ISO 20387: 2018 Checklist

Name of Biobank : .....

ISO 20387: 2018 Requirements	For Biobank		For Assessor
	Y, N, N/A	Objective evidence	Comments on compliance and refer to findings
4 General requirements 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.			
4.1.2 When possible, the biobank should be aware of the minimal requirements for biological material and/or associated data destined for downstream application(s) to ensure that biological material and associated data are handled in a way to enable reproducible research.			
4.1.3 The biobank's mission should be defined and available			
4.1.4 Information relevant to biobank activities, processes and procedures shall be documented in a comprehensible format.			
4.1.5 The documentation shall include relevant information generated from procedures pertaining to the quality management system (see Clause 8) as well as the management of facilities/dedicated areas.			
4.1.6 The biobank shall comply with relevant regional, national and international ethical principles for biological material and associated data. NOTE For more information and for guidance on social responsibility, see ISO 26000.			
4.1.7 The biobank should document the identity of personnel performing activities encompassing procedures as referred to in 4.1.1.			
4.1.8 The biobank should define the time period for retention of documented information and associated data relating to each biological material, after the complete distribution, disposal or destruction of that biological material.			
4.2 Impartiality 4.2.1 Biobanking shall be structured and managed so as to safeguard impartiality			

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4.2.2 The biobank management shall be committed to impartiality. NOTE For more information and for guidance on social responsibility, see ISO 26000.			
4.2.3 The biobank shall be responsible for the impartiality of its biobanking and shall not allow internal and/or external pressure(s) to compromise impartiality.			
4.2.4 The biobank shall identify risks to its impartiality on an on-going basis. NOTE A relationship that threatens the impartiality of the biobank can be based on ownership, governance, management, personnel, shared materials and associated data, finances, contracts, marketing (including branding), payment of a sales commission or other inducement for the referral of new users, etc.			
4.2.5 If a risk to impartiality is identified, the biobank shall demonstrate how it eliminates or minimizes such risk.			
4.3 Confidentiality 4.3.1 The biobank shall protect the confidential information and proprietary rights of providers/donors, recipients and users, particularly during storage and transmission of data.			
4.3.2 The biobank shall be responsible, through legally enforceable commitments, for the management of confidential information obtained or created during the performance of biobanking. When sharing data or biological material and associated data, the biobank shall inform the provider/donor, where possible, of how their privacy and confidentiality are protected. The biobank shall only release information regarding biological material and associated data according to relevant agreements and approvals (e.g. contractual agreements, legally binding documents, ethical approvals).			
4.3.3 When the biobank is required by law to release confidential information, the provider/donor shall be notified of the information provided, unless prohibited by law.			
4.3.4 All personnel having access to confidential data of the biobank shall be bound to confidentiality (see 6.2.1.2).			
5 Structural requirements 5.1 The biobank shall be a legal entity, or a defined part of a legal entity, that is legally responsible for all its activities. NOTE For the purpose of this document a governmental biobank is deemed to be or have equivalence of a legal entity on the basis of its governmental status.			
5.2 The biobank shall identify top management that has overall responsibility for the biobank.			
5.3 The biobank shall have a governance body/advisory board guiding and advising management on scientific, technical			

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and/or administrative and other matters.			
5.4 The biobank shall be responsible for activities performed in its facilities/dedicated areas.			
5.5 The biobank shall have a course of action to define and address liabilities arising from its activities.			
5.6 The biobank shall carry out its activities in such a way as to meet the requirements of this document, its documented agreements and/or legally binding documents, relevant authorities and organizations providing recognition.			
5.7 The biobank shall define and document the range of activities for which it conforms with this document. The biobank shall only claim conformity with this document for its defined range of activities, excluding externally provided biobank activities.			
5.8 The biobank shall: a) define the governance structure, including the organization and management of the biobank, its place in any parent organization, and the relationships between management, technical operations and support services; b) 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.			
5.10 The biobank management shall ensure that: a) changes to the quality management system are monitored and controlled; b) communication takes place with interested parties, including personnel, regarding the performance indicators of the quality management system and any need for improvement; c) the importance of meeting the requirements of recipient(s)/user(s), and other applicable requirements (including			

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those described in this document) is communicated to and understood by relevant biobank personnel.			
6 Resource requirements 6.1 General 6.1.1 The biobank shall have available personnel, facilities/dedicated areas, equipment, information system(s) and support services necessary to perform biobanking. NOTE Information system(s) can be electronic or paper based.			
6.1.2 The biobank shall have a documented strategy to enable continued financial viability for its activities. This strategy shall be reviewed periodically.			
6.2 Personnel 6.2.1 General 6.2.1.1 All personnel of the biobank, either internal or external, who can impact biobank activities, shall act impartially (see 4.2).			
6.2.1.2 All personnel having access to the biobank's confidential data shall be bound to confidentiality in respect to that data (see 4.3.4).			
6.2.1.3 The biobank shall have documented procedures for personnel management and maintain documented information to indicate compliance with relevant requirements.			
6.2.1.4 The biobank shall communicate to all personnel their duties, responsibilities and authorities as detailed in job descriptions.			
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.			
6.2.2 Competence and competence assessment 6.2.2.1 The biobank shall define and document the competence required for personnel involved in biobank activities.			
6.2.2.2 The biobank shall ensure that all its personnel are competent on the basis of appropriate education, training, demonstrated skills and/or experience necessary to perform assigned duties and activities.			
6.2.2.3 The biobank or the legal entity of which it is a part shall maintain documented information for personnel that			

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provide evidence of all appropriate professional competence and education/training (see 6.2.3).			
6.2.2.4 Personnel appointed to perform processes shall be subject to competence assessment according to the biobank's established criteria.			
6.2.2.5 Personnel shall receive appropriate and relevant assessment at regular intervals to determine what is required to acquire and retain their necessary competence.			
6.2.3 Training 6.2.3.1 Each personnel shall receive appropriate and relevant re-/training (internal and/or external training) with regular updates to acquire and retain the necessary competence. The training shall be documented.			
6.2.3.2 Personnel undergoing training shall be supervised until the biobank confirms the personnel as competent to perform assigned tasks.			
6.2.3.3 An introduction policy for the integration of new personnel shall be implemented. New personnel shall be provided with appropriate orientation to the biobank.			
6.3 Facilities/dedicated areas and environmental conditions 6.3.1 The requirements for facilities/dedicated areas and the environmental conditions necessary for the performance of biobanking shall be documented.			
6.3.2 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. This includes procedures to maintain fitness for intended purpose, biosafety, and biosecurity of biological material and associated data.			
6.3.3 Where necessary, there shall be effective separation between areas that host incompatible activities. Measures shall be taken to avoid cross contamination.			
6.3.4 The facilities/dedicated areas and their environmental conditions shall be suitable for biobanking and should not adversely affect the fitness for the intended purpose. NOTE Influences that can adversely affect the fitness for the intended purpose can include, but are not limited to, microbial contamination, cross contamination, dust, electromagnetic disturbances, radiation, humidity, electrical supply, temperature, sound and vibration.			
6.3.5 The biobank shall measure, monitor, control and record environmental conditions in the biobanking			

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facilities/dedicated areas, as required or where they influence the quality of the biological material and associated data, and/or the health and safety of personnel.			
6.3.6 The biobank should address future expansion of its capacity to allow further addition, subdivision and/or processing of biological material.			
6.3.7 The biobank shall have a contingency plan to ensure the maintenance of the required environmental conditions in the biobank facilities/dedicated areas according to the risk. EXAMPLE It can be a contingency plan for natural and human-made disasters such as electrical failure, extreme weather conditions, earthquakes, and sabotage.			
6.4 Externally provided processes, products and services NOTE In this subclause, the term “product” encompasses items used in biobank processes except the biological material.			
6.4.1.1 The biobank shall: a) determine requirements for externally provided critical processes, products and services; b) document and communicate these requirements to the external provider; c) retain relevant information about such communication; d) ensure that the externally provided processes, products and services conform to biobank requirements. Nonconformities shall be communicated to the external provider.			
6.4.1.2 The biobank shall determine and apply criteria for the evaluation, selection, monitoring and reevaluation of performance of external providers based on their ability to provide processes or products and services in accordance with requirements. The biobank shall retain documented information of these activities and any necessary actions arising from the evaluations.			
6.4.1.3 The biobank shall determine which externally provided processes, or parts of these, shall be communicated to the provider/recipient/user.			
6.4.1.4 The biobank shall ensure that externally provided processes, products and services do not adversely affect the biobank’s ability to consistently preserve and supply authenticated biological material and associated data. The biobank shall determine and assess the risks associated with externally provided processes, products and services. Measures shall be taken to avoid negative effects on the			

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conformity of the preservation and authentication of biological material, when necessary			
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.			
6.4.1.6 When the biobank decides to use externally provided preservation, storing and/or authentication activities, it shall ensure that: a) the process and all the interrelated processes are validated according to the provisions of this document; b) internal audits of these processes are planned by the external provider and performed regularly using a risk-based approach (see also ISO 19011); c) relevant documented information related to these activities is retained.			
6.5 Equipment 6.5.1 The biobank shall be furnished with or have controlled access to all equipment required for performance of biobanking. NOTE The term “equipment” encompasses the items of equipment and associated software when applicable.			
6.5.2 The biobank shall establish, document and implement procedures for controlled implementation, safe handling, transport, storage and planned maintenance of all equipment, including procedures for calibration, where necessary.			
6.5.3 The biobank shall have instructions on the use and operation of all relevant equipment.			
6.5.4 The biobank shall categorize equipment (including backup equipment) with potential to impact on the quality of the biological material and associated data in order to identify equipment which is critical for biobanking (e.g. using a risk-based approach).			
6.5.5 The biobank shall establish and maintain a register listing equipment defined under 6.5.1 and 6.5.2 including information for categorization, performance, maintenance, verification and, if applicable, validation of each item.			
6.5.6 The biobank shall verify, upon installation and before use, that equipment is capable of achieving the necessary performance and complies with relevant requirements.			
6.5.7 Critical equipment shall be capable of achieving the accuracy required and support compliance with specifications relevant to the processing methods or test methods concerned.			
6.5.8 The biobank shall retain documented information for critical equipment, which shall include at least the			

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following: a) equipment and software identity; b) the manufacturer's name, type identification, and serial number or other unique identification; c) checks that equipment complies with specifications; d) the current location, where appropriate; e) the manufacturer's instructions, if available, or reference to their location; f) results, reports, and certificates of calibrations, adjustments, acceptance criteria, and associated date(s) [documented in a standard format preferably according to ISO 8601 (see Note to 7.1.3)]; g) the due date of next calibration [documented in a standard format preferably according to ISO 8601 (see Note to 7.1.3)]; h) the maintenance plan, where appropriate, and maintenance carried out to date; i) any damage, malfunction, modification, or repair to the equipment.			
6.5.9 Critical equipment and its software shall be safeguarded from adjustments which would invalidate the process output.			
6.5.10 Where applicable, the biobank shall establish and maintain metrological traceability of its measurement results by means of a documented unbroken chain of calibrations or comparisons, linking them to an appropriate reference.			
6.5.11 Equipment shall be taken out of service if: a) it is subject to overloading or mishandling; b) it generates potentially compromised process output/results; c) it has been shown to be defective or outside of specification limits. It shall be isolated to prevent use or clearly labelled or marked as being out of service until repaired and shown by calibration or test to perform correctly			
6.5.12 The biobank shall examine the effect of any defect or departure from specifications using appropriate measures in accordance with 7.11.			
7 Process requirements 7.1 General 7.1.1 The life cycle stages of the biological material and associated data in the biobank shall be identified, and			

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appropriate processes shall be defined and verified. A workflow shall describe these stages followed by detailed procedures (see 4.1.1) for each relevant process (e.g. collection, accession, acquisition, identification, preservation, long-term storage, quality control, transport, disposal). All procedures shall be documented, implemented and specific to the biological material and associated data. All critical activities within each procedure shall be identified and documented (see also 7.8.2.7).			
7.1.2 All procedures and processes shall be kept up to date and shall be made readily available to personnel.			
7.1.3 The date of critical life cycle stages shall be documented in a standard format for all biological materials. The time of critical life cycle stages (e.g. preparation start time or duration, freezing time) should be documented in a standard format. The date and time documentation should be formatted according to ISO 8601. NOTE The date can be expressed as YYYY-MM-DD (e.g. 2018-04-25) and time can be expressed as hh:mm:ss (e.g. 04:26:55).			
7.2 Collection of biological material and associated data 7.2.1 Documented information requirements 7.2.1.1 When the biobank is responsible for collection of biological material, it shall define and document information related to the collection of the biological material. This shall include the date, place and procedure of collection, and any other information relevant to accomplish the objectives of the biobank (e.g. taxonomic information). This should also include the time of the collection of the biological material. The date and time documentation should be formatted according to ISO 8601 (see Note to 7.1.3).			
7.2.1.2 When the biobank acquires biological material (i.e. the biobank is not responsible for collection), it should define required/recommended information and retain appropriate documented information related to the collection procedure.			
7.2.2 Pre-acquisition information 7.2.2.1 Whenever possible, the biobank shall document and/or retain information related to stages prior to the reception of the biological material that can affect the properties of the biological material to allow the assessment of its fitness for the intended purpose. Further details and requirements are included in Annex A. Annex B gives additional information.			
7.2.3 Collection procedure			

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7.2.3.1 The collection procedure shall be defined either by the biobank and/or the recipient/user, according to the intended use of the biological material, proven techniques, or relevant standards.			
7.2.3.2 Where relevant and available, pre-analytical workflows according to existing ISO documents should be implemented (e.g. ISO 20166-1, ISO 20166-2 and ISO 20166-3, ISO 20184-1 and ISO 20184-2, ISO 20186-1, ISO 20186-2 and ISO 20186-3, ISO/TS 20658).			
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. When biological material requiring clinical assessment and/or diagnosis is also deemed suitable for biobanking, the preparation, dissection (where appropriate), evaluation of the gross pathology and collection, shall be performed by competent personnel (e.g. specifically trained, experienced, board certified or qualified personnel). The collection of biological material and/or data for research shall never adversely affect patient care and diagnosis, or donor wellbeing.			
7.2.3.4 The collection of human biological material shall be performed in accordance with relevant ethical requirements (e.g. relevant ethical approvals or waiver of consent of the patient/donor, etc.).			
7.3 Reception and distribution of biological material and associated data 7.3.1 Access principles 7.3.1.1 The principles governing access to and distribution of biological material and associated data shall be defined, documented and, where relevant, published. The biobank shall ensure that documented requirements established with interested parties comply with these principles.			
7.3.2 Reception 7.3.2.1 The biobank shall establish, document and implement procedures for receiving or acquiring biological material and associated data (e.g. internal transfers or external shipments/transfers). NOTE Such procedures are sometimes referred to as accession/logging procedures.			
7.3.2.2 The biobank shall define the acceptance criteria of biological material and associated data, including biosafety, biosecurity and intellectual property rights. The identification of the biological material and associated data shall be verified upon acquisition/reception according to the defined acceptance criteria.			
7.3.2.3 When appropriate and applicable, (e.g. for cell lines and microorganisms), the biobank shall authenticate the biological material according to relevant and available International Standards or guidelines.			

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7.3.2.4 Biological material and associated data received or acquired by a biobank, whether individual, part of or an entire collection, shall be segregated (see 7.7.5) to prevent final storage until legal, ethical, documentation, and quality compliance of the biological material and associated data has been assessed and managed.			
7.3.2.5 The biobank should obtain relevant documented information, in particular, information needed to assess the fitness for the intended purpose associated with the received or acquired biological material.			
7.3.2.6 Where the biobank has not been responsible for collection or sampling, this shall be documented.			
7.3.3 Distribution 7.3.3.1 The distribution and any exchange of biological material and associated data shall take place in accordance with the biobank's access principles (see 7.3.1.1), reporting specifications (see 7.12) and in compliance with other relevant requirements [e.g. material transfer agreement (MTA), data transfer agreement (DTA)].			
7.3.3.2 When providing biological material and associated data to a recipient/user outside the biobank, the biobank shall ensure that a documented agreement or legally binding document (e.g. contract, written and signed commitment, binding online acceptance of terms and conditions) outlining the conditions governing the provision and use of biological material and/or associated data are used. Any changes to such a document shall be documented.			
7.3.3.3 The biobank shall establish, document and implement procedures for the preparation and distribution of biological material and/or associated data fulfilling the conditions of the documented agreement or legally binding document according to 7.3.3.2.			
7.3.3.4 When distributing biological material and/or associated data to a recipient/user, predefined information according to 7.12 shall also be provided, unless the biobank has valid reasons for not doing so, such as data protection compliance.			
7.4 Transport of biological material and associated data 7.4.1 The biobank shall establish, document and implement procedures for shipping and receiving biological material, including appropriate conditions for the continued maintenance of biological material integrity in accordance with Annex A. Examples are given in Annex B.			
7.4.2 The biobank shall maintain critical chain of custody records for all biological material from point of dispatch to point of receipt. Whenever shipping can alter the quality of the biological material (or if deemed necessary), it shall be tracked and monitored for those elements pertinent to biological material integrity, e.g. timelines/duration(s),			

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temperature, humidity and light as appropriate to the biological material. The chain of custody records shall detail any deviations from specified parameters according to 7.11.			
7.4.3 The biobank shall have procedures for safe handling, packaging, transport and reception relevant to the biological material concerned.			
7.4.4 Within the biobank or legal entity of which it is a part, biological material should not be left unattended, unless in designated custody zones as indicated by relevant procedures.			
7.4.5 Only competent personnel shall prepare biological material for shipment.			
7.4.6 Prior to the transfer of biological material, the requirements of 7.3.3.2 shall be fulfilled and arrangements shall be made for biological material distribution and reception with relevant parties.			
7.4.7 The biobank shall establish, document and implement procedures for shipping and receiving data. The transfer of data shall be designed to ensure integrity and prevent breach of data privacy. Prior to the transfer of data, arrangements shall be made for data reception and/or distribution with relevant parties.			
7.5 Traceability of biological material and associated data 7.5.1 The biobank shall ensure traceability of biological material and associated data from collection (where relevant), acquisition or reception to distribution, disposal or destruction, as follows: a) Biological material shall be appropriately tagged so that identification is maintained throughout the life cycle under the custody of the biobank. Special attention shall be focused on persistent tagging [e.g. use of externally applied or integrated options including printed labels, barcodes, two dimension (2D) codes, radio frequency identification systems (RFID), micro electro mechanical systems (MEMS)] of biological material through the use of unique identifiers. The biobank shall have a documented tagging procedure that is also compliant with environmental requirements including relevant storage conditions. b) Each biological material and associated data shall be linked to the documented information with detail of permissions or restrictions associated for its use. c) An inventory or tracking system shall allow for the annotation and query of relevant information associated with any handling procedure, including collection, packaging, transportation, preparation, preservation, storing, and distribution procedures. This system should allow any deviation in biobanking procedure(s) to be flagged. d) A link between biological material and associated data shall be established and maintained for unambiguous			

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traceability. e) It shall be possible to identify the location of any biological material and associated data at all times. f) It shall be possible to identify biological material and associated data already distributed to a recipient/user or already disposed of.			
7.5.2 The information should be accessible by personnel to allow querying the data as needed, e.g. upon receiving complaints or inquiries regarding distributed biological material.			
7.5.3 The biobank shall establish, document and implement procedures for the disposal and transfer of biological material and/or data, both as a planned event and as a result of an emergency (see 7.1.1).			
7.6 Preparation and preservation of biological material 7.6.1 The method(s) of preparation and/or preservation shall be defined according to an evidencebased documented processing method (e.g. an International Standard) or as specified in agreement with the provider/recipient/user.			
7.6.2 Critical activities of the preparation and/or preservation procedure (see A.4) shall be monitored and the relevant parameters documented. Each preservation step shall be individually documented.			
7.6.3 The date of each preparation and/or preservation step shall be documented in a standard format for all biological material. The time of each related step should be documented in a standard format. The date and time documentation should be formatted according to ISO 8601 (see Note to 7.1.3).			
7.7 Storage of biological material 7.7.1 The biobank or the legal entity of which it is a part should establish a disaster protection plan with use of alternative methods of safeguarding to avoid loss of biological material.			
7.7.2 The biobank shall have documented procedures in place for the storage and tracking of biological material including at least: a) the tagging information containing at least the unique identifier of the biological material; b) the type of container and environmental conditions for the biological material storage; c) mechanism(s) for traceability (see 7.5); d) a short-term back-up plan for maintaining accurate storage conditions/temperatures in the case of emergency challenges in maintaining defined storage conditions.			
7.7.3 During the execution of critical activities performed during storage, relevant processing parameters shall be			

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measured, monitored and documented. The date (see Note to 7.1.3) and, where necessary, the time(s) of critical activities during storage, and personnel (see 4.1.7) accessing the biological material shall be documented for each biological material. The documentation of the date and time should be formatted according to ISO 8601 (see Note to 7.1.3).			
7.7.4 The biobank shall document and verify the storage location of all biological material and associated data. Traceability of each biological material and each storage transaction shall be ensured at all times.			
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.			
7.7.6 The storage conditions shall comply with 6.3			
7.7.7 The biobank should verify the biological material inventory at planned intervals by a defined procedure.			
7.7.8 When applicable, the biobank shall establish, document and implement procedures supporting the patient/ donor right to withdraw consent for storage and use of biological material and associated data.			
7.8 Quality control of biological material and associated data 7.8.1 General 7.8.1.1 Critical activities having an impact on the quality of the biological material and associated data shall be identified by the biobank, provider, recipient or user. The biobank shall establish, document and implement quality control (QC) procedures related to such activities.			
7.8.1.2 The biobank shall provide biological material and associated data fit for purpose. The biobank shall define a minimum set of QC procedures to be performed on the biological material and associated data or a subset of it. Exceptions can be justified for rare or legacy biological material and associated data and QC procedures which lead to biological material elimination. NOTE “Legacy biological material and associated data” refers to the biological material and associated data acquired or received by the biobank before the biobank has implemented this document.			
7.8.1.3 The QC procedures shall: a) be defined according to proven techniques and fitness for the intended purpose; b) be regularly updated; c) ensure that provider/recipient/user requirements are met where possible.			

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7.8.2 Quality control of processes 7.8.2.1 The biobank shall establish, document and implement procedures specifying QC activities throughout the biobanking processes, including QC criteria corresponding to predefined specifications, to demonstrate fitness for the intended purpose of the biological material and associated data.			
7.8.2.2 The QC activities shall be performed according to planned intervals. The biobank shall retain documented information of QC activities and results.			
7.8.2.3 QC data shall be analysed. If predefined criteria are not met, actions shall be taken to control reporting of invalid data and/or distribution of non-compliant biological material and associated data.			
7.8.2.4 The biobank shall ensure that identified limitations are clearly documented and communicated to the recipient/user. During the biological material and associated data distribution process, it is the responsibility of the recipient/user to decide on the acceptance of receiving biological material and associated data with documented and communicated limitations.			
7.8.2.5 The biobank shall ensure that information of QC results is provided to the recipient/users as specified by documented requirements.			
7.8.2.6 QC results shall be periodically analysed for trends and used as input for the continuous improvement process.			
7.8.2.7 The biobank shall document all process-related data in accordance with Annex A			
7.8.2.8 As part of the QC system, the biobank should have appropriate QC materials (e.g. internal control material). QC materials employed by the biobank shall be periodically examined to assess important quality characteristics of the biological material, including stability, the performance of the processing methods and the accuracy/precision of the QC procedures.			
7.8.2.9 The biobank shall use approaches to provide objective evidence to demonstrate the comparability of biological material quality (the processing or testing output), where such approaches are available and appropriate. Such approaches include external quality assessment (EQA) programs, proficiency testing programs, interlaboratory comparisons or the biobank may develop its own approaches, including the use of: a) certified reference materials, where available, produced by a reference material producer fulfilling the requirements of ISO 17034; b) samples previously examined;			

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c) samples previously shared with other biobanks; d) control materials that are tested regularly in EQA programs.			
7.8.2.10 If the biobank participates in (an) interlaboratory comparison program(s), the biobank shall monitor relevant results of the interlaboratory comparison program(s), and perform and document corrective actions when predetermined performance criteria are not fulfilled.			
7.8.3 Quality control of data 7.8.3.1 The biobank shall identify the critical data, and establish, document and implement QC procedures applying at least to these critical data.			
7.8.3.2 The biobank shall define the type and frequency of the QC performed. QC shall focus on accuracy, completeness and consistency of data.			
7.9 Validation and verification of methods 7.9.1 General 7.9.1.1 The biobank shall use validated and/or verified methods for critical activities according to 7.9.2 and 7.9.3 at all stages of the biological material life cycle.			
7.9.2 Validation 7.9.2.1 When the biobank provides/applies methods for critical activities the biobank shall ensure that these methods have been validated, in order to ensure fitness for the intended purpose. When the validation is performed by the biobank, it shall document and retain for a defined period of time the results obtained, the procedure used for the validation, and a statement as to whether the method is fit for purpose.			
7.9.2.2 The validation shall be as extensive as is necessary and confirm, through the provision of objective evidence (in the form of performance characteristics), that the specific requirements for the intended use have been fulfilled.			
7.9.2.3 When changes are made to a validated method, the impact of such changes shall be documented and, when appropriate, a new validation shall be carried out.			
7.9.3 Verification 7.9.3.1 Validated methods used without modification shall be subject to verification by the biobank before being used.			
7.9.3.2 The verification by the biobank shall confirm, through obtaining objective evidence (in the form of performance characteristics) that the set criteria for the method have been met.			

ISO 20387: 2018 Requirements	For Biobank		For Assessor
	Y, N, N/A	Objective evidence	Comments on compliance and refer to findings
7.9.3.3 The biobank shall document the procedure used for the verification and the results obtained			
7.10 Management of information and data 7.10.1 The biobank shall define the required information and data related to biological material and shall have a system in place for tracking. The biobank shall make reasonable efforts to support interoperability of such information and data.			
7.10.2 The biobank shall address future expansion of its capacity to allow further addition and/or processing of data associated with biological material.			
7.10.3 A procedure for implementation, modification and use of computer system software, hardware, and database(s) shall be in place, when used for biobanking. The procedure shall at least include data integrity, security controls and backup system to prevent loss or corruption of data.			
7.10.4 The biobank shall have access to the data and information needed to provide a service specified by contractual agreements.			
7.10.5 The biobank should provide interested parties with access to a catalogue of available biological material and associated data.			
7.10.6 The biobank shall retain access to the appropriate data associated with the biological material, as necessary for research purposes and/or in compliance with applicable requirements and 7.3.3.2.			
7.11 Nonconforming output 7.11.1 General 7.11.1.1 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 (see also 7.3.3.2) and/or the agreement with the provider.			
7.11.1.2 The biobank shall ensure that output that does not conform to predefined requirements is identified and controlled to prevent unintended use or supply			
7.11.1.3 The biobank shall implement appropriate procedures to disclose information about nonconforming output to relevant parties and, where appropriate, to enable the recipient/user to determine the fitness for the intended purpose.			
7.11.1.4 The biobank shall take appropriate corrective action (see 8.7) based on the nature of the nonconforming			

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output and its effect on the fitness for the intended purpose or use of the output. This shall also apply to nonconforming output detected after supply of the biological material and associated data.			
7.11.1.5 The procedures for nonconforming output shall address: a) responsibilities and authorities for the management of nonconforming output; b) evaluation of the significance of nonconforming output, including the effect on further use of the output; c) decision on the acceptability, segregation, containment, return, suspension of provision or recall of nonconforming output; d) persistence of nonconforming output, when 1) remedy of the nonconformity is impossible; 2) remedy of the nonconformity is considered impractical; or 3) the output can have an impact on the results produced by third parties; e) communication of nonconforming output and the authorization for acceptance by the recipient/user.			
7.11.1.6 The procedures for nonconforming output shall also apply to biological material and associated data collected or acquired prior to the first adoption of this document.			
7.11.2 Control of nonconforming output 7.11.2.1 The biobank shall mitigate the impacts of nonconformity, implement corrective actions in proportion to the risk(s) presented by nonconforming output, and prevent recurrence. Remedial actions appropriate to the effects shall be taken within defined limits and shall be controlled when nonconforming output is corrected (see also 8.7).			
7.11.2.2 The requirements of 8.7.3 apply.			
7.11.2.3 Decision(s) on recall shall be taken in a timely manner to limit the use of nonconforming output.			
7.12 Report requirements 7.12.1 General 7.12.1.1 The biobank shall provide a report at least as specified in 7.12.2. This shall include the required information as agreed upon in the documented agreement or other legally binding document with the recipient/user (see 7.3.3.2). NOTE Reports are sometimes called certificates.			
7.12.1.2 A report according to 7.12.2 may be issued as hard copy or by electronic data transfer or by an electronic data			

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	Y, N, N/A	Objective evidence	Comments on compliance and refer to findings
entry in an accessible database.			
7.12.1.3 The biobank should include a statement specifying that the report shall not be reproduced except in full.			

7.12.2 Content of the report
7.12.2.1 Each report shall include at least the following, unless the biobank has documented valid reasons for not doing so:
a) a title (e.g. “Quality report” or “Material certificate”);
b) the name and address of the biobank, and the location where activities referred to in the report were carried out, if different from the address of the biobank;
c) the date of issue of the report in a standard format according to ISO 8601 (see Note to 7.1.3);
d) unique identification of the report (such as a serial number), with an identification on each page to ensure that the page is recognized as a part of the report, and a clear identification of the end of the report;
e) biological material identification or specific properties;
f) relevant quality information of the biological material and associated data;
g) method(s) used for identification or characterization of the biological material;
h) testing results with, where appropriate, the units of measurement;
i) method(s) used for testing;
j) method(s) used for collection/acquisition, preparation and/or preservation, as applicable;
k) storage conditions;
l) the name(s), function(s) of person(s) authorizing the report.			

7.12.2.2 The biobank shall be responsible for all the information provided in the report, except when information is 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.			
7.13 Complaints 7.13.1 The biobank shall establish, document and implement procedures to receive, evaluate and make decisions on complaints.			
7.13.2 A description of the handling process for complaints shall be made available upon request. Upon receipt of a complaint, the biobank shall confirm whether the submitted complaint relates to activities for which it is responsible			

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and, if so, shall address it. The biobank shall be responsible for all levels of complaint handling.			
7.13.3 The process for handling complaints shall include at least the following elements and methods: a) description of the process for receiving, accepting, investigating the complaint, and deciding what actions are to be taken in response to it; b) tracking and recording complaints, including actions undertaken to resolve them; c) ensuring that any appropriate action is taken.			
7.13.4 The biobank receiving the complaint shall be responsible for gathering and verifying all necessary information to accept the complaint. The biobank shall acknowledge receipt of the complaint.			
7.13.5 Whenever possible, the biobank shall provide the complainant with a progress report			
7.13.6 Impartial review shall be performed for each complaint. The outcome of this review shall be communicated to relevant parties.			
7.13.7 Whenever possible, the biobank shall give formal notice of the end of the complaint handling to the complainant.			
8 Quality management system requirements 8.1 Options 8.1.1 General The biobank shall establish, document, implement and maintain a quality management system that is capable of supporting and demonstrating the consistent achievement of the requirements of this document and assuring the quality of biobanking. In addition to meeting the requirements of Clauses 4 to 7, the biobank shall implement a quality management system in accordance with option A or option B.			
8.1.2 Option A As a minimum the quality management system of the biobank shall address the following: a) documented information for the quality management system (see 8.2); b) control of quality management system documents (see 8.3); c) control of records (see 8.4); d) actions to address risks and opportunities (see 8.5); e) improvement (see 8.6);			

ISO 20387: 2018 Requirements	For Biobank		For Assessor
	Y, N, N/A	Objective evidence	Comments on compliance and refer to findings
d) corrective action for nonconforming outputs (see 8.7); f) internal audits (see 8.8); g) quality management reviews (see 8.9).			
8.1.3 Option B A biobank that has established and maintains a quality management system, in accordance with the requirements of ISO 9001, and that is capable of supporting and demonstrating the consistent fulfillment of the requirements of Clauses 4 to 7 also fulfils at least the intent of the quality management system requirements specified in 8.2 to 8.9. NOTE Explanations for option B are given in Annex C.			
8.2 Documented information for the quality management system (Option A) 8.2.1 The biobank shall manage the documented 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.			
8.2.2 The biobank management shall establish, document, and maintain policies and objectives for the fulfilment of the purpose of this document and shall ensure that the policies and objectives are acknowledged and implemented at all levels of the biobank.			
8.2.3 The policies and objectives shall address the competence, impartiality and consistent operation of the biobank.			
8.2.4 The biobank management shall provide evidence of commitment to the development and implementation of the quality management system and to continually improving its effectiveness.			
8.2.5 All documentation, processes, systems, records, etc. related to the fulfilment of the requirements of this document shall be included in, or referenced to the quality management system.			
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 Control of quality management system documents (Option A) 8.3.1 The biobank shall control the documents (internal or external) that relate to the fulfilment of this document.			

ISO 20387: 2018 Requirements	For Biobank		For Assessor
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8.3.2 The biobank shall ensure that: a) documents are approved for adequacy prior to issue by authorized personnel; b) documents are periodically reviewed and updated as necessary; c) the changes and the current revision status of documents are identified; d) relevant versions of applicable documents are available at points of use and where necessary their distribution is controlled; e) documents are uniquely identified; f) the unintended use of obsolete documents is prevented, and suitable identification applied to them, if they are retained for any purpose.			
8.4 Control of records (Option A) 8.4.1 The biobank shall establish and maintain legible records to demonstrate fulfilment of the requirements in this document.			
8.4.2 The biobank shall implement the controls needed for the identification, storage, protection, backup, archive, retrieval, retention time, and disposal of its records. The biobank shall retain records for a period consistent with its contractual and legal obligations.			
8.4.3 Access to these records shall be consistent with the confidentiality arrangements and records shall be readily available.			
8.5 Actions to address risks and opportunities (Option A) 8.5.1 The biobank shall consider the risks and opportunities associated with its biobank activities in order to: a) give assurance that the quality management system can achieve its intended results; b) enhance opportunities to achieve the purpose and objectives of the biobank; c) prevent or reduce undesired impacts and potential failures in biobanking, including discontinuation of operations of the biobank; d) achieve continuous improvement.			
8.5.2 The biobank shall develop, implement and document: a) action plan(s) to address these risks and opportunities;			

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b) action plan(s) to safeguard biological material and associated data in the event of a disaster; c) action plan(s) to address discontinuation of operations in particular handling of concerned biological material and associated data; NOTE This can be a legacy plan. d) approach(es) to: 1) integrate and implement these actions into its quality management system; 2) evaluate the effectiveness of these actions; 3) handle the end of business in case of the biobank's closure under any circumstances.			
8.5.3 Actions taken to address risks and opportunities shall be proportionate to the potential impact on and the validity of biobanking. NOTE 1 Options to address risks can include identifying and avoiding threats, taking risk in order to pursue an opportunity, eliminating the risk source, changing the likelihood or consequences, sharing the risk, or retaining risk by informed decision. NOTE 2 Opportunities can lead to expanding the scope of the biobanking, addressing new recipients/users, using new technology and other possibilities to address recipient/user needs.			
8.6 Improvement (Option A) 8.6.1 The biobank shall identify and select opportunities for improvement and implement any necessary actions. NOTE Opportunities for improvement can be identified through the review of the operational procedures, the use of the policies, overall objectives, audit results, corrective actions, management review, risk assessment, analysis of data, and proficiency-testing results.			
8.6.2 The biobank shall seek feedback, both positive and negative, from its provider(s)/ recipient(s)/user(s). The feedback shall be analysed and used to improve the quality management system, biobanking and provider/recipient/user services. NOTE Examples of the types of feedback include provider/recipient/user satisfaction surveys and review of reports with provider/recipients/users.			
8.7 Corrective action for nonconforming output (Option A) 8.7.1 When nonconforming output according to 7.11 occurs, the biobank shall:			

ISO 20387: 2018 Requirements	For Biobank		For Assessor
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a) react to the nonconforming output and, as applicable: 1) take action to control and correct it; 2) deal with the consequences; b) evaluate the need for action to eliminate the cause(s) of the nonconforming output, so that it does not recur or occur elsewhere, by: 1) reviewing and analysing the nonconforming output; 2) determining the cause(s) of the nonconforming output; c) determine if similar nonconformities exist, or could potentially occur; 1) developing, implementing and documenting any corrective action needed; 2) reviewing the effectiveness of any corrective action taken; 3) updating risks and opportunities determined during planning, if necessary; 4) making changes to the quality management system, if necessary.			
8.7.2 Corrective actions shall be appropriate to the effects of nonconforming output encountered.			
8.7.3 The biobank shall retain documented information as evidence of: a) the nature of nonconforming output, cause(s) and any subsequent actions taken; b) the results and effectiveness of any corrective action.			
8.8 Internal audits (Option A) 8.8.1 The biobank shall: a) plan, implement and maintain an audit programme including the frequency, methods, responsibilities, planning requirements and reporting, which shall take into consideration the importance of the activities concerned, changes affecting the biobank, and the results of previous audits; b) define the audit criteria and scope for each audit; c) ensure that the results of the audits are reported to relevant management; d) implement appropriate correction and corrective actions without undue delay; e) retain records as evidence of the implementation of the audit programme and the audit results. NOTE ISO 19011 provides guidance for internal audits.			
8.8.2 The biobank shall conduct internal audits at planned intervals to provide information on whether the quality			

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management system: a) conforms to: 1) the biobank's own requirements for its quality management system; 2) the requirements of this document; b) is effectively implemented and maintained.			
8.9 Quality management reviews (Option A) 8.9.1 The biobank top management shall review its quality management system at planned intervals, in order to ensure its continuing suitability, adequacy and effectiveness, including the stated policies and objectives related to the fulfilment of this document.			
8.9.2 The inputs to management review shall be documented and shall include information related to the following: a) changes in internal and external issues that are relevant to the biobank; b) fulfilment of objectives; c) suitability of policies and procedures; d) status of actions from previous management reviews; e) outcome of recent internal audits; f) corrective actions; g) assessments by external bodies; h) changes in the volume and type of work or in the range of the biobank's activities; i) provider/recipient/user feedback; j) complaints; k) effectiveness of any implemented improvements; l) adequacy of biological material and associated data; m) results of risk identification; n) outcomes of the quality control; o) other relevant factors, such as monitoring activities and training.			
8.9.3 The outputs from the management review shall record decisions and actions related to:			

ISO 20387: 2018 Requirements	For Biobank		For Assessor
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a) the effectiveness of the quality management system and its processes; b) improvement of the activities related to the fulfilment of the requirements of this document; c) provision of required biological material and associated data; d) any need for change			

Part of Biobank:
This template identifies the clauses of ISO 20387: 2018. It is the responsibility of the Biobank to identify the changes between the standards, determine the impact of these on its systems, and then make and implement any required alterations as necessary.

Details of alterations made to systems should be recorded in this template and the completed template provided to BLQS (as an MS Word document). The submission of the template should be supported by documentation demonstrating how new or changed requirements are met. Effective implementation will be assessed at the site visit. If the Biobank considers that it currently meet a changed requirement and does not need to make changes to its system, then this should be stated in the template.

Completed by	..... (.....) Name & Signature ..... Position	Date: .....

Part of BLQS Assessors: After reviewing the information and documentation supplied by the Biobank and completing the assessment to confirm appropriate implementation, you should place your comments regarding the Biobank's conformity with the new requirements in this template. If any findings are raised relating to new or changed requirements these should be recorded in this form.		
Additional Notes:		
Team Leader/Assessor	..... (.....) Name & Signature	Date: .....

Remark :
Y = Implementing with document or evidence
N = Not implement /No document or evidence
NA= Not Applicable
Please specific Document procedures or quality manual pages which corresponds to the answer Y