ISO 20387 ASSESSMENT WORKSHEET

Self-assessment

This self assessment worksheet may be used in preparation for an assessment. It does not need to be returned to NATA.

4 GENERAL REQUIREMENTS

4.1 General & Impartiality

Clause No.	General Requirements	Evidence (outcome of discussions with staff observations; procedures & documentation reviewed)
4.1.1	Biobanks • shall have procedures for each type of biological material and associated data held • shall include collecting, receiving, tagging, accessioning, classifying, examining, preparing, preserving, storing, managing data, destroying, packaging, distribution and transporting • shall have procedures to ensure compliance with biosecurity / biosafety requirements • procedures shall address risks and opportunities using a risk assessment	
4.1.2	Biobank should be aware of downstream application(s) for biological material and associated data to enable reproducible research	
4.1.3	The Biobank mission should be defined and available	
4.1.4	Biobank activities, processes and procedures shall be documented	
4.1.5	Biobank documentation shall include information regarding the QMS as well as management of facilities / dedicated areas	
4.1.6	Biobank shall comply with relevant regional, national and international ethics requirements for biological material and associated data	

Clause No.	General Requirements	Evidence (outcome of discussions with staff observations; procedures & documentation reviewed)
4.1.7	Biobank shall document the identity of personnel performing procedural activities	
4.1.8	Biobank should define time period for retention of documented information and associated data for each biological material after its distribution, disposal or destruction	

4.2 Impartiality

Clause No.	General Requirements	Evidence (outcome of discussions with staff observations; procedures & documentation reviewed)
4.2.1	Biobanking • shall be structured and managed to safeguarded impartiality *Is the biobank able to demonstrate this*	
4.2.2	Biobank management • shall be committed to impartiality *Is the biobank able to demonstrate this*	
4.2.3	Impartiality is the Biobank responsibility internal or external pressures shall not compromise impartiality • *How is this demonstrated?*	
4.2.4	Biobank shall identify risks to impartiality on an ongoing basis and include those arising from – its activities – its relationships – relationships of personnel	
4.2.5	Risk mitigation - If risk is identified • the Biobank shall demonstrate how risk to impartiality is eliminated or minimised	

4.3 Confidentiality

Clause No.	General Requirements	Evidence (outcome of discussions with staff observations; procedures & documentation reviewed)
4.3.1	Biobank • Shall protect the confidential information and rights of donors, recipients & users • inform the provider / donor in advance of the information it intends to place in the public domain	
4.3.2	Biobank through legally enforceable commitments, • shall manage all information obtained or created during the performance of biobanking • shall inform provider / donor (where possible) how privacy and confidentiality are protected • shall only release information according to agreements and approvals	
4.3.3	When required by law to release confidential information • the provider/donor shall be notified of information provided (unless prohibited)	
4.3.4	All personnel with Biobank access bound by confidentiality	

5 STUCTURAL REQUIREMENTS

Clause No.	General Requirements	Evidence (outcome of discussions with staff observations; procedures & documentation reviewed)
5.1	Legal status • the biobank shall be a legal entity responsible for activities	
5.2	Biobank management • identify management that has overall responsibility for the biobank	
5.3	Biobank shall have a governance body (advisory board) • body provides advice on scientific, technical and administrative matters	
5.4	Biobank is responsible to activities in its facilities / dedicated areas	
5.5	Biobank • shall have a course of action to define and address liabilities arising from activities	
5.6	Biobanking shall conduct activities as to meet the requirements of – the Standard – customer requirements – regulatory authorities – NATA	
5.7	Scope of conformance • the biobank shall define and document the range of activities to which it claims conformity to the Standard • shall only claim conformity for its defined range of activities *excluding* externally provided activities	

Clause No.	General Requirements	Evidence (outcome of discussions with staff observations; procedures & documentation reviewed)
5.8	Biobank a) shall define the governance structure - including biobank organisation and management Define the biobank's place in any parent organisation, and the relationship between management, technical operations and support services b) specify the responsibilities, authorities and interrelationships of those who manage, perform or verify work affecting biobank output	
5.9	Biobank shall have personnel with authorities and resources including: a) available to implement, maintain and improve the management system b) able to identify deviations in the management system or biobanking procedures c) able to assess the impact of deviations, and develop / implements appropriate actions d) report to biobank management the performance of the QMS and needs for improvement	
5.10	Biobank management responsibilities a) changes to QMS monitored and controlled b) ensure communication with interested parties(including personnel) on performance indicators of QMS and need for improvement c) the importance of meeting the standard requirements is communicated and understood by biobank personnel	

6 RESOURCE REQUIREMENTS

6.1 General

Clause No.	General Requirements	Evidence (outcome of discussions with staff observations; procedures & documentation reviewed)
6.1.1	Available resources • Biobanks to have available personnel, facilities, equipment, systems and support services necessary to manage and perform biobanking	
6.1.2	Biobank • To have a documented strategy for continued financial viability • strategy to be reviewed periodically	

6.2 Personnel

Clause No.	General Requirements	Evidence (outcome of discussions with staff observations; procedures & documentation reviewed)
6.2.1.1	Impartiality • all personnel (internal or external) associated with the biobank that could influence the biobank shall act impartially	
6.2.1.2	Confidentiality • all personnel having access to confidential data shall be bound to confidentiality	
6.2.1.3	Biobank • shall have documented procedures and records for personnel management	
6.2.1.4	Biobank • shall have detailed job descriptions communicating personnel duties, responsibilities and authorities.	

Clause No.	General Requirements	Evidence (outcome of discussions with staff observations; procedures & documentation reviewed)
6.2.1.5	Biobank • shall ensure heath and safety requirements are meet • level of safety training shall be determined from a risk assessment of the biological and chemical material, processes and equipment	
6.2.2	**Competence and Competence assessment**	
6.2.2.1	Biobank • Shall define and document required competence for personnel • Including support functions (IT, facility infrastructure)	
6.2.2.2 /3	Documentation of competency requirements • to include education, qualification, training, technical knowledge, skills and experience to perform assigned duties and activities	
6.2.2.4 / 5	Personnel • shall be subject to competence assessment according to established criteria • Assessed at regular intervals	
6.2.3	**Training**	
6.2.3.1	Personnel • Shall receive appropriate training to acquire necessary competence • Regular updated to retain competence • Training shall be documented	
6.2.3.2	Supervision • Personnel undergoing training shall be supervised until biobank confirms competency	

Clause No.	General Requirements	Evidence (outcome of discussions with staff observations; procedures & documentation reviewed)
6.2.3.3	Introduction • Biobank shall have an introduction policy for new personnel • Appropriate orientation shall be provided	

6.3 Facilities / dedicated areas and environmental conditions

Clause No.	General Requirements	Evidence (outcome of discussions with staff observations; procedures & documentation reviewed)
6.3.1	Requirements for facilities and environmental conditions for biobanks shall be documented	
6.3.2	Biobank • Shall determine, control and maintain facilities in condition required for conformity • Includes procedures to maintain fitness for purpose , biosafety and security of biological material and data	
6.3.3	Separation between areas • there shall be effective separation between biobanking areas that host incompatible activities • there shall be measures taken to avoid cross contamination	
6.3.4	Biobank • facilities and dedicated areas shall be suitable for biobanking and not affect intended purpose	
6.3.5	Biobank shall • Monitor, control and record the environmental conditions in accordance with the relevant specifications, methods and procedures	

Clause No.	General Requirements	Evidence (outcome of discussions with staff observations; procedures & documentation reviewed)
6.3.6	Biobank • Should address future expansion requirements	
6.3.7	Biobank • Shall have a contingency plan to ensure required environmental conditions are maintained • Contingency plan should consider risk	

6.4 Externally provided products and services

Clause No.	General Requirements	Evidence (outcome of discussions with staff observations; procedures & documentation reviewed)
6.4.1.1	Biobank shall a) determine the requirements for externally provided processes, products and services b) document requirements and communicate these to external provider c) retain information regarding communication d) ensure externally provided processes, products and services conform to biobank requirements	
6.4.1.2	Procedure and records for • defining criteria for evaluation, selection, monitoring of performance and re-evaluation of external providers • retain documented information including any actions arising from the evaluations	
6.4.1.3	Biobank shall determine which externally provided processes shall be communicated to the provider/ recipient/ user	
6.4.1.4	Biobank • shall ensure externally provided processes, products, services	

Clause No.	General Requirements	Evidence (outcome of discussions with staff observations; procedures & documentation reviewed)
	have no adverse affect on biobanks ability to operate • shall determine risks associated with externally provided processes, products and services • steps taken to avoid negative effects on conformity of product	
6.4.1.5	Biobank • shall determine verification necessary to ensure externally provided processes products and services meet the biobanks requirements	
6.4.1.6	If biobanks uses externally provided preservation, storing and/or authentication activities • All processes need to be validated according to provisions • Internal audits conducted on provision of services and scheduled regularly using a risk based approach • Relevant documentation related to activities is retained	

6.5 Equipment (and Software)

Clause No.	General Requirements	Evidence (outcome of discussions with staff observations; procedures & documentation reviewed)
6.5.1	Availability of equipment • Biobank has controlled access to all equipment required for performance	
6.5.2	Biobank shall establish, document and implement procedures for all equipment including • Controlled implementation • Safe handling • Storage • Planned maintenance • Calibration	

Clause No.	General Requirements	Evidence (outcome of discussions with staff observations; procedures & documentation reviewed)
6.5.3	Biobank shall have instructions on use and operation of all equipment	
6.5.4	Biobank shall categorise equipment (including backup equipment) with potential to impact quality of biological material in order to categorise equipment critical for biobanking	
6.5.5	Biobank shall maintain an equipment list detailing • Categorization • Performance • Maintenance, • Verification / validation	
6.5.6	Biobank shall verify on installation and before use that equipment is capable of achieving necessary performance and complies with relevant requirements	
6.5.7	Critical equipment shall be capable of achieving the accuracy required and support compliance with required processes	
6.5.8	Biobank shall retain documentation for critical equipment including a) Equipment and software identity b) Manufacturers name, identification, serial number and unique identification c) Check equipment complies with specifications d) Current location where appropriate e) Manufacturers instructions f) Results, reports, certificates of calibrations, adjustments, acceptance criteria, and dates g) Due date of next calibration h) Maintenance plan and maintenance history i) Any damage, malfunction, modification or equipment repair	
6.5.9	Critical equipment and software shall be safeguarded from adjustments which would invalidate output	

Clause No.	General Requirements	Evidence (outcome of discussions with staff observations; procedures & documentation reviewed)
6.5.10	Biobank shall (where applicable) establish and maintain metrological traceability of its measurement results	
6.5.11	Equipment shall be taken out of service to prevent use if: • Subject to mishandling / overloading • Generates compromised outputs / results • Is defective or outside specification limits Shall be isolated and clearly labelled until repaired and shown by calibration / test to perform correctly.:	
6.5.12	Biobank shall examine the effect of defect or departure from specifications Refer 7.11	

7 PROCESS REQUIREMENTS

7.1 General

Clause No.	General Requirements	Evidence (outcome of discussions with staff observations; procedures & documentation reviewed)
7.1.1	Life cycle stages of biological material and associated data • shall be identified and processes shall be defined and verified • Workflow shall describe stages with detailed procedures for each process (collection, accession, identification, preservation, storage, quality control, transport , disposal) • Procedures shall be documented, implemented and specific to biological material and associated data. • All critical activities in each procedure shall be identified and documented	
7.1.2	All procedures and processes shall be kept up to date and shall be readily available to personnel	
7.1.3	Date for critical stages / processes shall be documents in a standard format	

7.2 Collection of biological material and associated data

Clause No.	General Requirements	Evidence (outcome of discussions with staff observations; procedures & documentation reviewed)
7.2.1 Documented information requirements		
7.2.1.1	Where the biobank collects biological material: • It shall define & document information related to the collection • Shall include the date, time, place & procedure of collection and other relevant information	

Clause No.	General Requirements	Evidence (outcome of discussions with staff observations; procedures & documentation reviewed)
7.2.1.2	Where the Biobank acquires biological material (Biobank not responsible for collection): • It should define the required information • It should retain appropriate documentation related to the collection procedure	
7.2.2 Pre-acquisition information		
7.2.2.1	Where possible the Biobank shall document / retain any information related to stages prior to the reception of the biological material that can affect the properties of the biological material to allow assessment of its fitness for the intended purpose	
7.2.3 Collection procedure		
7.2.3.1	Collection procedure • Shall be defined either by biobank/ recipient / user according to the intended use of the biological material, proven techniques or standards	
7.2.3.2	Where relevant pre-analytical workflows should be implemented according to ISO requirements e.g. ISO 15189, 17025	
7.2.3.3	Qualified & authorised personnel shall collect the biological material according to defined procedures • Where clinical material collection and evaluation of material needs to be by competent personnel • Collection shall never affect patient care & diagnosis	
7.2.3.4	Collection of Human biological material shall be performed in accordance with relevant ethical requirements *(include ethical approvals or donor consent waiver)*	

7.3 Reception and distribution of biological material and associated data		
Clause No.	**General Requirements**	**Evidence** (outcome of discussions with staff observations; procedures & documentation reviewed)
7.3.1 Access principles		
7.3.1.1	Principles governing access to and distribution of biological material and associated data: • Shall be defined, documented and where required published • Biobank shall ensure documented requirements with interested parties comply with these principles	
7.3.2 Reception		
7.3.2.1	Biobanks shall • Establish • Document • Implement procedures for receiving or acquiring biological material and associated data	
7.3.2.2	Biobanks shall define acceptance criteria of biological material and associated data incl; • Biosafety • Biosecurity • *Intellectual property* rights Identification of biological material and associated data shall be verified on acquisition (reception) according to defined acceptance criteria	

7.3 Reception and distribution of biological material and associated data		
Clause No.	**General Requirements**	**Evidence** (outcome of discussions with staff observations; procedures & documentation reviewed)
7.3.2.3	When applicable the biobank shall authenticate the biological material according to relevant international standards	
7.3.2.4	All biological material and associated data acquired by a biobank (individually or part of a collection) shall be segregated from final storage until: • Legal, • Ethical • Documentation • Quality compliance Has been assessed and managed	
7.3.2.5	Biobank should obtain relevant documented information needed to assess fitness for the intended purpose of the acquired biological material	
7.3.2.6	Where the biobank has not been responsible for collection / sampling this shall be documented	
7.3.3 Distribution		
7.3.3.1	Distribution and exchange of biological material and associated data shall be in accordance with the: • biobank's access principles • reporting specifications • other relevant requirements (including material / data transfer agreements)	
7.3.3.2	Biobank shall ensure that a documented / legally binding agreement is used that outlines conditions for provision and use when providing biological material and data Any changes to such documents shall be documented	

7.3 Reception and distribution of biological material and associated data		
Clause No.	**General Requirements**	**Evidence** (outcome of discussions with staff observations; procedures & documentation reviewed)
7.3.3.3	Biobank shall establish, document implement procedures for the preparation and distribution of biological material and associated data Biobank needs to fulfil conditions of documented agreement	
7.3.3.4	When distributing biological material and associated data to recipient / user predefined information according to 7.12 shall be provided (unless by agreement)	

7.4 Transport of biological material and associated data

Clause No.	**General Requirements**	**Evidence** (outcome of discussions with staff observations; procedures & documentation reviewed)
7.4.1	Biobank shall establish, document and implement procedures for shipping and receiving biological material Including conditions for the maintenance of biological material integrity	
7.4.2	Biobank shall maintain chain of custody for all biological material from *point of dispatch to point of receipt* When shipping can alter quality (or it is deemed necessary) biological material shall be: • tracked, • monitored for elements pertinent to integrity (incl: duration, temp, humidity, light) The chain of custody shall detail any deviations from specified parameters. See7.11	
7.4.3	Biobank shall have procedures for : • safe handling • packaging • transport • reception	

Clause No.	General Requirements	Evidence (outcome of discussions with staff observations; procedures & documentation reviewed)
	of biological material	
7.4.4	Biological material should not be left unattended - unless in designated custody zones	
7.4.5	Only competent personnel shall prepare biological material for shipment	
7.4.6	Prior to transfer of biological material the requirements for use (see7.3.3.2) shall be fulfilled and arrangements in place for biological material distribution and reception with relevant parties	
7.4.7	Biobank shall establish & document procedure for shipping and receiving data. Data transfer shall be designed to ensure integrity and prevent breach of data privacy Prior to data transfer arrangements shall be made for data reception and distribution between parties.	

7.5 Traceability of biological material and associated data

Clause No.	General Requirements	Evidence (outcome of discussions with staff observations; procedures & documentation reviewed)
7.5.1	Biobank shall ensure traceability of biological material and associated data over the lifecycle including: • collection / acquisition • reception • distribution disposal / destruction a) Biological material shall be uniquely identified / tagged so id is maintained throughout lifecycle Biobank shall have a documented procedure for tagging biological material that is compliant with environmental requirements including relevant storage conditions b) Biological material and associated data *shall be linked* to the documented permissions/ restrictions for use c) Inventory system shall allow for annotation and query of any relevant information associated with handling procedures including - collection, packaging, transportation, preparation, preservation, storing and distribution. System should allow deviations in procedures to be flagged d) Biobank shall establish a link between biological material and associated data for unambiguous traceability e) Biobank shall be able to identify the location of any biological material and associated data at all times f) Biobank shall be able to identify biological material and associated data already distributed to a recipient / user or already disposed of.	
7.5.2	Biobanking information should be accessible to all persons querying the data as needed	

Clause No.	General Requirements	Evidence (outcome of discussions with staff observations; procedures & documentation reviewed)
	- Including for inquiries regarding biological material distribution and complaints	
7.5.3	Biobank shall establish, document and implement a procedure for • the disposal and transfer of biological material and / or data due to a planned event or as a results of an emergency	

7.6 Preparation and preservation of biological material

Clause No.	General Requirements	Evidence (outcome of discussions with staff observations; procedures & documentation reviewed)
7.6.1	Biobank method(s) of preparation and / or preservation shall be defined according to • evidence based documented processes (international standards) • as agreed with provider / recipient / user	
7.6.2	Critical activities in preparation / preservation shall be monitored and relevant parameters documented Each preservation step shall be individually documented	
7.6.3	Date of preparation / preservations steps shall be documented in standard format Time for each step should be documented in standard format	

7.7 Storage of biological material

Clause No.	General Requirements	Evidence (outcome of discussions with staff observations; procedures & documentation reviewed)
7.7.1	Biobank shall establish a *disaster protection plan* To include alternative methods of safeguarding to avoid loss of biological material	
7.7.2	Biobank shall have a documented procedure in place for the storage and tracking of biological material including: a) tagging information containing unique identifier of biological material b) type of container and environmental conditions for biological material storage c) mechanism for traceability d) short term back up plan for maintaining accurate storage conditions / temperatures in case of emergency challenges in maintaining defined storage conditions	
7.7.3	Critical activities during storage shall be measured, monitored and documented, Date & time of critical activities and when *personnel access* the biological material shall be documented	
7.7.4	Biobank shall document and verify the storage location of all biological material and associated data Traceability shall be ensured at all times	
7.7.5	Biobank storage locations and processes shall be designed *to minimise risk contamination* And to ensure maintenance of biological material integrity	
7.7.6	Biobank storage conditions shall comply with facility requirements and environmental conditions (6.3)	
7.7.7	Biobank shall *verify the biological material inventory* at planned intervals by a defined procedure	

Clause No.	General Requirements	Evidence (outcome of discussions with staff observations; procedures & documentation reviewed)
7.7.8	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

Clause No.	General Requirements	Evidence (outcome of discussions with staff observations; procedures & documentation reviewed)
7.8.1 General		
7.8.1.1	Critical activities that have an impact on quality of biological material and associated data shall be identified Biobank shall establish, document and implement QC procedures related to such activities	
7.8.1.2	Biobank shall provide biological material and associated data fit for purpose. Biobank shall define minimum set of QC procedures to be performed on biological material and associated data. Exceptions can be justified for rare or legacy biological material and associated data and QC procedures which lead to biological *material elimination.*	
7.8.1.3	QC procedures shall: a) be according to proven techniques and fitness for purpose b) be regularly updated c) ensure all requirements are met where possible	
7.8.2 Quality control of processes		
7.8.2.1	Biobank shall establish, document and implement QC procedures throughout the biobank process Needs to include QC corresponding to	

Clause No.	General Requirements	Evidence (outcome of discussions with staff observations; procedures & documentation reviewed)
	predefined specifications QC needs to demonstrate fitness for intended purpose of biological material and associated data	
7.8.2.2	QC activities shall be performed at planned intervals Biobanks shall retain documented information of QC activities and results	
7.8.2.3	QC data shall be analysed If defined QC 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	Biobanks shall ensure that *identified limitations* are clearly documented and communicated to the user During product distribution it is the responsibility of the recipient / user to decide on the acceptance of receiving material and associated data with documented and communicated limitations	
7.8.2.5	Biobank shall ensure information of QC results is provided to the user 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	Biobank shall document all process related data in accordance with documentation requirements - Appendix A	
7.8.2.8	Biobank should have appropriate QC materials (e.g. internal control material) QC material shall be periodically examined to assess quality characteristics of the biological material - including stability, performance of processing methods and accuracy / precision of QC procedures	
7.8.2.9	Biobank shall use approaches to provide	

Clause No.	General Requirements	Evidence (outcome of discussions with staff observations; procedures & documentation reviewed)
	objective evidence to demonstrate comparability of biological material quality (processing or testing output) This could include: • EQA programs • Proficiency testing programs • Interlaboratory comparisons Individual lab approaches including: a) reference material b) previous samples c) previously shared samples d) control material that are tested regularly in EQA programs	
7.8.2.10	For interlaboratory comparison programs - the biobank shall monitor results of the program Where criteria are not met the biobank shall perform and document corrective actions	
7.8.3 Quality control of <u>data</u>		
7.8.3.1	Biobank shall identify critical data and establish, document and implement QC procedures applying to these critical data	
7.8.3.2	Biobank shall define type and frequency of QC performed. QC shall focus on accuracy, completeness and consistency of data	

7.9 Validation and verification of methods

Clause No.	General Requirements	Evidence (outcome of discussions with staff observations; procedures & documentation reviewed)
7.9.1 General		
7.9.1.1	Biobank shall use validated/verified methods for critical activities 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 - biobanks *shall ensure there methods have been validated* to ensure fitness for purpose If biobanks performs validation it shall document and retain results obtained, details of the procedure used and a fit for purpose statement	
7.9.2.2	Validation shall be as extensive as necessary and confirm through objective evidence that specific requirements for intended use have been filled	
7.9.2.3	When changes are made to validated methods, the impact of the changes shall be documented and a new validation carried out when required	
7.9.3 Verification		
7.9.3.1	Validated methods used without modification shall be subject to verification by the biobank before use	
7.9.3.2	Biobank verification shall confirm through objective evidence that method set criteria have been met	
7.9.3.3	Biobank shall document procedure used for verification and results obtained	

7.10 Management of information and data

Clause No.	General Requirements	Evidence (outcome of discussions with staff observations; procedures & documentation reviewed)
7.10.1	Biobank shall define required information and related data to biological material Biobank shall have a system in place for tracking information and data Biobank shall reasonably support interoperability of information and data	
7.10.2	Biobank shall address future capacity expansion to allow further addition of biological material processing data	
7.10.3	Biobank shall have in place a procedure for the : • implementation • modification • use for the computer system, software , hardware and database in place Procedure shall include data integrity, security control and backup systems to prevent loos or corruption of data	
7.10.4	Biobank shall have access to the data and information needed to provide a service specified by contractual arrangements	
7.10.5	Biobank should provide interested parties with access to a catalogue of available material and associated data	
7.10.6	Biobank shall retain access to the appropriate data associated with the biological material as necessary for research purposes and in compliance with applicable requirements (7.3.3.2)	

7.11 Nonconforming output

Clause No.	General Requirements	Evidence (outcome of discussions with staff observations; procedures & documentation reviewed)
7.11.1 General		
7.11.1	Biobank shall establish, document and implement procedures for management of output that does not conform to predefined biobank / recipient / user /provider requirements	
7.11.1.2	Biobanks shall ensure that output that does not conform to requirements is identified and controlled to prevent unintended use / supply	
7.11.1.3	Biobank shall implement procedures to disclose information about non-conforming output to relevant parties Recipient / users to determine fitness for intended purpose	
7.11.1.4	Biobank shall take appropriate corrective action based on the non-conforming output and its effect on fitness for purpose / use This shall also apply to nonconforming output detected after supply of biological material and associated data	
7.11.1.5	Procedure for nonconforming output shall address: a) responsibilities and authorities for the managements 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 the nonconforming output d) persistence of nonconforming output when; 1. remedy of non-conformity impossible 2. remedy of nonconformity is impractical 3. output can have an impact	

Clause No.	General Requirements	Evidence (outcome of discussions with staff observations; procedures & documentation reviewed)
7.11.1 General		
	on results produced by third parties e) communication of non-conforming output and authorization for acceptance by recipient / user	
7.11.1.6	Procedures for nonconforming output shall also apply to biological material and associated data collected or acquired prior the he first adoption of this document	
7.11.2 Control of nonconforming output		
7.11.2.1	Biobank shall mitigate impacts on nonconformity, implement corrective actions in proportion to the risk presented by nonconforming output and prevent recurrence Remedial actions appropriate to effects shall be taken within defined limits and shall be controlled when non-conforming output is corrected	
7.11.2.2	Biobank shall retain documents regarding non-conformance See 8.7.3	
7.11.2.3	The decision on recall shall be taken in a *timely manner* to limit the use of nonconforming output	

7.12 Report requirements

Clause No.	General Requirements	Evidence (outcome of discussions with staff observations; procedures & documentation reviewed)
7.12.1 General		
7.12.1.1	Biobank shall provide a report that shall include required information as agreed on in the documented agreement with recipient / user Reports can be called certificates	
7.12.1.2	Report may be issued as hard copy or by electronic data transfer or by an electronic data entry in an accessible database	
7.12.1.3	Biobank should include statement specifying that report should not be reproduced except in full	
7.12.2 Content of the report		
7.12.2.1	Each report shall include (unless a valid reason not to) a) a title b) name & address of biobank - and location where activities in the report were carried out if different c) date of report issue d) unique id *of report* with id on each page to ensure that each page is recognised as part of report, and clear identification of report end e) biological material identification (or specific properties) f) quality information of biological material and associated data g) methods used for identification / characterisation of biological material h) testing results with units of measurement i) methods for testing j) methods for collection / acquisition / preparation / preservation k) storage conditions l) name(s) & function of person authorising report	

Clause No.	General Requirements	Evidence (outcome of discussions with staff observations; procedures & documentation reviewed)
7.12.2.2	Biobank shall be responsible for all information provided in report - except when information is provided by provider / recipient / user Where biobank not responsible for collection report shall state that it relates to biological material as received by biobank	

7.13 Complaints

Clause No.	General Requirements	Evidence (outcome of discussions with staff observations; procedures & documentation reviewed)
7.13.1	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 On receipt of a compliant the biobank shall confirm if it relates to biobank activities and if so shall address it Biobank shall be responsible for all levels of complaint handling	
7.13.3	Complaint handling process shall include: a) description of process for receiving, accepting, investigation complaint and deciding what responsive action required b) tracking and recording complaints - including resolving actions c) ensuring appropriate action taken	
7.13.4	Biobank receiving complaint shall be responsible for verifying all information necessary to accept complaint. Biobank shall acknowledge receipt of complaint	

Clause No.	General Requirements	Evidence (outcome of discussions with staff observations; procedures & documentation reviewed)
7.13.5	Biobank shall provide complainant with progress report where possible	
7.13.6	Impartial review shall be performed for each complaint Outcome of review shall be communicated to relevant parties	
7.13.7	Biobank shall give formal notice of end of complaint handling to complainant where possible	

8 MANAGEMENT SYSTEM REQUIREMENTS

8.1 Options

Clause No.	General Requirements	Evidence (outcome of discussions with staff observations; procedures & documentation reviewed)
8.1.1 General		
8.1.1	Management system • supports and demonstrates the consistent achievement of the requirements of the Standard • assures the quality of the biobank results • allows the requirements of clauses 4 to 7 to be met • is in accordance with either Option A or Option B	

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Option A

The biobank must address clauses 8.2 to 8.9.

Option A: 8.2 Documented information for the quality management system

Clause No.	General Requirements	Evidence (outcome of discussions with staff observations; procedures & documentation reviewed)
8.2.1	Biobank shall manage the internal and external documented information necessary for planning and operation in order to comply with requirements and demonstrate competence This shall include: a) identify information to be documented b) ensure documented information is created and updated as required c) ensure documented information is controlled	
8.2.2	Policies and objectives • are established, documented for the fulfilment of the Standard • are acknowledged and implemented at all levels of the biobank	
8.2.3	Competence, impartiality and consistent operations • are addressed by the policies and objectives	
8.2.4	Biobank management • shall provide evidence of commitment to the development and implementation of the quality management system • continually improves the quality management system's effectiveness	
8.2.5	All documentation, processes, systems and records related to the fulfilment of the requirements of this document shall be included (or referenced) to the quality management system	
8.2.6	Access to parts of the management	

Clause No.	General Requirements	Evidence (outcome of discussions with staff observations; procedures & documentation reviewed)
	system • is available to all personnel	

Option A: 8.3 Control of management system documents

Clause No.	General Requirements	Evidence (outcome of discussions with staff observations; procedures & documentation reviewed)
8.3.1	Control of documents • both internal and external documents relating to the fulfilment of the requirements of the Standard	
8.3.2	Document control process a) documents are approved by authorised personnel prior to issue b) documents are periodically reviewed and updated as necessary c) changes and current revision status of documents are identified d) relevant versions of documents are available and their distribution controlled as necessary e) documents are uniquely identified f) unintended use of obsolete documents is prevented and they are clearly identified as obsolete if retained	

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Option A: 8.4 Control of records

Clause No.	General Requirements	Evidence (outcome of discussions with staff observations; procedures & documentation reviewed)
8.4.1	Biobank shall establish and maintain legible records • to demonstrate fulfilment of the requirements of the Standard	
8.4.2	Controls of records • are implemented for – identification – storage – protection – back-up – archive – retrieval – retention times – disposal • are established for – retention periods to satisfy contractual /legal obligations – confidentiality commitments – access and availability	
8.4.3	Access to records shall be • consistent with confidentiality arrangements • be readily available	

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Option A: 8.5 Actions to address risks and opportunities

Clause No.	General Requirements	Evidence (outcome of discussions with staff observations; procedures & documentation reviewed)
8.5.1	Risks and opportunities are considered with biobank activities a) to assure the management system achieves its intended goals b) to achieve the biobank objectives c) to prevent (or minimise) undesired impacts and potential failures - including biobank discontinuation d) to achieve continuous improvement	
8.5.2	Biobank shall develop, implement and document a) action plan to address risks and opportunities b) action plan to safeguard biological material and associated data in event of disaster c) action plan for discontinuation of operations (a legacy plan) d) approaches to implement actions into QMS evaluate effectiveness of actions in case of closure handle the end of business	
8.5.3	Actions to address risks and opportunities • are proportional to the potential impact on the validity of the biobank	

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Option A: 8.6 Improvement

Clause No.	General Requirements	Evidence (outcome of discussions with staff observations; procedures & documentation reviewed)
8.6.1	Biobank shall identify • Opportunities for improvement and any necessary action implemented	
8.6.2	Customer feedback • both positive and negative are sought, analysed and used to improve the management system, biobank activities and customer service	

Option A: 8.7 Corrective actions

Clause No.	General Requirements	Evidence (outcome of discussions with staff observations; procedures & documentation reviewed)
8.7.1	Nonconformities • when occur, the biobank shall a) react and, as applicable, take action, correct the issue and address the consequences b) evaluate the need for action to eliminate the cause so that it does not recur c) determine if similar non-conformances exist review the effectiveness of any corrective action update any risk and opportunities makes any necessary changes to the management system	
8.7.2	Corrective action taken • is appropriate to the effects of the nonconformity	
8.7.3	Records retained a) of the nature of the nonconformity, cause(s) and any action(s) taken	

Clause No.	General Requirements	Evidence (outcome of discussions with staff observations; procedures & documentation reviewed)
	b) of the outcomes of corrective action	

Option A: 8.8 Internal audits

Clause No.	General Requirements	Evidence (outcome of discussions with staff observations; procedures & documentation reviewed)
8.8.1	Biobank audit requirements a) is planned and implemented, including frequency, defined responsibilities and reporting, taking into account – the importance of the biobank activities concerned – changes affecting the biobank – the results of previous audits b) audit criteria and the scope of each audit are defined c) audit results are reported to relevant management d) corrective actions, where necessary, are implemented promptly e) records of the audit program, including outcomes, are retained	
8.8.2	Conducted at planned intervals a) to establish whether the management system b) conforms to – the biobank's requirements, including biobank activities – the requirements of the Standard is effectively implemented and maintained	

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Option A: 8.9 Quality Management reviews

Clause No.	General Requirements	Evidence (outcome of discussions with staff observations; procedures & documentation reviewed)
8.9.1	Review of management system • is conducted at planned intervals by biobank management to ensure – continued suitability, adequacy and effectiveness – covers the stated policies and objectives related to the fulfilment of the Standard	
8.9.2	Inputs to management review shall be documented and include a) changes in internal and external issues relevant to biobank b) fulfilment of objectives c) suitability of policies and procedures d) status of actions from previous management reviews e) outcomes of recent internal audits f) corrective actions g) assessment by external bodies h) changes in volume, type and range of biobank 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) any other relevant factors including monitoring activities and training	

Clause No.	General Requirements	Evidence (outcome of discussions with staff observations; procedures & documentation reviewed)
8.9.3	Records of outputs • include all decisions and actions relating to a) effectiveness of the management system b) improvement of activities relating to satisfying the requirements of the Standard c) provision of required biological material and associated data d) any need for change(s)	

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Option B

Where 1) to 6) below are confirmed, a document review of the biobank's management system does not need to be formally performed. The Lead Assessor is still, however, to be familiar with the management system documentation and hence a copy of the documentation is to be provided by the biobank.

A limited review of records at assessment is to be performed to specifically confirm 6) e.g. management review, an internal audit, example of corrective action etc.

The required extent of assessment will be dependent on the evidence provided in 3) and 4) below.

Where nonconformities are identified, these are to be raised against clause 8.1.3.

Where 1) to 6) cannot be confirmed, then assessment of the biobank's management system shall be against Option A requirements.

If the Biobank has adopted Option B	Evidence
1) evidence the management system is certified by a certification body (CB) accredited by JAS-ANZ, or by another signatory to the International Accreditation Forum (IAF) Multilateral Recognition Agreement (MLA).	
2) evidence that the CB's accreditation covers ISO/IEC 17021 Parts 1 and 3. If Part 3 is not specifically listed in the CB's scope of accreditation, then it must be clear that its accreditation covers the certification of Quality Management Systems (QMS) to ISO 9001 (which may be included in the scope of accreditation or other documentation provided by the accreditation body signatory to the IAF MLA).	
3) copies of the most recent certification audit report(s) issued by the CB covering the biobank's management system in full.	
4) confirmation from the CB of the close out of any nonconformities raised during certification audits.	
5) evidence the certification of the management system covers the biobank activities covered by its NATA scope of accreditation.	
6) supports the facility fulfilling consistently the requirements of ISO/IEC 17025 to assure the quality of results.	