

# SOP

## INTERNAL AUDIT



Document number	1.04.004
Version	1.0
Category	Organisation Management
Sub-category	Improvement
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Effective date	February 22, 2019

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# A. GENERAL INFORMATION

## A1. SCOPE

This SOP provides guidance on auditing the Biobank, including the management of the audit program and the principles for conducting efficient internal audits. It does not apply to external audit processes.

## A2. OBJECTIVES

- › Ensure that BB conducts internal audits at regular intervals to provide information on whether the QMS is efficiently implemented and maintained.
- › Ensure that the audit activities are performed by trained auditors, which shall be objective, independent, and impartial.
- › Ensure that the audit program has been established, implemented, monitored, and reviewed to include improvements.
- › Ensure that each audit is based on previously defined audit objectives, scope, and criteria.
- › Ensure that audit reports are maintained in the Document Management System.
- › Ensure that records on the implementation of the audits are maintained in the Document Management System.

## 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.**

Audit = a documented review of processes, procedures, records, personnel competencies and functions, equipment, materials, facilities, in order to determine to which extent (acceptance degree) the BB adheres to the previously established audit criteria.

Audit criteria = reference against which conformity is determined

Audit evidence = records, statements of fact or other information which are relevant to audit criteria and verifiable

Audit findings = results of the collected audit evidence against audit criteria

Audit conclusion = outcome of an audit, after consideration of the audit objectives and all audit findings

Audit program = description of the arrangements set up for one or more audit plans

Audit plan = description of the activities and the arrangements for an individual audit

Auditee = organisation/department/unit/laboratory being audited

Auditor = person who conducts an audit

Internal auditor = a designated person knowledgeable with the specific activity or process to be audited but not directly involved in that.

See Glossary from SBP 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

### BI. ROLES AND RESPONSIBILITIES

BB personnel	Responsibility / role
BB Manager/Director	<ul style="list-style-type: none"> <li>&gt; Develops the audit program</li> <li>&gt; Reviews the audit program</li> </ul>
QR	<ul style="list-style-type: none"> <li>&gt; Develops the audit program</li> <li>&gt; Implements the audit program</li> <li>&gt; Monitors the audit program</li> <li>&gt; Reviews the audit program</li> <li>&gt; Selects and appoints the internal auditor/s</li> <li>&gt; Performs Quality Control</li> </ul>
Auditor	<ul style="list-style-type: none"> <li>&gt; Performs the audit activities</li> <li>&gt; Writes and approves the audit report</li> </ul>
Auditee	<ul style="list-style-type: none"> <li>&gt; Approves the audit report</li> </ul>

## C. PROCESS MANAGEMENT

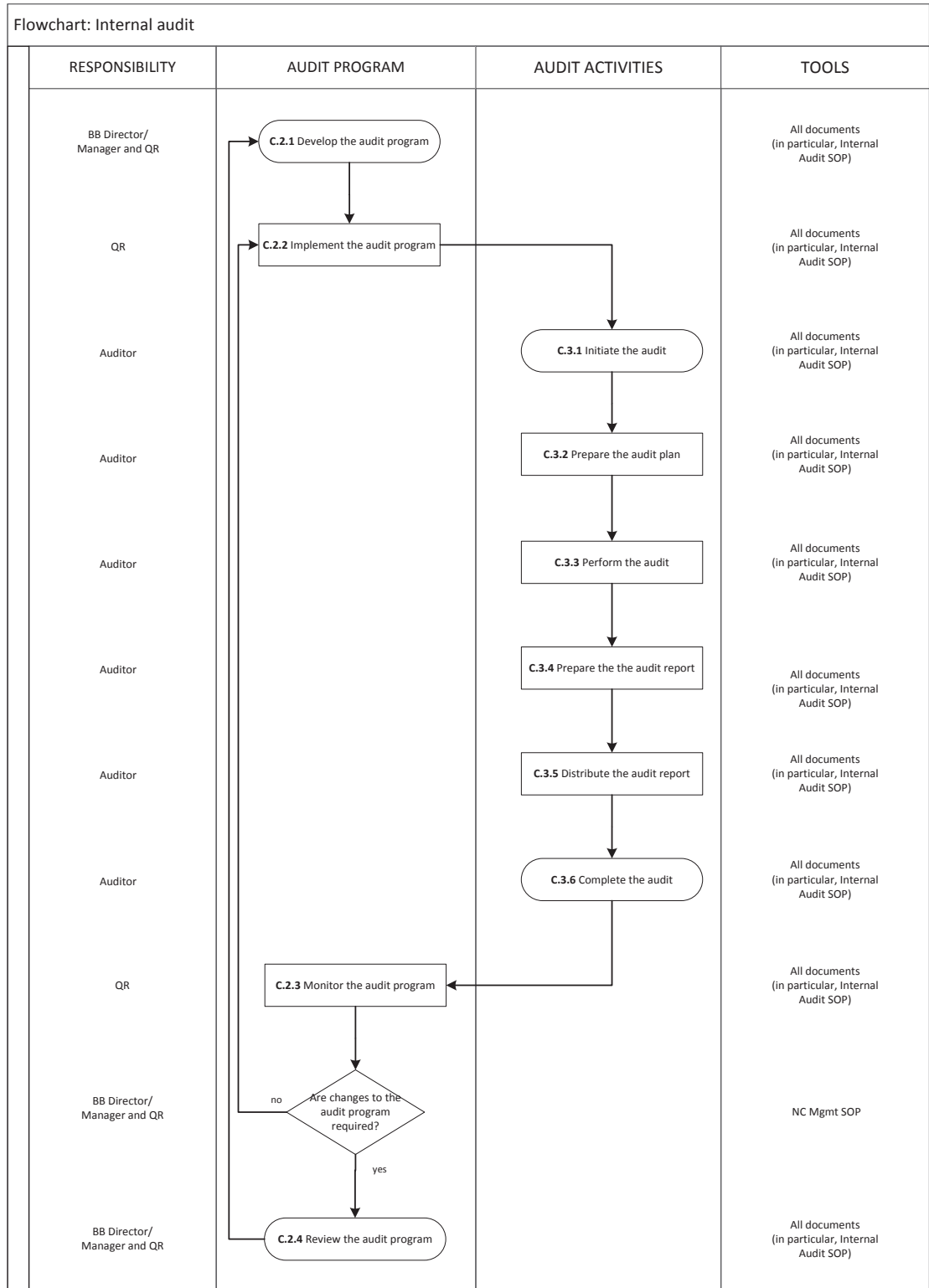
### CI. INTERNAL AUDIT

#### CI.1. General Information on the audit

The following points should be the object of an audit (this list is not exhaustive):

- > Governance Management, including compliance with legal and ethical requirements.
- > Processes;
- > Personnel proficiency and functions;
- > Facility infrastructure, equipment, and materials;
- > Documentation and record keeping;
- > IT systems, including BIMS and/or database and Document Management System;
- > Organisation Management, including audit program, quality policy, quality objectives, sustainability, continual improvement;

As illustrated in the following flowchart, the audit procedure involves two distinct phases: the management of the audit program and the audit activities themselves.



## C2. MANAGEMENT OF THE AUDIT PROGRAM

### C2.1. Developing the audit program

- The audit program shall describe the arrangements for one or more audits planned for specific purposes and for a specific timeframe. The audit program shall include the following items:
  - 2a. Audit objectives for the whole audit program. For example, fulfillment of legal and ethical requirements and audit criteria, improvement of the BB, assessment of the effectiveness of the QMS, alignment of the QMS to policies and governance, determination of the compliance of activities and processes with written BB SOPs and Work Instructions.
  - 2b. Scope and frequency of the individual audits: scheduled dates, location, departments to be audited, activities and processes to be audited, period covered by the audit.
  - 2c. Audit criteria. It includes policies, SOPs, legal and ethical requirements, and QMS requirements.
  - 2d. Audit sampling methods. The audit sampling method shall be accurately described as it explains how the auditor should select samples/specimens and/or documents during the audit to produce audit evidence.
  - 2e. Requirements for selecting internal auditors. The auditor/s shall be competent, impartial, and objective. To ensure the auditor impartiality and objectivity, the auditor shall be selected from departments not directly associated with the auditee. Moreover, the auditor should be selected on the basis of their competencies in auditing.
- The audit program shall focus to allocate resources to audit those processes and activities that directly impact the effectiveness of the QMS.
- The BB Manager/Director and the QR shall also identify and evaluate the risks for the audit program.

### C2.2. Implementing the audit program

- The QR shall ensure that the objectives, the scope, and the criteria of the individual audits are consistent with the audit program.
- The QR shall determine the extent (acceptance degree) of conformity of the QMS to be audited, or parts of it.
- The QR shall select and appoint the auditors for the individual audits based on the requirements of the audit program.

### C2.3. Monitoring the audit program

- The QR shall ensure that the number of audits, the scheduled dates, and the objectives described in the audit program are respected and continuously monitored.

### C2.4. Reviewing the audit program

- The BB Manager/Director and the QR shall manage the audit conclusions as well. This includes the following activities: review the causes of the audit findings, review the audit reports, and determine the necessity of any follow-up audit.
- In case of non-conformities detected during the audit and recorded in the audit report, the audit program should be modified. Follow-up audits to verify the completeness and the effectiveness of the CAPA undertaken shall be included in the revised audit program. The audit report, as well as the changes to standards and to legal requirements, should modify the objectives of the audit program.

## C3. AUDIT ACTIVITIES

### C3.1. Initiating the audit

- The auditor shall determine the feasibility of the audit activities by assessing if appropriate information is available for planning and conducting the audit. The auditor also shall evaluate if the time and the resources made available by the BB are adequate for conducting the audit.

### C3.2. Preparing the audit plan

- The auditor shall prepare the audit plan based on the information reported in the audit program. An audit check-list, which includes details on the activities/processes to be audited, should be prepared.
- The BB should take into account the risks due to the audit activities.
- It should set up additional measures for data protection and confidentiality as well as safety.

**C3.3. Performing the audit**

- › The auditor shall conduct an opening meeting to introduce himself/herself to the auditee. During the opening meeting, all parties confirm their agreement to the audit plan and ensure that all planned activities can be performed.
- › The auditor shall review documents and records to determine if the audit criteria are fulfilled, based on the audit sampling method.
- › The auditor shall collect information via appropriate sampling and verify it. Only the information that has been verified shall be accepted as audit evidence. The audit evidence shall be assessed against the audit criteria to determine the audit findings, which are, thus, recorded.
- › The auditor shall prepare the audit conclusions, indicating the need for CAPA and/or improvement actions. The following issues shall be addressed: the extent of conformity with the audit criteria, the effectiveness of the QMS, possible implementation and improvement of the QMS, the achievement of the audit objectives listed in the audit program, and the audit findings. If required by the audit program, the auditor provides recommendations for the continual improvement of the BB or future audit activities.

**C3.4. Preparing and approving the audit report**

- › The auditor shall prepare the audit report in accordance with the audit program. The audit report should include: the audit objectives, the audit scope, identification of the auditor/s, the dates and the locations where the audit has been carried out, the audit criteria, the audit findings, the audit evidence, and the audit conclusions.
- › The audit report shall be dated, reviewed, and approved by the auditor and the auditee in accordance with the audit program.

**C3.5. Distributing the audit report**

- › The auditor shall conduct a closing meeting within an agreed period to distribute and explain the audit report.
- › The audit report shall be distributed to the BB Director/Manager, the QR, and all other concerned parties.

**C3.6. Completing the audit**

- › The audit shall be considered as complete when all planned activities have been carried out.
- › If required by the audit program, a subsequent audit shall verify if the CAPA and improvement actions have been successfully undertaken by the auditee within an agreed period.

**C4. QUALITY CONTROL**

- › The QR controls that the audit activities have been carried out by qualified auditors, whose tasks are listed in the Personnel file (Document 2.02.001), as established in the Personnel Management SOP (Document 1.02.001).
- › The QR controls that the audit activities have been carried out as established in the audit program.
- › 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****DI. 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

## 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
- > ISO 19011:2011

### E2. REFERENCE TO OTHER SBP DOCUMENTS

- > 1.04.001 Document Management SOP
- > 1.02.001 Personnel Management SOP
- > 1.04.002 Non-conformity Management SOP

### E3. APPENDICES

- > 2.04.009 Quality Control Results
- > 2.02.001 Personnel file

### E4. REVISION HISTORY

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