological order the steps for operation of the piece of equipment*
* *Refer, if applicable, to related SOPs*
* *Write in imperative as much as possible*
* *Take the basic knowledge of the user into account when writing this procedure*
* *Describe all the activities of the procedure: technical, administrative and control activities*
* *This chapter can be divided into different paragraphs at its discretion (think of introduction, materials needed, method, controls, waste disposal, etc.)*]

## 9. Problem solving

[*Describe the most common errors. Referring to a manual is allowed (provide the page numbers)*]

## 10. Related Documents

[*Provide a list of related document such as related SOPs, QM chapters, log sheets, package inserts, evaluation/assessment reports, equipment manuals, software manuals, etc. When the documents are not coded according to the quality management system: provide for each document the location where it can be found.*

*For example:*

* *QM1 “General”*
* *Biosafety Manual, in every laboratory room and the administration office*
* *Logbook <title>, room name/number*]

## 11. Related Forms

[*Provide a list of forms that are relevant to this SOP such as request forms, work-forms, batch forms, etc. Provide for each document the location if it is not controlled (coded) according to the quality management system.*

*For example:*

* *P43F1 “Induction checklist”*]

## 12. References

[*Refer to literature used for writing this SOP.*

*Book: Title, edition, author(s), publisher, year, city, first page – last page*

*Journal: Journal name, year + volume + issue, title of article, author(s), first page – last page*]

## 13. Attachments

[*Provide a list of annexes. These can both be controlled documents and uncontrolled documents. For uncontrolled documents: provide the location where they can be found.*

*For example:*

* *P1A1 “Framework for developing Equipment SOPs”*]

# 1. [*Framework for developing Analysis SOPs*]

[*Change the above title into the title of the Analysis SOP that is going to be written*]

## 2. Objectives & Scope

[*Describe briefly the objective of the SOP, the scope and to whom this SOP is applicable*]

## 3. Abbreviations and definitions

[*List the abbreviations and terms that are present in this SOP and give their definition. For abbreviations that are general and used in all the quality documents, refer to the first chapter of the quality manual that lists all the frequently used abbreviations*]

## 4. Tasks, responsibilities and accountabilities

[*Describe, in the table below, the responsibilities and authorizations related to the execution of the procedure as described under paragraph 11. “Procedure” of this SOP*]

For general authorizations refer to the Authorization Matrix.

|  |  |  |
| --- | --- | --- |
| **Task** | **Authorized** | **Responsible** |
|  |  |  |
|  |  |  |

## 5. Principle

[*Provide a short description of the principle of the analysis: method, detection limits, specificity, reference values. Describe briefly how the results must be interpreted*]

## 6. Safety and environment

[*Describe the possible risks for safety and the environment related to performing the analysis. Only describe the specific dangers related to this analysis and refer to the biosafety manual regarding the general safety rules.*

*Practical issues such as waste segregation, personal protection and the use of biosafety cabinets can be described in chapter 11. “Procedure”. Provide, if applicable, the Risk and Safety sentences of the reagents and chemicals used. Refer to the biosafety manual for waste disposal and labeling of reagents and chemicals*]

## 7. Sample

[*Describe:*

* *Type of material: Serum, EDTA-blood, heparin plasma, urine, liquor, etc.*
* *Quantity: Minimal amount needed*
* *Storage location, duration and conditions: Provide the storage location, the duration of storage and   
  the temperature for storing until analysis.*

*This can also be presented in a table*]

## 8. Equipment and supplies

[*Describe the equipment and supplies needed and provide, per item, the details necessary for performing the analysis (name of the piece of equipment, location). Refer to the appropriate SOP if applicable.*

*For example:*

***Supplies:***

*Pipet tips, 10 µl Room A3, cabinet 1*

*Pipet tips, 200 µl Room A3, cabinet 1*

***Equipment:***

*ELISA washer (B3) Room A1*

*ELISA reader (B2) Room A2*

*Multichannel pipet, 100 µl Room A1*]

## 9. Reagents and chemicals

[*Provide a list of all the reagents and chemicals needed in a table. Provide per item the name, storage location and storage conditions. Also describe the method of preparation (e.g. dissolve/dilute), shelf life, storage conditions, release of new lot numbers, or refer to an SOP if applicable.*

*For example:*

***Item (SOP for reference) Storage location Storage condition***

*BSA 2% (P20) Refrigerator 2 4°C*

*5-AS solution (P20) Refrigerator 2 4°C, dark*

*H2O2 0,05% (P20) Refrigerator 3 4°C, dark*]

## 10. Quality Control

[*Provide a list of the quality controls. Describe per control the name, preparation, shelf life and storage conditions.*

*Describe also:*

* *The limits of the controls (only if these never change) or refer to the list that provides up to date limits*
* *How the results of the controls should be interpreted and processed*
* *Which actions should be taken in case control results are outside the acceptable limits, whom should perform these actions and how this is registered*]

## 11. Procedure

* [*Write in imperative as much as possible*
* *Take the basic knowledge of the user into account when writing this procedure*
* *Describe all the activities of the procedure: technical, administrative and control activities*
* *This chapter can be divided into different paragraphs at its discretion (think of introduction, safety, materials needed, preparation of work, preparation of sample, method, processing of results, storage, controls, waste disposal, labeling, archiving, etc.)*
* *Refer to other SOPs if necessary*
* *Describe in chronological order the procedure:*
  + *Processing the request: describe the processing of the request or refer to the appropriate SOP if applicable.*
  + *Preparation of the sample: describe the preparation of the sample, for example: “centrifuge x times g and/or rpm in centrifuge y by z°C”*
  + *Controls: describe when and how controls should be measured, what they should comply with and where and how they should be recorded*
  + *Equipment: refer, if applicable, to the appropriate equipment SOP for calibration, controls, maintenance and operation of equipment*
  + *Samples: describe how patient samples must be analyzed.*
  + *Processing the results: record the results, describe the calculations and rounding of numbers, how results should be processed (for example: introduction into the laboratory information system), first authorization, second authorization, when results can be reported to the requester and how they should be reported.*
  + *Archiving: provide the storage locations of different records (log sheets, raw data, etc.)*
  + *Cleanup: describe what should be cleaned using which cleaning products (refer to relevant SOPs)*]

## 13. Related document

[*Provide a list of related document such as related SOPs, QM chapters, log sheets, package inserts, evaluation/assessment reports, equipment manuals, software manuals, etc. When the documents are not coded according to the quality management system: provide for each document the location where it can be found.*

*For example:*

* *QM1 “General”*
* *Biosafety Manual, in every laboratory room and the administration office*
* *Logbook <title>, room name/number*]

## 14. Related Forms

[*Provide a list of forms that are relevant to this SOP such as request forms, work-forms, batch forms, etc. Provide for each document the location if it is not controlled (coded) according to the quality management system.*

*For example:*

* *P43F1 “Induction checklist”*]

## 12. References

[*Refer to literature used for writing this SOP.*

*Book: Title, edition, author(s), publisher, year, city, first page – last page*

*Journal: Journal name, year + volume + issue, title of article, author(s), first page – last page*]

## 13. Attachments

[*Provide a list of annexes. These can both be controlled documents and uncontrolled documents. For documents without code: provide the location where they can be found.*

*For example:*

* *P1A1 “Framework for developing Analytical SOPs”*]

# Annex [*number*]: [*Framework for developing Annexes and Forms*]

[*Change the above title into the title of the Annex or Form that is going to be developed*]

[*An annex or form can be drafted at your own discretion but is coupled to an SOP or QM chapter*]