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KENYA
ACCREDITATION
SERVICE

ACC-CD-38-01

Criteria for the Accreditation of Biobanking Laboratories

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1 Background Information

1.1 Process Overview

This guidance document specifies the accreditation criteria for organisations undertaking biobank services seeking accreditation from KENAS. It is intended that after four years and on a need basis the content of this document will be revised.

The requirements for accreditation are laid down in ISO 20387, Biotechnology — Biobanking — General requirements for biobanking. These requirements apply to all types of medical testing but in certain instances, additional guidance is necessary to take to account the technologies involved.

1.2 Purpose

This document has been prepared by a Technical Working Group for Biobanking and authorized for adoption by KENAS. It supplements ISO 20387 standard and provides specific guidance on the accreditation of biobanking services for use by KENAS assessors and by laboratories preparing for accreditation.

1.3 Scope

This document covers the application of ISO 20387 for the accreditation of bio-banks and will be applied in conjunction with those in the Assessor Guide and Terms of Reference ACC-CD-02-01, procedure for Management and Reporting of Assessments ACC-PR-07-01, Sampling during Assessment and Internal Audits ACC-PR-03-01, Policy for Management of Extraordinary Events PL-13-01, Policy for dealing with objection of assessors/experts PL-30-01 and the relevant IAF Mandatory Documents. Accreditation shall be based on demonstrated competence of the biobanking services in accordance with the requirements of ISO 20387

1.4 Roles and Responsibilities

Role	Responsibility
Manager Medical Laboratories	Process owner
Principal Accreditation Officer Medical Laboratories	Reviewer
Chief Manager Laboratory	Recommender
Chief Executive Officer	Approval
Biobanking Service Providers	Compliance

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2 Terms and Definitions

For the purpose of this guidance document, the following terms and definitions shall apply in addition to those given in ISO/IEC 17000 and the Kenya Accreditation Service Act 2019.

2.1 Acronyms and Abbreviations

CAB	Conformity Assessment Body
KENAS	Kenya Accreditation Service
QC	Quality Control
EQA	External Quality Assessment

2.2 Definition of Terms

2.2.1 Accreditation

Third-party attestation related to a conformity assessment body conveying formal demonstration of its competence to carry out specific conformity assessment tasks.

2.2.2 Scope of accreditation

The specific conformity assessment services for which accreditation is sought or has been granted.

2.2.3 Biobanking

Process of acquisitioning and storing, together with some or all of the activities related to collection, preparation, preservation, testing, analysing and distributing defined biological material as well as related information and data.

2.2.4 Biological Material

Any substance derived or part obtained from an organic entity such as a human, animal, plant, microorganism(s) or multicellular organism(s) that is(are) neither animal nor plant (e.g. blood, cell culture, pathogens, body fluids).

2.2.5 Biosafety

Containment principles, technologies and practices that are implemented to prevent unintentional exposure to pathogens and toxins, or their accidental release.

2.2.6 Biosecurity

Institutional and personal security measures and procedures designed to prevent the loss, theft, misuse, diversion or intentional/unintentional release of pathogens, genetically modified organisms, toxin-producing organisms, or parts thereof, as well as such toxins that are held, transferred and/or supplied by the biobank.

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2.2.7 Chain of custody

Responsibility for or control of materials and associated data as they move through each step of a process.

2.2.8 Competence

Ability to apply knowledge, experience, and skills to achieve intended results.

2.2.9 Critical

Having a potential impact on the fitness for the intended purpose of biological material and/or associated data

2.2.10 Donor

Organic entity such as a human, animal, plant, microorganisms, etc. from which the biological material and/or associated data is collected for biobanking.

2.2.11 Preparation

Activities, taking place in a laboratory after acquisitioning, to make biological material ready for further use in the life cycle, storage or distribution.

2.2.12 Recipient

Person or entity to whom/which the biological material and/or associated data is distributed. It can refer to the person hosting the biological material or person in charge of chain of custody.

2.2.13 Unique identifier

Code that is associated with a single entity within a given system.

2.2.14 Technical area

This is an area characterized by similar activities, products or services and the related environmental aspects.

2.2.15 Shipment:

The process of moving or distributing biological material from one location to another either locally or internationally using any available means of transport.

2.2.16 Interoperability

The ability of two or more systems to exchange information and use information once its received.

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3 Criteria

3.1 General Requirements

3.1.1 All KENAS assessments are done in accordance with ISO 20387 and the relevant KENAS policies and procedures. KENAS documents are available on the KENAS Website (https://www.kenas.go.ke/). For entities handling human materials procured and used for diagnostic and treatment purposes ISO 15189 and other clinical standards shall apply first and foremost.

3.1.2 The CAB is responsible to define the scope of biobanking and to have a criteria with respect to samples to be retained.

3.1.3 Personnel

3.1.3.1 The person who oversees the biobank services shall be identified and shall possess the following minimum qualifications:

a) A Diploma in Biological sciences or other relevant fields.
b) Shall have a minimum of 3 years' experience working in a Biobank.
c) Shall have completed a certification course in Biobanking e.g. ISBER Biobanking courses

3.1.4 Biobank establishments and environmental conditions

3.1.4.1 Biobank establishments shall be managed according to the documented Institutional Biosafety guidelines and applicable regulations depending on the containment levels.

3.1.4.2 The Biobank shall:

a) Determine, control, and maintain facilities under conditions required for conformity to the documented institutional guidelines and applicable regulations. The biobank staff shall monitor, control, and record the environmental conditions in accordance with the relevant specifications, methods and procedures.
b) Develop and maintain protocols/procedures for biosafety and security of biological material and data.
c) Facilities and dedicated areas shall be suitable for biobanking and not affect the intended purpose.
d) There shall be effective separation between biobanking areas and incompatible activities. There shall be measures taken to control access and avoid cross-contamination.
e) The biobank shall have a documented contingency plan to ensure that required environmental conditions are maintained. The contingency plan should consider the identified risks including relevant safety measures to be applied to mitigate against the identified risks.

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f) The biobank shall report all accidents to the institutional biosafety committee with details of the circumstances, location of the accident, quantities of material involved in the accident and any information necessary to assess the effects of the accident on human beings, animals and the environment.
g) The biobank shall adhere to all the ethical considerations when handling samples.

3.1.5 Equipment and Software

3.1.5.1 Access to Biobank equipment shall be controlled to authorised users.

3.1.5.2 The biobank shall establish, document, and implement procedures for all equipment including:

a) Controlled implementation (Equipment selection, validation/verification, installation, and setup, Standard Operating Procedures, and user training).
b) Safe Handling.
c) Safe Storage.
d) Planned maintenance.
e) Calibration.
f) Safe Disposal.

3.1.5.3 The biobank shall categorise equipment (including backup equipment) with potential to impact quality of biological material to categorise equipment critical for biobanking.

3.1.5.4 The biobank shall maintain an equipment list detailing.

a) Categorization (Storage equipment, processing, analysis, safety, monitoring, labelling, and tracking).
b) Performance as per manufacturers specifications.
c) Maintenance.
d) Verification / validation.

3.1.5.5 The biobank shall verify on installation and before use that equipment can achieve necessary performance and complies with relevant requirements and be capable of achieving the accuracy required and support compliance with required processes.

3.1.5.6 The biobank shall retain documentation for all equipment including:

a) Equipment and software identity
b) Manufacturers name, identification, serial number, and unique identification
c) Check that the equipment complies with specifications.
d) Current location where appropriate

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e) Manufacturer's 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

3.1.5.7 The biobank shall (where applicable) maintain metrological traceability of its measurement results.

3.1.5.8 Equipment shall be taken out of service to prevent use if it:

a) Generates compromised outputs/results.
b) Is defective or outside specification limits.
c) Poses a safety hazard to laboratory personnel or the surrounding environment.
d) Not maintained and calibrated as per the schedules.

3.1.5.9 The equipment shall be isolated and clearly labelled until repaired and proven through calibration/testing to perform correctly.

3.2 Process Requirements

3.2.1 General

3.2.1.1 The life cycle stages of biological material and associated data shall:

a) Identify defined and verified processes.
b) Describe workflow stages with detailed procedures for each process (collection, accession, identification, preservation, storage, quality control, transport, disposal).
c) Document procedures implemented and specific to biological material and associated data.
d) Identify and document all critical activities in each procedure.

3.2.1.2 The management shall ensure all procedures and processes are kept up to date and readily available to personnel.

3.2.2 Collection of biological material and associated data

3.2.2.1 Where the biobank collects biological material:

a) It shall define & document information related to the collection.
b) Shall include the date, time, place & procedure of collection and other relevant information.
c) Collect data within the specifications of local, national, international regulations (i.e. ethical standards/ material transfer agreements) e.g. NBA regulations and Nagoya Protocol.

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3.2.2.2 Where the biobank acquires biological material (where the biobank is not responsible for sample collection):

a) It should define the required information.
b) It should retain appropriate documentation related to the collection procedure.

3.2.2.3 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.

3.2.2.4 The collection procedure shall be defined either by the biobank/recipient or user according to the intended use of the biological material, proven techniques or standards.

3.2.2.5 Where relevant pre-analytical workflows should be implemented according to ISO requirements e.g. ISO 15189, ISO/IEC 17025.

3.2.2.6 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 and the collection shall never affect patient care & diagnosis.

3.2.2.7 Collection of Human biological material shall be performed in accordance with relevant ethical requirements (This includes ethical approvals or donor consent waiver)

3.2.3 Reception and distribution of biological material and associated data

3.2.3.1 The principles aligned to approved Biosafety & Biosecurity guidelines, governing access to and distribution of biological material and associated data shall be defined, documented and where required published. The biobank shall also ensure documented requirements with interested parties comply with these principles.

3.2.3.2 Biobanks shall establish, document and implement procedures for receiving or acquiring biological material and associated data including labelling requirements as applicable.

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3.2.3.3 The biobank shall define acceptance criteria for biological material and associated data including biosafety, biosecurity and intellectual property rights. Identification of biological material and associated data shall be verified on acquisition (reception) according to defined acceptance criteria.

Optimal sample handling and transport conditions shall be adhered to e.g. temperature and time of despatch and delivery to the recipient.

3.2.4 Reception and distribution of biological material and associated data

3.2.4.1 Where applicable the biobank shall authenticate the biological material according to relevant international standards. (Cartagena and Nagoya protocols)

3.2.4.2 All biological material and associated data acquired by a biobank (individually or part of a collection) shall be segregated from final storage until the legal, ethical documentation and quality compliance have been assessed and managed by Biobanking establishment.

3.2.4.3 The biobank should obtain relevant documented information needed to assess fitness for the intended purpose of the acquired biological material.

3.2.4.4 Where the biobank has not been responsible for collection/sampling this shall be documented.

3.2.4.5 Distribution and exchange of biological material and associated data shall be in accordance with the biobank's access to information principles, reporting specifications and other relevant requirements (including material/data transfer agreements) as guided by Nagoya and Cartagena protocols.

3.2.4.6 The 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.

3.2.4.7 The biobank shall establish, document and implement procedures for the preparation and distribution of biological material and associated data. Biobank needs to fulfil conditions of documented agreement.

3.2.4.8 When distributing biological material and associated data to the recipient/user predefined information shall be provided (unless by agreement).

3.2.5 Shipment of biological material and associated data

3.2.5.1 Biobank shall establish, document and implement procedures for shipping and receiving biological material including conditions for the maintenance of biological material integrity.

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3.2.5.2 The biobank shall maintain chain of custody for all biological material from point of dispatch to point of receipt. When shipping can alter the quality, biological material shall be tracked and monitored for elements pertinent to integrity including duration, temperature, humidity and light. The chain of custody shall detail any deviations from specified parameters. See 3.2.1.1

3.2.5.3 Transboundary movement transit handling and use of all living modified organisms form one country to another should be in strict adherence to Nagoya and Cartagena protocols. The biobank shall have an import certificate issued by the National Biosafety Authority.

3.2.5.4 The biobank shall have procedures for safe:

a) Handling
b) Packaging
c) Shipment/transfer
d) Reception

3.2.5.5 The biological material should not be left unattended - unless in designated custody zones.

3.2.5.6 Preparation of biological material for shipment shall be undertaken under the supervision of the biobank specialist with IATA training for shipment.

3.2.5.7 Prior to the transfer of biological material, the requirements for use (see 4.2.4.6) shall be fulfilled and arrangements put in place for biological material distribution and reception with relevant parties.

3.2.5.8 The biobank shall establish & document procedures 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.

3.2.6 Traceability of biological material and associated data

3.2.6.1 Biobank shall ensure traceability of biological material and associated data over the lifecycle including collection, acquisition, reception distribution and disposal/destruction. It is important to note that the:

a) Biological material shall be uniquely identified / tagged so identification 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 approved ethics, permissions/ restrictions for use.
c) Inventory system shall allow for annotation and query of any relevant information associated with handling procedures including - collection,

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packaging, transportation, preparation, preservation, storing and distribution. The 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.

3.2.6.2 The biobanking information shall be accessible only to authorised persons.

3.2.6.3 The 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 result of an emergency.

3.2.7 Preparation and preservation of biological material

3.2.7.1 Biobank method(s) of preparation and / or preservation shall be defined according to

a) Evidence-based documented processes (international standards) and existing national regulations.
b) As agreed with provider/recipient/user.

3.2.7.2 Critical activities in preparation / preservation shall be monitored and relevant parameters documented. Each preservation step shall be individually documented.

3.2.7.3 The date of preparation/preservation steps shall be documented in a standard format. The time for each step should be documented in a standard format.

3.2.8 Storage of Biological Material

3.2.8.1 Biobanks shall document the nature and quantities of stored biological specimens and the purpose of storage.

3.2.8.2 Implement access control measures to restrict access to the biobank facility and sample storage areas as per institutional biosafety guidelines.

3.2.8.3 Establish quality assurance/quality control procedures to monitor sample integrity and ensure compliance with applicable quality standards.

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3.2.8.4 The biobank shall establish a contingency disaster protection plan to include alternative methods of safeguarding to avoid risk of loss of biological material and loss of containment leading to unintended exposure as stipulated by Biosafety regulations.

3.2.8.5 The biobank shall have a documented procedure in place for the storage and tracking of biological material including:

a) Tagging information containing unique identifiers of biological material.
b) Type of container and environmental conditions for biological material storage.
c) Mechanism for traceability.
d) Short-term backup plan for maintaining accurate storage conditions/temperatures in case of emergency challenges in maintaining defined storage conditions.

3.2.8.6 Critical activities during storage shall be measured, monitored and documented. The date & time of critical activities and when the personnel access the biological material shall be documented as well.

3.2.8.7 The biobank personnel shall document and verify the storage location of all biological material and associated data.

3.2.8.8 The biobank storage locations and processes shall be designed to minimise the risk of contamination and to ensure the maintenance of biological material integrity.

3.2.8.9 Biobank storage conditions shall comply with facility requirements and environmental conditions.

3.2.8.10 Biobank shall verify the biological material inventory at planned intervals by a defined procedure.

3.2.8.11 The biobank shall establish, document and implement procedures supporting the patient/donor's right to withdraw consent for storage and use of biological material and associated data.

3.2.8.12 The biobank shall establish a biosecurity protection plan to prevent risks associated with biological materials". Biobank shall establish, document and implement QC procedures throughout the biobank process.

3.2.8.13 The QC activities shall be performed at planned intervals. Personnel shall retain documented information on QC activities and results.

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3.2.8.14 QC data shall be analysed. If defined QC criteria are not met - actions shall be taken to control the reporting of invalid data and /or distribution of non-compliant biological material and associated data.

3.2.8.15 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.

3.2.8.16 The qualified personnel shall ensure information on QC results is provided to the user as specified by documented requirements.

3.2.8.17 Biobank shall use approaches to provide objective evidence to demonstrate comparability of biological material quality (processing or testing output). This could include: EQA programs, proficiency testing programs and Interlaboratory comparisons Individual laboratory approaches including:

a) Reference material
b) EQA samples
c) Control materials that are tested regularly in EQA programs.

3.2.8.18 For interlaboratory comparison programs - the biobank shall monitor the results of the program. Where criteria are not met the biobank shall perform and document corrective actions.

3.2.8.19 The personnel shall identify critical data and establish, document, and implement QC procedures applying to these critical data.

3.2.8.20 Biobank shall define the type and frequency of QC performed. The QC shall focus on the accuracy, completeness, and consistency of data.

3.2.9 Validation and Verification of Methods

3.2.9.1 The personnel shall use validated/verified methods for biobanking activities at all stages of the biological material life cycle.

3.2.9.2 When the biobank provides/applies methods for biobanking activities, biobanks shall ensure that their methods have been validated to ensure that they are fit for purpose. Where biobanks perform validation and verification of the methods it shall document and retain results obtained, details of and a fit-for-purpose statement of the procedure used.

3.2.9.3 Validation shall be as extensive as necessary and confirmed through objective evidence that specific requirements for intended use have been fulfilled.

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3.2.9.4 When changes are made to validated methods, the impact of the changes shall be documented, and a new validation carried out when required.

3.2.9.5 Validated methods used without modification shall be subject to verification by the biobank before use by qualified personnel of the biobank the biobank before use.

3.2.9.6 Biobank verification shall be confirmed through objective evidence that method set criteria have been met.

3.2.9.7 The personnel shall document the procedure used for verification and the results obtained.

3.2.10 Management of Information and Data

3.2.10.1 Develop policies and procedures for data governance, including data ownership, access rights, and data sharing agreements.

3.2.10.2 Biobanks shall ensure compliance with relevant local, national, international regulations on access to data and data management.

3.2.10.3 Biobanks shall reasonably support interoperability of information and data.

3.2.10.4 Biobanks shall have in place a procedure for the implementation, modification and use of the computer system, software, hardware, and database in place. The procedure shall include data integrity, security control and backup systems to prevent loss or corruption of data.

3.2.10.5 The biobank shall have access to the data and information needed to provide a service specified by contractual arrangements.

3.2.10.6 The biobank should provide interested parties with access to a catalogue of available material and associated data as per data management, privacy and sharing guidelines.

3.2.10.7 The biobank shall control access to data associated with the biological material as necessary in compliance with guidelines in 3.2.11.5.

3.2.11 Nonconforming output

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

3.2.11.2 The biobanks shall ensure that output that does not conform to requirements is identified and controlled to prevent unintended use/supply.

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3.2.11.3 The biobank shall implement procedures to disclose information about nonconforming output to relevant parties. Recipient/users shall determine fitness for the intended purpose of the biological material.

3.2.11.4 Biobank shall take appropriate corrective action based on the nonconforming output and its effect on fitness for purpose/use.

3.2.11.5 Procedure 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 the nonconforming output.
d) action(s) to be taken for nonconforming output Communication of nonconforming output and authorization for acceptance by recipient/user.

3.2.11.6 Procedures for nonconforming output shall also apply to biological material and associated data collected.

3.2.11.7 Biobanks shall mitigate impacts on nonconformity, implement corrective actions in proportion to the risk presented by nonconforming output and prevent recurrence.

3.2.11.8 Biobank shall retain documentation regarding non-conformance.

3.2.11.9 The decision on recall shall be taken in a timely manner to limit the use of nonconforming output.

3.2.12 Report requirements.

3.2.12.1 Biobank shall provide a report that shall include the required information as agreed on in the documented agreement with the recipient/user. Reports can be called certificates.

3.2.12.2 Report may be issued as hard copy or by electronic data transfer or by an electronic data entry in an accessible database.

3.2.12.3 Biobank should include statement specifying that report should not be reproduced except in full.

3.2.12.4 Each report shall include (unless a valid reason not to)

a) Title
b) Name & address of biobank - and location where activities in the report were carried out if different.
c) Date of report issue

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d) Unique identification of report with identification on each page to ensure that each page is recognised as part of the 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) Methods for testing
i) Testing results with units of measurement
j) Methods for collection/acquisition/preparation/preservation
k) Storage conditions Name(s) & function of the person authorising the report.

3.2.12.5 The biobank shall be responsible for all information provided in report - except when information is provided by the provider/recipient/user. Where the biobank is not responsible for the collection, the report shall state that it relates to biological material as received by the biobank.

3.2.13 Complaints

3.2.13.1 The personnel shall establish, document, and implement procedures to receive, evaluate and make decisions on complaints.

3.2.13.2 A description of the process for handling of complaints shall be made available upon request including timelines.

3.2.13.3 Complaint handling process shall include:

a) Description of process for receiving, accepting, investigation complaint and deciding what responsive action is required.
b) Tracking and recording complaints - including resolving actions
c) Ensuring appropriate action is taken.

3.2.13.4 The biobank receiving the complaint shall be responsible for verifying all information necessary to accept a complaint. The biobank shall acknowledge receipt of a complaint.

3.2.13.5 The biobank shall provide the complainant with a progress report where possible.

3.2.13.6 The impartial review shall be performed for each complaint and the outcome of the review shall be communicated to the relevant parties.

3.2.13.7 Biobank shall give formal notice of end of complaint handling to complainant where possible.

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3.3 Management System Requirements

3.3.1 Options

3.3.1.1 General

Management system. supports and demonstrates the consistent achievement of the requirements of the Standard, assures the quality of the biobank results, and is in accordance with either Option A or Option B.

3.3.2 Option A: Documented information for the quality management system

3.3.2.1 The 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.

3.3.2.2 The policies and objectives are established, and documented for the fulfilment of the standard are acknowledged and implemented at all levels of the biobank.

3.3.2.3 Competence, impartiality, and consistent operations shall be addressed by policies and objectives.

3.3.2.4 The biobank management shall provide evidence of commitment to the development and implementation of the quality management system and continually improve the quality management system's effectiveness.

3.3.2.5 All documentation, processes, systems, and records related to the fulfilment of the requirements of this document shall be included (or referenced) in the quality management system.

3.3.2.6 Access to parts of the management shall be made available to all personnel.

3.3.3 Option A: Control of management system documents

3.3.3.1 Control of documents both internal and external documents relating to the fulfilment of the requirements of the Standard.

3.3.3.2 Document control process:

a) Documents shall be approved by authorised personnel prior to issue.
b) Documents shall be periodically reviewed and updated as necessary.
c) Changes and current revision status of documents shall be identified.
d) Relevant versions of documents are available, and their distribution shall be controlled as necessary.

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e) Documents shall be uniquely identified.
f) Unintended use of obsolete documents shall be prevented, and they need to be clearly identified as obsolete if retained.

3.3.4 Option A: Improvement

3.3.4.1 The biobank shall identify opportunities for improvement and any necessary action to be implemented.

3.3.4.2 Customer feedback both positive and negative shall be sought, analysed and used to improve the management system, biobank activities and customer service.

3.3.5 Option A: Corrective Action

3.3.5.1 When nonconformities 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 and make any necessary changes to the management system.

3.3.5.2 Records shall be retained of the nature of the nonconformity, cause(s) and any action(s) taken and of the outcome of the corrective action.

3.3.6 Option A: Internal Audits

3.3.6.1 Conduct regular internal audits of biobank operations to assess compliance with regulatory requirements, quality standards, and best practices. Biobank Audit Requirements;

a) Are 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.

3.3.6.2 The management shall ensure that internal audits are conducted at planned intervals to establish whether the management system conforms to the biobank's requirements, including biobank activities and that the requirement of the standard is effectively implemented and maintained.

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3.3.7 Option A: Quality Management Reviews

3.3.7.1 A review of the management system shall be conducted at planned intervals by management to ensure the continued suitability, adequacy and effectiveness and covers the stated policies and objectives related to the fulfilment of the Standard.

3.3.7.2 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.

3.3.7.3 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
d) Any need for change(s)

3.4 Use of KENAS accreditation symbol on examination reports

The rules for the use of the KENAS symbol are set in the *PL-54 Policy on the Use of KENAS Marks, Combined Marks and Reference to Accredited Status*.

4 Associated Documents

Ref	Document Identifier	Document Title
1.	ISO 15189:2012	Medical laboratories- Requirements for quality and competence
2.	ISO 15190:2003	Medical Laboratories- Requirements for Safety

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Ref	Document Identifier	Document Title
3.	N/A	Nagoya and Cartagena Protocol
4.	ISO 9001:2015	Quality Management Systems Requirements
5.	ISO 20387	Biotechnology — Biobanking — General requirements for biobanking

5 Revision/Amendment Records

Date	Version	Revised by	Reason for Revision
24/10/2024	01	SDE	Newly developed document

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Annex 1: Contingency Disaster Plan for Biobanking

It is important to incorporate a contingency disaster plan into the criteria for the accreditation of bio-banking laboratories in order to ensure the integrity, safety, and continuity of biological samples stored within the facilities. The key aspects to consider in the contingency disaster plan include:

i) Conduct a thorough risk assessment to identify potential hazards and disasters that could affect the bio-banking laboratory and its stored samples. This may include natural disasters (e.g. earthquakes, floods), technical failures (e.g. power outage, equipment malfunction), human errors, and security breaches.

ii) Establish an emergency response team that will be responsible for overseeing disaster preparedness and response efforts. This team should include designated individuals with clear roles and responsibilities during emergencies.

iii) Develop and implement an inclusive communication protocol to ensure effective communication during emergencies. This includes establishing primary and alternate communication channels (e.g. communication apps) and maintaining contact information for key stakeholders.

iv) Define evacuation routes and shelter-in-place procedures specific to the bio-banking laboratory. Conduct regular drills to familiarize staff with these procedures and ensure their readiness in case of an emergency.

v) Implement measures to protect biological samples from potential hazards. This may include redundant storage systems (e.g. backup freezers, cryogenic tanks, backup biobank institutions), off-site storage options, and contingency plans for transferring samples to alternative facilities if necessary.

vi) Establish protocols for regular data backup of sample information and research data. Ensure that backup systems are geographically separated from the primary location to mitigate risks of data loss due to disasters.

vii) Ensure availability of emergency power sources (e.g. generators, uninterruptible power supply systems) to maintain critical operations during power outages. Regularly test and maintain these systems to ensure their reliability.

viii) Implement stringent security measures to prevent unauthorized access to biological samples and laboratory facilities during emergencies. This may include restricted access protocols, surveillance systems, and emergency response procedures for security incidents.

ix) Conduct regular training sessions and awareness programs for laboratory staff on disaster preparedness and response procedures. Ensure that all personnel are familiar with their roles and responsibilities in various emergency scenarios.

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x) Maintain comprehensive documentation of all contingency plans, procedures, and incident reports. Review and update these documents regularly to reflect changes in facility operations, technology, and regulatory requirements.

xi) Establish partnerships and communication channels with local emergency response agencies, regulatory bodies, and other relevant stakeholders. Collaborate on mutual aid agreements and disaster response protocols to facilitate coordinated efforts during emergencies.

xii) Establish regulation viability check for samples kept in the main facility and the respective backup.

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