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# Standards for Biorepository Accreditation

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2013 Edition

# College of American Pathologists Biorepository Accreditation Program Standards for Accreditation

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## **Preamble**

A biorepository is an entity that receives, stores, processes, and disseminates specimens as needed for research. Biorepositories ensure that quality biospecimens are available for clinical research, drug discovery, and personalized medicine. Biorepositories may perform some or all of the following activities: acquisition of patient consent, specimen collection, specimen processing, scientific analysis, specimen quality control, specimen storage, documentation of data on specimens and patients, sample release and tracking, and use of information technology to support its activities. A biorepository may be part of an academic medical center, a community hospital, an independent biobank, or other biostorage or transport facility.

The four Standards for Accreditation (Standards) in this document constitute the core principles of the College of American Pathologists (CAP) Biorepository Accreditation Program (BAP). The objective of the Standards is to ensure that accredited biorepository facilities meet the need for quality biospecimens used to support clinical research. The CAP accredits biorepository facilities that conform to the Standards. The specifics of how the Standards are applied to laboratories are found in the CAP Accreditation Checklists and Terms of Accreditation.

The CAP is committed to helping biorepository facilities comply with the Standards through peer-based education. However, the ultimate responsibility for compliance rests with the director and the biorepository facility organization.

## **Standard I – Director and Personnel**

The director must meet the qualifications specified by the Biorepository Accreditation Program and have authority to direct the biorepository. The director must have had four or more years of full-time general laboratory training and experience of which at least two years were spent acquiring proficiency in biorepository operations and management. The director must be qualified to assume professional, scientific, organizational, administrative, and educational responsibilities for the services provided.

The director is responsible for maintaining the Standards for Biorepository Accreditation, implementing the requirements of the CAP Accreditation Checklists, and documenting compliance. The director must have the authority to fulfill these responsibilities effectively. The biorepository shall be staffed with a sufficient number of personnel to perform quality biorepository services. The biorepository shall be organized to ensure that the director's responsibilities are fulfilled, lines of authority with the biorepository are defined, and individuals who work within the biorepository fulfill their responsibilities and interact effectively with one another.

## **Standard II – Physical Resources**

There shall be sufficient resources to support the activities of the biorepository. Such resources include, but are not limited to, physical space, physical environment, equipment and supplies, reagents, information processing and communication systems, ventilation, public utilities, and storage and disposal facilities. Biorepository personnel and visitors shall be protected from hazardous conditions.

**Standard III – Quality Management**

The biorepository shall have policies and procedures to ensure quality management that addresses the scope of services. These requirements include, but are not limited to validation of processes, quality control, proficiency testing, human resource management, information management, ongoing quality improvement, internal audits, storage of specimens, and appropriate communication with researchers, study collaborators, and clients.

**Standard IV – Administrative Requirements**

Biorepositories accredited by the CAP Biorepository Accreditation Program must comply with the requirements specified in the Terms of Accreditation and Accreditation Checklists. These requirements include, but are not limited to, periodic on-site inspection, possible interim inspection, interim self/desk assessment, participation in proficiency testing, maintenance of appropriate records and documentation, payment of accreditation fees, cooperation with the Commission on Laboratory Accreditation, and adherence to its policies.

**INTERPRETATION OF STANDARDS****Standard I – Director and Personnel**

A. The director of the biorepository facility should have the appropriate training and background to be able to discharge the following responsibilities:

1. Quality Management—Assume responsibility for implementation of the quality management plan. The director and professional biorepository personnel must participate as members of the quality improvement committees of the institution, if applicable.
2. Education—Provide educational direction for the biorepository staff and participate in educational programs of the institution, if applicable.
3. Research and Development—Plan and direct research and development appropriate to the biorepository facility.
4. Personnel—Ensure there are sufficient qualified personnel with adequate training and experience to meet the needs of the biorepository facility.
5. Safety—Implement a safe biorepository facility environment in compliance with good practice and applicable regulations.
6. Interaction With Others—Relate and function effectively with applicable accrediting and regulatory agencies, appropriate administrative officials, and the clients served.
7. Validation of all methods and procedures—Ensure that all methods and procedures are scientifically validated.
8. Standards of Performance—Define, implement, and monitor standards of performance in quality control and cost-effectiveness of the biorepository service(s).
9. Certifying review—Establish systems for appropriate review and certification of all chain of custody for biospecimens.
10. Strategic Planning—Perform planning for setting goals and developing and allocating resources appropriate to the biorepository facility environment.
11. Administration and Management—Provide effective and efficient administration of the biorepository service, including budget planning and control with responsible

financial management, in accordance with regulatory requirements and institutional assignment of such responsibilities.

12. Selection of Equipment, Methods, and Reagents—Provide input into the selection of equipment, methods, and reagents appropriate to the needs of the biospecimens, the scope of the biorepository services, and the financial constraints on the biorepository facility or institution.
13. Record Keeping—Establish and implement an adequate record-keeping system in the biorepository facility and monitor adequacy of and adherence to that system.

All biorepository personnel must be in compliance with applicable federal, state, and local laws and regulations.

#### B. Delegation of functions

The director need not perform all functions personally. Administrative functions may be delegated to qualified managers and supervisors. Biorepository functions may be delegated to qualified personnel as appropriate. The director, however, remains responsible for the overall operation and administration of the facility to assure that quality biorepository services are provided and for documentation of compliance with these requirements.

### **Standard II – Physical Resources**

The resources of the facility include space, instrumentation, furnishings, communication and data processing systems, supplies, ventilation, piped gases and water, public utilities, and storage and waste disposal facilities. There must be controlled access to specimens, data, records, and reports. The environment within the biorepository facility should be favorable for the effective performance of its personnel. Bench and storage space for the proper handling of specimens and housing of equipment and supplies should be adequate and convenient. Special work areas should be provided for procedures that require a controlled environment. Work areas should be arranged for ease of communication and smooth workflow.

Reasonable accommodation should be made for disabled biorepository personnel. The facility should be a safe working place for personnel and visitors. It should comply with the safety codes of applicable jurisdictional authorities. The safe collection and handling of samples and of chemicals should be an integral part of the biorepository safety program. Solid, liquid, and gaseous wastes should be discharged or disposed of consistent with regulatory requirements and environmental responsibility. Provision should be made for all reasonably foreseeable emergencies.

### **Standard III – Quality Management**

#### A. Quality control

The director must define and oversee the overall quality control program for the biorepository. The purpose of the quality control (QC) system is to prevent, detect and remedy errors in the biorepository processes. The director must define goals, policies, procedures, delegation of functions, and regular review by appropriate levels of personnel. The program must include acceptability limits and corrective action procedures to use when limits are exceeded.

#### B. Instrument maintenance

The director must define and oversee a program that monitors, ensures, and documents the proper calibration, function, and maintenance of instruments and biorepository equipment.

### C. Performance improvement

The director must systematically monitor and evaluate the quality and appropriateness of the biorepository services. When problems are identified, whether systematic or localized, the director must address them, both within the department and with other departments, if applicable. The director must ensure that the biorepository participates, if applicable, in the institutional quality management plans that deal with areas and outcomes relevant to biorepository processes. The quality management plan should be developed in accordance with the requirements of all applicable laws, regulations, and external review organizations. The program should be directed toward continuing improvement in quality, including identifying actions that can anticipate and prevent problems.

### D. Proficiency testing

The director must ensure that the proficiency testing system covers the complexity of the biorepository's procedures to the extent required by the CAP. The director must monitor the results of proficiency testing and participate in the documentation of corrective action.

### E. Scientific relevance

The director is responsible for ensuring that the processes performed by the biorepository are relevant and based upon sound science. A process is deemed relevant if its use is well established in practice, described in textbooks, or supported by relevant guidelines or peer-reviewed literature.

## **Standard IV – Administrative Requirements**

Eligibility for participation in the Biorepository Accreditation Program will be determined in accordance with the policies of the CAP. Biorepository facilities will be evaluated in accordance with the Standards for Biorepository Accreditation of the CAP and the applicable version of the Accreditation Checklists.

The biorepository must submit to periodic on-site inspection and such interim inspections or self/desk assessments as the CAP shall determine. The conduct of inspections and evaluation of results shall be in accordance with the policies and procedures of the CAP.

Biorepositories undergoing a change in directorship, location, ownership, or scope of service must notify the CAP. They are subject to reinspection and reevaluation.

Biorepositories enrolled in the Biorepository Accreditation Program are required to perform periodic self-evaluations. When deficiencies are noted, the biorepository shall take appropriate corrective action that shall be documented and subject to review by the CAP.

The director and the biorepository must cooperate in any CAP investigation or inspection. Each accredited biorepository must comply with the Terms of Accreditation listed in the official notice of accreditation sent to the biorepository by the CAP.

### **Revision History**

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