Management and Handling of Samples and Calibration Materials

This document aims to address the requirements of Section 7, Clause 7.4. of AS ISO/IEC 17025:2018 (ISO 17025). Sample management is critical to the accuracy and reliability of testing and therefore provides Australians with confidence and trust in the laboratory test results for therapeutic products.

Scope

Sample management and handling procedures are applicable to all samples, regardless of the reason for testing. All testing sections must comply with the Laboratories Business Operations Section (LBOS) sample handling documents. Any sample handling procedures that do not comply with these documents require approval for an exemption from the Assistant Secretary. Any procedures that have obtained an exemption are to be documented in section-specific quality documents and should be referenced in LBOS sample handling documents. Any deviations from the LBOS specified sample lifecycle will be documented and actioned.

Sample Management

The Laboratories Branch (LB) performs sample management in accordance with LBOS specified sample lifecycle documents which describe the general sample management procedures including the initiation of a testing process, sample collection, transportation, receipt, identification, traceability, testing, storage, protection, retention, return and disposal.

Physical handling of samples is covered by general laboratory safety documents. Appropriate procedures should be followed when handling samples throughout the building, as well as in the field when sampling or sample collection is required. There are also instructions for handling specific sample types, such as hazardous or dangerous substances.

The entirety of the sample lifecycle is designed to ensure integrity of the sample and subsequent results. All storage and handling requirements are conducted in a manner that ensures samples are protected from deterioration, loss or damage during storage. No samples are for personal use, and they shall not be provided to others for their personal use.

Unique identification of a sample must be performed as soon as the LB obtains custody of the sample. The sample is registered in the Laboratory Information Management System (LIMS), and a unique identification number is generated. Where possible, registration in the system occurs prior to physical arrival, as soon as the LB agrees to test the sample. This ensures traceability of all associated records is maintained, including transportation information prior to the sample arriving in the testing facility, if available.

As soon as the sample enters the testing facility, the LB is responsible for maintaining a clear chain of custody of the sample. On arrival, the sample is linked to the registration and labelled accordingly. Samples that arrive without corresponding prior registration are registered immediately and assigned a unique identification number. For all samples, this number is maintained throughout the testing process and must be used to link all associated documentation.

The sample will remain in secure storage rooms within an access-controlled facility. Each dedicated sample storage room is treated as a restricted area and is equipped with the Department's Electronic Access Control System. Access to these restricted areas must be approved by an authorised delegate, the Director of LBOS. Sample security is additionally supplemented with CCTV for the common sample storage areas.

Test Reference Standards & Materials

Test reference standards, materials or cultures are maintained in each laboratory area for use as required. Full records are kept, including at a minimum: the identity and source of the material, date acquired, and amount acquired, documentation of the assigned identity, values and technique by which the values were established, date of certification and period of validity.

In some sections, such as the Chemistry section, a curator is responsible for all calibrations of standards and materials and for maintaining and replenishing stocks as required. Other sections incorporate this process into the general maintenance of their culture or reference standards and materials.

All calibrations or verifications of identity are traceable to SI units of measurement or to certified reference materials. Checks needed to maintain confidence in the standards and reference materials are carried out as required to prescribed schedules.