SOP
NON-CONFORMITY MANAGEMENT

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TABLE OF CONTENT

SWISS BIOBANKING PLATFORM

A. GENERAL INFORMATION

A1. SCOPE

The scope of this procedure is the management of non-conformities (NC), including the implementation of preventive and corrective actions (CAPA) to minimise the risk, the occurrence, and the impact of non-conformities on the sample quality as well as on the Quality Management System (QMS) of the biobank.

A2. OBJECTIVES

- Ensure that the samples and specimens handled by the BB fulfil the accepatance criteria defined in the Sample Acceptance Criteria list (Document 2.03.003)
- Ensure that Immediate Corrections and CAPA have been implemented as required.
- Ensure that all Immediate Corrections and CAPA are appropriate for the size and the impact of the NC.
- Ensure that every NC has been recorded appropriately in the Non-conformity Report (Document 2.04.007) and/or the Biobank Information Management System (BIMS) so that it can be tracked if necessary.

A3. ABBREVIATIONS AND DEFINITIONS

For this document, the following abbreviations apply.
BB = Biobank
BIMS = Biobank Information Management System
CAPA = Corrective Action / Preventive Action
Mgmt = Management
NC = Non-conformity
QMS = Quality Management System
QR = Quality Representative
SBP = Swiss Biobanking Platform
SOP = Standard Operating Procedure

For this document, the following definitions apply.

- Non-conformity: Non-fulfilment of a requirement that affects or might affect the quality of the sample and the QMS. It can be a consequence of a user error, a failure of equipment, a catastrophic event, as well as a deliberate intrusion or hacking.
- Immediate Correction: Immediate action to fix the NC
- Preventive action: Action undertaken to prevent a potential NC from happening
- Corrective Action: Action undertaken to eliminate the cause of the NC

See SBP Glossary for other 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

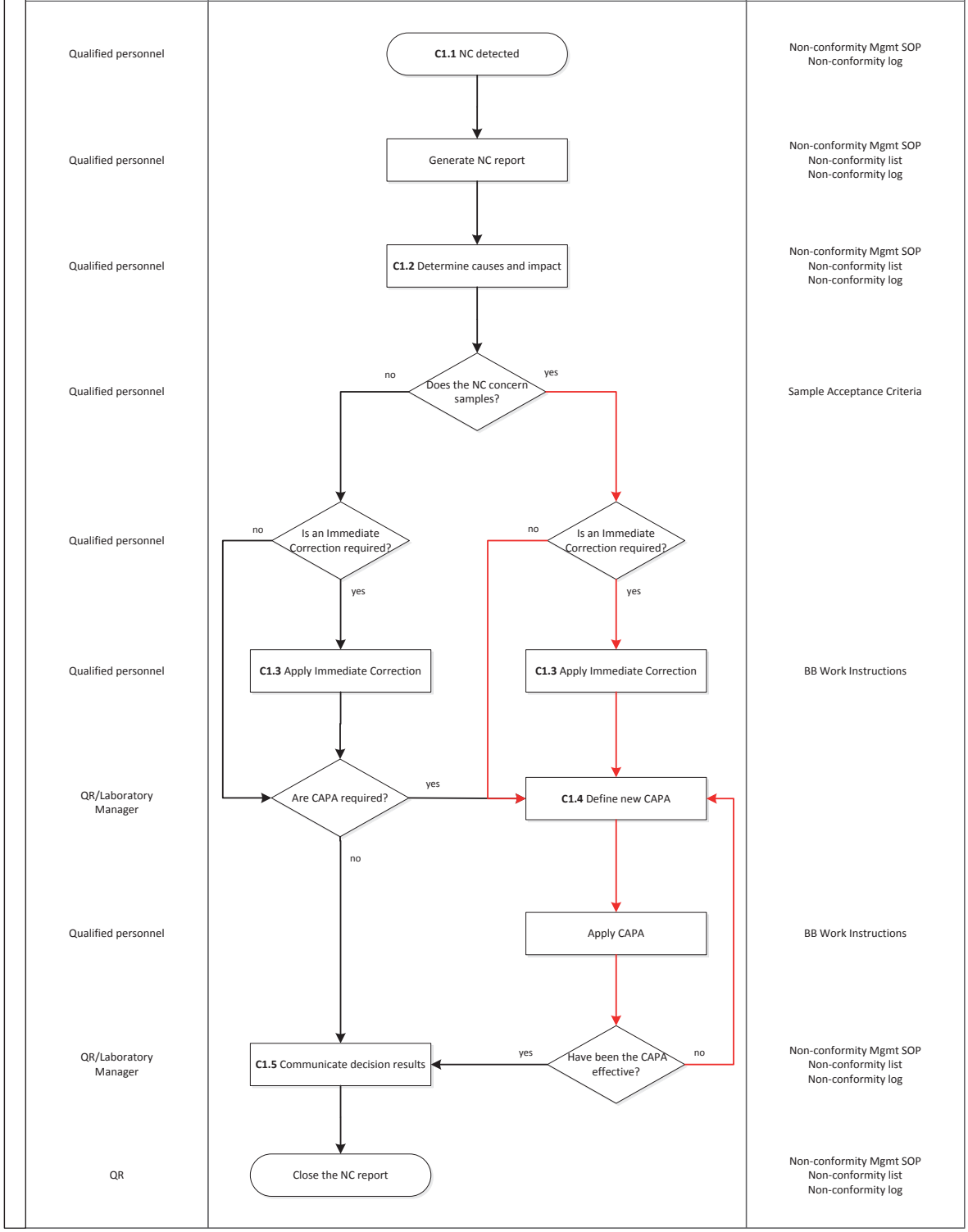
BB personnel	Responsibility / role
Qualified personnel	› Detect and report potential and actual NCs › Determine the causes and the impact of the NCs › Implement CAPA and Immediate Corrections
Laboratory manager	› Defines new CAPA › Reviews the effectiveness of CAPA
QR	› Maintain a system for reporting and recording NCs › Defines new CAPA › Reviews the effectiveness of CAPA › Performs Quality Control

C. PROCESS MANAGEMENT

C1. PROCEDURES

The following flowchart represents the steps for managing NCs.

Flowchart: Management of Non-conformities



C1.1. Identification of a new or recurring NC

- Qualified personnel shall fill the Non-conformity Report (Document 2.04.007) and Non-conformity log (Document 2.04.008) for every NC detected.
- The Laboratory Manager should monitor if personnel report correctly NCs.

C1.2. Determination of the causes and impact of NC

- Qualified personnel shall perform an accurate root-cause analysis to investigate what has caused the NC. They shall also estimate the severity and the impact of the NC.
- The list of Sample Acceptance Criteria (Document 2.03.003) shall be followed to establish if the NC affects or might affect the quality of the sample.
- If the NC affects or might affect the sample quality, the NC shall be treated as urgent and prioritised. The QR shall maintain the NC Report and shall record the nature and the impact of the NC as well as the outcomes of the implementation of Immediate Corrections and CAPA.

C1.3. Implementation of Immediate Correction

- After the NC has occurred, the laboratory personnel shall evaluate if an Immediate Correction is necessary to fix the NC. Laboratory personnel shall carry out an Immediate Correction when required.

C1.4. Implementation of CAPA

- If required, the QR and/or the Laboratory Manager shall formulate CAPA based on the outcomes of the cause analysis.
- If the NC affects or might affect the sample quality, CAPA shall be defined and implemented.
- Trained and qualified laboratory personnel shall implement the CAPA by following BB Work Instructions.
- After the implementation of CAPA, the Laboratory Manager and/or the QR shall assess the effectiveness of the CAPA undertaken. If the CAPA undertaken have not been effective, a new root-cause analysis should be performed, and new CAPA should be formulated and implemented, if necessary.

C1.5. Closing the NC report

- If the Laboratory Manager and/or the QR decide that the implementation of CAPA and/or Immediate Correction is not necessary, the course of action should be chosen from the following list: do nothing, accept the NC, monitor the NC. These decisions shall be communicated to all personnel and shall be recorded.
- After all undertaken actions have been successfully implemented, the QR shall update the Non-conformity log (Document 2.04.008), the Non-conformity Report (Document 2.04.007) and/or the BIMS.

C1.6. Documentation of NC and CAPA

- An NC Report shall be generated and maintained for every NC detected.
- The NC Reports should be readily accessible for audits, as further explained in the Internal audit SOP (Document 1.04.004).
- The Non-conformity Report (Document 2.04.007) enables the laboratory personnel to understand whether the CAPA of previous NCs have worked. If, after implementation of CAPA, the occurrence of the NC is still on the list, the Laboratory Manager will be aware that those CAPA undertaken have not been completely effective.

C4. QUALITY CONTROL

- The QR controls that personnel is trained in the identification of NCs, in the implementation of Immediate Corrections and CAPA, in the use of the NC Report.
- The QR controls that personnel, who are responsible for the non-conformity 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

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 managing samples and equipment

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]
- ISO 9001:2015

E2. REFERENCE TO OTHER SBP DOCUMENTS

- 1.04.001 Document Management SOP
- 1.02.001 Personnel Management SOP
- 1.04.004 Internal Audit SOP

E3. APPENDICES

- 2.04.007 Non-conformity Report
- 2.04.008 Non-conformity log
- 2.04.011 Risk-biosafety checklist
- 2.04.009 Quality Control Results
- 2.02.001 Personnel file
- 2.03.003 Sample Acceptance Criteria

E4. REVISION HISTORY

Document number	Revision date	Author	Details of revision
1.04.002		SBP	Initial release