TRAIN-THE-TRAINER WORKSHOP ON BIOBANKING (ISO 20387)

MANAGEMENT SYSTEM, OPTIONS A AND B

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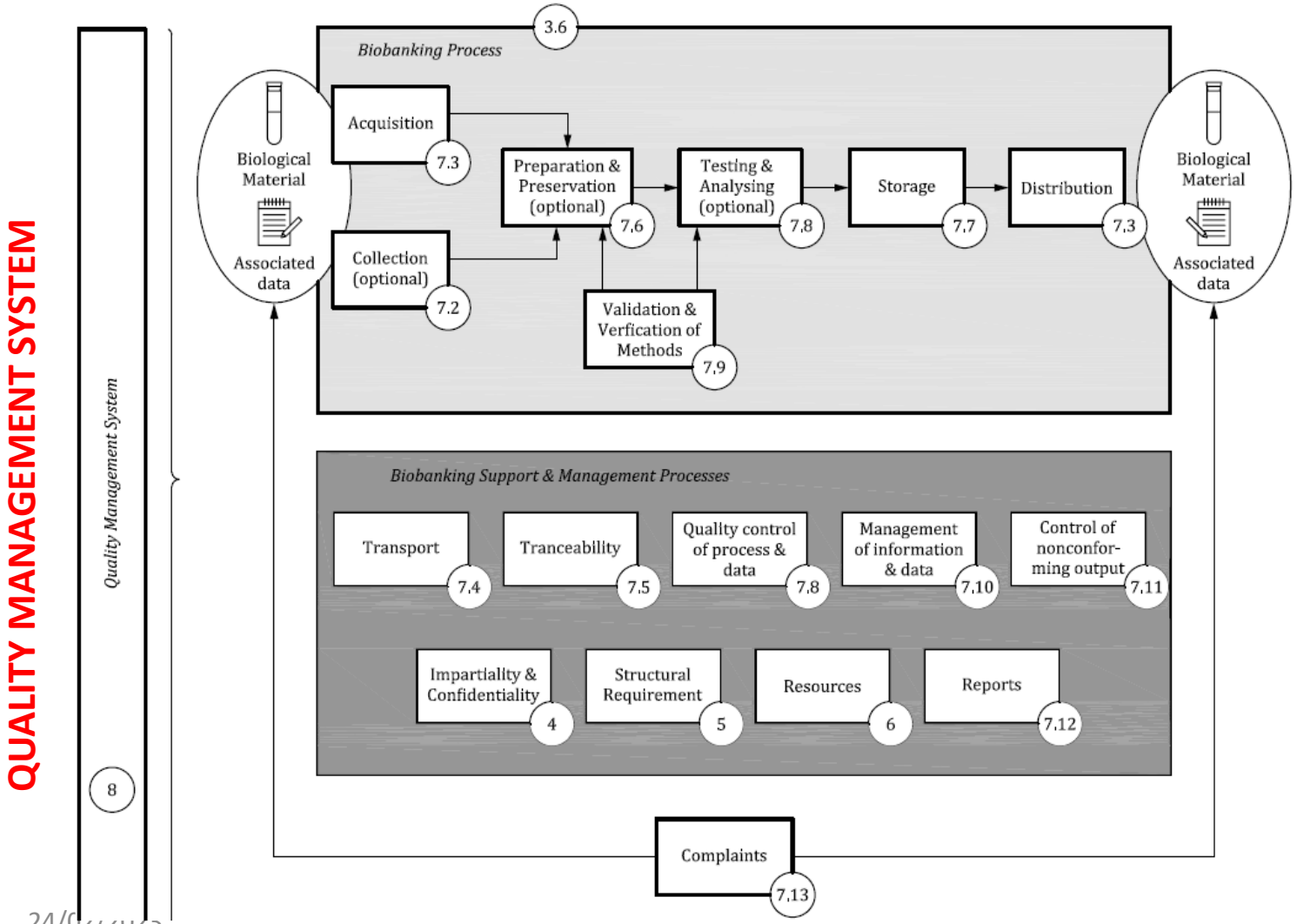
MANAGEMENT SYSTEM - FUNDAMENTALS

- **QUALITY MANAGEMENT SYSTEM**:
  - It comprises the activities by which the organisation identifies its objectives and determines the processes and resources required to achieve the intended results.
  - It manages the interacting processes and resources required to deliver value and realise results for the relevant stakeholders.
  - It permits top management to optimise the use of resources by considering the long-term and short-term consequences of its decisions.

UNI EN ISO 9000:2015

QUALITY MANAGEMENT SYSTEM – FUNDAMENTALS AND VOCABULARY

MANAGEMENT SYSTEM - PROCESSES



PRIMARY PROCESSES

SUPPORT AND MANAGEMENT PROCESSES

rif. ISO/TR 22758:2020 – IMPLEMENTATION GUIDE FOR ISO 20387

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§8 QUALITY MANAGEMENT SYSTEM REQUIREMENTS – OPTION A AND OPTION B

The quality management system is the subject of §8, but of course the management system cuts across all requirements and is the basis on which all requirements are based.

- **ISO 20387 provides two options for a biobank to follow for its QMS. Both options seek to achieve the same result in the performance of quality management, and require compliance with Clause 4 to 7 of ISO 20387:2018.**

- **The Biobank shall implement a quality management system in accordance with option A or option B.**

§8 QUALITY MANAGEMENT SYSTEM REQUIREMENTS – OPTION A AND OPTION B

- OPTION A

lists the minimum requirements for implementation of a quality management system in a biobank. Care has been taken to incorporate all those requirements of ISO 9001 that are relevant to the scope of biobanking that are covered by the quality management system. Biobanks that comply with Clauses 4 to 7 and implement Option A of Clause 8 will therefore also operate generally in accordance with the principles of ISO 9001.

- OPTION B

allows biobanks to establish and maintain a quality management system in accordance with the requirements of ISO 9001, in a manner that supports and demonstrates the consistent fulfilment of Clauses 4 to 7. Biobanks that implement Option B of Clause 8 will therefore also operate in accordance with ISO 9001. Conformity of the quality management system within which the biobank operates to the requirements of ISO 9001 does not, in itself, demonstrate the competence of the biobank to produce technically valid data and outputs. This is accomplished through compliance with Clauses 4 to 7.

§8 QUALITY MANAGEMENT SYSTEM REQUIREMENTS – OPTION A AND OPTION B

- OPTION B

allows biobanks to establish and maintain a quality management system in accordance with the requirements of ISO 9001, in a manner that supports and demonstrates the consistent fulfilment of Clauses 4 to 7. Biobanks that implement Option B of Clause 8 will therefore also operate in accordance with ISO 9001. Conformity of the quality management system within which the biobank operates to the requirements of ISO 9001 does not, in itself, demonstrate the competence of the biobank to produce technically valid data and outputs. This is accomplished through compliance with Clauses 4 to 7.

GOOD STARTING POINT

GAP ANALYSIS

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OPTION A

As a minimum the quality management system of the biobank shall address the following:

a) Document information for the quality management system

b) Control of quality management system documents

c) Control of records

d) Action to address risks and opportunities

e) Improvement

f) Corrective action for nonconforming outputs

g) Internal audits

h) Quality management reviews

8.2.1 Documented information for the quality management system

The biobank shall manage the document information (internal and external) necessary for its planning and operation, in order to comply with applicable requirements, and to ensure its competence to perform biobanking. To do so, the biobank shall:

a) Identify the information that shall be documented

b) Ensure that the documented information is appropriately created and updated

c) Ensure that the documented information is appropriately controlled.

EXTERNAL ORIGIN
E.g. Applicable mandatory legislation, Technical Standards, AB Regulations

INTERNAL ORIGIN
E.g. Manual, Procedures, Work Instructions, Records

HOW?
- ✓ Analysing the context in which it operates
- ✓ Identifying within the Standard all the Procedures that MUST be documented
- ✓ Using a risk analysis approach

To remember:
«shall» indicates a requirement
«should» indicates a recommendation
«may» indicates a permission
«can» indicates a possibility or a capability

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8.2.2 – 8.2.3 policies and objective

Documented information must also include

POLICIES AND OBJECTIVES

- **They must be acknowledged and implemented at all levels of the biobank**
- They shall address the COMPETENCE, IMPARTIALITY AND CONSISTENT OPERATION OF THE BIOBANK
- They are defined by the biobank management

8.2.6 All personnel involved in biobanking activities shall have access to the parts of the quality management system documentation and related information that are applicable to their responsibilities.

8.3 – 8.4 control of QMS documents and records

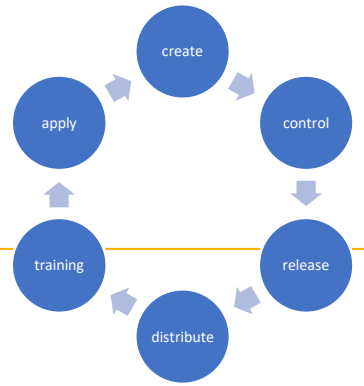
ON-SITE ASSESSMENT

§ 8.3 CONTROL OF QUALITY MANAGEMENT SYSTEM **DOCUMENTS**

Es. PROCEDURES
STANDARDS
INSTRUCTIONS

- Documents are approved for adequacy prior to issue by authorized personnel
- Documents are periodically reviewed and updated as necessary
- The changes and current revision status of documents are identified
- Relevant versions of applicable documents are available at points of use and where necessary their distribution is controlled
- Documents are uniquely identified
- The unintended use of obsolete documents is prevented, and suitable identification applied to them, if they are retained for any purpose

DOCUMENT REVIEW



§8.4 CONTROL OF **RECORDS**

- Record is defined in ISO 9000:2015, 3.8.10 as document (ISO 9000:2015, 3.8.5) stating results achieved or providing evidence of activities performed.
- Records can be used, for example, to formalize traceability (ISO 9000:2015, 3.6.13) and to provide evidence of verification (ISO 9000:2015, 3.8.12), preventive action (ISO 9000:2015, 3.12.1) and corrective action (ISO 9000:2015, 3.12.2).
- Records produced by the biobank can include but are not limited to: a) original observations, raw data, calculations, test results, traceability data for equipment; b) results from tests performed during the installation, maintenance, and control, including calibration, of equipment; c) evidence of personnel qualifications and participation in training courses (such as the course designation, program, date, duration, and identification of the trainer) and resulting competencies and authorizations; d) reports of audits; e) reviews of the quality management system; f) report(s) of nonconformities (including complaints) and any actions taken to correct and avoid recurrence of nonconformities (see ISO 20387:2018, 8.7.3).

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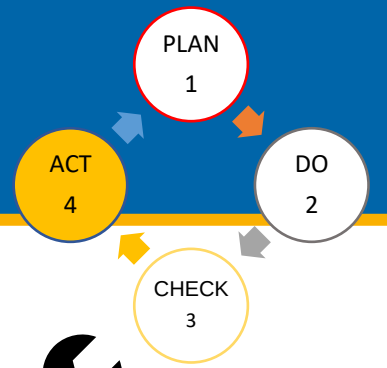
8.6 IMPROVEMENT



QMS improvement is a dynamic and important process.

The biobank can collect, review and analyze information on its QMS performance and use this information as a basis for improvement. Information collected can include:

a) Results of internal audits (See ISO 20387:2018, 8.8 Internal Audits);

b) Analysis of quality performance indicators in fulfilment of QMS objectives;

c) Assessment of operational, support, and management processes;

d) Results of risk assessments (see ISO 20387:2018, 8.5 Actions to Address Risks and Opportunities);

e) Nonconformities (see ISO 20387:2018, 7.11 Non-conforming Outputs);

f) Corrective actions (see ISO 20387:2018, 8.7 Corrective Actions);

g) Proficiency-testing results, etc. (see ISO 20387:2018, 7.8.2 Quality Control of Processes);

h) Feedback, e.g. user assessment of whether BMaD was fit for the intended purpose (see ISO 20387:2018, 8.6.2)

TOOLS FOR IDENTIFYING OPPORTUNITIES FOR IMPROVEMENT

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8.7 CORRECTIVE ACTION FOR NON CONFORMING OUTPUT

This requirement is closely linked to §7.11 – Nonconforming output

The biobank shall establish, document and implement procedures for management of output that does not conform to the predefined requirements of the biobank and/or the agreement with the recipient/user and/or the agreement with the provider

The biobank shall demonstrate

- reacts to the nonconforming output and, as applicable:
  - take action to control and correct it
  - deal with the consequences
- cause analysis
- impact analysis
- corrective action
- effectiveness of any corrective action
- retain documented information as evidence

NONCONFORMING
deviating from a particular from a particular requirement
(§3.6.9 – ISO 9000)

CORRECTIVE ACTION:
Action to eliminate a non-compliance and to prevent its recurrence
(§3.12.2 – ISO 9000)

CORRECTION:
Action to eliminate a detected non-compliance
(§3.12.3 – ISO 9000)

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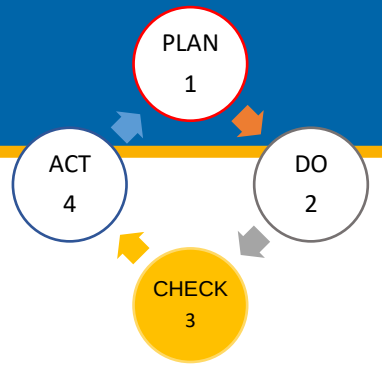
8.8 INTERNAL AUDITS



The biobank shall demonstrate:

AUDIT PROGRAMME

- Plan, implement and maintain in audit programme including the frequency, methods, responsibilities, planning requirements and reporting.
- Audit criteria and scope
- Ensure that the results of the audits are reported to relevant management (i.e. management review)
- Implement appropriate correction and corrective actions without undue delay
- Retains records as evidence of the implementation of the audit programme and the audit results

ISO 19011:2018
GUIDELINES FOR AUDITING MANAGEMENT SYSTEM

The concept of IMPARTIALITY is a requirement according to the principles for auditing introduced in ISO 19011, e.g., the auditor is independent of the activity being audited.

The biobank shall demonstrate to be conform to:

- Requirements for its quality management system;
- Requirements of **ISO 20387**

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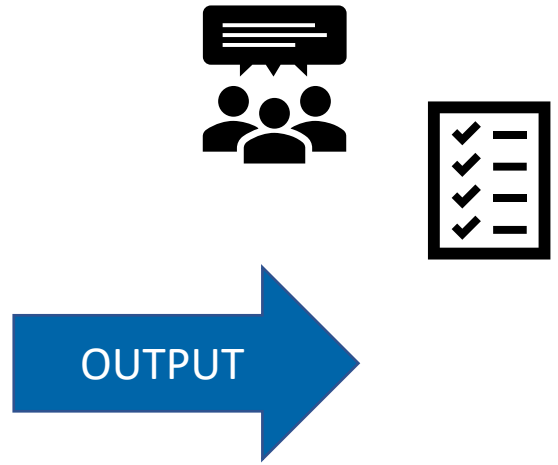
8.9 QUALITY MANAGEMENT REVIEWS

INPUT

- ✓ Changes in internal and external issues that are relevant to the biobank
- ✓ Fulfilment of objectives
- ✓ Suitability of policies and procedures
- ✓ Status of actions from previous management reviews
- ✓ Outcome of recent internal audits
- ✓ Corrective actions
- ✓ Assesments by external bodies;
- ✓ Changes in the volume and type of work or in the range of the biobank's activities
- ✓ Provider/recipient/user feedback
- ✓ Complaints
- ✓ Effectiveness of any implemented improvements
- ✓ Adequacy of biologiacal material and associated data
- ✓ Results of risk identification
- ✓ Outcomes of the quality control
- ✓ Other relevant factors, such as monitoring activities and training

8.9 QUALITY MANAGEMENT REVIEWS

- ✓ The effectiveness of the quality management system and its processes
- ✓ Improvement of the activities related to the fulfilment of the requirements of this document
- ✓ Provision of required biological material and associated data
- ✓ Any need for change



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RISK BASED APPROACH

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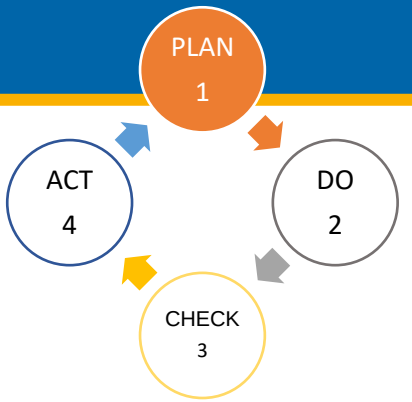
8.5 ACTION TO ADDRESS RISKS AND OPPORTUNITIES



- The biobank shall consider the risks and opportunities associated with its biobank activities in order to:
  - Give assurance that the quality management system can achieve its intended results
  - Enhance opportunities to achieve the purpose and objectives of the biobank
  - Prevent or reduce undesired impact and potential failures in biobanking, including discontinuation of operation of the biobank
  - Achieve continuous improvement.

ACTION PLAN

- TO ADDRESS THESE RISKS AND OPPORTUNITIES
- TO SAFEGUARD BIOLOGICAL MATERIAL AND ASSOCIATED DATA IN THE EVENT OF A DISASTER
- TO ADDRESS DOSCONTINUATION OF OPERATIONS IN PARTICULAR HANDLING OF CONCERNED BIOLOGICAL MATERIAL AND ASSOCIATED DATA

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RISK BASED APPROACH

ISO 31000
Risk management - Guidelines

- The consideration of risks and opportunities is an inherent part of the quality management system planning (i.e., setting objectives, defining processes). Examples include:

  - addressing risks

  - addressing opportunities

- The risk-based approach is intended to systematically integrate considerations of risks and opportunities into the planning of processes, and to link those to the expected quantity or quality of the process output. This can lead to the observation that some activities in a process are less prone to have a negative impact on the process output than others; consequently they are submitted to less control than others. Or, it can be found out that a specific step in a process is extremely important to achieve the intended sample quality, so that only trained staff and validated equipment can be used.

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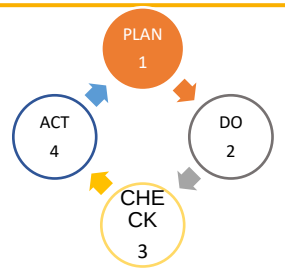

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RISK BASED APPROACH

4.1 General

4.1.1 The biobank shall have procedures addressing biobanking of each type of biological material and associated data held. This includes processes such as collecting/procuring and/or acquiring and receiving, tagging, accessioning/logging, cataloguing/classifying, examining, preparing, preserving, storing, managing data, destroying, packaging as well as safeguarding, distributing and transporting. The biobank shall have procedures to ensure compliance with relevant biosecurity and biosafety requirements. The procedures shall also address risks and opportunities using a risk assessment.

EXAMPLES OF REQUIREMENTS WHERE RISK/RISK ANALYSIS IS MENTIONED

4.2.4 The biobank shall identify risks to its impartiality on an on-going basis.

6.2.1.5 The biobank or the legal entity of which it is a part shall ensure that health and safety requirements are established, documented, implemented and maintained. The level of safety training required shall be determined using a comprehensive risk assessment of the biological and chemical materials, processes and equipment being handled.

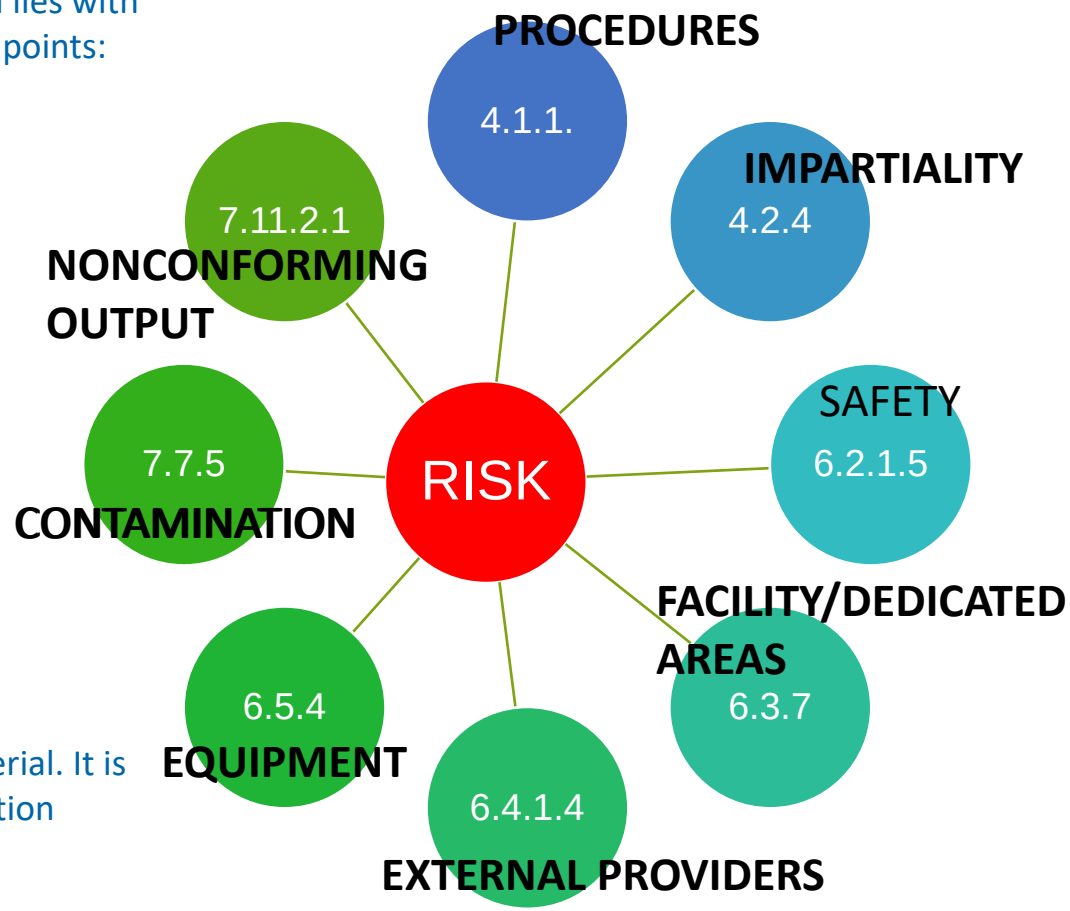
7.7.5 The storage locations and processes shall be designed to minimize risk of contamination, and to ensure maintenance of inherent biological material integrity.

RISK BASED APPROACH

The responsibility for deciding which risks and opportunities need to be established lies with BBK, it being understood that the standard requires a risk analysis for the following points:

§4.1.1 biosecurity and bio protection
§4.2.4 impartiality
§6.2.1.5 biosecurity
§6.3.7 contingency plan
§6.4.1.4 processes, products, services provided externally
§6.4.1.6 b) planning of internal audits of the external supplier
§ 6.5.4 equipment
§7.7.5 storage of biological material
§7.11.2.1 control of non-compliant output

A risk analysis is also recommended for at least the following points:
§7.6.2. choice/definition/identification of critical activities
§7.7.3 choice/definition/identification of critical activities and relevant processing parameters
§7.7.7 intervals and methodologies for carrying out the inventory of biological material. It is recommended to consider among the risks also those related to the use of information systems.



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TRAIN-THE-TRAINER WORKSHOP ON BIOBANKING (ISO 20387)

PERSONNEL

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6.2 PERSONELL

ISO 20387 – SCOPE
This document specifies general requirements for **the COMPETENCE, IMPARTIALITY and consistent operation** of biobanks including quality control requirements to ensure biologiacal material and data collections of appropriate quality.

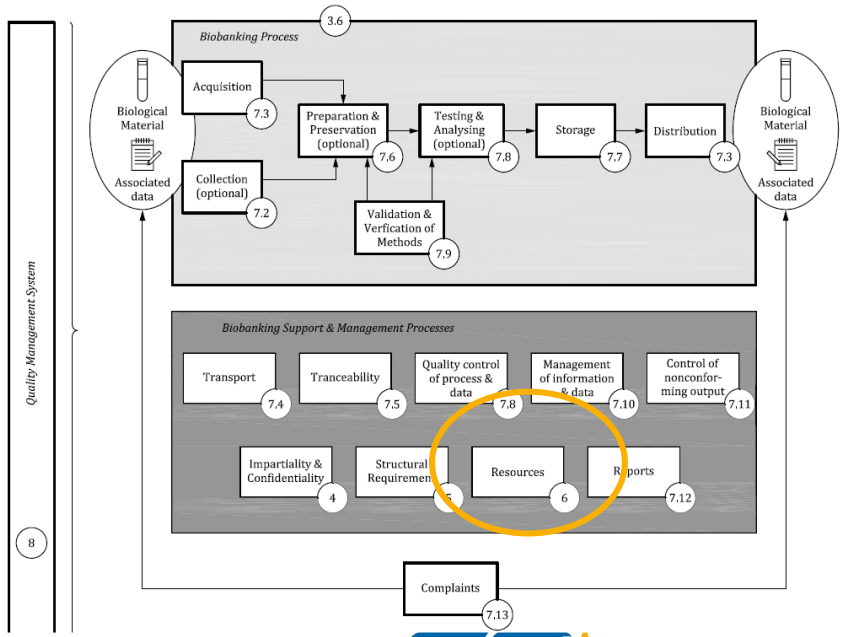
!

All accreditation standards are based on COMPETENCE AND IMPARTIALITY.

For this reason, the management process of personnel working within or supporting the biobank is of paramount importance.

6.2.1.1 All personnel of the biobank, either internal or external, who can impact biobank activities,
shall act impartially.

DOCUMENTED PROCEDURES FOR PERSONNEL MANAGEMENT



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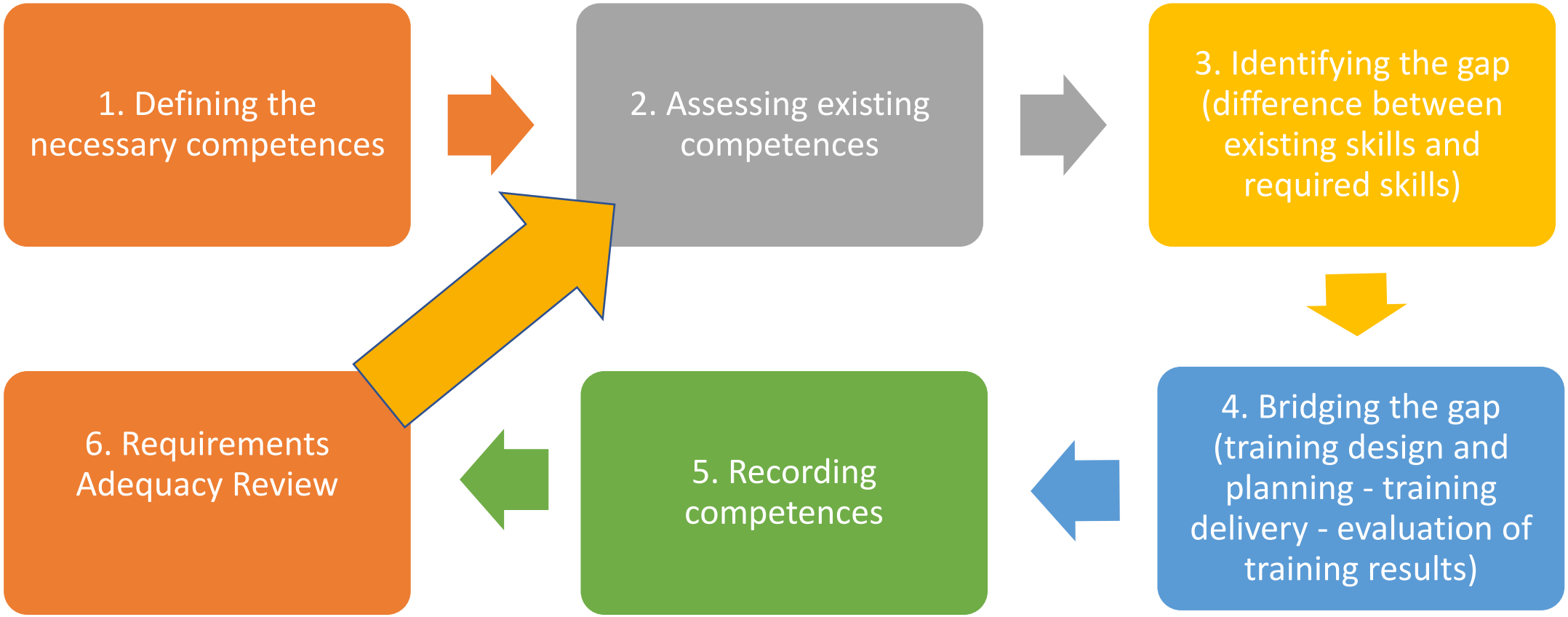
6.2 COMPETENCE AND COMPETENCE ASSESSMENT

- Competent personnel contribute to proficient execution of biobanking tasks, including support functions (e.g. IT, facilities infrastructures, human resources, legal).
- Job or task descriptions can address any general, managerial and operational activities for which qualification is required. Individual descriptions can include responsibilities, and authorities of biobank personnel, and skills or competencies required to fulfil these activities.
- Any regulatory or statutory requirements can also be considered

6.2.2 COMPETENCE AND COMPETENCE ASSESSMENT



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6.2.3 TRAINING

Training plans aligned with biobank competence need can be useful. Such training plans can be established for all personnel in the biobank entity and/or for individuals. Identified training needs can be fulfilled by internal training provided by personnel of the organization, or by eternall training organizations. The biobank can periodically assess the effectiveness of the training, e.g., by a test or evaluation.

DOCUMENTED EVIDENCE

NEW PERSONNEL

New personnel typically go through a multi-faceted orientation, parts of which are applicable to all (e.g. familiarization with the organization, principles of confidentiality and impartiality, use of information and communication techology tools) and other parts of which are specific to the job (e.g. health and safety requirements, job-specific tasks and tools). This orientation can conclude with approval of the competence of the trainee, and formal authorization to perform the trained activities.

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OTHER PERSONNEL-RELATED REQUIREMENTS

Please note!
Within the standard, in addition to point 6, there are other requirements concerning personnel, here are some examples:

4.1.7	The biobank should document the identity of personnel performing activities encompassing procedures as referred to in 4.1.1
4.3.4	All personnel having access to confidential data of the biobank shall be bound to confidentiality (see 6.2.1.2).
5.8	The biobank shall (…) specify the responsibility, authority and interrelationship of personnel who manage, perform, validate or verify work affecting biobanking output.
5.9	The biobank shall have personnel who, irrespective of other responsibilities, have the authority and resources needed to carry out their duties, including: a) implementation, maintenance, monitoring and improvement of the quality management system; b) identification of deviations from the quality management system or from the procedures for performing biobanking; c) assessment of the impact of deviations, and development and implementation of appropriate actions (see 7.11 on nonconforming outputs and 8.7 on corrective action); d) reporting to biobank management on the performance of the quality management system and any need for improvement
7.2.3.3	Qualified and authorized personnel, and/or recipient(s)/user(s) as applicable, shall collect the biological material according to defined procedures.
7.4.5	Only competent personnel shall prepare biological material for shipment.
8.2.6	All personnel involved in biobanking activities shall have access to the parts of the quality management system documentation and related information that are applicable to their responsibilities.

THANK YOU FOR YOUR ATTENTION

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