Accreditation of Biobanks to ISO 20387:2018

Section 6 – Resource Requirements

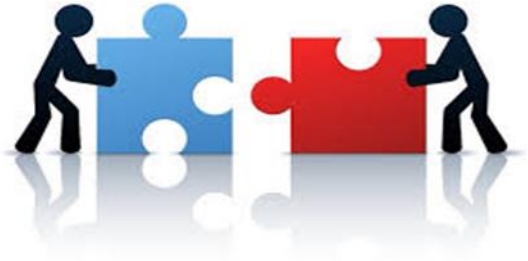
Section 7 – Process Requirements

ISO 20387:2018

- Section 6. Resource Requirements – "*What one needs to have*"
- General requirements – **6.1.2 – Financial Viability**

- Personnel – competency requirements and assessment, training

- Facilities
- Externally provided processes, products and services
- Equipment



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- Section 6. Resource Requirements – "*What one needs to have*"
- 6.3 Facilities/dedicated areas and environmental conditions
- The requirements for facilities/dedicated areas and the environmental conditions necessary for the performance of biobanking shall be documented
- The biobank or the legal entity of which it is a part shall determine, control and maintain the facilities/dedicated areas to provide the conditions required for conformity with defined quality control (QC) criteria
- …maintain fitness for intended purpose, biosafety, and biosecurity of biological material, associated data, separation of activities as required, management of environmental conditions to prevent loss or contamination
- Future expansion plans should be considered

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- Section 6. Resource Requirements – "*What one needs to have*"
- 6.4.1.1 The biobank shall:
- determine requirements for externally provided critical processes, products and services;
- document and communicate these requirements to the external provider;
- retain relevant information about such communication;
- ensure that the externally provided processes, products and services conform to biobank requirements. Nonconformities shall be communicated to the external provider
- 6.4.1.5 The biobank shall determine the verification, or other activities, necessary to ensure that the externally provided processes, products and services meet the biobank's requirements

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- Section 6. Resource Requirements – "*What one needs to have*"
- 6.5 Equipment
- 6.5.1 The biobank shall be furnished with or have controlled access to all equipment required for performance of biobanking
- Requirements include – establishing, documenting, and implementing control procedures, for safe handling, transport, storage and planned maintenance, instructions of use and operation, equipment records and register, Identification and management of critical equipment and performance, management of defective equipment

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- ILAC P10: 07/2020 ILAC Policy on Metrological Traceability of Measurement Results
- In the 2020 update the references to ISO/IEC 17025:2005 have been deleted and the policy has been made independent of the Accreditation Standard being used (e.g. ISO/IEC 17020, ISO 20387 etc..).

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- ILAC P10: 07/2020 ILAC Policy on Metrological Traceability of Measurement Results

Describes the ILAC policy with regard to the metrological traceability requirements in testing and calibration. This policy also applies to other conformity assessment activities where measurement is involved – i.e. medical laboratories; inspection bodies; **biobanks**; reference material producers and proficiency testing providers.

- Equipment Calibration by Accredited Calibration Lab, or NMI or Lab with suitable calibration processes (assessed via ISO 17025 for traceability etc.)
- Certified Reference Materials – produced by NMIs or an accredited

CRM producer or certified values assigned to CRMs are covered by entries in the Joint Committee for Traceability in Laboratory Medicine (JCTLM) database

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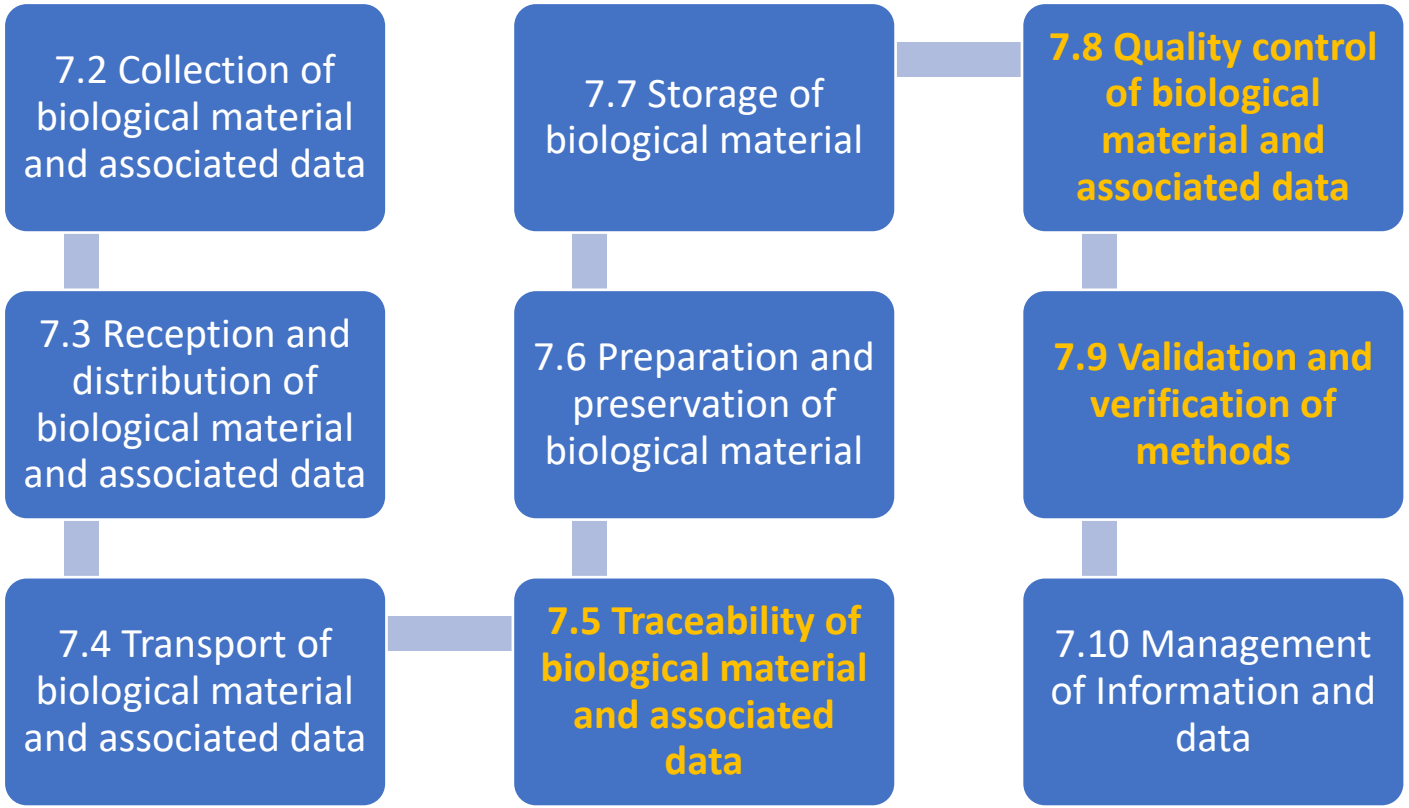
- Section 7 Process requirements – “*what one needs to do*”



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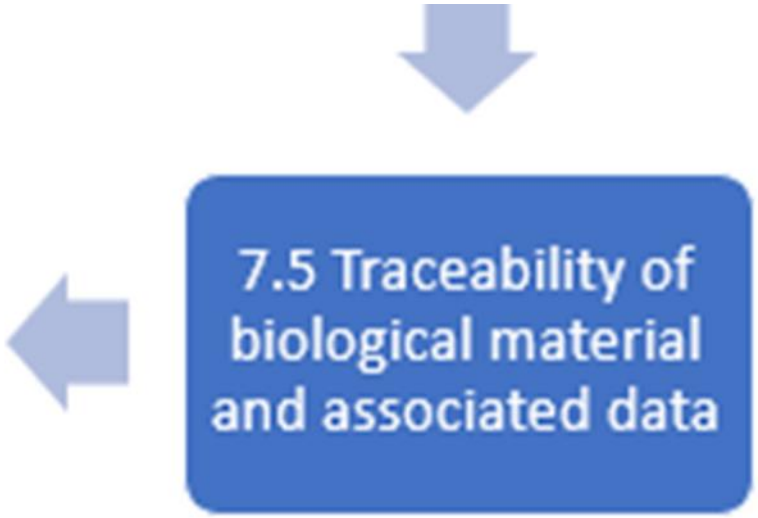
Section 7. Process Requirements - "*What one needs to do*"



- MUST ensure traceability of biological material and associated data from collection (where relevant), acquisition or reception to distribution, disposal or destruction
- Identification of the material MUST be maintained throughout its life-cycle under custody of the biobank
- Special attention to tagging and there MUST be a procedure that also complies with any storage conditions

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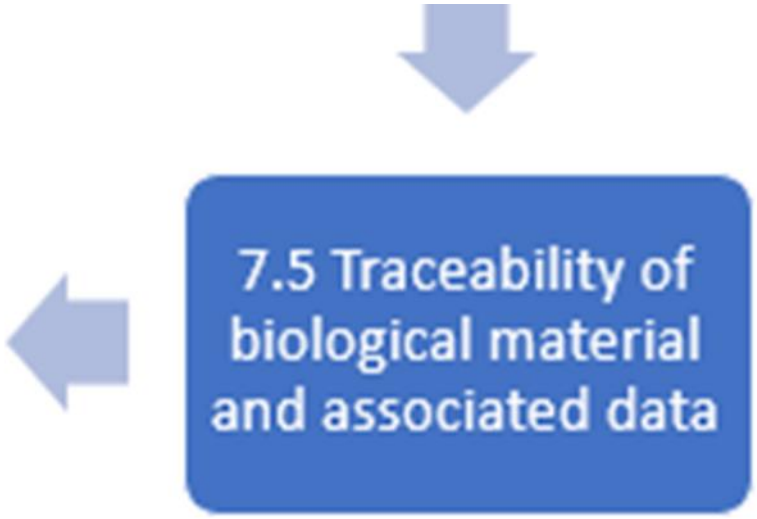
- Section 7. Process Requirements - “What one needs to do”



- **MUST** link material and data to consent/ permissions/ restrictions for use
- Tracking system **MUST** allow for annotation and queries
- Can deviations to procedure be flagged in the tracking/inventory system?
- Link between material and data **MUST** be established and maintained
- **MUST** be able to locate, at all times, including being able to identify material & data already distributed to a recipient/user or disposed

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Section 7. Process Requirements - "*What one needs to do*"

Put simply – How does the Biobank know -

- What material and data do they have?
- What consent is in place for its use including any restrictions?
- Which data is linked to which material?
- Where is the material and data is at any point in its lifecycle?
- And…
- How should they handle this material and data?
- How do they manage the material and data routinely and if a "never event" occurs?

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- Section 7. Process Requirements – "*What one needs to do*"

- **MUST** identify CRITICAL ACTIVITIES having an impact on the quality of the biological material and associated data
- **MUST** establish, document and implement quality control (QC) procedures related to CRITICAL ACTIVITIES

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- Section 7. Process Requirements – "*What one needs to do*"

What might impact on the fitness for purpose of the material and/or data the Biobank are managing?
How are these controlled?
Have they considered the stages of the lifecycle of the material and data.
If a QC procedure might corrupt or eliminate material or data what other mechanisms or mitigating actions could the Biobanks use at different stages to provide assurance?

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- Section 7. Process Requirements – "*What one needs to do*"

- Once the Biobanks has determined what they need to control, they need to determine WHEN they need to control and document it
- What are the acceptance criteria?
- What do the Biobank do if these are not met?
- How does the Biobanks communicate with the end user? (RECORDS)
- What material and/data does the Biobanks use to conduct quality control?
- When does the Biobank review its quality characteristics?

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- Section 7. Process Requirements – "*What one needs to do*"

- How does the Biobank demonstrate comparability of biological material quality?
- EQA
- ILC
- PT
- Internal programs e.g. repeat testing, known outputs, control materials regularly tested in EQA programs

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Any Questions?

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Section 7 – Process Requirements - continued

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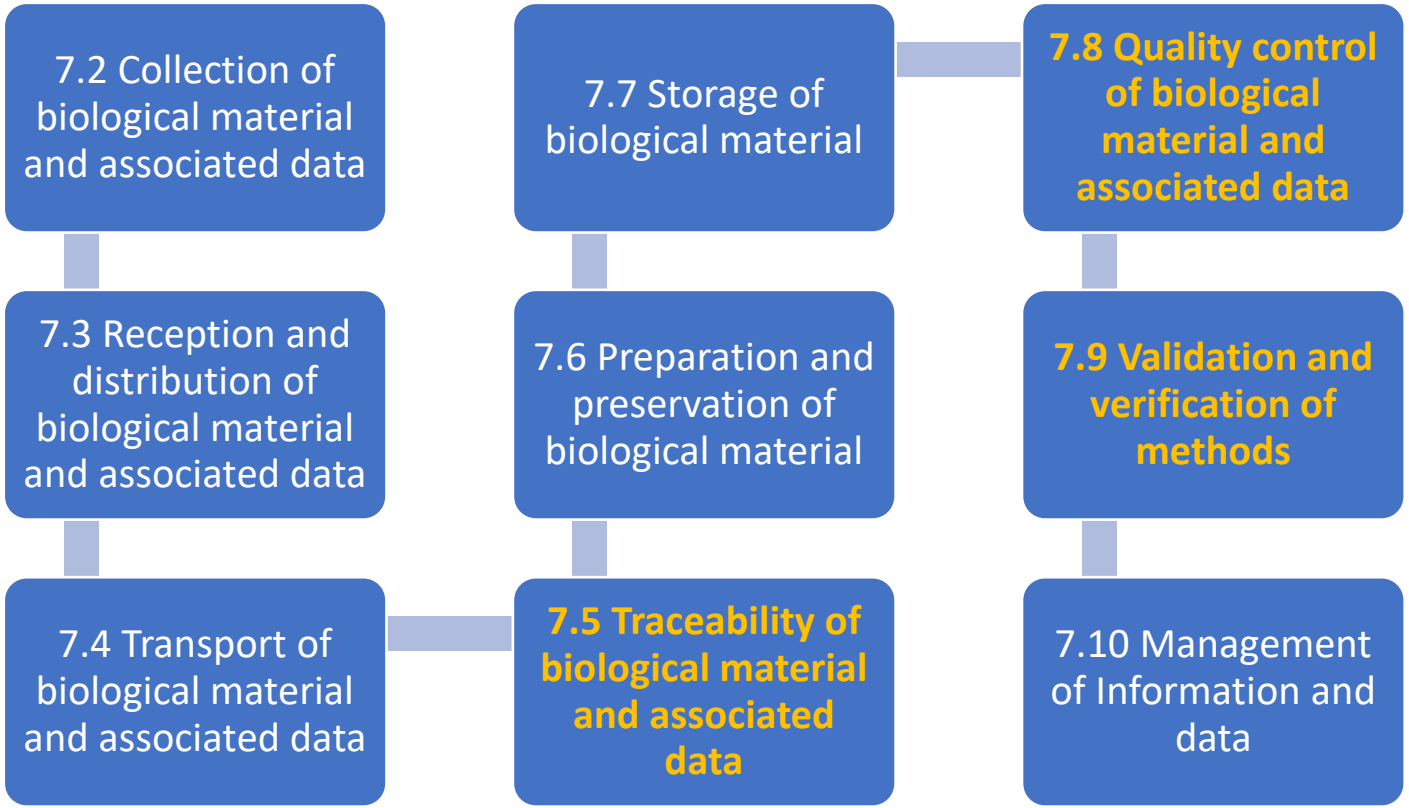
- Section 7 Process requirements – “*what one needs to do*”



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- Section 7. Process Requirements – "*What one needs to do*"

- Validation is –
- confirmation, through the provision of objective evidence, that the requirements for a specific intended use or application have been fulfilled

- 7.9.1.1 The Biobank SHALL use validated and/or verified methods for critical activities at ALL stages of the biological materials life cycle.

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- Section 7. Process Requirements – "*What one needs to do*"

- What methods do you use for critical activities?
- Validation can be achieved through a variety of means, including tests, peer-reviewed research, simulations, etc.. to provide the required evidence for the achievement of the fitness for an intended purpose.
- The biobank must retain a record including a statement regarding the fitness for purpose of the method.

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- Section 7. Process Requirements – "*What one needs to do*"

- Verification

confirmation, through the provision of objective evidence, that specified requirements have been fulfilled

Biobanks can do it with their own staff, their equipment and in their environment and achieve the same outcome as the method validators!

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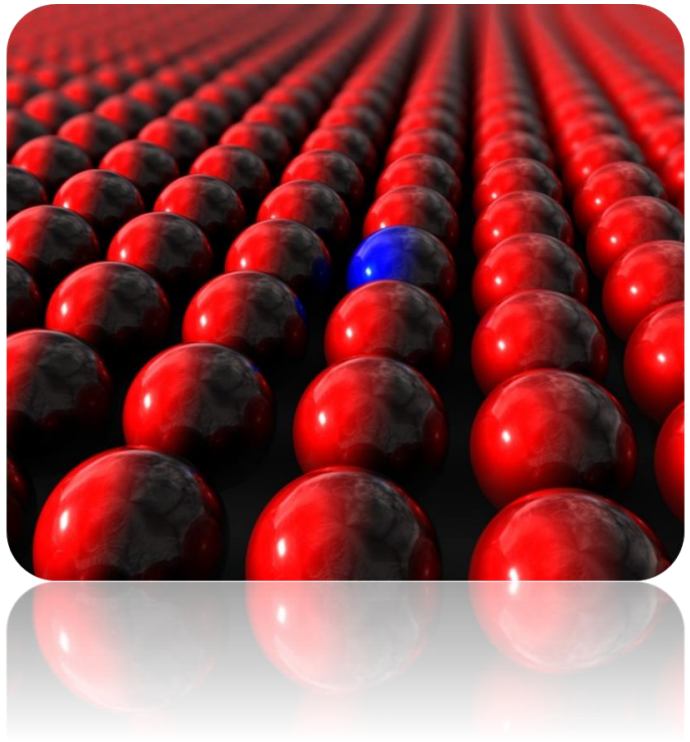
- Section 7. Process Requirements – "*What one needs to do*"



- 7.11 Nonconforming output – **whether material OR data**
- Procedure(s) in place for management of the output that does not conform to the predefined requirements of the Biobank and or the agreement with the recipient/customer
- Ensuring that unintended use or supply is prevented
- Procedures in place to ensure that should this occur that information is disclosed to relevant parties to enable the recipient to determine f the material/data is fit for intended use

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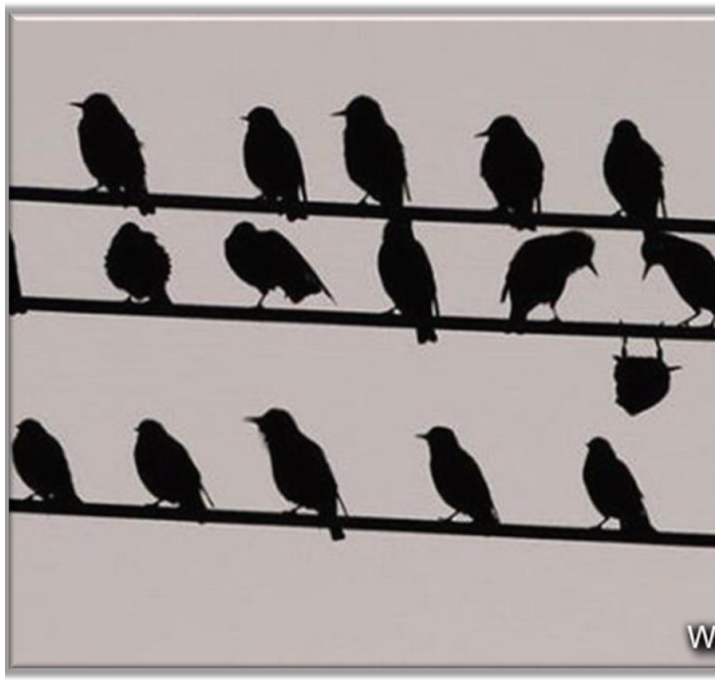
- Section 7. Process Requirements – "*What one needs to do*"



- 7.11 Nonconforming output

- Appropriate Corrective Action (8.7) shall be taken
- Procedure shall address:
- Who is responsible for managing the nonconforming output
- Evaluation of the significance of the NW output – including effect on further use of that output
- Decision on acceptability, segregation, containment, return suspension etc.. of the material/data
- Persistence of that NC output where remedy is not possible, impractical or could have a result on third party results

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- Section 7. Process Requirements – "*What one needs to do*"

- 7.12 Report Requirements

- The Biobank SHALL provide a report
- Content of that report 7.1.12.2.1 a-l.
- Similar as for other standards - title, name and address of the biobanks, date of issue, unique ID, biological material ID, relevant quality info of material and associated data, methods used, testing results (as relevant) methods used for collection/acquisition, preparation and/or preservation, storage as well as the name of person authorizing the report

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- Section 7. Process Requirements – "*What one needs to do*"

- 7.12 Report Requirements
- The biobank is responsible for **all** of the information provided in the report, except hen the information as provided by the provider/recipient,/user.
- Where the Biobank has not been responsible for collection or sampling, the report SHALL state that it relates to the biological material as received by the biobank.

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- Section 7. Process Requirements – "*What one needs to do*"
  - 7.13 Complaints……
  - Standard requirements
  - As found in ISO/IEC 17025, 17034, & ISO 15189…

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Associated documents:

ISO 21899:2020. Biotechnology — Biobanking —
General requirements for the validation and verification of processing methods for biological material in biobanks

ISO/TR 22758:2020 Biotechnology — Biobanking — Implementation guide for ISO 20387

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Any Questions?