Where to start – writing SOPs and risk assessments

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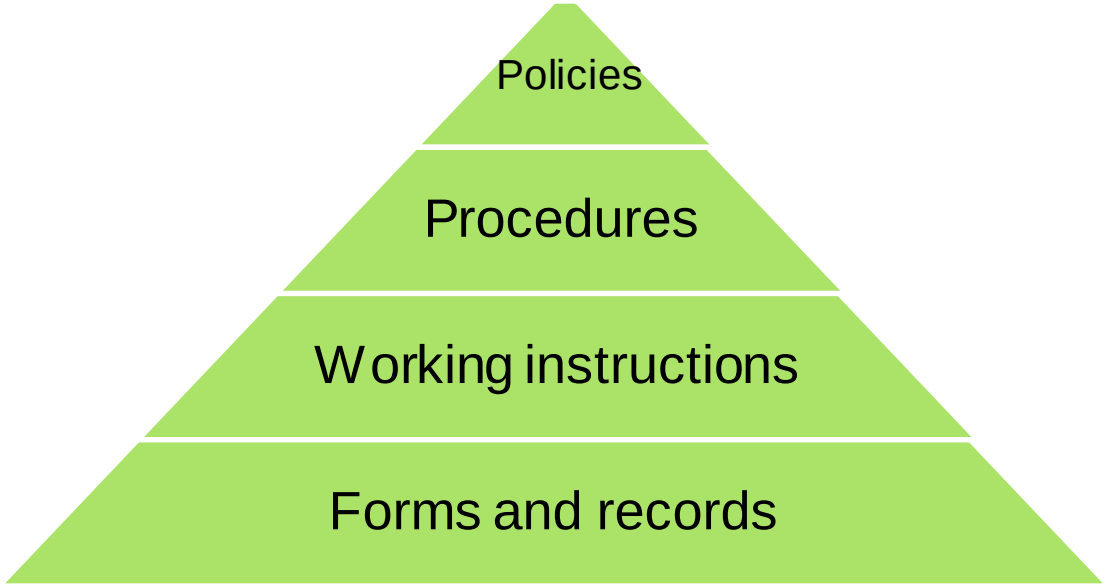
What is a SOP

"SOP" stands for "Standard operating procedure" is a set of written step-by-step instructions on how to enact each policy or perform each different activity in the work place.

SOP documentation may be paper-based, electronic or (preferably) both.



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Why do we need SOPs

- SOPs support the accuracy and precision of the results or products or outcomes of a procedure
  - They should enable anyone (with the appropriate level of training) to carry out a complete procedure by following the written instructions and steps
- Paramount within the context of quality control (QC) and quality assurance (QA).
- SOPs are relevant
  - Management
  - Laboratory
  - Clinical procedures
  - Quality

Types of SOPs in a diagnostic laboratory

SOPS may be divided in to:

- Management Procedures
  - Control of Process and quality records, personnel management, health and safety, management of data and information etc.
- Laboratory Procedures (good lab practice, maintenance and use of equipment, methods)
  - Laboratory Protocols (experimental)
  - Laboratory Equipment
  - Laboratory Processes
    - (receiving samples, storage of samples, storage of reagents, making reagents etc)
  - Reporting results
- Quality Procedures
  - Evaluation and improvement

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Where to start with writing SOPs

- Involve ALL laboratory personnel from the BEGINNING
- Make a list of all individuals tests carried out in the laboratory as a **“master list”** or **“master index”**
  - All the necessary SOP documentation for all the procedures will stem from the complete list of tests

Some basic principles

For each document

- "Write what you do" – (so you can) "do what you write"
- "Write everything – but just once"
- Use a hierarchical approach for documentation, allowing individual documents to be revised without the need to revise overall management procedures (but also avoid having too many SOPs)
- Cross-reference between documents
  - E.g. working instructions on how to use a machine can be referred to both within a procedure and published separately
  - If a procedure requires something to be recorded on a form, the form must be referred to in the procedure

Harper et al, Hum Reprod, 2010

With the “master list” ready - go on to evaluate the laboratory procedures

Prepare a “sub-list” of related SOPs by considering the following

- The detailed test procedure
  - Its aim
  - How was it validated
  - Limitations etc
- Reagents & Consumables
  - How made, stored etc.
- Required equipment
  - Appropriately installed
  - Calibrated
  - Maintained
  - Instructions for use
- Log-in of specimens
- Reporting of results
- Personnel
- Quality control
  - Internal
  - External
- External services & supplies
  - Procedure for selecting e.g. out-sourced genetic test confirmation, external suppliers of critical consumables etc.
- Risk assessments (health & safety)

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Thus, the list should include

Laboratory procedures

- Specimen
  - collecting and handling
  - transportation
  - reception
- Examination procedures (detailed protocols)
  - (the number depends on range of examinations performed, the number of associated protocols e.g. equipment used etc)
- Reporting results
- Referral to other laboratories
- Ensuring the quality of examinations

Organizing the SOP documentation

Differentiate between procedures that are clearly within a specific test versus procedures that may be relevant for >1 test.

The organization can be done according to individual laboratory preference, for example:

- Internal quality control of a test
  - usually test specific, so maybe better documented within each test SOP
- Equipment
  - generally shared between tests, so better documented as a separate SOP per instrument with clear links to specific tests SOPs (may be included within latter too?)
- Generic forms

Main sections in a typical SOP for a laboratory procedure.

Generally, more information within each SOP > better quality and more effective SOPs .

- **Title**
- **Date**
- **Name of Author of SOP**
- **Names of SOP Reviewers**
- **Purpose**
- **Scope and Applicability**
- **Personnel Qualifications**
- **Introduction**
- **Materials and Supplies**
- **Analytical Instrumentation**
- **Cautions**
- **Actual Protocol**
- **References**

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Laboratory procedure SOP - Sections in more detail (1)

Page 1 (Front page)

- **Title** – a clear, succinct title
- **Document number**, number of copies and location of copies
- **Date** – date (including year) of authorship of the current SOP. If the SOP has been revised, then include “Date of Revision”, “Revision Number” and review history
- **Name of the Author of the SOP** – self explanatory
- **Names of SOP Reviewers** - names of those individuals who have reviewed and approved the SOP for use in the laboratory. Signatures and dates should be provided whenever possible as well.

Page 2: Table of contents

- **Headings of the rest of the contents**

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Title of Hospital/Trust/Institute	File name Document 5
Title of the laboratory or department	Page 1 of 4
	Date of issue

TITLE

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EDITION No	
DATE OF ISSUE	
REVIEW INTERVAL	
AUTHORISED BY	
AUTHOR	
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LOCATION OF COPIES	1. 3..

Laboratory procedure SOP - Sections in more detail (2)

- **Purpose** – Brief explanation of the purpose of this SOP and the conditions under which it can be reliably used and limitations.
- **Scope and Applicability** – under what specific conditions can this protocol be used reliably; are there any known interferents or other limitations on the protocol's effective use?
- **Personnel Qualifications** – what (if anything) the user must know or be able to do before being able to carry out this protocol, i.e.,
  - is any prior training required, and if so
  - what specific kind/form of training?
- **Introduction** – relevant background information on the system, methods and instruments used.
- **Materials and Supplies** – list of any reagents/materials including names of suppliers used in this procedure. If the suppliers are obscure sources, a list of addresses and contact information should be provided as well.

Laboratory procedure SOP - Sections in more detail (3)

- **Analytical Instrumentation** – list all analytical instruments, including manufacturer and model numbers, used in the procedure.
- **Cautions (including referral to COSHH forms relevant to protocol)**– are there any specific health and safety precautions that should be considered. For example,
  - should gloves be worn? If so, what kind?
  - How should spills, if they occur, be cleaned up? Decide if these be written separately as well
  - Are there any special procedures that should be followed in order to safely dispose of waste?
- **Risk assessment** (see below)

Laboratory procedure SOP - Sections in more detail (4)

- **Actual Protocol** – step-by-step set of instructions for accomplishing the procedure of interest reliably.
  - Very detailed, refer to exact location of reagents, equipment, room numbers, drawer names etc etc.
  - If appropriate, include calculations for analyzing the data, and provide an example.
  - Include Figures and tables showing laboratory apparatus, representative data.

- **References** - any relevant references to the peer-reviewed literature
  - List of any other documentation e.g. equipment manual, risk assessment forms, management procedure, etc. Anything used in writing the procedure

Example SOP for a laboratory procedure

WebGURU University
Department of Coffee Science & Technology
STANDARD OPERATING PROCEDURES

TITLE: Preparation of the Perfect Cup of Coffee by the Drip Method		
Date of Preparation: 1/1/20	**Date of Revision: N/A**	**Revision No.: N/A**

Submitted by: Dr. AB	Approved by: Professor Ex

Purpose: Provide an example of a standard operating protocol or SOP.

Scope and Applicability: The following protocol can be used wherever quality coffee beans, good drinking water, and a drip coffee maker are available.

Introduction: Coffee is the beverage of choice of many laboratory staff. Properly prepared the beverage provides an invigorating and revitalizing effect. One of the most frequently used methods of preparation is the drip method. In this method, water, heated to near boiling temperatures, is slowly added to finely ground coffee beans held in a filter unit. The coffee beverage is collected below the filter unit in a glass carafe. Today this procedure is frequently accomplished using a semi-automated process in an electronic coffee maker. The procedure below outlines a reliable method for preparing drip coffee using any commercially available drip coffee maker, high quality ground coffee beans, and filtered water.

Example SOP continued

References. For information on coffee beans, the standard methods of preparation of coffee, and recipes see.....

Materials and Supplies. Freshly ground XXXX coffee (any flavor you prefer; medium grind works best with most commercial coffee makers), commercial drip coffee maker including filter (gold mesh preferred but high quality paper filter may be used), good quality drinking water (Spring or similar quality source recommended), coffee cup, and additives (as desired: sugar or sugar alterative, cream or milk).

Cautions: Hot coffee can scald and burn. Water is an electrical conductor. If spills occur during the brewing process, wait until the brewing process is complete, turn of the electricity, and disconnect the unit from the electricity before attempting to clean up any spills. Accidental spills may be cleaned up with a kitchen sponge and dishwashing detergent such as .... Used coffee grounds can be disposed of in the regular rubbish. Be sure to carefully read the directions that accompanied your coffee maker before attempting to use it. In particular .....

Personnel Qualifications – No special knowledge or training is required to make coffee. However, due to the potential risk of burns, it is recommended that anyone performing this procedure who is less than ten years old be actively supervised by an adult.

Protocol:

1. Make sure that the coffee maker is .....

Monitoring SOPs

- Reviewing & Revising SOPs and QMS
  - Reviewing means “check for continued fitness for purpose”. Revision is only necessary if the SOP ceases to be fit. Reviews must be done regularly, but not so often as to prevent all other work being done! (Especially if large number of forms!)
- Management must ensure that personnel use THE LATEST SOP version
  - (destroy all previous hard copies, clearly label electronic versions as EXPIRED)
- Establish and implement procedures for identification, indexing, access, storage, maintenance and safe disposal of quality and technical records

Risk assessment (RA)

- The purpose of a risk assessment is to identify possible causes of harm and measures needed to avoid these - before an accident occurs.
- A **hazard** is anything with the potential to cause harm.
- The **risk** is the likelihood that someone will be harmed by the hazard and the severity of the harm caused. A high risk is one which is very likely to occur and/or may cause death or serious injury/illness. A low risk is extremely unlikely and/or would result in trivial or no injury/illness. A medium risk is in between these two.

Simple Risk Estimation

- RISK = POSSIBLE SEVERITY OF HARM FROM HAZARD x LIKELIHOOD OF THAT OCCURRING
- POSSIBLE SEVERITY RATINGS:
- 1 = Slight harm (< 3 days off work)
  2 = Serious harm (> 3 days off work)
  3 = Major harm (death or major injury)
- LIKELIHOOD RATINGS (taking control measures into consideration):
- 1 = Harm of that severity occurring is unlikely
  2 = Harm of that severity is quite likely to occur
  3 = Harm of that severity is near certain to occur
- A RISK OF:
- 6-9 = High Risk (Immediate Action)
  4-5 = Medium Risk (High Priority)
  1-3 = Low Risk (Lower Priority)

Risk assessment (RA) 1

1. Full description of workplace hazard:

- Storage and use of materials and chemicals. Possible hazards: inappropriate or damaged packaging or wrong storage location, resulting in spillages or contamination which may result in minor injury to handler.

2. Existing safety controls:

- All chemicals should be checked on delivery for, appropriate packaging and storage conditions.
- Spillages procedure in place.
- First aid box and first aider available.
- Personal protective equipment available for handling chemicals and clean ups.
- Suitable storage spaces are pre-allocated for chemicals and materials.
- Fire evacuation procedure in place.

Risk assessment (RA) 2

3. All possible staff groups & individuals likely to be affected by the work:

- All staff and visitors e.g. admin staff, scientists, visitors, students and cleaning staff.

4. Additional controls to be implemented to minimise risk:

- Monitoring of storage spaces to ensure adequate space and safety.

5. Information, instruction, training required:

- Safety information and instructions for spillages and first aid measures available for individual chemicals in the chemical COSHH assessment & Safety Data Sheet folder.

Risk assessment (RA) 3

6. Monitoring procedure to ensure implementation of (4):

- Storage spaces checked on (date) - re-assessed annually.

7. Level of residual risk after controls in place & assessment of situation:

- Risk: 1 x 1 = 1, low risk.
- There is a minimal risk of injury to personnel due to storage of materials and chemicals.
  - Have an **ACTION PLAN to minimise risk if necessary**

8. Signed and dated:

9. Review date:

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COSHH -*Control of substances hazardous to health*

- Before performing a procedure you must be familiar with the relevant COSHH assessments, with particular reference to disposal and spillage procedures.
- Any new chemicals or reagents must have a COSHH assessment and if used in a new procedure must have a risk assessment.

COSHH example

Ethidium Bromide		
□ Very toxic ■ Toxic □ Corrosive ■ Harmful ■ Irritant Risk to unborn child.	□ Flammable ■ Mutagen ■ Carcinogen □ Combustible □ Explosive	Control methods: Wear gloves, laboratory coat and weigh and handle powder in safety cabinets/fume hood with safety sash in down position.
		Actions taken to control risk: Avoid contact with skin and eyes. Avoid formation of dust and aerosols. Provide appropriate exhaust ventilation at places where dust is formed. Dilute form (<0.01%) used in laboratory. Only used to stain pre-run gels and not put into gel buffers. Refer to the relevant MSDS* in the MSDS folder located on shelf 2, lab 28.
		Spillage: Equip yourself with personal protective equipment. Avoid exposure, ventilate area and alert others. Use absorptive material from the spill kit (lab 302C) or paper tissues to soak up spill, dispose in clinical waste bin, wash the area with plenty of water.
		Disposal Procedure: Pour diluted ethidium bromide solution into labelled canister located in lab 302C. Contact Jo Bloggs at XXLAB waste services (Tel: 012345678), for disposal

*material safety data sheet

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SOPs for management procedures

- Document control
- Control of process and quality records
- Control of clinical material
- Personnel management
- Health and safety
- Procurement and management of equipment
- Management of data and information
- Management of reagents, calibration and control materials

Example of SOP on Personnel management

0 Introduction
- 0.1 Scope and purpose
- 0.2 Responsibility
- 0.3 References
- 0.4 Definitions
- 0.5 Related documents

- 1 Recruitment and selection
- 2 Personnel records
- 3 Induction
- 4 Training
- 5 Continuing education
- 6 Joint review
- 7 Meetings and communication
- 8 Disciplinary action

Writing SOPs and risk assessments

Concluding comments:

Make a solid "master index"
Keep SOPs simple

Make the initial (huge) effort – the time spent is worth it in the long run.

References and acknowledgements

- Harper et al, Accreditation of the PGD laboratory. Hum Reprod 2010
- http://www.webguru.neu.edu

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