SOP
EQUIPMENT MANAGEMENT

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SWISS BIOBANKING PLATFORM

A. GENERAL INFORMATION

A1. SCOPE

This SOP describes how equipment should be managed. It describes the procedures to carry out for calibration, preventive maintenance, repair and replacement of pieces of the equipment.
This SOP does not cover safety procedures for using equipment; personnel shall follow BB safety guidelines and Risk-biosafety checklist (Document 2.04.011)

A2. OBJECTIVES

- Ensure that preventive equipment maintenance and calibration procedures are carried out at regular preestablished intervals and according to manufacturer's instructions.
- Ensure that equipment maintenance and calibration records are maintained and recorded in the Document Management System or BIMS.
- Ensure that equipment is used under optimal conditions.
- Ensure that repair and replacement procedures are carried out promptly.
- Ensure that the equipment inventory system is in place and that an equipment inventory (Document 2.02.004) is regularly maintained. The inventory documents contain relevant information required to identify, track, and locate the equipment at all times as well as information on the current operating status of the equipment.

A3. ABBREVIATIONS AND DEFINITIONS

For this document, the following abbreviations apply.
BB = Biobank
BIMS = Biobank Information Management System
QR = Quality Representative
SBP = Swiss Biobanking Platform
SOP = Standard Operating Procedure

See SBP Glossary for definitions.

The SBP SOPs are based on Good Biobanking Practices to ensure an optimal setup for the biobanking activities.
Additionally, the SBP SOPs can serve as a reference for BBs to develop site-specific Work Instructions.

B. PERSONNEL MANAGEMENT

B1. ROLES AND RESPONSIBILITIES

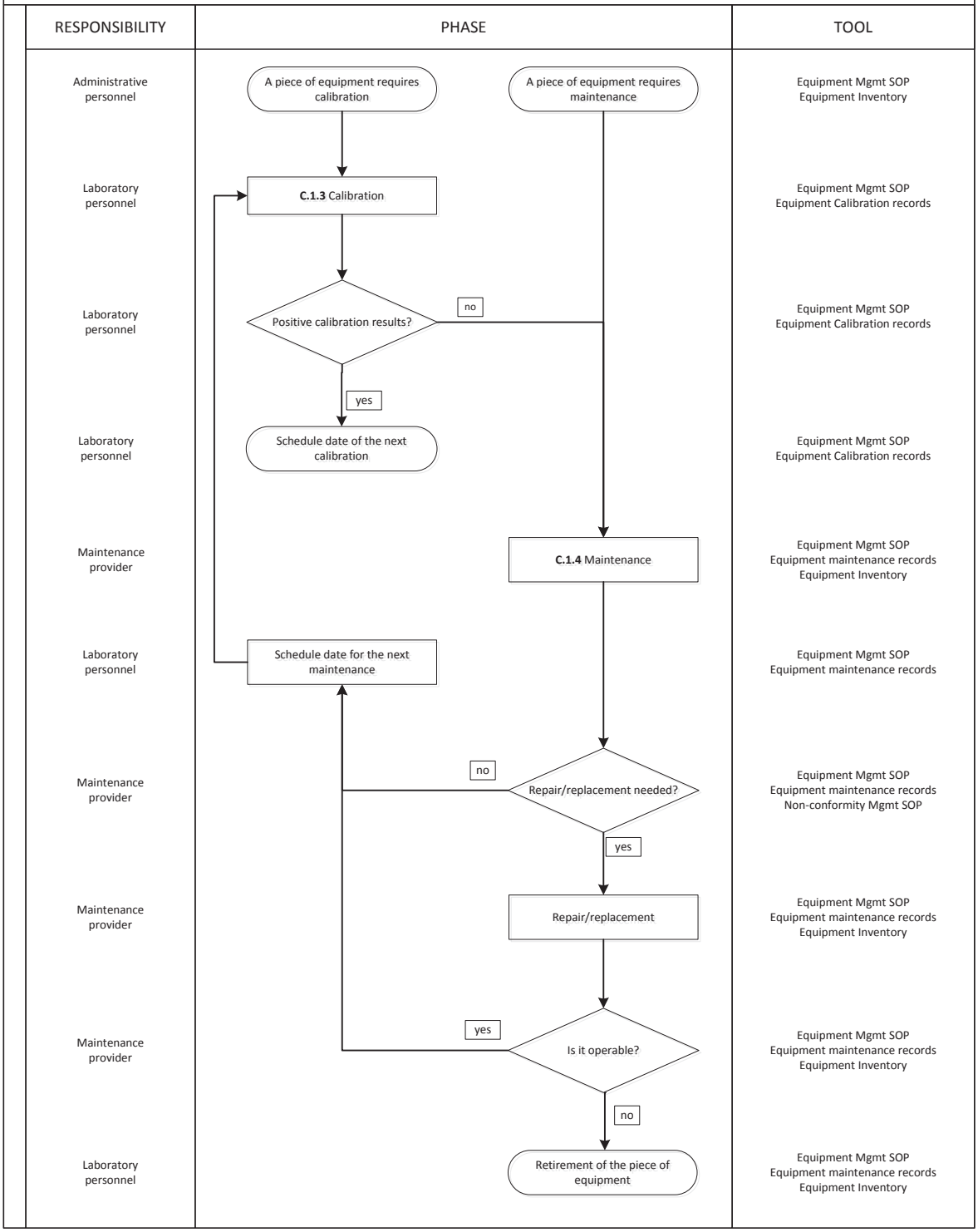
BB personnel	Responsibility / role
Administrative personnel	› Purchase new pieces of equipment › Inform laboratory personnel of a scheduled calibration › Prepare and sign contracts for maintenance services
Laboratory personnel	› Calibrate equipment according to manufacturer's instructions › Schedule dates for preventive maintenance and calibration › Maintain the equipment and the expiring consumables inventories › Define the operating status of each piece of equipment › Update the Document Management System or BIMS
Maintenance provider	› Provides maintenance services, such as preventive equipment maintenance and repair/replacement of pieces of equipment
QR	› Performs Quality Control

C. PROCESS MANAGEMENT

C1. EQUIPMENT MANAGEMENT

The following flowchart describes the activities to be carried out to manage the laboratory equipment.

Flowchart: Equipment Management



C1.2 General equipment requirements

- The BB shall maintain an equipment inventory (Document 2.02.004) and an expiring consumables inventory (Document 2.02.005).
- Every piece of equipment shall have a unique identifier or inventory number.
- Equipment shall be maintained in good operating order and according to manufacturer's requirements.
- Documentation related to the Equipment Management shall be made accessible for internal and external audits, as further explained in the Internal audit SOP (Document 1.04.004).
- Only personnel qualified by training shall use the equipment to ensure that no mishandling or misusing activities are carried out.
- Personnel, who are responsible for equipment, shall be trained in the use of the Document Management System or BIMS as well.
- A service level agreement (Document 2.04.010) shall be established in case of outsourcing services as in the case that the maintenance provider is the vendor or the manufacturer.

C1.3 Equipment calibration

- Administrative personnel shall inform the laboratory personnel of the scheduled calibration of a new or already existing piece of equipment, based on the Equipment calibration records (Document 2.02.002).
- A new piece of equipment shall undergo calibration before use or test.
- Calibration shall be carried out by personnel qualified by training and following the manufacturer's instructions.
- Equipment that has undergone maintenance shall be calibrated before use.
- Equipment requiring calibration shall be labelled indicating the calibration status and shall not be used.
- After a satisfactory calibration, the date for the next calibration shall be scheduled. The frequency of calibration is defined by the BB Work Instructions.
- If a satisfactory calibration cannot be achieved, the piece of equipment shall undergo maintenance. In the presence of any non-conformities, the Laboratory personnel shall follow the procedures described in the Non-conformity Management SOP (Document 1.04.002).
- Equipment calibration records (Document 2.02.002) shall be maintained and recorded in the Document Management System or BIMS.

C1.4. Equipment maintenance

- Preventive maintenance procedures shall be performed according to the manufacturer's instructions and/or BB Work Instructions. The frequency of the maintenance is defined by the BB Work Instructions.
- Administrative personnel shall inform the laboratory personnel of the scheduled maintenance of a new or already existing piece of equipment, based on the Equipment maintenance records (Document 2.02.003).
- Equipment, which has been mishandled, gives unreliable results, or has been shown to be defective, shall be taken out of service and labelled accordingly to prevent use until maintenance and calibration occur. In the presence of any non-conformities, the laboratory personnel shall follow the procedures described in the Non-conformity Management SOP (Document 1.04.002).
- Maintenance shall be either carried out by personnel qualified by training or outsourced to service providers, who demonstrate competence, measurement capability, and traceability.
- After a satisfactory maintenance or a repair or replacement, a date for the next maintenance shall be scheduled.
- Preventive maintenance, repair, or replacement of pieces shall be documented in the Equipment Maintenance Records (Document 2.02.003) and shall be recorded in the Document Management System or BIMS.

C2. QUALITY CONTROL

- The QR performs periodical quality control activities to confirm the reliability of each piece of equipment and consumables.
- The QR controls that personnel, who are responsible for the equipment management, are qualified for the task, as reported in the Personnel file (Document 2.02.001), as established in the Personnel Management SOP (Document 1.02.001).
- Every time the QR performs quality control on the process outputs, quality control details (date of QC, outcomes) shall be recorded in the Quality Control Results (Document 2.04.009).

D. RESOURCE MANAGEMENT

D1. MATERIALS AND EQUIPMENT

The materials and equipment in the following list are recommendations only and may be substituted by alternative/equivalent products more suitable for the specific task or procedure.

Materials and equipment
Consumables
Equipment
Appropriate labels for equipment

D2. PROTECTIVE WEAR AND SAFETY EQUIPMENT

Personnel shall follow institutional safety requirements and Risk-biosafety checklist (Document 2.04.011) at all times.

Safety equipment/ protective wear
Safety equipment for equipment calibration and maintenance.

E. REFERENCES

E1. REFERENCE TO LAWS, REGULATIONS, AND GUIDELINES

- SBP - Ethical, legal and professional compliance list for human research biobanks applicable in Switzerland [Status as of 1 March 2018]

E2. REFERENCE TO OTHER SBP DOCUMENTS

- 1.04.001 Document Management SOP
- 1.02.001 Personnel Management SOP
- 1.03.002 Validation of Methods SOP
- 1.04.002 Non-conformity Management SOP
- 1.04.004 Internal audit SOP

E3. APPENDICES

- 2.02.002 Equipment calibration records template
- 2.02.003 Equipment maintenance records template
- 2.02.004 Equipment inventory template
- 2.02.005 Expiring consumables inventory template
- 2.04.010 Service level agreement
- 2.02.001 Personnel file
- 2.04.009 Quality Control Results
- 2.04.011 Risk-biosafety checklist

E4. REVISION HISTORY

Document number	**Revision date**	**Author**	**Details of revision**
1.02.002		SBP	Initial release