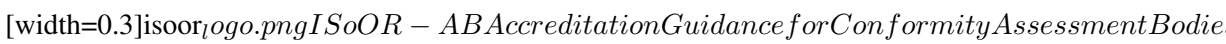

Based on the ISoOR-ISOB Standard

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Prepared by: ISoOR Accreditation Body (ISoOR-AB) Secretariat

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Document Control

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1.0	August 26, 2025	Initial release	ISoOR-AB Secretariat	ISoOR-AB Director

Contents

1 Introduction

1.1 Purpose of This Guidance Document

This document has been developed as a comprehensive guidance resource for Conformity Assessment Bodies (CABs) seeking accreditation from the International Society of Organoid Research Accreditation Body (ISoOR-AB) for the evaluation and certification of organoid biobanks in accordance with the ISoOR-ISOB Standard.

It aims to clearly outline the knowledge areas, operational competencies, technical and management system requirements, documentation expectations, and compliance obligations that applicant CABs must demonstrate to successfully complete the ISoOR-AB accreditation process.

By following this guidance, CABs will be able to:

- Understand the full scope and detailed requirements of the ISoOR-ISOB Standard.
- Prepare their internal systems, teams, and assessment methodologies to meet accreditation readiness.
- Implement quality management and ethical oversight measures to minimize the risk of nonconformities during ISoOR-AB assessments.
- Establish ongoing mechanisms for maintaining compliance and continuous improvement after accreditation.
- Facilitate clear communication and collaboration with ISoOR-AB assessors during all stages of evaluation.

This guidance also serves as a reference for internal training, competency development, and process standardization within CABs.

1.2 Scope and Applicability

This guidance is applicable to all Conformity Assessment Bodies intending to perform assessments of organoid biobanks, regardless of whether activities are conducted in research, clinical, or commercial settings.

While the primary reference is the ISoOR-ISOB Standard, CABs are expected to be familiar with and meet the relevant requirements of the following international standards, as applicable to their scope:

- ISO/IEC 17065 Requirements for certification bodies assessing products, processes, or services.
- ISO/IEC 17025 General requirements for the competence of testing and calibration laboratories.
- ISO 20387 General requirements for biobanking operations.
- ISO/IEC 17011 General requirements for accreditation bodies accrediting CABs, particularly concerning operational integrity and impartiality.

This guidance also addresses ethical, legal, biosafety, and biosecurity considerations, providing a framework for CABs to ensure responsible and compliant organoid biobank evaluations.

1.3 Intended Audience

The document is intended for a wide range of stakeholders, including:

- CAB managers and technical personnel preparing for ISoOR-AB accreditation.

- Quality managers responsible for ensuring ongoing compliance with accreditation and standard requirements.
- Assessment teams within CABs who will interact directly with ISoOR-AB evaluators.
- Decision-makers, policy developers, and stakeholders in organoid research and biobanking seeking clarity on accreditation expectations and procedures.
- Training coordinators responsible for assessor competency development and continuous professional development programs.

1.4 Structure of This Document

The document provides a step-by-step roadmap for CABs, covering:

1. An overview of ISoOR-AB and the ISoOR-ISOB Standard.
2. Detailed guidance on the accreditation application, evaluation, and decision-making processes.
3. Requirements for technical, management system, ethical, and biosafety compliance.
4. Post-accreditation obligations, surveillance, and continuous improvement mechanisms.
5. Practical appendices containing checklists, templates, reference standards, and illustrative examples to assist CABs in preparation, internal auditing, and training.

2 Overview of ISoOR-AB and the ISoOR-ISOB Standard

2.1 About ISoOR-AB

The International Society of Organoid Research Accreditation Body (ISoOR-AB) is the dedicated accreditation arm of the International Society of Organoid Research (ISoOR). ISoOR-AB was established to provide independent, impartial, and internationally recognized accreditation for Conformity Assessment Bodies (CABs) involved in evaluating organoid biobanks.

ISoOR-AB operates in full compliance with ISO/IEC 17011, which defines requirements for the competence, consistent operation, and impartiality of accreditation bodies. ISoOR-ABs mandate is not to perform testing, inspection, or certification itself; rather, it assesses and formally recognizes CABs that are competent to carry out these activities according to defined standards.

Key functions of ISoOR-AB include:

- Developing and maintaining accreditation criteria specific to organoid biobanking, aligned with the ISoOR-ISOB Standard.
- Assessing CABs to determine their technical competence, management system compliance, and adherence to ethical and biosafety standards.
- Granting, maintaining, suspending, or withdrawing accreditation based on documented performance and compliance.
- Conducting ongoing monitoring and surveillance of accredited CABs to maintain stakeholder confidence in the accreditation process.
- Supporting continuous improvement and alignment with international best practices in organoid biobanking assessment.

ISoOR-AB emphasizes transparency, consistency, and impartiality in all its operations, ensuring that CABs meet the highest standards of quality and ethical responsibility.

2.2 About the ISoOR-ISOB Standard

The ISoOR-ISOB Standard (International Standard for Organoid Biobanking) is a sector-specific framework developed by ISoOR to define requirements, best practices, and quality benchmarks for organoid biobank operations and evaluations.

This standard draws upon internationally recognized references, including:

- ISO 20387 General requirements for biobanking.
- ISO/IEC 17025 General requirements for the competence of testing and calibration laboratories.
- ISO/IEC 17065 Requirements for bodies certifying products, processes, and services.
- ISoORs ethical guidelines and organoid-specific operational protocols.

The ISoOR-ISOB Standard addresses both technical and management system requirements, ensuring that organoid biobanks:

- Maintain the integrity, traceability, and quality of biological materials.
- Implement robust quality management systems for operational consistency.
- Comply with ethical, legal, and biosafety standards, including donor consent and data protection.
- Provide reliable and reproducible data to support research, clinical, and industrial applications.

By adopting this standard, CABs can ensure that their evaluations reflect both scientific rigor and ethical responsibility, providing confidence to stakeholders across research, healthcare, and industry sectors.

2.3 The Role of ISoOR-AB in the Accreditation Ecosystem

Within the global accreditation landscape, ISoOR-AB serves as a specialized accreditation body for the organoid biobanking sector. Unlike national accreditation bodies (e.g., CNAS, NATA, UKAS), which may provide general biobanking accreditation, ISoOR-AB focuses on the niche, rapidly evolving field of organoid biobanks, where specialized technical knowledge and ethical considerations are critical.

ISoOR-AB works to ensure that:

- CABs demonstrate full technical competence and operational capability in assessing organoid biobanks against the ISoOR-ISOB Standard.
- Assessment practices are consistent, transparent, and aligned with international norms.
- Stakeholders, including researchers, clinicians, and industry partners, have confidence in the objectivity and reliability of accredited CABs.

By integrating the ISoOR-ISOB Standard into its accreditation processes, ISoOR-AB ensures that accredited CABs can demonstrate compliance with technical, managerial, and ethical requirements, reinforcing public trust and supporting the responsible advancement of organoid research.

3 Accreditation Process Overview

The ISoOR-AB accreditation process is designed to ensure that only competent, impartial, and well-governed Conformity Assessment Bodies (CABs) are authorized to evaluate organoid biobanks in accordance with the ISoOR-ISOB Standard. The process follows the ISO/IEC 17011 framework and incorporates organoid-specific assessment methodologies developed by ISoOR, ensuring that evaluations are rigorous, transparent, and reproducible.

The process is structured into five main stages, each designed to verify different aspects of CAB competence, management system integrity, ethical compliance, and operational capability.

3.1 Application Stage

CABs seeking ISoOR-AB accreditation must submit a formal application, including a completed Accreditation Application Form and all supporting documentation. The application must demonstrate the CABs readiness to meet ISoOR-ISOB and ISO/IEC requirements.

Required information and documentation include:

- Legal and organizational details (e.g., official name, legal entity status, governance structure).
- Scope of accreditation requested, clearly specifying the types of organoid biobanks to be evaluated.
- Quality Management System (QMS) documentation, including manuals, policies, procedures, and records of previous assessments if applicable.
- Evidence of technical competence, such as assessor qualifications, sector-specific training, and relevant experience.
- Ethical compliance documentation demonstrating adherence to ISoORs Code of Ethics and other sector-specific ethical guidelines.

Key expectations:

- CABs must demonstrate impartiality and independence, avoiding conflicts of interest that could arise from operating as both an accreditation body and a CAB within related scopes.
- Applicants should self-assess readiness to ensure that documentation, systems, and personnel meet ISoOR-AB requirements before submission.

3.2 Document Review Stage

Once the application is accepted, ISoOR-AB conducts a desk review to verify the completeness, accuracy, and alignment of the submitted documentation with accreditation requirements.

Review focus includes:

- QMS alignment with applicable standards, including ISO/IEC 17025, 17020, 17065, and ISoOR-ISOB provisions.
- Adequacy of technical procedures to ensure CABs can evaluate organoid biobanks effectively.
- Evidence of compliance with ethical, biosafety, and biosecurity guidelines.

During this stage, ISoOR-AB may request clarifications, additional records, or supplementary documentation. Only after satisfactory review will the process proceed to the on-site evaluation stage.

3.3 On-Site Evaluation Stage

The on-site evaluation is the core of the accreditation process. A team of qualified ISoOR-AB assessors, with accreditation experience and sector-specific expertise, conducts a thorough review of CAB operations, personnel, and assessment practices.

Evaluation activities include:

- Opening meeting to confirm scope, objectives, and the schedule of evaluation activities.

- Observation of CAB assessment activities to verify assessor competence, adherence to procedures, and application of the ISoOR-ISOB Standard.
- Review of records and documentation, including QMS records, assessment reports, technical evidence, and corrective actions.
- Interviews with key personnel, covering technical knowledge, ethical understanding, biosafety awareness, and management system processes.
- Facility inspection to confirm that infrastructure, equipment, and biosafety measures meet the required standards.

At the end of the visit, the evaluation team conducts a closing meeting, presenting preliminary findings, highlighting any nonconformities, and identifying opportunities for improvement.

3.4 Accreditation Decision Stage

Following the on-site evaluation, the ISoOR-AB Accreditation Committee reviews all evidence and assessment reports to determine the accreditation outcome.

Possible decisions include:

- Granted: All requirements fully met.
- Granted with conditions: Minor nonconformities exist, with corrective actions to be completed within a defined timeframe.
- Deferred or Denied: Major nonconformities remain unresolved or the CAB fails to demonstrate compliance.

The decision-making process is independent from the assessment team, ensuring impartiality and objectivity. Formal notification is issued to the CAB along with a summary of findings and recommendations.

3.5 Surveillance and Reassessment Stage

Accreditation is not permanent. Accredited CABs are subject to ongoing surveillance and periodic full reassessment to maintain compliance and demonstrate continuous competence.

Surveillance activities include:

- Follow-up visits to verify the implementation of corrective actions.
- Review of changes in personnel, facilities, or operational processes.
- Sampling of recent assessments conducted by the CAB to ensure consistency and technical competence.
- Verification of continued compliance with ethical, biosafety, and quality management requirements.

Full reassessments are conducted at defined intervals (typically every four years) to ensure sustained alignment with ISoOR-ISOB and ISO/IEC standards. Failure to maintain compliance may result in suspension or withdrawal of accreditation.

4 Key Competency Requirements for CABs

For a Conformity Assessment Body (CAB) to achieve and maintain ISoOR-AB accreditation for the evaluation of organoid biobanks, it must demonstrate technical competence, organizational integrity, and adherence to ethical, legal, and biosafety standards. These competencies are drawn from ISO/IEC

17025, 17020, 17065, 17011, and the ISoOR-ISOB Standard. CABs are expected to maintain these competencies continuously and to provide verifiable evidence during assessments.

4.1 Technical Knowledge and Expertise

CAB personnel must possess the sector-specific knowledge required to evaluate organoid biobanks effectively. Key areas include:

- Understanding of organoid biology and biobanking:
  - Cell culture techniques, organoid generation, long-term storage, cryopreservation, and recovery methods.
  - Quality control procedures, including genetic fidelity, contamination checks, and viability assessments.
- Familiarity with ISoOR-ISOB criteria:
  - How technical, operational, ethical, and biosafety requirements apply to biobank practices.
- Awareness of international standards, regulations, and guidelines:
  - WHO biosafety guidelines, OECD best practices for biobanking, national regulations, and ethical frameworks.
- Practical experience:
  - Personnel conducting assessments must have demonstrated experience in laboratory operations, quality systems, and auditing or inspection methodologies.

Example: An assessor should be able to identify deviations in cryopreservation protocols that could compromise organoid viability or genetic integrity.

4.2 Ethical and Regulatory Compliance Competence

CABs must ensure that all assessors understand and apply ethical and legal principles, including:

- ISoOR Code of Ethics and organoid-specific research ethics.
- Informed consent procedures relevant to donors and contributors.
- Data protection and privacy regulations, particularly for genomic and personal health information.
- Prohibition of unethical practices, including misuse of human-animal chimeras, unauthorized commercialization, or misrepresentation of biobank capabilities.

Importance: Ethical competency is critical to maintain public trust and ensure global credibility of ISoOR-AB-accredited CABs.

4.3 Biosafety and Biosecurity Proficiency

CAB assessors must demonstrate competence in managing biological risks, including:

- Biosafety level classifications (BSL-1, BSL-2, BSL-3) and their facility requirements.
- Risk assessment and mitigation: managing pathogens, cross-contamination, and sample integrity.
- Biosecurity measures: preventing unauthorized access, theft, or misuse of biological materials.
- Evaluation capabilities: assessors must be able to review facilities, procedures, and staff training for biosafety compliance.

Example: Detecting improper storage of human-derived organoids in a laboratory not compliant with BSL-2 requirements.

4.4 Assessment and Audit Skills

CABs must demonstrate that personnel are trained and experienced in assessment methodologies:

- Planning and conducting assessments aligned with ISO/IEC 17011 principles.
- Sampling techniques to examine representative operations within a biobank.
- Interviewing and evidence-gathering skills, ensuring accurate information collection without introducing bias.
- Report preparation: producing clear, objective, actionable documentation of compliance and nonconformities.

Example: Writing a report that clearly distinguishes between minor procedural deviations and critical nonconformities affecting organoid quality.

4.5 Impartiality and Conflict of Interest Management

CABs must demonstrate independence and transparency, including:

- Prohibiting assessors from evaluating facilities in which they have prior involvement.
- Separating CAB activities from unrelated commercial services to avoid conflicts of interest.
- Documenting conflict-of-interest management procedures in line with ISO/IEC 17011 impartiality requirements.

Example: An assessor who previously provided consulting to a biobank cannot participate in its accreditation evaluation.

4.6 Continuous Professional Development (CPD)

Competence must be maintained and updated through structured CPD programs:

- Periodic training on updates to ISoOR-ISOB standards, ISO requirements, and international guidelines.
- Refresher courses on ethics, biosafety, and quality management systems.
- Participation in scientific and technical conferences, workshops, or webinars relevant to organoid research and biobanking.
- Documentation of CPD activities for all personnel involved in assessments.

Example: An assessor attends a workshop on emerging organoid cryopreservation technologies and incorporates the knowledge into subsequent biobank evaluations.

5 Documentation and Record-Keeping Requirements

For a CAB to achieve and maintain ISoOR-AB accreditation for the evaluation of organoid biobanks, comprehensive documentation and accurate record-keeping are essential. Proper documentation ensures transparency, traceability, and compliance with ISO/IEC 17011, relevant conformity assessment standards, and the ISoOR-ISOB Standard. All records must be current, controlled, and readily available for review during both initial accreditation and surveillance assessments.

5.1 Quality Management System (QMS) Documentation

CABs must maintain a robust Quality Management System that demonstrates governance, control, and continual improvement:

- Quality Manual describing the CABs scope, policies, quality objectives, and alignment with ISoOR-ISOB requirements.
- Organizational Structure detailing roles, responsibilities, reporting lines, and decision-making authority for accreditation-related activities.
- Document Control Procedures ensuring all documents are reviewed, approved, updated, version-controlled, and archived.
- Internal Audit Program with schedules, audit reports, findings, corrective actions, and follow-up documentation.
- Management Review Records demonstrating that leadership evaluates the effectiveness of the QMS and implements improvements.

Example: Documented evidence that leadership reviews nonconformities identified during audits and assigns corrective actions with deadlines.

5.2 Technical Records

Technical records must be complete, accurate, and traceable to specific assessments:

- Assessment Plans and Schedules detailing scope, timelines, assigned assessors, and facility locations.
- Checklists and Criteria Matrices structured to ensure consistent evaluation against ISoOR-ISOB requirements.
- Evidence Logs recording all samples, observations, and documents reviewed during the assessment.
- Assessment Reports signed and dated by lead assessors, providing clear findings, justification, and recommendations.

Example: A checklist showing BSL compliance, donor consent verification, and sample traceability for each organoid batch assessed.

5.3 Personnel Records

CABs must maintain up-to-date records for all personnel involved in assessment activities:

- Curricula Vitae (CVs) highlighting qualifications, certifications, training, and relevant work experience.
- Training Records documenting initial training, competency evaluations, and ongoing professional development.
- Conflict of Interest Declarations updated annually or before new assignments, signed by all personnel.
- Performance Evaluations periodic reviews of assessor competency, technical performance, and professionalism.

Example: Evidence that an assessor completed annual biosafety training and was evaluated for adherence to impartiality policies.

5.4 Ethical Compliance Records

To ensure conformity with ISoOR ethical standards, CABs must maintain:

- Signed Code of Ethics Acknowledgments for all assessors and technical staff.
- Records of Ethical Training including informed consent, donor rights, data protection, and responsible use of organoid materials.
- Incident Reports documenting any ethical or compliance issues identified during assessments, with corrective actions taken.

Example: A report detailing an instance where donor consent documentation was incomplete, and the corrective measures implemented.

5.5 Biosafety and Biosecurity Records

CABs must demonstrate that assessors are competent in biosafety and biosecurity practices:

- Biosafety Risk Assessments conducted for each facility and type of organoid material assessed.
- Training Logs proving assessors are current with biosafety and biosecurity procedures.
- Incident and Accident Logs recording any breaches or near-misses observed during assessments, with follow-up actions.

Example: Documentation showing a corrective action taken after observing improper storage of BSL-2 samples.

5.6 Record Retention and Security

CABs must implement strict policies for retention, confidentiality, and disaster recovery:

- Retention Period All accreditation-related records must be maintained for at least five years, or longer if required by local regulations.
- Confidentiality and Access Control Records must be securely stored with access limited to authorized personnel.
- Backup and Disaster Recovery Electronic and physical records must have reliable backup and recovery systems to prevent loss.

Example: Encrypted digital storage with routine backups and secure off-site archiving for sensitive assessment data.

6 Evaluation Process and Criteria

The ISoOR-AB evaluation process for accrediting Conformity Assessment Bodies (CABs) assessing organoid biobanks is designed to ensure competence, impartiality, and compliance with the ISoOR-ISOB Standard and relevant ISO/IEC standards. The process is structured, evidence-based, and transparent, allowing CABs to prepare thoroughly and understand expectations at each stage.

Evaluation consists of document review, on-site assessments, interviews, and witnessing of CAB-conducted assessments, with all findings documented. CABs are given opportunities to respond to nonconformities and provide corrective action evidence.

6.1 Application Review

Upon receipt of an accreditation application, ISoOR-AB will:

- Verify completeness of the application package and all supporting documentation.
- Confirm that the scope of services aligns with ISoOR-ISOB requirements for organoid biobank assessments.
- Check for potential conflicts of interest that could compromise impartiality.
- Communicate any deficiencies or clarifications required before proceeding to the next stage.

6.2 Preliminary Document Review

ISoOR-AB assessors perform a desk review to evaluate the CABs documentation against:

- ISoOR-ISOB Standard requirements.
- Relevant ISO/IEC standards (ISO/IEC 17020, ISO/IEC 17025, or ISO/IEC 17065, depending on the CABs scope).
- Applicable ethical, biosafety, and data protection regulations.

If documentation is incomplete or unclear, the CAB will be requested to submit additional information or corrective documentation before advancing to the on-site assessment stage.

6.3 On-Site Assessment

The on-site evaluation is the central stage of the accreditation process. Activities include:

- Opening Meeting to present objectives, scope, and schedule.
- Facility Inspection to verify that premises, equipment, and resources are suitable for conducting organoid biobank assessments.
- Interviews with assessors, technical staff, and management to evaluate competence, knowledge of ISoOR-ISOB requirements, and adherence to ethical and biosafety standards.
- Observation of Processes including how the CAB plans, conducts, and documents its own assessments.

The on-site assessment may be supplemented by documented observations of internal quality processes, including audits and management reviews.

6.4 Witness Assessments

Where necessary, ISoOR-AB may require witnessing of a CABs assessment activities at a client site. This allows evaluators to:

- Assess the application of assessment criteria in practice.
- Verify accuracy, consistency, and reliability of findings.
- Evaluate the CABs handling of ethical, biosafety, and security considerations during real-world operations.

Witness assessments provide critical evidence of the CABs operational competence.

6.5 Evaluation Criteria

CABs will be considered competent for accreditation if they demonstrate:

1. Full Compliance with ISoOR-ISOB and relevant ISO/IEC standards.
2. Technical Competence of assessors and technical experts, including training and experience.
3. Impartiality and Independence in all assessment activities, with clear conflict-of-interest management.
4. Robust Quality Management System, with effective internal audits, management reviews, and continual improvement processes.
5. Ethical and Biosafety Compliance, including transparency, protection of donor rights, and adherence to regulatory requirements.
6. Adequate Record-Keeping and Traceability for all assessment activities, enabling verification and accountability.

6.6 Nonconformities and Corrective Actions

- Minor Nonconformities require documented corrective action within a defined period (typically 60 days).
- Major Nonconformities necessitate immediate action; accreditation may be withheld until resolved.
- CABs must provide corrective action plans with evidence of implementation, which will be reviewed and verified by ISoOR-AB.

All nonconformities and responses are formally documented in the evaluation report.

6.7 Decision and Accreditation Granting

- The final accreditation decision is made by the ISoOR-AB Accreditation Decision Committee, which operates independently from the assessment team to ensure impartiality.
- If approved, the CAB will receive a formal Certificate of Accreditation, specifying:
  - Scope of accredited activities.
  - Validity period (typically three years).
  - Any conditions or limitations, if applicable.
- Accreditation status, including suspensions, extensions, or withdrawals, is maintained on the ISoOR-AB registry and communicated to relevant stakeholders.

7 Post-Accreditation Obligations

Achieving ISoOR-AB accreditation represents a commitment to ongoing excellence, competence, and ethical integrity. Accreditation is conditional on continuous compliance with the ISoOR-ISOB Standard, relevant ISO/IEC standards, and all applicable regulations. Failure to meet these obligations may result in suspension or withdrawal of accreditation.

7.1 Continuous Compliance

Accredited CABs must maintain all operational, technical, and ethical standards at all times, including:

- Keeping the Quality Management System (QMS) current, controlled, and reflective of actual practices.
- Ensuring the technical competence of assessors and support staff through ongoing training, skills development, and participation in professional activities.
- Maintaining impartiality and preventing conflicts of interest in all assessment activities.
- Regularly reviewing and updating assessment procedures to incorporate changes in standards, technology, or best practices.
- Monitoring compliance with ethical, biosafety, and data protection requirements on an ongoing basis.

7.2 Surveillance Assessments

ISoOR-AB conducts surveillance assessments at least annually to verify continued compliance. These assessments may include:

- Partial or focused document reviews.
- On-site inspections of facilities, equipment, and critical processes, particularly areas of prior nonconformities.
- Witnessing of assessment activities performed by the CAB.
- Verification of corrective actions implemented from previous findings.

Surveillance ensures CABs maintain consistent quality and competence throughout the accreditation period, beyond the initial evaluation.

7.3 Reporting Requirements

Accredited CABs must submit periodic reports to ISoOR-AB to maintain transparency and accountability. Reports may include:

- Changes in organizational structure, key personnel, or scope of activities.
- Records of internal audits, management reviews, and QMS updates.
- Summaries of client complaints, disputes, or adverse events and corrective actions taken.
- Updates to procedures, technical methods, or documentation relevant to the ISoOR-ISOB scope.

Failure to submit timely and accurate reports may trigger additional surveillance or suspension of accreditation.

7.4 Handling Changes in Scope or Capability

CABs must notify ISoOR-AB of any planned changes to scope or technical capabilities, including:

- Introduction of new assessment methods, technologies, or services related to organoid biobanks, which may require updated documentation and possible on-site evaluations.
- Reduction or loss of key capabilities, which must be reported within 10 working days.

Formal approval from ISoOR-AB is required before changes are reflected in the accredited scope.

7.5 Maintaining Impartiality and Transparency

CABs must ensure ongoing impartiality and transparency in all operations:

- Declare any relationships, partnerships, financial interests, or shared ownership that could compromise impartiality.
- Avoid situations that may create real or perceived conflicts of interest with assessed organizations.
- Ensure clients and stakeholders are informed of the CABs accreditation status and scope.

7.6 Renewal of Accreditation

Accreditation is typically valid for three years. CABs must undergo full reassessment prior to expiration to renew their status. Renewal assessments are:

- Comparable in scope and rigor to initial accreditation.
- Designed to ensure the CAB remains technically competent, impartial, and aligned with evolving standards and best practices.
- Required to update all QMS and technical documentation, reflecting any organizational or procedural changes since the last accreditation cycle.

8 Common Pitfalls and How to Avoid Them

To support Conformity Assessment Bodies (CABs) in successfully achieving and maintaining ISoOR-AB accreditation, it is essential to recognize frequent challenges observed during evaluations. Proactively addressing these pitfalls reduces nonconformities and ensures smooth initial and ongoing accreditation processes.

8.1 Incomplete or Outdated Documentation

Pitfall:

- Submitting documents that are outdated, uncontrolled, or inconsistent with current operations.
- Missing Standard Operating Procedures (SOPs), forms, or records required for ISoOR-ISOB compliance.

How to Avoid:

- Implement a document control system with version tracking, approval workflows, and scheduled reviews.
- Ensure all QMS documents, checklists, and policies reflect actual practices.
- Maintain a controlled document register for easy reference during audits.

8.2 Insufficient Technical Competence of Assessors

Pitfall:

- Assessors lacking adequate training in organoid biobanking or relevant assessment methods.
- Inadequate understanding of ISoOR-ISOB requirements, ISO/IEC standards, or ethical guidelines.

How to Avoid:

- Conduct formal training programs covering organoid science, ISoOR-ISOB standards, ISO/IEC requirements, and biosafety.
- Maintain detailed training records and CVs for all assessors.
- Schedule periodic refresher courses and competency evaluations.

8.3 Noncompliance with Impartiality Requirements

Pitfall:

- Conflicts of interest, such as assessors evaluating biobanks where they have prior involvement.
- Financial or organizational ties that could compromise objectivity.

How to Avoid:

- Develop and enforce a conflict of interest policy.
- Require annual declarations from all personnel.
- Ensure separation of evaluation functions from other services to maintain independence.

8.4 Weak Internal Audit and Corrective Action Processes

Pitfall:

- Internal audits are irregular, superficial, or fail to identify operational gaps.
- Corrective actions are not implemented, documented, or verified.

How to Avoid:

- Schedule and conduct regular internal audits across all operational areas.
- Document findings, assign responsibilities, and track corrective actions to closure.
- Review internal audit results in management reviews to ensure effectiveness and follow-up.

8.5 Ethical and Biosafety Oversights

Pitfall:

- Noncompliance with ISoOR ethical guidelines or biosafety standards.
- Missing informed consent records, improper handling of donor material, or inadequate risk assessments.

How to Avoid:

- Ensure all assessors are trained in ethical standards, biosafety, and biosecurity.
- Maintain complete records of consent forms, biosafety assessments, and incidents.
- Include ethical and biosafety checkpoints in assessment checklists.

8.6 Lack of Traceability and Record Management

Pitfall:

- Assessment evidence is incomplete, unorganized, or difficult to retrieve.
- Records of previous evaluations, corrective actions, or technical observations are missing.

How to Avoid:

- Implement a centralized record-keeping system, electronic or paper-based.
- Retain records for at least five years (or longer if required by regulation).
- Conduct periodic audits of record-keeping practices to ensure traceability and accessibility.

8.7 Failure to Address Changes in Scope or Operations

Pitfall:

- CAB introduces new services, technologies, or procedures without notifying ISoOR-AB.
- Key personnel changes or organizational restructuring are not reported.

How to Avoid:

- Establish a change management procedure that triggers prompt notification to ISoOR-AB.
- Update QMS documents, training records, and assessment procedures whenever significant changes occur.

Conclusion: By proactively addressing these common pitfalls, CABs strengthen their operational reliability, uphold impartiality and ethical standards, and improve their likelihood of successfully achieving and maintaining ISoOR-AB accreditation.

9 Maintaining Accreditation and Continuous Improvement

Achieving ISoOR-AB accreditation is a significant milestone for a Conformity Assessment Body (CAB), but maintaining accreditation requires ongoing commitment to quality, competence, and compliance. Continuous improvement ensures that the CAB remains effective, responsive to evolving standards, and aligned with best practices in organoid biobanking.

9.1 Continuous Monitoring and Internal Audits

CABs must implement ongoing internal monitoring mechanisms to ensure that all operations remain compliant with ISoOR-ISOB and relevant ISO/IEC standards. Key actions include:

- Conducting regular internal audits to review both technical procedures and management system processes.
- Identifying nonconformities or areas for improvement and documenting findings systematically.
- Implementing corrective and preventive actions to resolve deficiencies and prevent recurrence.
- Ensuring that audit results are reviewed by management and incorporated into planning cycles and strategic decisions.

9.2 Management Review and Strategic Oversight

Management review is a central element in maintaining accreditation. CAB leadership must:

- Periodically evaluate the effectiveness of the Quality Management System (QMS).
- Assess performance metrics, audit results, and client feedback to identify improvement opportunities.
- Make decisions regarding resource allocation, training needs, and procedural updates.

- Ensure that strategic goals and operational activities remain fully aligned with ISoOR-AB accreditation requirements.

9.3 Training and Competency Development

Continuous professional development is essential for maintaining technical competence and ethical standards. CABs should:

- Provide ongoing training in ISoOR-ISOB requirements, ISO/IEC standards, and sector-specific technical knowledge.
- Offer refresher courses on biosafety, bioethics, and regulatory compliance.
- Monitor assessor performance and skill development through regular evaluations and competency assessments.
- Document all training activities to demonstrate compliance with accreditation obligations.

9.4 Continuous Improvement of Assessment Procedures

CABs are expected to actively review and refine their assessment methodologies:

- Update checklists, scoring systems, and evaluation criteria based on feedback from ISoOR-AB and internal audits.
- Incorporate lessons learned from previous assessments, both within the CAB and across the organoid biobanking sector.
- Introduce new technologies or methods that improve assessment efficiency and accuracy while remaining compliant with ISoOR-ISOB standards.
- Regularly review process effectiveness and implement enhancements to maintain high-quality assessment outcomes.

9.5 Surveillance and Reassessment Preparation

CABs must prepare for ISoOR-AB surveillance assessments by:

- Maintaining current records of all assessments conducted.
- Documenting corrective actions taken in response to previous nonconformities.
- Reviewing changes in standards, regulations, or sector practices and updating internal procedures accordingly.

Full preparation reduces the risk of nonconformities and demonstrates the CABs ongoing commitment to excellence and compliance.

9.6 Engagement with the ISoOR-AB Community

CABs are encouraged to maintain active engagement with ISoOR-AB and the broader organoid biobanking community:

- Participate in workshops, training sessions, and technical forums.
- Share best practices and lessons learned with peers to enhance sector-wide quality.
- Stay informed about updates to ISoOR-ISOB and related international standards.

Engagement ensures that CABs remain at the forefront of developments in the field and continuously enhance the quality and reliability of their assessments.

10 Appendices

The appendices provide practical tools, templates, and reference materials to assist Conformity Assessment Bodies (CABs) in preparing for ISoOR-AB accreditation and ensuring ongoing compliance. These resources complement the guidance presented in Sections 19.

10.1 Appendix A Sample Accreditation Application Checklist

This checklist helps CABs ensure that all required documents and information are included in the application package:

- Completed Accreditation Application Form
- Clearly defined scope of accreditation
- Quality Management System (QMS) documentation
- Assessor qualifications and training records
- Ethics and biosafety compliance evidence
- Conflict of interest declarations
- Previous assessment reports (if applicable)

10.2 Appendix B CAB Assessment Preparation Checklist

Used internally by CABs to prepare for on-site evaluations:

- Ensure all QMS documents are current and version-controlled
- Prepare assessment schedules and planning records
- Confirm availability of personnel for interviews
- Organize technical, ethical, and biosafety records
- Review previous nonconformities and corrective actions
- Ensure all facilities and equipment are ready for inspection

10.3 Appendix C Sample Internal Audit and Corrective Action Form

A template to record:

- Audit findings
- Responsible personnel for corrective actions
- Deadline for completion
- Verification of effectiveness

10.4 Appendix D Assessor Competency Record Template

Includes fields for:

- Name and role
- Qualifications and experience
- Training courses completed
- Date of last competency evaluation
- Signature of responsible supervisor

10.5 Appendix E Ethical and Biosafety Compliance Checklist

Ensures assessors and CAB operations align with ISoOR ethical and biosafety standards:

- Code of Ethics acknowledgment signed by all personnel
- Records of informed consent for all donor materials
- Biosafety risk assessments completed for each biobank assessed
- Documentation of any ethical incidents and corrective actions

10.6 Appendix F Sample Evaluation Report Template

Guides assessors on preparing reports that meet ISoOR-AB requirements:

- Executive summary of findings
- Detailed evaluation of each ISoOR-ISOB criterion
- Nonconformities and recommendations
- Evidence referenced
- Signatures of assessors and management

10.7 Appendix G Reference Standards and Guidelines

Key documents and resources for CABs to consult:

- ISoOR-ISOB Standard Organoid Biobanking
- ISO 20387 General requirements for biobanking
- ISO/IEC 17025 Laboratory competence
- ISO/IEC 17065 Product/process certification
- ISO/IEC 17011 Accreditation body requirements
- ISoOR Code of Ethics and Code of Conduct

10.8 Appendix H Glossary of Terms

Provides clear definitions for terms commonly used in ISoOR-AB assessments:

- CAB Conformity Assessment Body
- AB Accreditation Body

- ISoOR-ISOB International Standard for Organoid Biobanking
- QMS Quality Management System
- Nonconformity A deviation from required standards or procedures
- Surveillance Assessment Periodic evaluation of CAB to ensure ongoing compliance

End of Document

This guidance document is intended to provide CABs with a comprehensive roadmap for achieving and maintaining ISoOR-AB accreditation. Following the procedures, maintaining records, and actively engaging in continuous improvement ensures competence, impartiality, and credibility in organoid biobank assessment.